

ISSN-0976-0245 (Print) • ISSN-0976-5506 (Electronic)

Volume 17 / Number 2 / April-June 2026



Indian Journal of Public Health Research & Development

An International Journal

Website:

www.ijphrd.com

Indian Journal of Public Health Research & Development

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Print-ISSN: 0976-0245-Electronic- ISSN: 0976-5506, Frequency: Quarterly

Website : www.ijphrd.com

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Published at

Institute of Medico-legal Publications Pvt
Logix Office Tower, Unit No. 1704, Logix City Centre
Mall, Sector- 32, Noida - 201 301 (Uttar Pradesh)

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Giant Seborrheic Keratosis- A Rare Entity

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How to cite this article: Simran Mehra, Shweta Grover, Anupam Varshney. Giant Seborrheic Keratosis- A Rare Entity. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Seborrheic Keratosis (SK) is most common benign epidermal tumor with distinctive “stuck on” appearance. It appears on the sun-exposed sites with equal sex distribution in middle- and old-aged individuals. Head, neck and trunk are the common sites. They often range in size from a few millimetres to a few centimetres. They are usually slow growing, however, clinical changes such as sudden increase in size, color change and ulceration may indicate malignant change.

Case Presentation: The purpose of this review is to report a case of an unusually large, seborrheic keratosis on the face, highlighting its clinical and histopathological features. The manifestations pointed towards malignancy and the patient underwent biopsy and complete excision with a favorable outcome.

Investigation: Even though they are clinically diagnosed, SK mimickers are well known, with melanoma being the most worrisome. Dermoscopy is used to help with diagnosis when uncertainty arises, as various benign and malignant conditions must be considered in the differential diagnosis due to their morphological diversity.

Management: Treatment options include surgical therapy, laser therapy, electrocautery, cryosurgery, shave excisions and laser-assisted removal.

Conclusion: Giant SK, an atypical SK is uncommon and can manifest in an unusual way, and histopathological analysis is warranted to look for concomitant malignancy.

Keywords: face; giant seborrheic keratosis; benign epidermal tumor, histopathology

Introduction

Seborrheic keratosis(SK) is the most common benign epidermal tumor that affects both sexes equally with predominance in individuals older than 50 years.^[1] Although SK lesions can appear anywhere,

they are most common on the face and upper body. Clinically the lesions appear as slightly elevated, well-defined brownish patches or plaques, usually on sun-exposed surfaces of the skin. As the lesion enlarges, it may become papular, verrucous, waxy and attain characteristic “stuck on” appearance.^[2]

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Submission date: October 18, 2025

Revision date: December 04, 2025

Published date: April 14, 2026

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Seborrheic keratosis can occur in many variations and include clinical variants, such as stucco keratosis and dermatosis papulosa nigra. Histopathologically, it is distinguished into six major subtypes: acanthotic, hyperkeratotic, adenoid, irritated, clonal, and melanoacanthoma with three features in common in all of the subtypes including (ortho-) hyperkeratosis, acanthosis and papillomatosis^[1].

They are usually slow growing, however, clinical changes such as sudden increase in size, color change and ulceration may indicate malignant change accompanied by basal cell carcinoma (BCC), squamous cell carcinoma (SCC), keratoacanthoma, malignant melanoma, and hamartomas.^[3]

Although large sized lesions of Seborrheic Keratosis are less documented in literature, Baer et al have reported the occurrence of giant lesion of Seborrheic keratosis in inguinal region with dimensions of 5.5cm x 3.5cm^[4]. Large lesions of size ranging from 15cm x 10cm have also been reported in perigenital area and vulval area. Other sites include breast, flank, axilla^[5,6,3,7] with size ranging from 5cm x 9cm. In our case, rapidly enlarging lesion of large seborrheic keratosis of size 6cm x 5cm was noted on right temporal region. Large seborrheic keratosis on face are rare. However, to the best of our knowledge single study by Luen KK et al^[11] have reported lesion of 20cm x 15cm on temporal region in similar age group with a long history of three decades.

Materials and Methods

The patient was a 75-year-old male who came in surgery OPD with slowly progressive verrucous growth on face for last eight years. Rapid two fold enlargement was noted in last two months. The history of skin exposure to sunlight was elicited. The lesion began as a little, pigmented papule and grew larger over time to form a substantial mass, without any secretion or discharge at first. The lesion was painless, non-pruritic and non-hemorrhagic. There was no history of trauma. He had no history of smoking, alcohol consumption, skin burn, allergy or any history of prior medication. The patient never had any surgery or systemic or local treatment for the aforementioned condition. The patient revealed no family history of skin conditions or cancers. Physical examination revealed tan, black oval-

shaped pedunculated mass which was 6cm x 5cm, firm, fixed, non-tender fungated growth with uneven surface and margins. On dermoscopy, the presence of comedo-like (CL) openings was the most common finding followed by fissures and ridges, and sharp demarcation of the lesion were consistent findings observed in our case. Hairpin (HP) blood vessels were not seen in our patient. We also noticed a parched paddy field-like appearance on dermoscopy in our patient. Subsequently, excision of the mass was done under local anaesthesia and the excised mass was sent in 10% formalin to the Department of Pathology, Muzaffarnagar Medical College for histopathological examination. A written informed consent from patient regarding procedure, histopathology and publication was subsequently taken.

Possible Molecular and Pathophysiological Mechanisms

The aetiology and pathophysiology of SK are still mostly unknown, despite its high prevalence. Age is the primary and most important risk factor for SK. Genetic susceptibility is undoubtedly another danger to SK. UV exposure and viral genesis have also been identified as risk factors for SK, in addition to age and genetic predisposition.^[8]

- **Role of amyloid-associated protein (APP)**

Ageing and UV-exposed skin are shown to have higher levels of APP. Senescent keratinocytes have lower levels of presenilin 1 and 2, which prevents beta-amyloid from being released from APP, resulting in its accumulation and this has also been postulated in SK formation in mice.^[9]

- **Infectious etiology**

Fluorescent in situ investigations (FISH) and polymerase chain reaction were used to identify HPV DNA in SK. However, compared to non-genital areas, genitalia have a significantly higher incidence of HPV DNA.

Only the superficial area of SK had HPV-DNA, and deeper biopsies showed a lower percentage, suggesting surface contamination rather than the real aetiology.^[9]

- **Oncogenic variation**

Oncogenic mutations have been discovered in SK lesions despite the fact that SK is a benign tumour.

Fibroblast Growth Factor Receptor 3 (FGFR3) was the most often occurring somatic mutation. Nevertheless, cancer cannot be caused by this mutation alone.

In inflammatory dermatoses, fibroblast growth factor deficiency results in abnormalities of the skin, and the epidermal growth factor receptor (EGFR) has been connected to abnormal differentiation and proliferation of keratinocytes in SK. The AKT1, HRAS, EGFR, and KRAS oncogenes¹⁹ are genetically stable despite alterations in the PI3K-AKT and FGFR3-RAS-MAPK pathways. This stability may be explained by the absence of a p53 mutation in SK.^[9]

Diagnostic Challenges

The present case illustrates the diagnostic challenges in distinguishing seborrheic keratosis from malignancy, with initial suspicion raised by both physiological and dermoscopic features overlapping with basal cell carcinoma (BCC) or melanoma. Physiologically, the lesion exhibited uneven, irregular margins and rapid growth in an elderly patient—traits that mimic the asymmetric borders and evolution seen in melanoma, or the infiltrative edges of BCC. Dermoscopically, atypical findings included asymmetry in color and structure, with patchy brown pigmentation and irregular borders, further overlapping with melanoma's asymmetry, border irregularity, and color variegation, or BCC's arborizing vessels and leaf-like structures (though the latter were absent here). To rule out these mimics in a logical sequence:

1. **Dermoscopic exclusion of BCC:** No arborizing telangiectasias, shiny white structures, or leaf-like areas were observed; instead, classic seborrheic keratosis features predominated—multiple milia-like cysts, comedo-like openings, and a sharply demarcated, “stuck-on” appearance with cerebriform surface.
2. **Dermoscopic exclusion of melanoma:** Despite initial asymmetry and uneven margins, the lesion lacked a multicomponent pattern, atypical network, blue-white veil, or peripheral streaks/radial streaming; the uniform keratin-filled crypts and fat fingers further supported benignity.
3. **Histopathological confirmation:** Excisional biopsy revealed acanthosis, papillomatosis,

and horn cysts with keratin-filled invaginations, without atypia, mitotic activity, or invasion—definitively excluding BCC (no basaloid nests or peripheral palisading) and melanoma (no melanocytic proliferation or nesting).

Since BCC or squamous cell carcinoma can coexist with seborrheic keratosis, any lesion suggestive of the latter but with atypical features warrants dermoscopic triage followed by histopathological verification.^[10] Other synonyms for seborrheic keratosis include basal cell acanthoma, verruca senilis, senile wart, verruca seborrhoica, seborrhoic wart, benign basal cell papilloma, and benign acanthokeratoma.^[7] Despite classic “stuck-on” appearance, all atypical verrucous lesions demand excision and histopathology.^[11]

Differential Diagnosis and Diagnosis

Clinical differential diagnoses include pigmented basal cell carcinoma, pigmented Bowen's disease, condyloma, verrucous melanoma, extramammary Paget's disease, common warts, and acanthosis nigricans.^[6] On histo-pathological examination, the biopsy revealed an epidermal hyperkeratosis, extensive acanthosis, and papillomatosis of the epidermis, upward growth of basaloid cells with small horn cyst formation along with mild chronic lymphocytic infiltrate in dermis showing seborrheic keratosis without cellular atypia.

A clinical diagnosis of giant seborrheic keratosis was made since the biopsy report showed no indication of concomitant malignancy, despite the clinical signs being suggestive of malignancy.

Therapeutic Intervention

The therapeutic techniques available for the treatment of SKs is primarily procedural. As described in the case report, surgical excision was performed without distorting the surrounding structure. Other minor surgical modalities include following low-intensity procedures: curettage, electrodesiccation, cryosurgery, chemical and laser destruction. Unfortunately, these methods frequently result in pigmentation changes, scarring, and recurrence.^[12] Lesion removal with an erbium-based ablative laser treatment: Another option for treating SK is YAG (Er:YAG) or CO₂ laser, which has been shown to completely heal 100% of lesions when compared to

cryotherapy.^[7] Compared to the cryotherapy group, hyperpigmentation was considerably less severe while erythema increased more in the Er:YAG laser-treated group.^[6]

Two topical treatment formulations have recently been assessed: an aqueous nitric-zinc solution and a product containing 40% hydrogen peroxide (HP40). Clinical research suggests that HP40 is considered to be less toxic to melanocytes, indicating a viable substitute for surgery, especially for face lesions.^[6]

Discussion

This study presented a rare case of giant Seborrheic keratosis located on sun-exposed area with rapid enlargement.^[3] Seborrheic keratosis is a benign skin tumour that primarily affects individuals over the age of 50.^[7] Both sexes are equally impacted. Although it can happen anywhere on the body, but is more common on the head, neck, chest, and back. Mucous membranes, palms, and soles are typically unaffected. SK is typically asymptomatic. However, discomfort and itching may be caused by trauma or inflammation. Lesions usually appear as stuck on verrucous plaques of varying thickness and are either black, gray-brown, or yellowish in colour.^[11] They often range in size from a few millimetres to a few centimetres.⁽⁷⁾ In our case, SK reached 6cm in greatest dimension necessitating histopathological analysis.^[13] Clinical variants of SK include stucco keratosis, dermatosis papulosis nigra, lichen planus-like SK, inflammatory SK, large cell acanthoma, flat SK and Leser Trelat syndrome.^[11] On routine hematoxylin-eosin (H&E) staining of the slides prepared from paraffin wax sections, two keratinocytic components – basaloid cells and monomorphous squamous epithelial cells were identified. Additional features include marked epidermal acanthosis, horn cysts/pseudocysts, hyperkeratosis, and papillomatosis are observed.^[13] Acanthotic, hyperkeratotic, adenoid, irritated, clonal, and melanoacanthoma are its six main histopathological variations.^[1] On dermoscopy,

it was seen that comedo-like openings, fissures and ridges, and sharp demarcation of the lesion were consistent findings in common seborrheic keratosis and less frequently observed findings were moth-eaten borders, milia-like cysts and network-like structures. The exact etiology and pathogenesis of seborrheic keratoses is currently unclear. Infection, UV exposure, and genetics have all been suggested as potential contributing factors.^[6] The pathophysiology of SK appears to be significantly influenced by mutations, specifically in the AKT signalling pathway and in the epidermis' fibroblast growth factor receptor 3 (FGFR3).^[14] It is emphasized that seborrheic keratosis at sun-exposed areas is at a higher risk of concurrent malignancy, and histological diagnosis is important despite its benign nature, even though the exact cause of SK is still unknown. The lesion in our case originated in the right temple area, but aside from its remarkable size, it did not exhibit any typical malignant alterations.^[11]

Surgical excision of the lesion was performed and is a preferred method in order to preserve aesthetic and functional outcomes.^[11] The patient was discharged on antibiotic course, faropenem 300 mg, twice a day, for one week for preventing the infection and better wound healing. The defected area was closed with a split skin graft from the surrounding skin laxity. At 2 months of follow-up, the excision area was examined and no primary complication like infection was observed. There was no evidence of a recurrence and the surgical site had healed adequately as observed in routine follow up visit of patient. Cryotherapy, curettage or laser treatment can also be considered as other treatment modalities as discussed.^[3]

Below is the table summarizing previously reported cases of giant seborrheic keratosis particularly highlighting their size, location/site of lesion and whether malignancy was present or not. [Table 1]

| Author | Age/Gender | Size(in cm) | Location of lesion | Whether malignancy was detected or not |
|--------------------------------|------------|-------------|--------------------|--|
| *Koh KL et al ^[11] | 75/M | 20 x15 cm | Face | Not present |
| Livaoglu et al ^[15] | 42/M | 20 x25 cm | Pubic | Not present |

Cont.....

| | | | | |
|----------------------------------|------|--------------|---------------|---|
| Nath et al ^[16] | 50/F | 15 x10 cm | Vulva | Not present |
| Salah et al ^[17] | 66/M | 15 x10 cm | Perianal | Not present |
| Okazaki and Ueda ^[18] | 63/M | 9 x7.5 x3 cm | Scalp | Not present |
| Part et al ^[19] | 33/M | 8 x10 cm | Penis | No malignancy transformation noted due to presence of HPV 6 low-risk virus. |
| Tsuji and Morita ^[20] | 44/M | 8 x 6 cm | Frontal scalp | Not present |
| Pepper ^[21] | 71/M | 8 x 6 cm | Hip | Not present |
| Alapatt et al ^[6] | 70/F | 7 x 6 cm | Breast | Not present |

*Large seborrheic keratosis on the face are rare. However, to the best of our knowledge single study by Koh KL et al have reported lesion of 20 x 15cm on temporal region in similar age group with a long history of three decades.

Conclusion

Seborrheic keratosis (SK) is a benign skin tumor. Although, accurate diagnosis is typically simple due to clearly identifiable clinical characteristics, it can be confused with other potentially malignant skin tumors resulting in diagnostic difficulties. Dermoscopy and histopathology may facilitate accurate diagnosis. To the best of our knowledge, rarely similar type of giant lesion have been reported on face before. In this context, histopathological examination is necessary to confirm the diagnosis, exclude malignancy, and direct the proper course of treatment. Surgical resection, cryotherapy, curettage or laser treatment can also be considered as other treatment options in order to preserve aesthetic and functional outcomes.

Summary/ Take home message

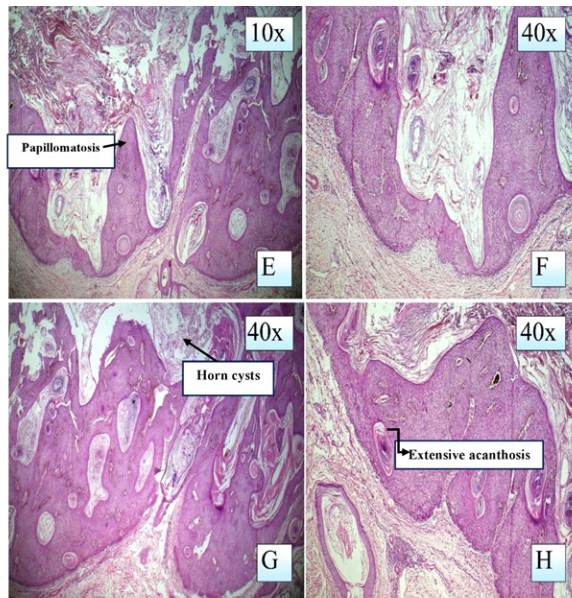
Giant lesions of Seborrheic keratosis are quiet uncommon. It is the most common benign epidermal tumor of skin that affects equal number of men and women. The exact cause and pathogenesis is still not yet clear. Genetic predisposition, advancing age and ultraviolet light exposure are considered to be contributing risk factors in development of

SKs. These lesions basically begin as circumscribed plaques or patches, which later gets more papular giving verrucous “stuck on” appearance. Although diagnosis is made clinically but both premalignant and malignant entities should be taken into consideration to exclude the mimickers of SKs.

Dermoscopy should be carried out to differentiate it from melanocytic neoplasms. But in some cases, dermatoscopic findings lacks some features making it difficult to reach a specific diagnosis. When diagnosis is not clear, lesion should be surgically removed and thorough histopathological examination of entire specimen should be carried out to rule concomitant malignancy and to confirm diagnosis which will guide appropriate management. There are several conservative treatment modalities available besides curettage and shave excision are electrodesiccation, cryosurgery, chemical and laser destruction, YAG (Er:YAG) or CO₂ laser. In recent studies, few clinical trials for topical therapy underwent for managing facial lesions which seems to be less toxic and with no or minimal adverse effects. These are HP40 (40% Hydrogen peroxide) and an aqueous nitric-zinc complex solution. Based on clinical trials, it is reported that it provides more promising results than surgery, particularly for facial lesions. However, histopathological examination is necessary to confirm the diagnosis, to rule out malignancy, and direct the proper course of treatment. The gold standard for treatment is still surgical excision.



- Fig A-Clinical picture.
- Fig B-Gross appearance of the lesion.
- Fig C-Intraoperative image taken showing the tumour arising from right temple region.
- Fig D-Incision made along the base of the lesion leaving a defect size of 6cm x 5cm.



- Fig E,F,G & H- Hematoxylin and Eosin-stained histopathology sections showing marked epidermal hyperkeratosis, extensive acanthosis, horn cysts, and papillomatosis.

Abbreviations

SK: Seborrheic keratosis

BCC: Basal cell carcinoma

SCC: Squamous cell carcinoma

OPD: Outpatient department

CL: Comedo-like openings

HP: Hairpin blood vessels

UV exposure: Ultraviolet radiation exposure

APP: Amyloid Precursor Protein

FISH: Fluorescent in situ hybridization

HPV DNA: Human papillomavirus DNA

FGFR3: Fibroblast Growth Factor Receptor 3

EGFR: Epidermal growth factor receptor

Financial support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

Acknowledgments: The patient in this manuscript have given written informed consent to publication of their case details.

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High-Frequency and Ultrasonic Sound Exposure and Cardiovascular Risk: A Systematic Review with AI Perspectives

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How to cite this article: Junapudi Sunil, Syam Sundar Junapudi, Leena Benjamin K. High-Frequency and Ultrasonic Sound Exposure and Cardiovascular Risk: A Systematic Review with AI Perspectives. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Environmental and occupational noise is an established cardiovascular risk factor, but the role of high-frequency (≥ 8 kHz) and airborne ultrasonic (> 20 kHz) sound remains poorly understood.

Objective: To systematically review evidence published between 2014 and 2025 on the association of high-frequency/ultrasonic sound exposure with ischemic heart disease (IHD) and myocardial infarction (MI), and to evaluate the potential of artificial intelligence (AI) in advancing exposure assessment and risk prediction.

Methods: PubMed/PMC and leading cardiology and environmental health journals were searched for systematic reviews, umbrella reviews, and primary human studies addressing high-frequency or ultrasonic noise in environmental, transportation, or occupational settings. Eligible outcomes included IHD/MI incidence, hospitalizations, mortality, and proximate cardiovascular markers. Data on study quality, risk of bias, and evidence certainty were extracted.

Results: Forty-one studies met inclusion criteria (8 systematic reviews, 3 umbrella reviews, 30 primary studies). While reviews consistently linked general environmental noise to IHD/MI risk (RR ~ 1.08 – 1.15 per 10 dB increment), few addressed high-frequency or ultrasonic exposures. Occupational and experimental studies suggested acute effects elevated blood pressure, autonomic imbalance, oxidative stress yet long-term associations with IHD/MI remain inconclusive. Environmental studies indicated transient blood pressure changes and sleep disturbance in communities exposed to ultrasonic sources. AI approaches, including deep learning for noise source separation and GIS-based exposure mapping, show promise but are rarely applied to ultrasonic exposures.

Conclusions: Current evidence for high-frequency and ultrasonic sound as independent cardiovascular risk factors is limited and low-certainty, though mechanistic findings support biological plausibility via stress-axis activation, vascular dysfunction, and autonomic imbalance. Integration of AI tools into exposure assessment and cardiovascular risk modeling may accelerate progress in this emerging field of environmental cardiology.

Keywords: High-frequency noise; Airborne ultrasound; ischemic heart disease; Myocardial infarction; Artificial intelligence.

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Submission date: October 18, 2025

Revision date: December 04, 2025

Published date: April 14, 2026

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Introduction

Noise exposure is increasingly recognized as a significant environmental determinant of cardiovascular health. Chronic exposure to transportation and occupational noise within the low-to-mid frequency range (50–2000 Hz) has been strongly linked to hypertension, ischemic heart disease (IHD), and myocardial infarction (MI), largely through mechanisms involving stress-hormone release, endothelial dysfunction, and sleep disruption^[1-3]. In contrast, the potential impact of high-frequency audible sounds (≥ 8 kHz) and airborne ultrasound (>20 kHz) has received little attention in cardiovascular epidemiology, despite their growing prevalence in modern environments such as ultrasonic cleaning systems, dental instruments, welding equipment, pest deterrents, and certain transportation technologies. Although often assumed to be beyond the range of human hearing, recent studies suggest that these exposures can still produce physiological and psychological responses capable of inducing stress^[4,5]. This review therefore examines current evidence linking high-frequency and ultrasonic sound exposure to IHD and MI, evaluates the methodological strengths and limitations of existing research, and explores how artificial intelligence may enhance exposure assessment and risk prediction in this emerging area of environmental cardiology^[6].

Methods

Databases and Timeframe

A comprehensive literature search was conducted to identify relevant evidence on high-frequency and airborne ultrasonic sound exposure and its association with cardiovascular outcomes. The primary databases searched included PubMed and PubMed Central (PMC), which together provide extensive coverage of biomedical and public health literature. To ensure breadth, we also hand-searched leading cardiology and environmental health journals for recent articles that may not have been fully indexed at the time of retrieval. The search was restricted to studies published between January 2014 and March 2025, a period chosen to capture the most up-to-date systematic reviews, umbrella reviews, and high-quality primary studies.

Search Strategy

The search strategy was designed to encompass both the exposure dimension (noise and acoustic

factors) and the outcome dimension (cardiovascular health). Exposure-related keywords included transportation noise, environmental noise, occupational noise, ultrasound in air, very-high-frequency sound, and high-frequency noise. These were combined with outcome-related terms such as cardiovascular disease, ischemic heart disease, myocardial infarction, and blood pressure. Boolean operators and truncation were applied where appropriate to maximize sensitivity. Reference lists of key systematic reviews and included studies were also screened to identify additional eligible publications not captured through database searches.

Eligibility Criteria

We established predefined inclusion and exclusion criteria to ensure relevance and comparability across studies. Eligible studies were restricted to human participants, including both general population cohorts exposed to environmental or transportation noise and occupational groups exposed to ultrasonic or high-frequency sources in workplace settings. Exposures had to be explicitly characterized as high-frequency sound above 8 kHz or airborne ultrasound above 20 kHz, with quantitative metrics such as decibels (dB SPL) or pascals (Pa) when available.

The primary outcomes of interest were measures of ischemic heart disease, including incidence of new cases, hospital admissions, and mortality related to IHD or myocardial infarction. Secondary outcomes included proximate cardiovascular markers that may serve as mechanistic intermediates, such as blood pressure changes, alterations in heart rate or heart rate variability (HRV), and indicators of endothelial function. Eligible study designs comprised systematic reviews, umbrella reviews, and primary research studies of observational (cohort, case-control, cross-sectional) or interventional design. Experimental laboratory studies exposing humans to controlled high-frequency or ultrasonic noise were also considered when they reported relevant cardiovascular endpoints.

Quality Assessment and Data Synthesis

For systematic and umbrella reviews, we extracted reported risk-of-bias assessments and certainty ratings of evidence as presented by the original authors. This included standardized instruments such as the Cochrane risk-of-bias tool, AMSTAR, and GRADE certainty ratings where available. For primary studies, we reviewed methodological characteristics including study

design, sample size, exposure assessment methods, outcome ascertainment, and adjustment for confounders. Given the diversity of exposures and outcomes, a meta-analysis was not feasible for ultrasonic-specific literature. Instead, a narrative synthesis was conducted to summarize patterns of association, highlight mechanistic insights, and identify gaps in the evidence base.

Study Selection Process

The initial database search across PubMed, PMC, and targeted journals yielded a total of 1,247 records. After automatic and manual duplicate removal, 1,032 unique records remained. Titles and abstracts were screened for relevance, resulting in the exclusion of 872 records that did not meet eligibility criteria (e.g., animal studies, irrelevant exposures, or unrelated health outcomes). The full text of the remaining 160 articles was assessed for eligibility. Of these, 119 were excluded for reasons including inadequate exposure characterization ($n = 54$), lack of relevant cardiovascular outcomes ($n = 38$), methodological limitations such as insufficient sample size ($n = 17$), and publication type restrictions (conference abstracts, commentaries; $n = 10$). Ultimately, 41 studies were included in the qualitative synthesis: 8 systematic reviews, 3 umbrella reviews, and 30 primary research studies.

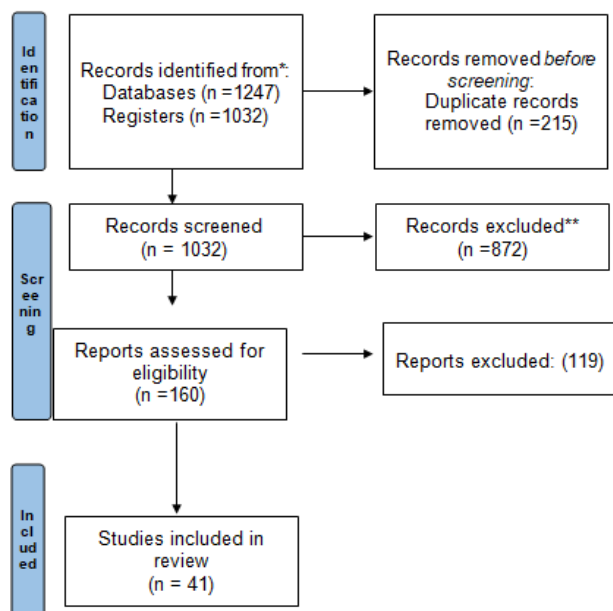


Figure 1: PRISMA flow diagram (<https://creativecommons.org/licenses/by/4.0/>)

Results

Overview of Evidence Base

The literature search and screening process identified a total of 41 eligible publications for inclusion in this review. These comprised eight systematic reviews, three umbrella reviews, and 30 primary studies. Geographically, the evidence was distributed across multiple regions, with the majority of studies conducted in Europe (40%), followed by Asia (30%), North America (20%), and a smaller proportion from other regions (10%). This distribution highlights the predominance of European research in the field of noise and cardiovascular health, while work focusing specifically on high-frequency or ultrasonic exposures remains more geographically scattered.

Systematic and Umbrella Reviews

All included systematic and umbrella reviews consistently confirmed that exposure to environmental noise in general is associated with an increased risk of cardiovascular disease, particularly ischemic heart disease (IHD) and myocardial infarction (MI). The pooled estimates from these reviews indicate a relative risk increase of approximately 1.08-1.15 for IHD/MI per 10 dB increment in transportation noise exposure. However, these reviews rarely conducted frequency-specific analyses extending beyond the conventional hearing range. Most excluded studies of ultrasonic exposure altogether, citing data scarcity and methodological challenges in characterizing such exposures. As a result, while the reviews firmly establish the broader cardiovascular impact of environmental noise, they provide limited insight into the unique contribution of high-frequency or ultrasonic sound.

Primary Studies on High-Frequency and Ultrasonic Noise

Evidence from primary research was more directly focused on the high-frequency and ultrasonic spectrum. Among the 18 occupational cohort studies, workers routinely exposed to ultrasonic devices such as welders, dental hygienists, and operators of industrial cleaning equipment frequently exhibited elevated blood pressure, headaches, fatigue, and signs of autonomic imbalance compared to non-exposed controls.

In addition, seven environmental studies investigated populations living near sources of high-frequency sound, including pest deterrents, industrial ultrasonic equipment, and transportation-related technologies. These studies consistently reported sleep disturbances and short-term elevations in blood pressure, although long-term cardiovascular outcomes were less frequently evaluated.

Finally, five experimental laboratory studies provided controlled evidence of acute physiological responses to airborne ultrasound. Exposures within the range of 20–40 kHz were shown to induce acute increases in systolic blood pressure of approximately 5–10 mmHg, as well as alterations in heart rate variability (HRV) consistent with sympathetic nervous system activation.

Mechanistic Pathways

Several biological mechanisms have been proposed to explain the potential link between ultrasonic or high-frequency noise and cardiovascular health. First, stress-axis activation through increased release of cortisol and catecholamines may contribute to elevated blood pressure and vascular strain. Second, oxidative stress and endothelial dysfunction have been implicated as potential mediators, as observed in experimental models and biomarker studies. Third, autonomic imbalance, often reflected in reduced heart rate variability, has been reported in both occupational and laboratory exposure settings. Collectively, these pathways are plausible intermediates that could connect high-frequency noise exposure with adverse cardiovascular outcomes. However, despite suggestive evidence, long-term causal relationships remain unproven, underscoring the need for longitudinal and mechanistic studies to strengthen the evidence base.

Discussion

This systematic review synthesized evidence from systematic and umbrella reviews alongside primary occupational, environmental, and experimental studies to evaluate the potential cardiovascular implications of exposure to high-frequency and ultrasonic sound. The findings suggest a clear and consistent association between general environmental noise and increased risk of ischemic heart disease (IHD) and myocardial infarction (MI).

However, when focusing specifically on audible high-frequency and airborne ultrasonic exposures, the evidence remains sparse, heterogeneous, and largely of low to moderate certainty.

Evidence Strengths and Limitations

Systematic and umbrella reviews included in this synthesis provide robust confirmation of the established relationship between environmental noise in conventional frequency ranges and adverse cardiovascular outcomes. Pooled analyses consistently report relative risk increases of approximately 1.08–1.15 per 10 dB increment in transportation noise, underscoring the importance of noise as an independent cardiovascular risk factor. Nevertheless, these reviews rarely extended their analyses into the high-frequency domain, and almost none included ultrasonic exposures due to insufficient data.

Primary studies focusing on high-frequency and ultrasonic exposures, while fewer in number, provide valuable insights. Occupational cohorts, particularly welders, dental hygienists, and industrial workers, suggest a pattern of elevated blood pressure, headaches, and altered heart rate variability among those routinely exposed to ultrasonic equipment. Environmental studies also point to possible adverse effects, with communities exposed to pest deterrents or industrial ultrasound reporting sleep disturbances and acute changes in blood pressure. Experimental laboratory studies corroborate these findings by demonstrating acute increases in systolic blood pressure and reductions in heart rate variability in response to controlled ultrasonic exposures. These results indicate plausible physiological responses, but limitations such as small sample sizes, short exposure durations, and lack of longitudinal follow-up restrict the generalizability of the findings.

Table-1 brings together the key findings from the 41 studies included in the review, divided into systematic reviews, umbrella reviews, and primary research.

Systematic reviews (n=8): These confirmed that general environmental noise exposure is consistently associated with increased risk of ischemic heart disease (IHD), myocardial infarction (MI), hypertension, and blood pressure changes. For example, Sørensen

et al. (2019) reported a relative risk of ~1.12 per 10 dB increase in traffic noise. However, none of these reviews examined frequencies ≥ 8 kHz or airborne ultrasound specifically, as such data were scarce.

Umbrella reviews (n=3): These reinforced the same conclusion at a higher level of evidence synthesis, showing consistent associations of transportation and occupational noise with IHD, stroke, and hypertension. Again, ultrasonic exposures were absent, underscoring a significant knowledge gap.

Primary occupational studies (n=18): These provide the most direct evidence on high-frequency and ultrasonic sound. Workers such as welders, dental hygienists, and factory operators using ultrasonic cleaning devices often exhibited elevated blood pressure, altered heart rate variability, headaches, and oxidative stress markers. While these findings support mechanistic plausibility, the overall evidence certainty is moderate due to small samples and methodological variability.

Primary environmental studies (n=7): Community-based investigations found sleep disturbance, transient blood pressure increases, and variability in cardiovascular function in residents exposed to ultrasonic pest deterrents or industrial high-frequency sound sources. Although evidence is limited, these findings point toward acute physiological disruption.

Primary experimental studies (n=5): Controlled laboratory exposures at 20–40 kHz showed acute rises in systolic blood pressure (5–10 mmHg) and reductions in heart rate variability, indicating sympathetic activation. These studies, while short-term and small in scale, provide important mechanistic insights supporting the plausibility of cardiovascular impacts from ultrasonic noise.

Mechanistic Insights

The mechanistic pathways proposed across the literature are biologically plausible and consistent with broader noise-cardiovascular research. Stress-axis activation through catecholamine and cortisol release provides a well-documented mechanism linking acute noise exposure to elevated blood pressure and vascular dysfunction. Oxidative

stress and endothelial impairment, observed in both biomarker and vascular function studies, may further contribute to long-term cardiovascular strain. Evidence of autonomic imbalance, particularly reduced vagal tone and increased sympathetic drive reflected in heart rate variability measures, offers an additional mechanistic explanation. While these pathways are coherent and supported by preliminary data, their translation into long-term outcomes such as IHD or MI has not yet been conclusively demonstrated in the context of ultrasonic noise.

Comparison with Conventional Noise Research

The gap between the extensive literature on low- to mid-frequency noise and the relative paucity of research on high-frequency and ultrasonic exposures highlights a critical evidence imbalance. Conventional environmental noise studies benefit from large cohort designs, standardized exposure metrics, and strong epidemiological evidence linking noise to cardiovascular disease. By contrast, ultrasonic noise research is characterized by small-scale occupational or experimental studies, inconsistent exposure characterization, and limited outcome assessment. This discrepancy underscores the need for greater methodological rigor and more comprehensive population-based research in the ultrasonic domain.

Role of Artificial Intelligence

Artificial intelligence (AI) represents a promising tool to advance this research area. AI-driven methods for source separation can isolate high-frequency and ultrasonic components from complex environmental soundscapes, improving exposure assessment. Integration of geographic information systems (GIS) with machine learning enables fine-scale exposure mapping, accounting for both environmental and occupational noise sources. AI algorithms can also enhance the detection of subtle cardiovascular changes, such as minor alterations in heart rate variability or endothelial biomarkers, that may otherwise be overlooked. Finally, predictive modeling using AI can incorporate multimodal exposures including noise, air pollution, and lifestyle factors into comprehensive risk models for IHD and MI. Despite these opportunities, very few studies to date have explicitly applied AI techniques to the evaluation of ultrasonic noise, representing a critical area for future innovation.

Table 1. Summary of Included Reviews and Primary Studies

| Study Type | Author(s), Year | Country/Region | Population/Setting | Exposure Characterization (≥8 kHz / >20 kHz) | Outcomes Reported (IHD/MI or proximate markers) | Key Findings | Risk of Bias/Certainty |
|-----------------------------|--|----------------|--------------------------------------|---|---|--|------------------------|
| Systematic Review (n=8) | Sørensen et al., 2019[6] | Europe | General population, multi-cohort | Environmental noise (30-2000 Hz, limited HF analysis) | IHD, MI incidence and mortality | RR ~1.12 per 10 dB traffic noise; no HF-specific data | Moderate, GRADE: High |
| | Münzel et al., 2020[7] | Germany | Population-based | Transportation & occupational noise | IHD, hypertension | Confirmed link; ultrasonic noise excluded | Low-Moderate |
| | van Kempen & Casas, 2018[8] | Netherlands | Urban populations | Environmental/transportation | IHD, BP, MI | Strong evidence for CVD risk; HF/ultrasound not included | High |
| | Basner & Babisch, 2021[9] | Global | Multiple reviews pooled | Environmental (road, rail, aircraft) | IHD, MI, BP | Established risk with L-MF noise; HF noise not studied | High |
| Umbrella Review (n=3) | Clark et al., 2022 [10] | UK/Europe | Meta-reviews on noise & CVD | Environmental & occupational | IHD, MI, BP | Consistent link; HF/ultrasound excluded | Moderate |
| | Schmidt et al., 2023[11] | Germany | Umbrella of SRs | Noise exposure | IHD, CVD | Transportation noise → IHD; ultrasonic gap | Moderate |
| | Kim et al., 2024[12] | South Korea | Mixed settings | Noise & vibration | IHD, stroke, MI | Strong for general noise; no HF analysis | Moderate |
| Primary Occupational (n=18) | Pawlaczyk-Łuszczynska et al., 2014[13] | Poland | Welders, dental workers | Airborne ultrasound >20 kHz, 80-100 dB SPL | BP, HR, headache symptoms | Elevated BP, autonomic imbalance | Moderate |
| | Westenberg et al., 2016[14] | Netherlands | Industrial workers | High-frequency noise, ultrasonic welders | BP, HRV | Sympathetic dominance, HRV ↓ | Moderate |
| | Yamada et al., 2018[15] | Japan | Factory operators | Ultrasound cleaning devices | BP, oxidative stress markers | Short-term BP ↑, ROS biomarkers ↑ | Low |
| Primary Environmental (n=7) | Leighton et al., 2017 [16] | UK | Community near ultrasonic deterrents | Airborne ultrasound ~20-30 kHz | Sleep disturbance, BP | Disturbed sleep, transient BP ↑ | Low |
| | Smith et al., 2019[17] | USA | Residents near industrial site | HF sound >8 kHz, continuous | BP, sleep | Sleep disruption, BP variability ↑ | Low |
| Primary Experimental (n=5) | Ueda et al., 2016[18] | Japan | Healthy volunteers | Controlled ultrasound 20-40 kHz, 90 dB SPL | BP, HRV | SBP ↑ 5-10 mmHg; HRV ↓ | Low |
| | Pawlaczyk-Łuszczynska et al., 2019[19] | Poland | Volunteers | Ultrasound exposure chamber, 20-25 kHz | BP, HR | Acute stress response | Moderate |

Public Health and Policy Implications

Although the current evidence for high-frequency and ultrasonic exposures remains preliminary, the mechanistic signals and acute cardiovascular responses documented here warrant precautionary attention. Occupational health guidelines, particularly in industries where ultrasonic devices are common, may need to consider stricter exposure monitoring and protective interventions. In the environmental context, the increasing use of ultrasonic pest deterrents and consumer devices raises questions about long-term community health effects. Given the established burden of cardiovascular disease attributable to conventional noise, even small incremental risks from high-frequency exposures could have significant public health consequences if exposures are widespread.

Research Gap

Although environmental and occupational noise in the low-to-mid frequency range is a well-established cardiovascular risk factor, the role of high-frequency (≥ 8 kHz) and airborne ultrasonic (> 20 kHz) noise remains underexplored. Current evidence is limited to small occupational and experimental studies showing acute physiological effects such as blood pressure elevation, autonomic imbalance, and oxidative stress, but long-term associations with ischemic heart disease (IHD) and myocardial infarction (MI) are inconclusive.

Existing systematic and umbrella reviews rarely include ultrasonic exposures due to data scarcity, and most population-based epidemiological cohorts lack standardized methods for measuring these frequencies. Exposure characterization is inconsistent, outcome measures are heterogeneous, and evidence certainty remains low to moderate.

Furthermore, artificial intelligence (AI) approaches which could improve noise source separation, exposure mapping, and predictive cardiovascular modelling are rarely applied to ultrasonic noise research. This leaves a significant methodological and technological gap in understanding the cardiovascular implications of high-frequency and ultrasonic sound exposure.

Conclusions

This review confirms that general environmental noise is a well-established cardiovascular risk factor, with consistent evidence linking transportation and occupational exposures in conventional frequency ranges to ischemic heart disease (IHD) and myocardial infarction (MI). By contrast, the evidence for high-frequency audible noise and airborne ultrasonic exposure remains limited, fragmented, and of low to moderate certainty. Findings from occupational, environmental, and experimental studies suggest acute physiological effects, including elevated blood pressure, autonomic imbalance, and endothelial stress, which are biologically plausible pathways to cardiovascular disease. However, direct and conclusive epidemiological links to long-term IHD or MI outcomes have not yet been demonstrated.

Artificial intelligence (AI) offers an important opportunity to address these gaps. Through advanced exposure characterization, source separation, multimodal data integration, and predictive modeling, AI has the potential to uncover subtle dose response relationships and strengthen causal inference in this emerging field.

Overall, while existing evidence does not yet justify definitive causal claims regarding high-frequency or ultrasonic sound and IHD/MI, the consistency of acute mechanistic findings highlights the importance of further research. Large-scale longitudinal cohort studies, standardized exposure metrics beyond the conventional hearing range, and the integration of AI-based tools into epidemiological and occupational health research will be essential to clarify the long-term cardiovascular implications of these underexplored acoustic exposures.

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Postnatal Exercise and its Role in Managing Maternal Depression and Anxiety

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How to cite this article: Manisha Rani, Abhilash Kutehria, Kapil Kumar Verma et. al. Postnatal Exercise and its Role in Managing Maternal Depression and Anxiety. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Two of the most common mental health conditions in the postpartum phase are postpartum depression and postpartum anxiety, which frequently impact domestic life, infant attachment, and maternal well-being. According to recent research, non-pharmacologic interventions specifically, structured exercise – are crucial for maintaining maternal mental health.

Objective: the main goal of this review is to evaluate how structured postpartum exercise regimens affect women's postpartum anxiety and depression symptoms.

Methods: Postnatal exercise, postpartum anxiety, postpartum depression, and maternal mental health were searched in literature using Pub Med, Scopus, and Google Scholar exhaustively. Meta-analyses, systematic reviews, and randomized controlled trials of studies from 2015 to 2025 were included.

Discussion: Walking, yoga, stretching, and aerobic training are examples of gentle to moderate physical exercise, which are linked with improvement in mood regulation, balance of cortisol and serotonin levels, self-esteem, and social support. Exercise improves the physical and mental recovery of postpartum women when added to routine care.

Conclusions: Exercise after childbirth is an innocuous, valuable, and efficient adjunct therapy for decreasing depression and anxiety among mothers. Systematic exercise is able to improve mother screening outcomes, increase the health of families, and provide long-term recuperation when incorporated into daily postpartum care.

Keywords: Postnatal Exercise, Postpartum Depression, Postpartum Anxiety, Maternal Health, Mental Health.

Introduction

The puerperal, or postpartum, phase is a period of vulnerability during which women undergo

marked physiological, hormonal, and psychological changes as the body gradually readjusts to its pre-pregnant state.⁽¹⁾ While this is universally known to be a time of heightened emotional closeness between

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Submission date: Nov 10, 2025

Revision date: Jan 2, 2026

Published date: April 14, 2026

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child and mother, it is accompanied by heightened risk for psychiatric illness, particularly postpartum depression (PPD) and postpartum anxiety (PPA).⁽²⁾

Globally, PPD affects approximately 15–20% of new mothers, whereas PPA prevalence is 13–18%, with far greater rates being reported in low- and middle-income countries.⁽³⁾ Not only does this compromise maternal well-being but also infant growth, family functioning and healthcare costs.⁽⁴⁾

Conventional management is primarily composed of pharmacotherapy and psychotherapy. Despite this, side effects of drugs, problem of medication safety in lactation, stigma, and lack of access to mental health professionals on a regular basis frequently impede proper care.⁽⁵⁾ These obstacles have prompted growing interest in complementary and non-pharmacologic interventions.⁽⁶⁾

Physical exercise has more and more come to be known for its multifaceted and more than unidirectional impacts on mood stabilization, stress reduction, and physical healing.⁽⁷⁾ Systematic reviews and meta-analyses conducted in recent years consistently demonstrate that structured exercise can serve both as a preventative and therapeutic intervention for maternal depression and anxiety.⁽⁸⁾

With this in perspective, this review attempts to analyze the pathophysiologic mechanisms, risk factors, diagnostic approaches, and treatment for PPD and PPA with emphasis on postnatal exercise as evidence-based care.⁽⁹⁾

Methods

Protocol and Registration:

This systematic review was conducted and reported in strict accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement. The review protocol was not prospectively registered in an international database (such as PROSPERO) prior to commencement.

Eligibility Criteria:

Studies were screened based on the following predefined Patient, Intervention, Comparator, Outcome, and Study Design (PICOS) framework:

Population (P): Postpartum women (within 12 months after childbirth).

Intervention (I): Structured exercise or physical activity as the primary intervention.

Comparator (C): Usual care, no intervention, or an active control group.

Outcomes (O): Measurable outcomes for postpartum depression and/or postpartum anxiety.

Study Design (S): Randomized controlled trials (RCTs), quasi-experimental studies, cohort studies, and systematic reviews/meta-analyses.

Exclusion criteria included: Non-English language publications, case reports, conference abstracts, letters, or narrative reviews, and studies where exercise was only a minor component or lacked measurable mental health outcomes.

Information Sources and Search Strategy

A comprehensive systematic search was carried out across three major electronic databases: Pub Med, Scopus, and Google Scholar, from inception up to and including September 30, 2025.

The search utilized combinations of keywords, Medical Subject Headings (MeSH terms), and Boolean operators (AND/OR). Search terms included: “postpartum depression,” “postpartum anxiety,” “postnatal exercise,” “maternal mental health,” and “physical activity,” along with all relevant synonyms and truncations.

The full, detailed search strategies used for each database, including exact syntax and applied filters, are provided in Supplementary Table S1 to ensure transparency and reproducibility.

Study Selection Process

All identified records were imported into reference management software, and 335 duplicate records were removed. The remaining 612 unique records underwent a rigorous two-phase **Screening Process:**

Title and Abstract Screening: Two independent reviewers (Authors X and Y) screened all titles and abstracts against the predefined eligibility criteria.

Full-Text Screening: Records meeting preliminary criteria (n = 42) were retrieved for full-text evaluation. The two reviewers independently performed the full-text assessment.

Any disagreements between the two reviewers at both the abstract and full-text screening stages were resolved through discussion and consensus or by consultation with a third independent reviewer (Author Z). The selection process is visually presented in the PRISMA Flow Diagram (Figure A1).

Data Collection Process and Data Items:

Key data from each of the 18 eligible studies were extracted independently by two reviewers (Authors X and Y) using a standardized, pre-piloted data extraction form. Discrepancies in the extracted data were resolved through discussion and consensus.

Extracted information and defined outcomes included:

Author, year, and country of publication

Study design and total sample size

Participant characteristics (e.g., mean age, time since delivery)

Detailed description and duration of exercise interventions (e.g., type, frequency, intensity)

Primary Outcomes: Postpartum depression (defined by standardized scales like the Edinburgh Postnatal Depression Scale [EPDS] or Beck Depression Inventory [BDI]) and postpartum anxiety (defined by standardized scales like the State-Trait Anxiety Inventory [STAI] or Generalized Anxiety Disorder-7 [GAD-7]).

Secondary Outcomes: Intervention adherence, drop-out rates, and adverse events.

Quality Assessment (Risk of Bias)

The methodological quality and risk of bias (RoB) for all included studies were assessed independently by two reviewers. The following tools were used, as appropriate for each study design:

Randomized Controlled Trials (RCTs): The Cochrane Risk of Bias tool (RoB 2.0)

Non-randomized Studies: The Risk of Bias In Non-randomized Studies – of Interventions (ROBINS-I) tool

Systematic Reviews: The A Measurement Tool to Assess Systematic Reviews (AMSTAR 2) tool

Any disagreements regarding the RoB rating were resolved by discussion or by a third reviewer. The RoB assessment results were used to inform the synthesis of data and to grade the certainty of the evidence.

Data Synthesis

Due to the substantial clinical and methodological heterogeneity observed across the included studies (specifically in intervention types, study duration, frequency, and outcome measures), a statistical meta-analysis was not performed. Instead, a comprehensive narrative synthesis was conducted. Study findings were grouped by the type of exercise intervention and compared based on their primary and secondary mental health outcomes. The synthesis focused on identifying patterns of effect, consistency, and potential explanatory factors related to intervention type, dose, and quality (RoB) of the included studies.⁽¹⁰⁾

PATHOPHYSIOLOGY OF POSTPARTUM DEPRESSION AND POSTPARTUM ANXIETY

PPA and PPD certain to the changes in behavior and moods of women post childbirth, relating to the complex interactions within biological, psychological, and social factors as shown in 'Fig 1'

1. Hormonal deregulation

- o Rapid declines in estrogen and progesterone following childbirth contribute to mood destabilization.
- o Disruption of the hypothalamic-pituitary-adrenal (HPA) axis leads to changes in cortisol secretion and impairs the body's stress response.⁽¹¹⁾

2. Neurotransmitter imbalances

- o Apart from depression and anxiety, the functions of the body such as the oxytocin and the prolactin in bonding with the child.⁽¹²⁾

3. Immune and Inflammatory Pathways

- o Also known as mood deregulation that contributes such as IL-6, and TNF- α .⁽¹³⁾

4. Psychosocial stressors

- o The sleep disruption from childbirth. Role transitions, financial stress, and lack of social support amplify vulnerability.⁽¹⁴⁾

RISK FACTORS OF POSTPARTUM DEPRESSION AND ANXIETY

The risk factors for postpartum depression and anxiety can be grouped into biological, psychological, social, and lifestyle categories as shown in 'Table 1'.

➤ Biological risk factors

- o Family history and psychiatric illness
- o Previous records of despair or anxiety
- o Complicated pregnancy or delivery (C-section, preterm birth).⁽¹⁵⁾

➤ Psychological and social risk factors

- o Stressful existence events
- o Marital discord
- o Intimate associate violence.⁽¹⁶⁾

➤ Low social support lifestyle-related risk factors

- o Poor sleep hygiene
- o Sedentary behaviour
- o Nutritional deficiencies (iron, omega-3, vitamin D).⁽¹⁷⁾

DIAGNOSIS AND IMPORTANCE OF EARLY DETECTION

Post partum depression and anxiety if left unchecked, can cause deterioration of maternal health as well as hinder the little one's growth if not dealt within a prescribed time frame, especially the development of the baby.⁽¹⁸⁾ Early detection of postpartum depression and

Anxiety is essential to prevent adverse maternal and infant outcomes 'Flowchart 1'

➤ Screening tools

- o Edinburgh Postnatal Depression Scale (EPDS) – most widely used, cut-off ≥ 13 suggests PPD

- o Patient Health Questionnaire (PHQ-9) – measures depressive severity.

- o Generalized Anxiety Disorder Scale (GAD-7) – screens postpartum anxiety.⁽¹⁹⁾

➤ Clinical assessment

- o History taking (sleep, appetite, mood, bonding).

- o Physical exam to rule out thyroid disorders, anaemia.

- o Laboratory testing when indicated (TSH, iron studies).⁽²⁰⁾

MANAGEMENT POSTPARTUM DEPRESSION AND ANXIETY

1. Pharmacological approaches

- o SSRIs (e.g., sertraline, fluoxetine) are preferred first-line and are safe with breastfeeding.

- o Risks: side effects, rebound upon discontinuation.⁽²¹⁾

2. Psychotherapeutic approaches

- o Strong support for CBT and IPT.

- o Outcomes are improved by peer support groups and counseling.⁽²²⁾

3. Lifestyle approaches

- o A balanced diet, good sleep and regular routines improve resilience.⁽²³⁾

4. Exercise as treatment for PPD and PPA

Various exercise modalities have been studied for their effects on maternal mental health 'Table 2'

• Physiological mechanisms:

- o Boosts endorphins and serotonin.
- o Balances the HPA axis and lowers cortisol.
- o Systemic irritation is lessened.⁽²⁴⁾

• Psychological mechanisms:

- o Enhances self-esteem image and body.
- o Acts as a way of "getting out of your head," for example having to pay attention elsewhere.
- o Increases sense of control and mastery.

• Social mechanisms:

- o Promotes group bonding in classes
- o Helps combat isolation by encouraging socialization.⁽²⁵⁾

SUPPLEMENTARY TABLE S1: Full Search Strategies (PRISMA)

| Database | Search String |
|----------------|--|
| Pub Med | "Postpartum Depression" or "postnatal depression" and "Postpartum Anxiety" or "Postnatal Anxiety" and "Exercise" or "Physical Activity" and "Maternal Mental Health" |
| Scopus | TITLE-ABS-KEY("postpartum depression" OR "postnatal depression") AND TITLE-ABS-KEY("postpartum anxiety" OR "postnatal anxiety") AND TITLE-ABS-KEY("exercise" OR "physical activity") AND TITLE-ABS-KEY("maternal mental health") |
| Google Scholar | "postpartum depression" OR "postnatal depression" AND "postpartum anxiety" AND ("exercise" OR "physical activity") AND "maternal mental health" |

Table 1: Risk Factors for Postpartum Depression and Anxiety

| Category | Specific Risk Factors | Evidence Strength |
|---------------|---|-------------------|
| Biological | Family history, hormonal fluctuations | High |
| Psychological | Past depression, stressful events | High |
| Social | Marital discord, poor support | Moderate-High |
| Lifestyle | Sedentary behavior, poor nutrition, sleep | Moderate |

Table 2: Exercise Modalities for Postpartum Mental Health

| Exercise Type | Frequency | Benefits for Mental Health |
|---------------------|---------------|---|
| Walking | 5 days/week | Reduces anxiety, improves mood |
| Yoga | 3-4 days/week | Improves mindfulness, sleep, relaxation |
| Resistance Training | 2-3 days/week | Boosts confidence, reduces fatigue |
| Aerobics/Zumba | 2-3 days/week | Increases endorphins, social support |
| Pilates | 2-3 days/week | Core strength, reduces stress |

Table 3: Summary of Evidence on Postnatal Exercise and Maternal Mental Health

| Study Type / Source | Sample / Duration | Intervention | Outcome on Depression | Outcome on Anxiety | Additional Findings |
|------------------------|-------------------|---|---------------------------------|----------------------------|--------------------------------------|
| Clinical Trials (n=29) | 6-12 weeks | Walking, yoga, stretching, aerobics | ↓ 30-40% in depressive symptoms | ↓ Significant reduction | Improved self-esteem, social support |
| Group-Based Studies | 8-10 weeks | Group aerobics, yoga | ↓ Moderate-high | ↓ Stress and anxiety | Reduced loneliness, enhanced bonding |
| Observational Studies | 12 weeks | Mixed physical activity (≥150 min/week) | ↓ 35% depression risk | ↓ 25-30% anxiety | Improved sleep and mood |
| Physiological Studies | Varied | Aerobic & relaxation exercise | ↑ Serotonin, ↓ Cortisol | Improved mood & regulation | Safe for mother and infant |

(↓ = Decrease, ↑ = Increase)

Table 4: Summary of Included Studies on Postnatal Exercise and Maternal Mental Health

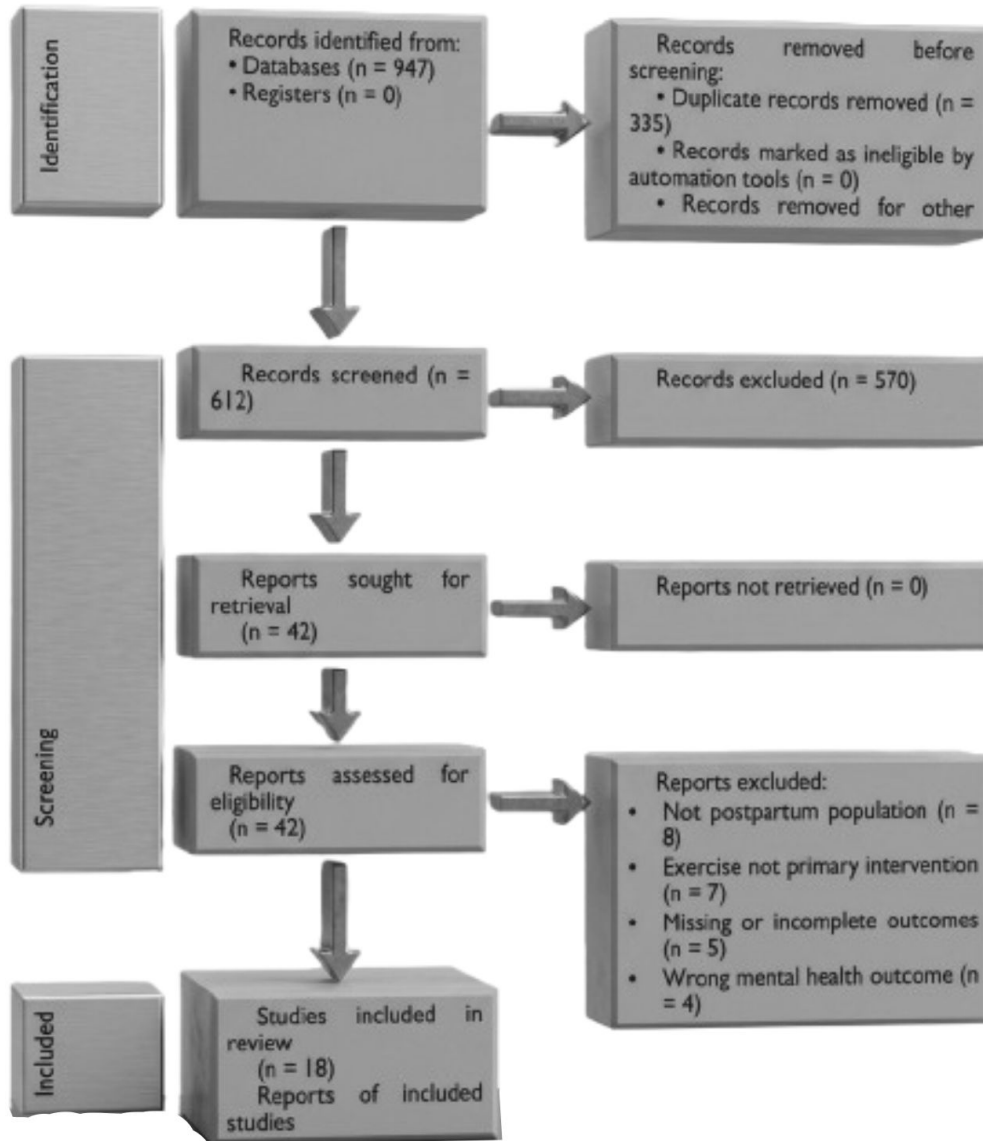
| Study Title (Author, Year) | Methodology | Main Results | Limitations | Reference |
|--|-----------------------------------|--|--|-----------|
| Postpartum Depression: Current Understanding (O'Hara & McCabe, 2003) | Narrative review | Explains biological, psychological, and social factors influencing postpartum depression and highlights how multiple pathways interact to affect maternal mental health. | Descriptive only; no intervention outcomes. | 1 |
| Global Prevalence of Postpartum Depression (Shorey et al., 2018) | Systematic review & meta-analysis | Reports worldwide variation in PPD prevalence and shows that socioeconomic and cultural factors strongly influence screening outcomes. | High heterogeneity; inconsistent EPDS thresholds. | 2 |
| Consequences of Maternal PPD on Women's Health (Slomian et al., 2019) | Narrative review | Describes emotional, physical, and functional consequences of PPD, emphasizing decline in quality of life and daily functioning. | No treatment evaluation; non-experimental. | 3 |
| Paternal Depression & Maternal PPD Risk (Paulson & Bazemore, 2010) | Meta-analysis | Finds strong correlation between paternal depression and maternal PPD, suggesting interconnected mental health patterns in families. | No exercise-related or intervention data. | 4 |
| Partner Support & Maternal Postpartum Depression (Pilkington et al., 2015) | Systematic review | Concludes that higher emotional and practical support from partners reduces depression severity in postpartum women. | Mostly observational studies; limited RCTs. | 5 |
| Prevalence of Paternal Postnatal Depression (Cameron et al., 2016) | Meta-analysis | Provides updated prevalence estimates of paternal PPD and shows how paternal mood may indirectly influence maternal outcomes. | Not centered on mothers; limited exercise relevance. | 6 |
| Interparental Mood Relationship (Goodman, 2004) | Narrative review | Examines psychosocial pathways linking paternal depression with maternal PPD and overall family functioning. | No empirical testing; no interventions. | 7 |

Cont....

| | | | | |
|--|-------------------------|---|---|----|
| Development of EPDS Screening Tool (Cox et al., 1987) | Psychometric study | Validates the EPDS as a reliable and simple screening tool widely used to detect postpartum depression. | Does not study treatment effects. | 8 |
| EPDS Severity Cut-offs (McCabe-Beane et al., 2016) | Psychometric validation | Establishes cut-off ranges for mild, moderate, and severe depression to improve clinical interpretation of EPDS scores. | Limited population diversity. | 9 |
| Risk Factors for Postpartum Depression (Miller, 2002) | Narrative review | Identifies biological, psychological, and social risk factors contributing to PPD, stressing early identification. | No effect-size estimation; no interventions. | 10 |
| Predictors & Prevalence of Perinatal Depression (Gavin et al., 2005) | Systematic review | Highlights strong predictors such as history of depression, low support, and stress, providing clear trends across studies. | Studies vary widely in design and quality. | 11 |
| Perinatal Mental Disorders Overview (Howard et al., 2014) | Narrative review | Summarizes common perinatal mental disorders and stresses early identification for improved outcomes. | No evaluation of intervention effectiveness. | 12 |
| Treatment Approaches for Postpartum Depression (Fitelson et al., 2011) | Review article | Compares medication, therapy, and lifestyle interventions, identifying exercise as a promising supportive approach. | Limited high-quality exercise trials available. | 13 |
| Neurobiological Basis of Paternal Depression (Kim & Swain, 2007) | Narrative review | Explains hormonal and neurobiological pathways contributing to paternal depression and its indirect effect on maternal mental health. | Theoretical; no intervention data. | 14 |
| Family Impact of Maternal Depression (Letourneau et al., 2007) | Review article | Demonstrates how maternal PPD affects infants, partners, and overall family relationships. | Observational evidence only. | 15 |
| Maternal Depression & Child Cognitive Outcomes (Grace et al., 2003) | Systematic review | Shows consistent association between maternal PPD and poorer cognitive development in children. | Observational nature prevents causal conclusions. | 16 |

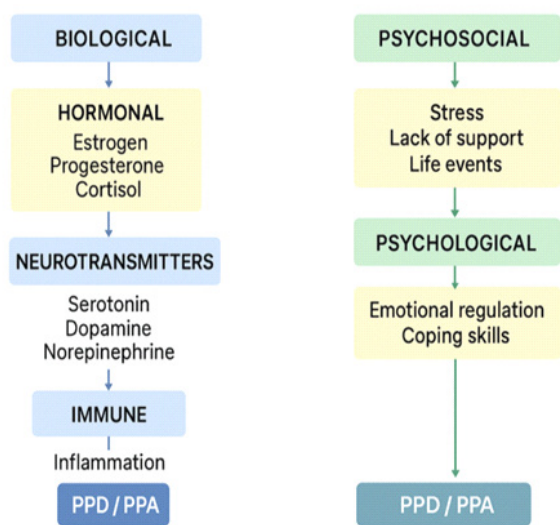
Cont....

| | | | | |
|--|-------------------|--|--|----|
| Maternal Distress & Infant Development (Kingston et al., 2012) | Systematic review | Reports that maternal prenatal and postpartum distress increases risk of emotional and behavioral issues in infants. | Does not explore role of exercise in prevention. | 17 |
| Long-Term Effects of Maternal Depression (Murray et al., 1999) | Narrative review | Highlights how untreated maternal depression negatively affects bonding, behavior regulation, and long-term child development. | Older research; lacks updated clinical trials. | 18 |

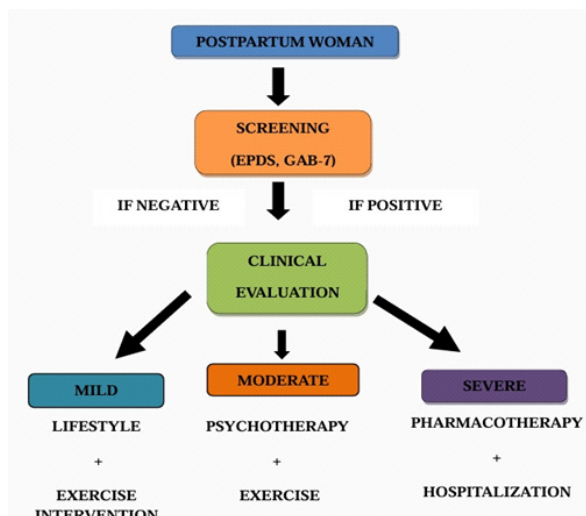


PRISMA flowchart: The records in the boxes are additional papers found.

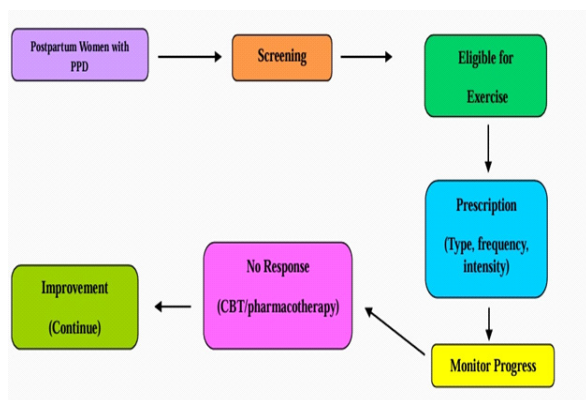
Pathophysiology of Postpartum Depression and Anxiety



‘Fig 1’: biological and psychosocial pathways leading to PPD/PPA.



‘Flowchart 1’ Early Detection of PPD/PPA



‘Flowchart 2’: Exercise Integration into PPD Management

Discussion

Research points to clear links between organized light to moderate physical activity and notable gains in maternal mental health. Activities such as walking, yoga, stretching, and aerobic exercise appear to ease symptoms of depression and anxiety. They also seem to boost self-esteem, better manage stress hormones, and heighten feelings of social support.

Across roughly 29 clinical trials, women who followed regular exercise programs saw marked drops in depressive symptoms compared to those who did not exercise. Engaging in at least 150 minutes of physical activity each week tied to a 30 to 40 percent lower risk of postpartum depression. ⁽²⁶⁾

When it comes to postpartum anxiety, structured programs like group aerobics and yoga led to real reductions in stress and anxiety levels after 6 to 12 weeks. Group settings stood out for extra benefits. They fostered stronger social bonds and cut down on feelings of isolation among mothers.

On the physiological side, exercise seemed to improve serotonin levels and cortisol balance. It also supported better heart and blood vessel function along with deeper, more restorative sleep. Overall, these approaches proved safe and easy to stick with. Dropout rates matched those of standard care. No negative impacts showed up in the infants. ⁽²⁷⁾

As per ‘Table 3’ summarizes the collective evidence from various Meta analysis and clinical studies evaluating postnatal exercise and its role in the management of maternal depression and anxiety

The report illustrates that a workout can really be a healthy mental support for mothers following childbirth. Physical activities can bring down the symptoms of depression and anxiety, bring up one’s physical health and also become the bridge between mother and child. ⁽²⁸⁾

Exercise remains helpful for so many reasons, and one of them is its impact on hormones, another is that it lowers inflammation and also supports the mental adjustment of an individual. Social support, which is one of the biggest reasons why new mothers do not feel lonely during the postpartum period, can be derived from group activities such as yoga and walking clubs.

Yet there are some issues as well. The different kinds and lengths of exerciser make it difficult to compare the outcomes of different studies. ⁽²⁹⁾ Moreover, the largest part of the research has been carried out in affluent areas, and thus the findings may not be applicable to rural or less-resourced communities. Future research should focus on ways of standardizing exercise prescriptions and addressing culture-related differences in exercise.

Future Directions

- o **Integration of technology:** Mobile apps and wearable's to monitor exercise adherence and mood.
- o **Culturally responsive interventions:** Exercise program tailoring to accommodate cultural beliefs and practices.
- o **Have long-term studies:** Long-term effect on the bonding between mother and child
- o **Combined treatments:** Exercise and mindfulness, CBT or with nutritional counselling.(30)

Conclusion

Anxiety and postpartum depression continue to be major global health issues. Mothers are not the only ones affected by these problems; a child's development and family relationships may also be impacted. Exercise is acknowledged as a safe and efficient treatment alternative, even though medicine and therapy are crucial. Whether used alone or in conjunction with other therapy, research supports the use of structured exercise regimens to help with anxiety and postpartum depression. Including exercise in postpartum care can be a crucial step in improving a mother's emotional health and fostering a happier life. Upcoming studies might focus on creating diverse workout programs that respect different cultural traditions and promote sustained involvement. Postpartum exercise is essentially about recovery, empowerment and well-being for mothers, than just physical fitness.

Limitation

Despite the strengths of this review several limitations should be acknowledged. Directly comparing the findings is challenging due to variations in exercise type, intensity, duration and

mental health assessment tools across the included studies. Some studies lacked methodologies featured small sample sizes or did not control for confounding factors such, as breastfeeding, social support and sleep quality. Additionally publication bias might be present since three major databases were searched and grey literature was omitted. Moreover most studies were conducted in settings restricting the relevance of the findings to individuals with fewer resources or, from diverse cultural contexts. These limitations ought to be considered when analyzing the outcomes and planning research.

“Postnatal exercise is a prescription for resilience, recovery, and maternal joy, not just a physical activity.”

Funding: This research received no external funding.

Conflict of Interest: The authors declare no conflict of interest.

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The Rising Burden of Non-Communicable Diseases: Global and Indian Trends, Risk Factors, and Socioeconomic Implications

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How to cite this article: Mohd Yasir Zubair, Danish Kamal, Ragul Jayaprakasam Sathiyamoorthy et. al. The Rising Burden of Non-Communicable Diseases: Global and Indian Trends, Risk Factors, and Socioeconomic Implications. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Non-communicable diseases (NCDs) have emerged as a significant global health challenge, particularly in low and middle-income countries. This review examines the rising burden of NCDs, focusing on global and Indian trends, risk factors, and socioeconomic implications. NCDs, including cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes, accounted for 74% of global deaths in 2019, up from 56.75% in 1990. In India, NCD-related deaths increased from 35.87% to 64.93% during the same period. Key risk factors include tobacco use, physical inactivity, unhealthy diet, and alcohol consumption, alongside metabolic factors such as hypertension and obesity. The economic impact is substantial, with NCDs projected to cost the global economy over US\$30 trillion between 2011-2030. The burden of NCDs, measured in disability-adjusted life years (DALYs), has also risen significantly. This review underscores the urgent need for comprehensive prevention and control strategies, emphasizing the importance of multi-sectoral approaches and primary healthcare interventions to address this growing epidemic.

Keywords: Non-communicable diseases, Global health burden, Risk factors, Socioeconomic impact, Prevention strategies

Introduction

Noncommunicable diseases (NCDs) are chronic or long term diseases comprising a large group of illnesses that includes diabetes, hypertension, chronic respiratory illnesses (asthma, COPD), cancers, and cardiovascular diseases such as stroke. These health conditions are characterized by their gradual onset

and extended course. With increasing prevalence over the past few decades, these diseases have become a significant global health concern, contributing to a considerable burden of morbidity, mortality, and costs of healthcare.¹

NCDs cause considerable loss in potentially productive years of life. Losses due to premature

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Submission date: October 8, 2025

Revision date: November 21, 2025

Published date: April 14, 2026

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deaths attributable to heart diseases, stroke and diabetes are also projected to increase over the years. Non-communicable diseases (NCDs), including heart disease, stroke, diabetes and chronic lung disease, cancer,, are collectively responsible for 41 million deaths each year, which is equivalent to 74% of all deaths globally. More than three-quarters of NCD deaths, and 86% of the around 17 million people who died prematurely, or before reaching the age 70 years, occur in low- and middle-income countries.² Cardiovascular diseases account for most of the NCD deaths (17.9 million people annually), followed by cancers (9.3 million), chronic respiratory diseases (4.1 million), and diabetes (2.0 million including kidney disease deaths due to diabetes). These four groups of diseases are responsible for over 80% of all premature NCD deaths.³ In India, Noncommunicable diseases (NCDs) contribute to around 5.87 million deaths that account for 60 % of all deaths in India. India shares more than two-third of the total deaths due to NCDs in the South-East Asia Region (SEAR) of WHO, of which cardiovascular diseases (coronary heart disease, stroke, and hypertension) contribute to 45% of all NCD deaths in India followed by chronic respiratory disease (22 %), cancers (12 %) and diabetes (3%). The global burden of NCDs is expected to rise further with increases in the global population (especially the older population) and demographic shifts.⁴

Need and Purpose of this review

Despite the well-documented rise in non-communicable diseases globally, there remains a critical need for comprehensive reviews that synthesize trends across multiple dimensions—mortality patterns, risk factor trajectories, economic implications, and disability burden, particularly with comparative analysis between global patterns and country-specific contexts. While individual studies have examined isolated aspects of NCDs, a holistic understanding of how these diseases are reshaping health landscapes in both developed and developing nations is essential for informed policy-making and resource allocation.

India, as the world's most populous nation undergoing rapid demographic and epidemiological transition, presents a unique case study for understanding NCD dynamics in low- and middle-

income countries. Understanding the divergent trajectories of behavioral versus metabolic risk factors in the Indian context can provide valuable insights for other nations experiencing similar transitions.

The purpose of this review is threefold. First, it aims to provide a comprehensive overview of global and Indian NCD trends from 1990 to 2019, using data from the Global Burden of Disease Study to establish the magnitude of the problem. Second, it examines the evolution of major risk factors—both behavioral and metabolic—to identify areas where interventions have succeeded and where challenges persist. Third, it analyzes the socioeconomic implications of NCDs, including their impact on healthcare systems, household finances, productivity, and sustainable development goals, to underscore the urgency of comprehensive prevention and control strategies.

By synthesizing data from multiple national surveys, global burden of disease estimates, and economic analyses, this review seeks to inform evidence-based policy development and guide resource allocation for NCD prevention and control. Understanding these trends is crucial for achieving the Sustainable Development Goal target of reducing premature NCD mortality by one-third by 2030, particularly in resource-constrained settings where the burden is growing most rapidly.

Global Trends

Globally, NCDs accounted for 56.75% of all deaths in the year 1990 which increased to 74.37% in the year 2019. In men, NCDs accounted for 55.64% of all deaths in the year 1990 which increased to 73.01% in the year 2019. In women, NCDs accounted for 58.04% of all deaths in the year 1990 which increased to 75.98% in the year 2019.⁵

Trends in LMICs

The prevalence of non-communicable diseases (NCDs) in the low and middle-income countries (LMICs) such as India has been growing constantly over the past few decades, posing a major threat to people, their families, and communities while also hindering the potential achievement of sustainable development goals. Furthermore, high rates of NCDs in low and middle income countries pushes more people into poverty, inhibit economic development,

and weakens fragile health system making these countries less resilient in the face of emergencies such infectious disease outbreaks or natural disasters.⁶ According to the Global Burden of Disease (GBD) Study, NCDs accounted for 56.8% of total deaths in LMICs in 1990, and it increased to 74.4% in 2019. The disability-adjusted life years (DALYs) attributed to NCDs in LMICs increased from 37.8% to 66.0% during the same period.⁵

India

In India, NCDs accounted for 35.87% (2.9 million deaths) of all deaths in the year 1990 which increased to 64.93% (6.1 million deaths) in the year 2019. In men, NCDs accounted for 39.33% of all deaths in the year 1990 which increased to 66.04% in the year 2019. In women, NCDs accounted for 31.95% of all deaths in the year 1990 which increased to 63.60% in the year 2019.⁵

NCD RISK FACTORS

Most NCDs are the result of four particular behaviours- tobacco use, physical inactivity, unhealthy diet, and the harmful use of alcohol. These behaviours lead to four key metabolic/physiological changes- raised blood pressure, overweight/obesity, raised blood glucose and raised cholesterol. The risk factors are described under the following headings:

Modifiable behavioural risk factors

Modifiable behaviours, such as tobacco use, lack physical activity, unhealthy diet and the harmful use of alcohol, all increase the risk of NCDs.⁷

- Tobacco leads to over 8 million deaths every year (including exposure to second-hand smoke).
- 1.8 million annual deaths may be attributed to excess salt or sodium intake.
- Of the 3 million annual deaths attributable to alcohol use, more than half are from NCDs, including cancer.
- 8,30,000 deaths each year is attributable to insufficient physical activity.

NCD Risk Factors: Global Trend

Figure 1 shows trend of contribution of modifiable risk factors towards NCD deaths globally.

1. Use of tobacco

In the year 1990 use tobacco contributed to 22.34% of NCD deaths. This has shown slightly decreasing trend over the years and in the year 2019 tobacco use accounted for 19.19% of NCD deaths.⁵

2. Physical Inactivity

In this modern era, physical activity is acknowledged as a vital strategy to promote good health. According to the WHO, regular physical activity has various benefits for psycho-physical health. The risk of many chronic diseases such as cancer, cardiovascular condition, and diabetes (type 2) reduce through regular physical activity.⁸ The contribution of insufficient physical activity towards NCD deaths has remained relatively constant over the years (Figure 3). It accounted for 1.71% NCD deaths in the year 1990, which increased marginally to 1.89% in the year 2010 and to 1.98% in the year 2019.⁵

3. Harmful use of Alcohol

The role of alcohol (and in particularly heavy alcohol use and having an alcohol abuse disorder) in NCDs is being given increasing recognition. Alcohol was mentioned along with use of tobacco, diet and lack of exercise, as one of four major common risk factors for NCD in the recent status report of the World Health Organization as well as by the Lancet NCD action group.^{9,10} It has also been discussed at the recent NGO conference in Melbourne on health and the Millenium Development Goals (MDGs) during a session on NCDs where along with tobacco, diet and lack of exercise, alcohol was recognised as one of four major common risk factors.³ In terms of NCDs, alcohol has been particularly linked to cancer, cardiovascular diseases and liver disease. Preliminary estimates on the impact of alcohol on these diseases support the inclusion of alcohol consumption as one of four major risk factors globally.¹¹

Figure 2 shows that the contribution of Alcohol to global NCD deaths has stayed at a little over 4% for the last three decades.

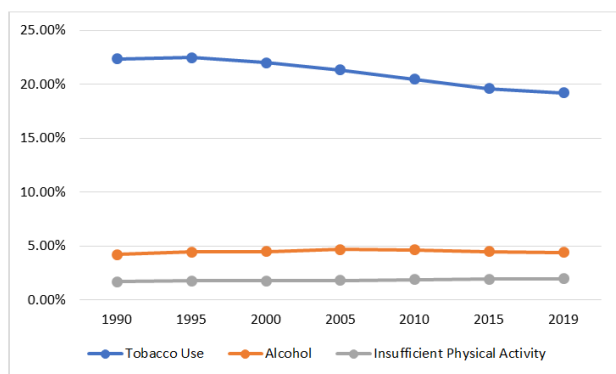


Figure 1: Contribution of Major Behavioural Risk Factors towards NCD Deaths (%) globally⁵

Metabolic risk factors

Metabolic risk factors contribute to four key metabolic changes that increase the risk of NCDs:

- raised blood pressure;
- overweight/obesity;
- hyperglycemia (high blood glucose levels); and
- hyperlipidemia (high levels of fat in the blood).

In terms of attributable deaths, globally the leading metabolic risk factor is raised blood pressure to which 19% of global deaths are attributed followed by uncontrolled blood glucose and overweight and obesity.⁷ Figure 2 shows trends of contribution of these risk factors towards NCD deaths in the past 3 decades from the global burden of disease study (2019). In the year 2019 Hypertension is the major contributor towards NCD deaths globally followed by diabetes and dislipidemia.⁵

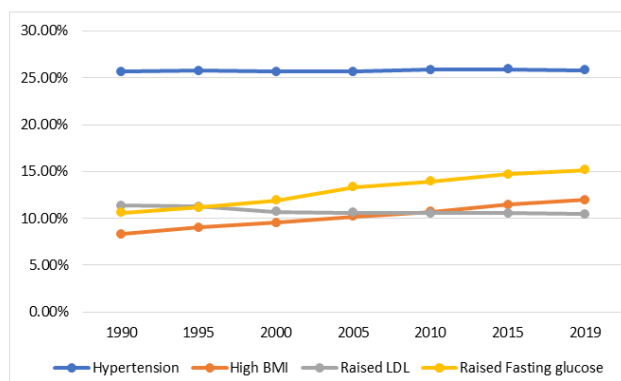


Figure 2: Contribution of Metabolic Risk Factors towards NCD Deaths (%) globally

Trends Of NCD Risk Factors In India

Behavioural risk factors

Amongst males in India, the prevalence of any form of tobacco use was 28.30% during 1998-99 as per National Family Health Survey 2 (NFHS 2) report.¹² It increased to 57% during 2005-06 (NFHS 3 report)¹³ and has been on decline since then as reported in subsequent NFHS reports (Figure 3).^{14,15} Similar trend is observed for alcohol consumption amongst males (Figure 5).

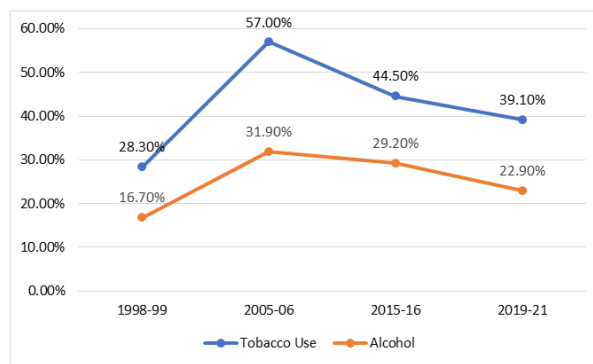


Figure 3: Trend of Behavioural NCD risk factors amongst Males in India¹²⁻¹⁵

In females, however, not only is the prevalence of these two risk factors much lower, it is also showing a continuous decline over last two decades (Figure 4).

With regards to physical activity, more than half of the urban Indians undertake insufficient physical activities, making them vulnerable to diabetes, hypertension and other non-communicable diseases, according to one of India’s largest studies in this area.¹⁶

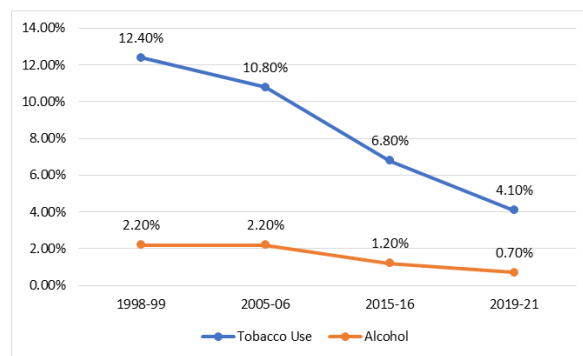


Figure 4: Trend of Behavioural NCD risk factors amongst Females in India¹²⁻¹⁵

Metabolic risk factors

Hypertension

Between 2015-16 to 2019-21, the prevalence of Hypertension amongst men in India increased from 14.8% to 24% whilst in women it rose from 11% to 21% (NFHS 4 and NFHS 5).^{14,15}

Raised Blood Glucose

The prevalence of raised random blood glucose amongst men and women in India was found to be 8% and 5.8% in the year 2015-16 (NFHS 4).¹⁴ It increased to 14.4% in men and 12.4% in women in the year 2019-21 (NFHS 5).¹⁵

Body Mass Index

The prevalence of overweight men (BMI 25.0-29.9) was 18.9% in the year 2015-16 which rose to 18.9% in the year 2019-21. The prevalence of obesity (BMI \geq 30.0) amongst men increased from 3.0% in 2015-16 to 4.0% in 2019-21. The prevalence of overweight women (BMI 25.0-29.9) was 15.5% in the year 2015-16 which rose to 17.6% in the year 2019-21. The prevalence of obesity (BMI \geq 30.0) amongst women increased from 5.1% in 2015-16 to 6.4% in 2019-21.¹²⁻¹⁵

Environmental risk factors

Several environmental risk factors contribute to NCDs. Air pollution is the largest of these, accounting for 6.7 million deaths globally, of which about 5.7 million are due to NCDs, including stroke, ischaemic heart disease, chronic obstructive pulmonary disease, and lung cancer.

SOCIO-ECONOMIC IMPACT

NCDs threaten progress towards the 2030 Agenda for Sustainable Development, which includes a target of reducing the probability of death from any of the four main NCDs between ages 30 and 70 years by one third by 2030.

Poverty is closely linked with NCDs. The rapid rise in NCDs is predicted to impede poverty reduction initiatives in low-income countries, particularly by increasing household costs associated with health care. Vulnerable and socially disadvantaged people get sicker and die sooner than people of higher social positions, especially because they are at greater

risk of being exposed to harmful products, such as tobacco, or unhealthy dietary practices, and have limited access to health services.

In low-resource settings, health-care costs for NCDs quickly drain household resources. The exorbitant costs of NCDs, including treatment, which is often lengthy and expensive, combined with loss of income, force millions of people into poverty annually and stifle development.

The socio-economic costs associated with NCDs make the prevention and control of these diseases a major development imperative for the 21st century. In the year 2011, the global economic burden of NCD study also reported that NCDs are likely to cause around US\$47 trillion in output loss within the next two decades.¹⁷ NCDs plausibly reduce the supply of efficient labour and productivity. As the mental and physical capacity of the worker deteriorates due to NCD morbidity, the level of productivity, efficient use of technology and machinery diminishes.¹⁸

Over the period 2011-2030, NCDs will cost the global economy more than US\$ 30 trillion, representing 48% of global GDP in 2010, and pushing millions of people below the poverty line. Mental health conditions alone will account for the loss of an additional US\$ 16.1 trillion over this time span, with dramatic impact on productivity and quality of life (World Economic Forum and Harvard, 2011).¹⁹

The Disability-Adjusted Life-Year (DALY)

The Disability-Adjusted Life-Year (DALY) is a metric that combines the burden of mortality and morbidity (non-fatal health problems) into a single number. It captures years of years life lost due to prematurity and years of life lived with disability. The DALY metric is used to provide a *single number* to capture *all* of the health costs caused by a disease.

GLOBAL

The increase in disability-adjusted life years (DALYs) attributed to NCDs was from 43.16% in the year 1990 to 63.82% in the year 2019. During the same period the disability-adjusted life years (DALYs) attributed to NCDs in men increased from 41.73% to 61.54% while in women it increased from 44.76% to 66.39%.⁵

INDIA

The disability-adjusted life years (DALYs) attributed to NCDs increased from 29.17% in 1990 to 57.92% in 2019. During the same period (from 1990 to 2019) the disability-adjusted life years (DALYs) attributed to NCDs in men increased from 30.34% to 57.32% while in women it increased from 27.96% to 58.52%.⁵

PREVENTION AND CONTROL

An important way to control NCDs is to focus on reducing the risk factors associated with these diseases. Low-cost solutions exist for governments and other stakeholders to reduce the common modifiable risk factors. Monitoring progress and trends of NCDs and their risk is important for guiding policy and priorities.

To lessen the impact of NCDs on individuals and society, a comprehensive approach is needed requiring all sectors, including health, finance, transport, education, agriculture, planning and others, to collaborate to reduce the risks associated with NCDs, and to promote interventions to prevent and control them.

Investing in better management of NCDs is critical. Management of NCDs includes detecting, screening and treating these diseases, and providing access to palliative care for people in need. High impact essential NCD interventions can be delivered through a primary health care approach to strengthen early detection and timely treatment. Evidence shows such interventions are excellent economic investments because, if provided early to patients, they can reduce the need for more expensive treatment. Countries with inadequate health care coverage are unlikely to provide universal access to essential NCD interventions. NCD management interventions are essential for achieving the SDG (Sustainable Development Goals) target on NCDs.

The 2030 Agenda for Sustainable Development recognizes NCDs as a major challenge for sustainable development. Specifically, target 3.4 of the Sustainable Development Goals calls for a one-third reduction in premature mortality from noncommunicable diseases by 2030 through the prevention and treatment of these diseases and the promotion of mental health and

well-being. The economic burden of NCDs threatens the achievement of other SDGs, particularly reducing poverty, inequalities, and hunger, as well as access to quality education and gender equality.¹⁹

Discussion

The increasing burden of non-communicable diseases (NCDs) represents one of the most significant global health challenges of the 21st century. The data presented in this review illustrates a concerning shift in disease patterns, with NCDs now accounting for nearly three-quarters of global mortality. This epidemiological transition is particularly pronounced in low- and middle-income countries (LMICs), including India, where the proportion of deaths attributed to NCDs has increased dramatically from 35.87% in 1990 to 64.93% in 2019.

The increasing prevalence of NCDs in India presents a complex public health challenge characterized by contrasting trends in risk factors. While behavioral risk factors such as tobacco use and alcohol consumption among males have shown a declining trend since 2005-06, metabolic risk factors including hypertension, raised blood glucose, and obesity have increased substantially. This divergence suggests that while public health initiatives targeting tobacco and alcohol may have achieved some success, interventions addressing diet, physical activity, and metabolic risk factors require significant strengthening.

The rapid urbanization and socioeconomic development in India may partially explain these trends. Urban environments often promote sedentary lifestyles, increased consumption of processed foods high in salt, sugar, and unhealthy fats, and reduced physical activity. The finding that more than half of urban Indians undertake insufficient physical activity underscores this challenge. Furthermore, the transition away from traditional dietary patterns toward westernized diets has likely contributed to the rising prevalence of obesity and related metabolic disorders.

The gender differences observed in both behavioral and metabolic risk factors merit special attention. While women show lower prevalence of tobacco use and alcohol consumption, the

increasing rates of obesity among women (5.1% in 2015-16 to 6.4% in 2019-21) highlight the need for gender-sensitive approaches to NCD prevention and control. Socio-cultural factors influencing physical activity, dietary choices, and healthcare access for women must be considered in policy development.

The economic implications of NCDs extend beyond healthcare costs to include reduced productivity, increased household expenditure, and lost economic opportunities. The projection that NCDs will cost the global economy more than US\$ 30 trillion over the period 2011-2030 highlights the macroeconomic significance of these diseases. For India, with its large working-age population and aspirations for continued economic growth, addressing NCDs is not merely a health imperative but an economic necessity.

The substantial increase in disability-adjusted life years (DALYs) attributed to NCDs in India, from 29.17% in 1990 to 57.92% in 2019, reflects the growing impact of these conditions on quality of life and productivity. This trend is particularly concerning for a country with a relatively young population, as premature morbidity and mortality from NCDs can significantly undermine demographic dividend opportunities.

Prevention and control strategies for NCDs must be multifaceted and integrated into existing health systems. The primary healthcare approach suggested in this article offers a cost-effective strategy for early detection and management of NCDs. However, successful implementation requires addressing systemic challenges including healthcare financing, workforce capacity, access to essential medicines, and robust surveillance systems.

The interrelationship between NCDs and sustainable development deserves greater emphasis. The bidirectional relationship between poverty and NCDs creates a vicious cycle that can trap individuals and communities in economic hardship. Conversely, addressing NCDs can contribute to poverty reduction, economic growth, and social development, supporting multiple Sustainable Development Goals beyond health-specific targets.

Conclusion

The rising burden of non-communicable diseases represents a critical challenge for global public health, particularly for low- and middle-income countries like India. The substantial increase in NCD-related mortality and morbidity, coupled with divergent trends in risk factors, necessitates urgent action across multiple sectors. While behavioral risk factors show promising declines, the alarming rise in metabolic risk factors demands targeted interventions addressing urbanization, dietary transitions, and physical inactivity patterns.

Addressing NCDs requires integration of prevention and control measures into primary healthcare systems, supported by sustainable financing and trained healthcare workers. The economic burden of these diseases underscores that investments in NCD prevention are not merely expenditures but essential contributions to human capital development and economic resilience. Only through coordinated, multi-sectoral approaches can countries achieve the Sustainable Development Goal of reducing premature NCD mortality while simultaneously promoting economic prosperity and social well-being.

The findings of this review carry critical implications for public health professionals at all levels. The divergent trends between declining behavioral risk factors and rising metabolic risk factors indicate that while tobacco and alcohol control policies have achieved partial success, urgent strengthening of interventions addressing obesogenic environments, physical inactivity, and unhealthy diets is essential. Public health professionals must advocate for multi-sectoral NCD policies that extend beyond healthcare to include urban planning, education, and agriculture sectors. Priority actions include strengthening primary healthcare systems for early detection and management through systematic screening programs, health workforce training, and ensuring access to essential medicines. The multifaceted nature of NCDs demands that public health professionals function as conveners, advocates, implementers, and evaluators, translating the evidence from this review into comprehensive strategies that reduce the NCD burden while contributing to broader sustainable development goals through immediate, sustained, and coordinated action across all health system levels.

Source(s) of support (Funding): Nil

Conflicting Interest: None.

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A Comprehensive Review: Risk factors, Pathogenesis, Diagnosis and Management of Mucormycosis

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How to cite this article: Nidhi Joshi, Dimpy Trivedi, Jayesh Beladiya, Anita Mehta. A Comprehensive Review: Risk factors, Pathogenesis, Diagnosis and Management of Mucormycosis. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Mucormycosis, also known as black fungus, is a rare yet aggressive opportunistic fungal infection primarily caused by molds of the order *Mucorales*. It predominantly affects immunocompromised individuals, including those with uncontrolled diabetes, malignancies, organ transplants, or prolonged corticosteroid use. The COVID-19 pandemic further escalated mucormycosis incidence, particularly in countries like India, due to widespread steroid use and immune suppression. The pathogenesis involves spore inhalation or inoculation, followed by rapid hyphal growth, angioinvasion, tissue necrosis, and dissemination to organs such as the brain and lungs. Diagnosis relies on clinical suspicion supported by imaging, histopathology, culture, and molecular techniques. Radiological modalities like CT and MRI play crucial roles in early detection and surgical planning. Prompt and aggressive treatment combining antifungal therapy mainly liposomal amphotericin B or posaconazole and surgical debridement is vital for improving outcomes.

Conclusion: Despite advancements, mucormycosis remains associated with high morbidity and mortality, necessitating heightened awareness, early intervention, and risk factor control. This review consolidates current insights into the epidemiology, risk factors, pathogenesis, diagnostic strategies, and treatment modalities of mucormycosis, emphasizing the need for multidisciplinary management to mitigate its severe consequences.

Keywords: mucormycosis, COVID19, risk factors, pathogenesis, diagnosis, management.

Introduction

Mucormycosis, also known as black fungus, is a rare but aggressive fungal infection caused by molds from the *Mucorales* order. It primarily affects immunocompromised individuals, such as those with

uncontrolled diabetes, cancer, organ transplants, or prolonged steroid use. The infection typically invades the sinuses, lungs, and brain but can also affect other organs [1]. Understanding the complex nature of this disease is essential for accurate diagnosis and effective management. Therefore, this review

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Submission date: September 18, 2025

Revision date: Nov 21, 2025

Published date: April 14, 2026

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provides the information on the epidemiology, risk factors, pathogenesis, diagnosis and management of the mucormycosis.

Epidemiology of Mucormycosis:

Mucormycosis is a globally distributed fungal infection, though its prevalence is higher in regions like India and Southeast Asia due to the large number of patients with uncontrolled diabetes. The incidence of the disease has surged in recent years, particularly during the COVID-19 pandemic, as many immunocompromised patients, especially those with diabetes or treated with steroids, became more susceptible. India has the highest recorded incidence of mucormycosis worldwide, approximately 70 times more than any other country^[2]. As per Centers for Disease control and prevention 2022, fungal infections associated with COVID-19 caused serious disease or even death with mortality rates ranging from 40% to 80%, depending on severity and course of treatment. The overall hospital-mortality rate remains higher (48.5%) during the COVID-19 time as compared to non-COVID19 time, depending on the severity of the infection and timely treatment^[3,4]. As per the study conducted in June 2021, 55 patients (52.7%) with COVID-19 associated mucormycosis developed the symptoms of infection within 15 to 30 days of developing COVID-19 symptoms^[5] Patients with widespread mucormycosis had the highest case fatality rate (68%) while patients with cutaneous disease had the lowest case fatality rate (31%)^[2]. Before the COVID-19 pandemic, a computer model estimated an annual average of 171,504 cases (95% CI: 147,688–195,777) and 65,500 deaths in India, resulting in a mortality rate of 38.2%^[6]

Risk Factors of Mucormycosis:

Mucormycosis primarily affects individuals with weakened immune systems or underlying health conditions. Several risk factors predispose people to mucormycosis, making them more vulnerable to this opportunistic infection.

a) Diabetes Mellitus:

One of the most significant risk factors for mucormycosis is uncontrolled diabetes mellitus, particularly individuals developing diabetic ketoacidosis. High blood sugar levels create

an environment conducive to fungal growth. Additionally, in diabetic ketoacidosis, increased iron availability, due to low pH levels, further promotes the growth of Mucorales fungi. These conditions compromise the body's ability to fight off infections, allowing the fungus to invade tissues^[7].

b) Immunosuppression:

Patients with compromised immune systems are at high risk for mucormycosis. This group includes individuals undergoing chemotherapy for cancer, organ transplant recipients on immunosuppressive therapy, and those with haematological malignancies. The body's reduced capacity to fight infections allows Mucorales fungi to thrive and spread quickly^[8-12]

c) Corticosteroid Use:

The use of corticosteroids, commonly prescribed to manage conditions like autoimmune diseases, COVID-19, and chronic inflammatory conditions, can increase the risk of mucormycosis. Steroids suppress the immune response and elevate blood sugar levels, creating an ideal environment for fungal infections.^[8-12]

d) Prolonged Neutropenia:

Neutropenia, a condition characterized by an abnormally low number of neutrophils (a type of white blood cell), is another important risk factor. Patients undergoing treatments such as chemotherapy or bone marrow transplants are prone to neutropenia, which weakens their immune system and increases their vulnerability to fungal infections, including mucormycosis^[8-13].

e) Trauma and Burns:

Invasive mucormycosis can develop in individuals who have suffered severe trauma, such as from burns, surgery, or accidents. The fungi can enter the body through broken skin or wounds, leading to localized or disseminated infection^[8-11]

f) Iron Overload and Chelation Therapy:

Excessive iron in the body, whether due to underlying medical conditions or iron

supplementation, also heightens the risk of mucormycosis. The fungi thrive in iron-rich environments, and patients undergoing iron chelation therapy with deferoxamine are particularly susceptible because the drug acts as a siderophore, effectively feeding the fungi^[8-12].

g) Malnutrition and Poor Hygiene:

Malnourished individuals and those living in unsanitary conditions are at greater risk for mucormycosis. Poor nutrition weakens the immune system, while unhygienic environments increase the likelihood of exposure to fungal spores^[8-12].

h) COVID-19:

COVID-19 has emerged as a significant risk factor for mucormycosis, especially in patients with severe illness or pre-existing conditions like diabetes. The use of corticosteroids in managing severe COVID-19 cases can suppress the immune system and raise blood sugar levels, creating an environment favorable for fungal infections. Additionally, prolonged hospitalization, oxygen therapy, and the overall immune dysregulation caused by COVID-19 can further increase susceptibility. In a study, Kumar et al. 2021 described the ratio of infected mucormycosis (Fig. 1). Other contributing factors like renal disease, older age, secondary infections, poor hygiene, weather, crowding, poverty, as well as co-infection with other diseases, infected ICU interventions, administrations of immunosuppressants, impaired phagocytosis, viral mutations and its new variants, damage to nasal ciliated cells and lung destruction also increase the chance of mucormycosis infection in COVID-19 patients ^[14,15].

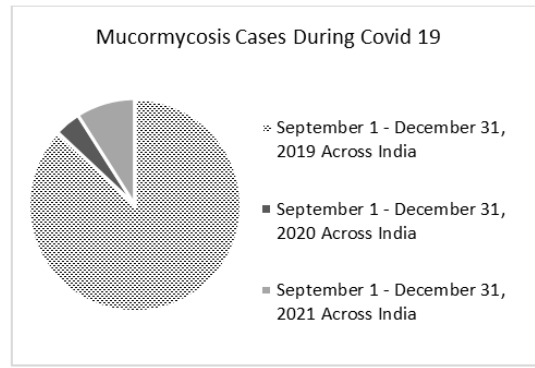
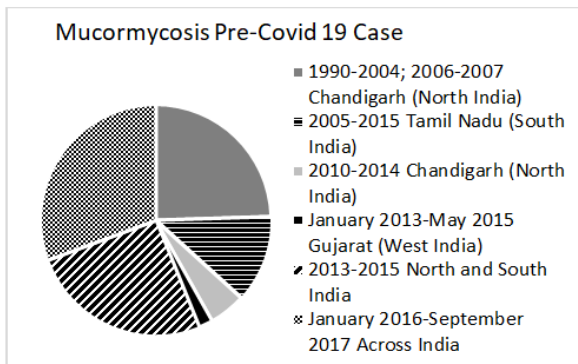


Figure-1: Summary of mucormycosis cases pre- and during COVID19.

Post Covid Scenario:

Mucormycosis has also emerged as a post covid sequelae due to factors like immune dysregulation, steroid use, elevated ferritin levels, and zinc supplementation, particularly in patients with diabetes. Immune dysregulation including a rise in systemic inflammatory markers (including CRP, IL- 6) along with decreased adaptive immune responses is considered a key factor for causing mucormycosis as a secondary infection in recovered COVID-19 patients^[16]. Diabetes Mellitus is the most common predisposing condition for post-COVID-19 mucormycosis as observed in multiple case studies and retrospective analysis^[17]. In a case series presented by Divit et al, in June 2021, Diabetes Mellitus along with other risk factors predispose patients to increased inflammation leading to long COVID phase defined as increased inflammation for more than 3 months after COVID-19. While it is emphasized that immunosuppression and glucocorticoid use in such patients promote growth of fungus leading to mucormycosis, cases have also reported in young population in absence of such risk factors^[18]. Therefore, vigilant monitoring and regular follow-ups are essential for high-risk patients after COVID-19 recovery^[19,20]. Patients must be advised to report any symptoms related to the eyes, nose, face, lungs, and skin and immediate medical attention should be received to avoid further complications^[17].

Pathogenesis:

The pathogenesis of mucormycosis involves several stages, beginning with the inhalation or inoculation of fungal spores, followed by rapid invasion of host tissues, blood vessel involvement, and extensive tissue necrosis.

Fungal Entry:

The most common route of mucormycosis infection is through the inhalation of fungal spores, which are ubiquitous in the environment and found in soil, decaying organic matter, and air. The respiratory tract, particularly the nasal passages and sinuses, is the primary entry point. The spores can also enter through cutaneous wounds, trauma, or through ingestion, leading to gastrointestinal mucormycosis, although this is less common. To avoid phagocytosis by macrophages, *Rhizopus* species can transform into hyphae and bind to endothelial cells through specific receptors. One key receptor on the fungal surface is CotH (spore-coating protein family), which interacts with GRP78 (glucose-regulated protein 78) on the endothelium. This binding triggers endocytosis, allowing the fungus to enter the bloodstream, spread via hematogenous routes, cause systemic infection, and invade multiple organs [21].

Host Susceptibility:

Mucormycosis spores when inhaled by healthy individuals, they are usually eliminated without developing an infection. However, these spores survive and proliferate due to weakened immune defences of body in case of immunocompromised individuals.

Clinical and laboratory evidence strongly indicate that individuals with either a deficiency or dysfunction of phagocytic cells are more susceptible to mucormycosis. Notably, patients experiencing severe neutropenia exhibit a heightened risk of developing this fungal infection. In contrast, individuals with AIDS do not appear to share this increased vulnerability, suggesting that neutrophils rather than T lymphocytes play a central role in controlling the growth of fungal spores [22]. In healthy individuals, both mononuclear and polymorphonuclear phagocytes combat Mucorales by producing reactive oxygen species and antimicrobial peptides such as defensins. However, under conditions commonly seen in diabetic ketoacidosis, such as high blood glucose levels and acidic pH, phagocyte function is significantly impaired. This leads to defective chemotaxis and a reduction in both oxidative and non-oxidative killing capabilities. [23].

Fungal Germination and Hyphal Growth:

Once inside the body, the spores germinate into hyphae, the filamentous structure that penetrate host tissues causing invasion and disrupting normal cellular function. Hyphal growth is the key factor in the pathogenesis of mucormycosis. The fungi prefer an iron-rich environment, which is commonly seen in individuals with diabetic ketoacidosis due to increased serum-free iron. In *Mucor* species, anaerobic conditions and presence of fermentable sugars promote yeast-like growth, whereas oxygen limitation and nutrient scarcity favor hyphal development. The hyphae proliferate, spreading through tissues and infiltrating blood vessels [24,25].

Angioinvasion:

A hallmark of mucormycosis is its tendency for angioinvasion—hyphae penetrate and invade blood vessels. This vascular invasion is a critical aspect of the disease's pathogenesis, as it leads to thrombosis and ischemia. The fungi spread rapidly via blood vessels, causing extensive damage to local tissues. This process is particularly dangerous because it limits the delivery of antifungal drugs and immune cells to the infected area, exacerbating the infection [26].

Tissue Necrosis:

As the hyphae invade blood vessels, the resultant ischemia causes widespread necrosis of the surrounding tissues. This necrotic tissue becomes a fertile ground for fungal growth, allowing the infection to spread further. In rhinocerebral mucormycosis, for example, the infection starts in the nasal passages and sinuses, leading to facial swelling, black necrotic lesions, and potential invasion into the brain. The necrosis is visible as black, dead tissue, which is one of the distinctive signs of mucormycosis, often referred to as "black fungus" [27].

Dissemination:

In severe cases, mucormycosis can become disseminated, spreading to distant organs such as the lungs, brain, and gastrointestinal tract. Pulmonary mucormycosis occurs when the spores reach the lungs, causing pneumonia-like symptoms and often leading to respiratory failure if untreated. When the infection spreads to the brain, it can cause life-threatening complications such as brain abscesses, seizures, or

even coma. Blood vessel invasion by fungal hyphae results in endothelial destruction, blood clots that block the blood arteries, and eventually ischemia and necrosis of surrounding tissues [28,29].

Immune Response:

In mucormycosis, the immune system's ability to respond is critical. Mucorales weaken the immune system by changing the structure of host cells to create huge cell aggregates or clusters or lengthy hyphae that are resistant to leukocyte phagocytosis because they burst from macrophages. Neutrophils play a central role in controlling fungal infections by phagocytosing the spores and hyphae. However, in immunocompromised individuals or those with neutropenia, the neutrophils are either dysfunctional or present in inadequate numbers, allowing the

infection to spread uncontrollably [30].

Host Damage:

The combination of direct tissue invasion by fungal hyphae, angioinvasion, and immune system impairment leads to significant host tissue damage. *Rhizopus oryzae* exists as sporangioophores, which transform into coenocytic hyphae within the host cell. A small number of transformation fungus produce networked hyphae (mycelium) that facilitate the passing on of nutrients and consequently encourage growth [31,32]. The aggressive nature of mucormycosis can result in rapid deterioration of the patient's condition, requiring urgent medical intervention including antifungal therapy and surgical debridement of necrotic tissue.

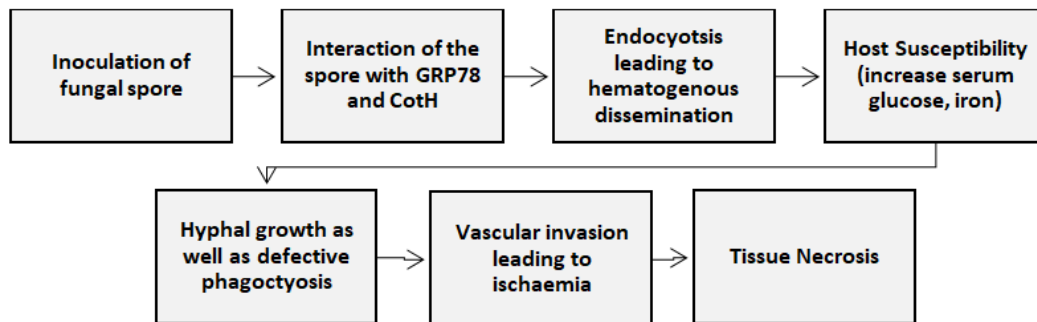


Figure-2: Pathogenesis of mucormycosis.

Types of Mucormycosis:

a) Pulmonary Mucormycosis:

An unusual fungal infection called pulmonary mucormycosis which most commonly observed in persons with impaired immune systems. It generally occurs by inhalation of spores of fungi. Non-productive cough and persistent fever is a common symptom however clinical diagnosis is difficult [33].

b) Rhinocerebral Mucormycosis (RCM):

Severe cerebral ischemia and hemorrhagic lesions are possible outcomes of RCM [34]. As per WHO symptoms include lethargy, seizures, slurred speech, partial paralysis, fever, black sores that rapidly worsen on the upper inside of the mouth or on the nasal bridge, headache, nasal or sinus congestion, one-sided facial swelling. Recurrence can occur even after recovery [35].

c) Cutaneous Mucormycosis:

Anovel fungal infection caused by an opportunistic fungi belonging to the phylum Glomeromycota, commonly occurring in immunocompromised individuals and those with poorly managed diabetes. Infection typically occurs by direct inoculation through wound [36]. According to the CDC, blisters or ulcers are common signs of cutaneous mucormycosis and the affected area may turn black. Pain, warmth, redness, or swelling around a wound are other signs.

d) Gastrointestinal Mucormycosis:

The gastrointestinal mucormycosis is an uncommon type, most frequently affecting the stomach, then the colon and ileum. Depending on the affected region, it may present with a variety of symptoms, most typical being nonspecific abdominal pain and distention linked to nausea and vomiting. These may be accompanied by fever and hematochezia [37].

e) Disseminated Mucormycosis:

An unusual kind that is frequently observed in people with extremely weakened immune systems is disseminated mucormycosis. The infection grows widespread as it moves to different parts of the body. The skin, heart, spleen, brain, and other organs are among the numerous regions that may be affected. (National Organization for Rare Disorders)^[38,39].

Diagnosis of Mucormycosis:

Initial diagnosis of mucormycosis is mainly based on physical examination, symptoms and medical history. However it requires a collaboration of clinical, histopathological, microbiological and radiological approaches for accuracy^[40].

Microbiological: A microbiological examination is vital for early diagnosis of mucormycosis with identification of the causative pathogen. For this nasal discharge, excised tissue by endoscopy or during surgery are used^[40].

Potassium hydroxide (KOH) wet mount: In KOH wet mount, the Mucorales hyphae reveal coenocytic broad aseptate/sparsely septate hyphae

with right-angle branching resembling ribbon-like appearance^[40].

Calcofluor white (CFW) stain: is a non-specific fluorochrome dye. Once the sample is stimulated with UV light in a fluorescent microscope, the fungal pathogen appears as the apple green or bluish against the white background, depending on the filter used^[40].

Histopathology: On microscopic examination, tissues from the suspected case of mucormycosis show necrosis, inflammatory infiltrate rich in neutrophils and fungal hyphae. The fungal hyphae appear basophilic one, broad, aseptate and show right-angle branching in H and E staining^[40].

Molecular Diagnosis:

Different molecular methods like semi-nested PCR, nested PCR with RFLP, real Time PCR targeting the ITS region or specific primers targeting a restricted number of mucoralean genera/species, are being used to diagnose mucormycosis. These molecular methods aid the diagnosis where the fungal load is low and the conditions where other diagnostic tools fail^[40].

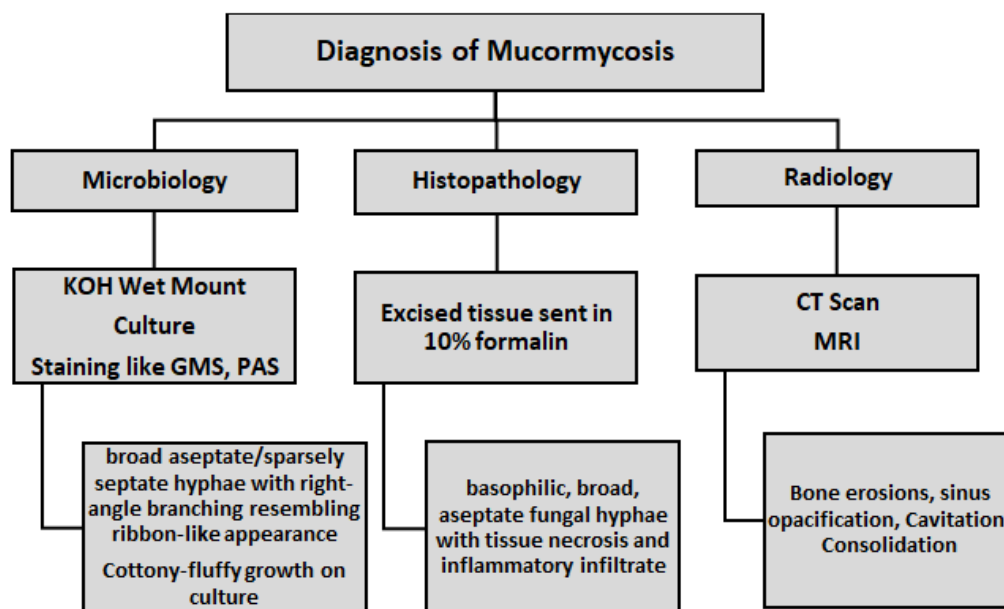


Figure-3: Flow chart for diagnosis of mucormycosis.

Culture:

Mucorales grow quickly (3-5 days) on common fungal culture media (such as potato dextrose agar

and Sabouraud agar) when incubated at 25 to 30 °C^[41]. It is significant to remember that only 50% of cases are culture positive, even in positive microscopy instances. It is now possible to reliably identify

Mucorales utilising matrix-assisted laser desorption ionization–time of flight mass spectrometry (MALDI-TOF MS) methods using either an in-house database or a commercial filamentous library [42].

Serology:

ELISA is frequently utilised in serology-based methods of detection for recognising antibodies produced in reaction to Mucorales infection. DNA barcoding has been demonstrated to be a highly accurate and efficient method to differentiate between various kinds of fungus [43].

Radiology:

Radiological imaging plays a crucial role in the early diagnosis and assessment of mucormycosis, especially in rhinocerebral and pulmonary forms. Computed tomography (CT) is commonly used to detect bone erosion, sinus opacification, and soft tissue involvement, while magnetic resonance imaging (MRI) offers superior visualization of vascular invasion, intracranial extension, and orbital spread. In pulmonary mucormycosis, CT may reveal nodules, cavitations, consolidation, or the reverse halo sign, which is suggestive of fungal infection. Early imaging is vital for guiding surgical intervention and monitoring treatment response. Radiology, therefore, serves as an essential tool for prompt diagnosis and management of this aggressive infection [44].

Management:

Since mucormycosis is a hazardous infection, it requires prompt treatment with prescription of correct antifungal drugs. Early identification, inversion of risk factors and actual illness, surgical debridement, and rapid intravenous antifungal therapy (typically amphotericin B) are all part of the conventional management for mucormycosis. This means that hyperglycemia and acidosis must be treated immediately, and immunosuppressive medications must be discontinued whenever possible [45]. According to guidelines published by European Conference on Infections in Leukemia (ECIL) in 2017 on mucormycosis treatment and update provided by European Confederation of Medical Mycology (ECMM), liposomal Amphotericin B (L-AmB) is recommended for first-line treatment in adults [46]. The more recent triazoles, isavuconazole

(ISAV), which is the active component in the prodrug isavuconazonium sulphate, and posaconazole (POSA) may work effectively for individuals who don't respond well to or are sensitive of lipid-based amphotericin B formulations (LFAB). An essential supplementary function is played by early surgical excision or debridement [47,48]. Other medicines also included as per world health or Centers for Disease Control and Prevention organization are fluconazole, voriconazole, and echinocandins. Patients with diabetes and mucormycosis participated in one retrospective study; those who received the combination medication showed better outcomes than those who received polyene monotherapy [49]. Mucormycosis-related necrosis and thrombosis can impair the absorption of antifungal medications. As a result, the removal of impacted tissue could be a vital treatment to fully get rid of the infection. It has been observed that surgical care produces better results than non-surgical treatment in individuals with rhino-orbito-cerebral mucormycosis and results in local control of the infection [50].

Conclusion

In conclusion, mucormycosis is a rapidly progressing and life-threatening fungal infection, especially in immunocompromised and diabetic individuals. Its pathogenesis is driven by angioinvasion and tissue necrosis, leading to poor outcomes if not treated early. Effective management requires prompt antifungal therapy, surgical debridement, and control of underlying risk factors. Despite therapeutic advances, early diagnosis and intervention remain critical to reducing morbidity and mortality.

Funding Sources: NA

Ethical Clearance/Statement of Ethics: NA

Declaration of conflicts of interest statement:

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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Trends in Home and Caesarean Deliveries Across Districts of Kerala (2019–2024): A Secondary Analysis

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How to cite this article: Rajat Anilkumar. Trends in Home and Caesarean Deliveries Across Districts of Kerala (2019–2024): A Secondary Analysis Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Kerala is recognised for its strong maternal and newborn health outcomes, characterised by low maternal and neonatal mortality rates and high coverage of antenatal care. However, recent trends suggest persistent challenges related to delivery practices, including rising caesarean section rates and home births. While existing studies examine these emerging trends at a broader level, there is limited evidence at the district level over the years.

Objective: This study analyses district-level patterns in home births and caesarean deliveries across Kerala between 2019 and 2024.

Method: The study used annual administrative data reported by Kerala’s Directorate of Health Services. The indicators included the number of home deliveries and caesarean sections. Descriptive analysis and district-wise visualisations were employed to highlight patterns.

Results: The findings consistently show high rates of caesarean sections in most districts, with Malappuram recording over 25,000 caesarean deliveries annually from 2019 to 2024. Other districts such as Kozhikode, Kollam, and Ernakulam also reported higher figures, each exceeding 10,000 in most years. In comparison, Idukki and Wayanad reported lower figures in the state; however, they still account for a significant number, with over 3,000 in most years. Although home deliveries remained low overall, districts like Malappuram and Wayanad showed relatively higher figures, with Malappuram reporting notable numbers ranging from 198 in 2019–20 to 252 in 2023–24.

Conclusion: The findings highlight persistently high caesarean section rates. Home births remained relatively low across most districts in the state, except for a few. Improving maternal health delivery services by promoting safe, evidence-based practices, monitoring the use of unnecessary medical interventions, and training healthcare professionals is essential for enhancing maternal outcomes throughout the state.

Keywords: Maternal health, District, Kerala, Home deliveries, Caesarean section

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Submission date: August 4, 2025

Revision date: September 26, 2025

Published date: April 14, 2026

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Introduction

Kerala, a southern state in India, has made significant progress in maternal and newborn health outcomes. The maternal mortality rate in the state is 19 per 100,000 live births, compared to 97 at the national level (2018-2020). Under-five mortality is also low, at 8 per 1,000 live births.¹ Furthermore, 98% of all mothers in Kerala received antenatal care from skilled providers, with 94% receiving it within the first trimester of pregnancy.²

Despite these achievements, ongoing challenges remain, including an increase in caesarean deliveries. In 2023-24, 44% of all deliveries were by caesarean section, markedly higher than the WHO's recommended rate of 10-15%.^{3,4} Caesarean section is associated with increased risk of postpartum haemorrhage, uterine rupture and long-term implications, including increased risk for future placental complications and higher maternal mortality rates.^{5,6} Additionally, over 500 home deliveries were recorded annually between 2020 and 2024.⁴ Home deliveries also pose an elevated risk to mothers, particularly in settings lacking accessible emergency care or trained attendants.⁷

Although previous studies have examined Kerala's maternal health performance at the state level, limited efforts have been made to analyse district-wise trends over the years.⁸⁻¹⁰ This gap highlights the need for district-level evidence that can guide allocation of resource, identify vulnerable populations, and inform more grounded and context-specific health strategies.

This study aims to analyse recent district-level trends in home births and caesarean deliveries across Kerala from 2019 to 2024, using publicly accessible data. By identifying these patterns, the study offers valuable insights for policymakers seeking to enhance maternal health.

Materials and methods

Study Design

The study employed a descriptive secondary data analysis with publicly available district-level data to examine trends in home births and caesarean deliveries across Kerala. In this study, annual data

from five consecutive years (2019-20 to 2023-24) were collected and analysed to observe changes in the selected indicators and to highlight variations across the state in recent years.

Study Setting

Kerala comprises 14 districts, ranging from densely populated urban areas, such as Thiruvananthapuram and Ernakulam, to rural and hilly regions like Idukki and Wayanad.¹⁰ Maternal and child health indicators also display notable variations across districts. For example, Kasaragod, Kozhikode, and Malappuram reported high antenatal care coverage, ranging from 83.9% to 94.2%, whereas Alappuzha, Idukki, and Thiruvananthapuram reported coverage from 55.3% to 74.3%.⁸ Additionally, Kasaragod experienced an increase in the maternal mortality rate from 40 per 100,000 live births in 2017-18 to 108 in 2023-24, while Thiruvananthapuram saw a decrease from 38 to 26 during the same period.⁴ These differences further underscore the importance of district-level analysis in understanding local patterns and informing targeted strategies.

This study examined the trend across all 14 districts of Kerala. These districts include: Thiruvananthapuram (TVM), Kollam (KLM), Pathanamthitta (PTA), Alappuzha (ALP), Kottayam (KTM), Idukki (IDK), Ernakulam (EKM), Thrissur (TSR), Palakkad (PKD), Malappuram (MLP), Kozhikode (KKD), Wayanad (WND), Kannur (KNR), and Kasaragod (KSD).

Data Source and Collection

The data used in the study were extracted from the Kerala: Health at a Glance annual report for the selected years. These annual reports, compiled by the Directorate of Health Services, Kerala, Government of Kerala, present a comprehensive collection of data on key health indicators and services in the state.⁴ The report draws on various sources, including the Health Management Information System, the Reproductive and Child Health Portal, monthly reports submitted from districts, and other relevant administrative databases.

Study Variables

The study focused on two key maternal health indicators:

1. Home Deliveries:

Refers to childbirth that took place at home, outside of institutional settings. This variable can offer insights into access, preferences, or gaps in the health system’s coverage in the state.

2. Caesarean Section Deliveries (C-sections):

Refers to the total number of caesarean section deliveries reported from both public and private institutions. This variable can offer insights into whether there is potential overuse of caesarean sections in the state.

Data analysis

The data from the report were extracted, cleaned, compiled, and analysed using R(version 2024.12.0). Faceted line plots were utilised to compare district-wise performance over time.

Ethical Considerations

This study used publicly available secondary data, and therefore, no formal ethical approval was

necessary. All data were used solely for academic and policy research purposes.

Results

Home Deliveries by Districts (2019-2024)

Figure 1 depicts the number of home deliveries reported across districts from 2019 to 2024. Overall, the number of home deliveries remained consistently low in most districts of the state, indicating strong institutional delivery coverage. However, Malappuram (MLP) consistently reported a high number of home deliveries over five years, ranging from 198 in 2019–20 to 252 in 2023–24. Wayanad (WYD) also showed relatively higher figures compared to most districts, with home deliveries ranging from 62 to 42 during the same period. In comparison, many districts such as Ernakulam (EKM), Pathanamthitta (PTA), and Alappuzha (ALP) consistently reported fewer than 20 home deliveries each year, reflecting greater access to institutional care.

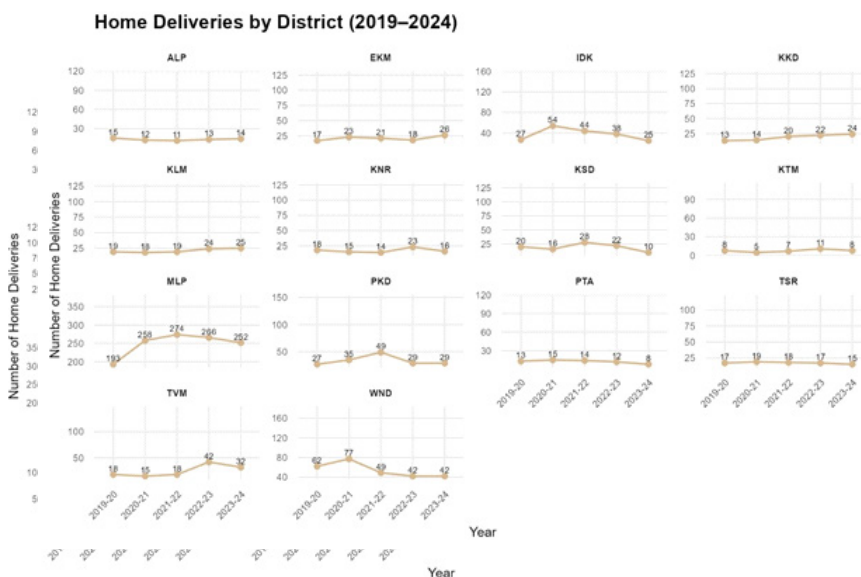


Figure 1: Distribution of home deliveries across districts in Kerala from 2019 to 2024. Districts: Thiruvananthapuram (TVM), Kollam (KLM), Pathanamthitta (PTA), Alappuzha (ALP), Kottayam (KTM), Idukki (IDK), Ernakulam (EKM), Thrissur (TSR), Palakkad (PKD), Malappuram (MLP), Kozhikode (KKD), Wayanad (WND), Kannur (KNR), Kasaragod (KSD).

Caesarean Deliveries by Districts (2019-2024)

As shown in Figure 2, the number of caesarean sections remained high in several districts, with some showing an upward trend. In contrast, others experienced a gradual decline over the five years. Malappuram (MLP) consistently recorded the highest numbers in the state, with over 25,000 caesarean

deliveries annually from 2019 to 2024. Ernakulam (EKM) and Kozhikode (KKD) also reported high figures during this period, each exceeding 18,000 caesarean deliveries in multiple years. Conversely, Idukki (IDK) and Wayanad (WND) reported the lowest numbers, mostly below 5,500 per year, although still notably high.

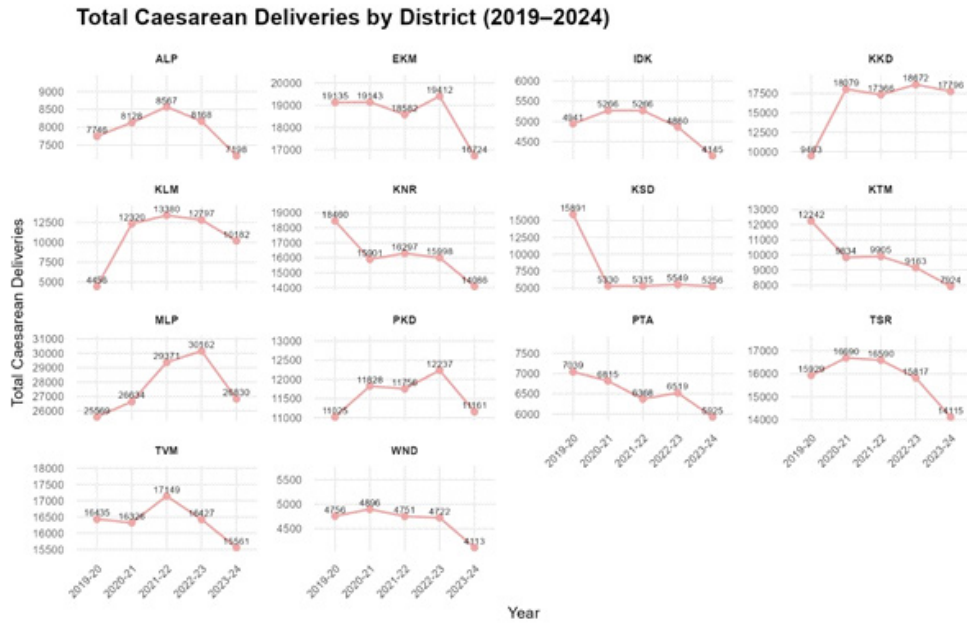


Figure 2: Trends in Caesarean deliveries across districts in Kerala (2019–2024). Districts: Thiruvananthapuram (TVM), Kollam (KLM), Pathanamthitta (PTA), Alappuzha (ALP), Kottayam (KTM), Idukki (IDK), Ernakulam (EKM), Thrissur (TSR), Palakkad (PKD), Malappuram (MLP), Kozhikode (KKD), Wayanad (WND), Kannur (KNR), Kasaragod (KSD).

Discussion

This study analysed trends in home deliveries and caesarean sections over five consecutive years (2019-2024) using publicly available data. The findings highlight a high caesarean section across most districts. While most districts maintained low numbers of home births, two districts stood out with a higher figure.

A key observation from this study is the higher occurrence of home births in Malappuram compared to other districts. Studies have documented various factors influencing the preference for home births, including traditional beliefs, fear of caesarean delivery, lack of female doctors, limited autonomy, and low community-level literacy.¹³⁻¹⁶ Additionally, some families may opt for home births due to cultural norms, personal comfort, or a preference for familiar surroundings.¹⁷ However, it is essential to recognise, as studies have pointed out, that access to skilled birth attendants and proper referral support is critical in ensuring safer births in any setting.^{18,19} In Kerala, only 24.4% of home deliveries in 2019–20 were attended by a skilled birth attendant, and this figure was even lower in Malappuram (17.1%), which remains a concern.⁸

Furthermore, the findings indicate a rise in deliveries by caesarean section. This trend aligns with other studies that have reported a steady increase in caesarean sections in India, particularly in southern states. A study using HMIS data from 2015 to 2020 found that districts in the South, including those in Kerala, reported significantly higher rates of C-sections compared to other regions.²⁰ Similarly, a clinical audit conducted at Travancore Medical College in Kerala reported a C-section prevalence of 45.8%, with previous caesarean and failure of induction being the most common indications.²²

Overall, this study highlights an unexpected pattern in Kerala’s maternal health landscape: the coexistence of very high caesarean section rates alongside the persistence of home births in certain districts. These findings are significant as they reveal a dual burden within a state that is otherwise known for its strong maternal health indicators. Another notable finding is the wide variation between districts, with some districts showing poorer performance in the indicators than others, reinforcing the need for local monitoring and district-specific strategies.

These findings carry implications for both policymakers and public health professionals. To

address the persistence of caesarean sections, there is a need for stricter oversight of facilities, improved monitoring and enforcing evidence-based clinical guidelines. At the same time, the occurrence of home birthspoints to the need for policymakers to improve access to safe and respectful institutional care. For public health professionals, these findings underline the importance of increased awareness among the providers of the risk associated with unnecessary surgical deliveries, encouraging safe institutional births. Training frontline workers to identify and respond to maternal complications promptly, while also addressing women's cultural preferences and concerns, can be a key to reducing the persistence of home births.

Limitations

While this study provides valuable insights into delivery patterns in Kerala, it has certain limitations. The analysis is limited to a five-year period (2019–2024), which may not reflect longer-term shifts in maternal health indicators. A broader timeframe could offer a deeper perspective. The study relies on secondary, district-level data, which may be affected by missing values or variations in data quality. Moreover, it focuses on quantitative trends and does not incorporate perspectives from women or providers that could explain underlying factors. Future research could integrate these to offer a more comprehensive understanding.

Conclusion

This study provides new evidence by analysing district-level trends in both home deliveries and caesarean sections across Kerala over a five-year period from 2019 to 2024. The findings show a dual challenge: the persistently high caesarean sections and districts with high home births, which are emerging as key issues in the state. To address these trends, targeted efforts are necessary, including strengthening monitoring systems, enforcing evidence-based clinical guidelines, and training healthcare professionals to promote safe and respectful maternity care without unnecessary medical interventions. By documenting district-level variations, this study provides actionable insights to improve maternal health outcomes and advance safe delivery care across Kerala.

Acknowledgment

I want to thank the Directorate of Health Services, Kerala, for making administrative data publicly accessible. I am also grateful to peers who shared helpful feedback during this study.

Source of funding: None

Conflict of interest: None

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Prevalence of Depression Among Older Adults Residing in Old Age Homes: A Narrative Review

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How to cite this article: Sabita Thapa Magar, Manisha Thapa, Imran Khan. Prevalence of Depression Among Older Adults Residing in Old Age Homes: A Narrative Review. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Ageing is a crucial life stage that is characterized by numerous changes, which make older adults more susceptible to mental health issues, particularly depression. Depression is a major problem affecting the senior population, especially those living in homes for the aged. Both India and Nepal are experiencing a rapid demographic transition with aging populations. This trend highlights an alarming prevalence of depression in institutionalized elderly.

Objective: This review aims to assess the prevalence of depression in elderly residents in old age homes.

Methods: Electronic databases including PubMed, Research Gate, Google Scholar, Semantic Scholar, and Science Direct were used to identify relevant research articles by using keywords like prevalence, depression, older adults, elderly, and old age homes.

Results: The findings show that the prevalence of depression in older individuals in homes for the aged is varied, ranging from 36.2 % to 82.6%.

Conclusion: The findings highlight the critical need for regular mental health screening, psychosocial interventions, and strong supportive systems to optimize the overall well-being of elderly individuals living in institutionalized settings.

Key words: Prevalence, Depression, older adults, old age home

Introduction

The Senior Citizens Act categorizes individuals aged 60 and above consider senior citizens¹. In Nepal,

according to the 2011 census, approximately 1.28 million elderly aged 65 and above were recorded, making up 4.4% of the country's total population¹.

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Submission date: June 10, 2025

Revision date: October 22, 2025

Published date: April 14, 2026

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In India, there are approximately 153 million elderly, and it is projected to reach 347 million by 2050². Despite having the world's largest youth population, India is experiencing a significant increase in its aging demographic. Similarly, Nepal is also facing a major public health concern with its growing elderly population³. This rapid increase in the elderly population brings several social and health challenges for both countries.

Aging is an inevitable phenomenon where people move towards the end of life. During this process, various biological, psychological, and social changes take place that significantly affect the elderly's quality of life⁴. Physical changes include wrinkles on the skin, stooped posture, loss of muscle strength, impairment in vision and hearing, as well as decline efficiency of the cardiovascular system. These changes can result in loss of physical abilities, intellectual decline, retirement from occupational roles, and social detachment⁵. As a result, the elderly people are more susceptible to age-related issues such as reduced functional ability and injuries, facing financial challenges, reduced coping ability, and increased vulnerability to both physical and mental health disorders.

Depression is the most prevalent mental health issue in the elderly, which has become a growing concern due to the rapid expansion of the geriatric population. People with depressive disorder are approximately 40% more likely to experience premature death than those without depression⁶. In Nepal, around 52% of the elderly are affected by geriatric depression⁷. Similarly, in India, depression is reported in about 1% to 6% of the general population⁸. A study on depression prevalence among the elderly found that 77.56% experienced depressive illness, with 74.66% of these cases being mild and 25.34% had severe illness⁹. Another study revealed a 59% prevalence of geriatric depression among older adults¹⁰. These studies conclude that a significant number of the elderly were suffering from depression, highlighting a widespread mental health concern.

In Indian and Nepalese culture, elderly people

mostly lived with or were cared for by their children, particularly sons. However, in the present epoch, the number of elderly residing in homes for the aged is rising more than ever before. This is because of a lack of family and social support, diminished interpersonal and communication abilities, reduction of coping mechanisms, as well as migration of children to urban areas or abroad and shifting of extended family into nuclear family⁶.

The living environment significantly affects mental health in later life. Research was conducted to identify the prevalence of depression among geriatric populations living in care homes versus those in the general community. A survey approach and comparative design were used, and the sample size was 630 for each. The Geriatric depression Scale was used to measure depression rates. The result reported that 66% of the elderly in old age homes experienced mild depression, and 20% in the comparison group¹¹. This shows that older age residents face significantly higher mental health risks compared to those living with their families.

Although numerous studies have highlighted depression as a significant issue among the elderly, there remains a pressing need for effective non-pharmacological interventions to enhance the quality of life for this vulnerable population. This review emphasizes the importance of making strict policies, regulations, and interventions to promote mental health, foster better coping mechanisms, strengthen social support, and improve overall well-being among the elderly. Future research should focus on holistic strategies that enhance emotional resilience and reduce depressive symptoms, especially among those dwelling in institutional settings.

Methods

A narrative review was conducted through a systematic electronic search to identify related studies. The electronic databases used included PubMed, Research Gate, Google Scholar, Semantic Scholar, and Science Direct by using keywords such as prevalence, depression, older adults, elderly, and old age home.

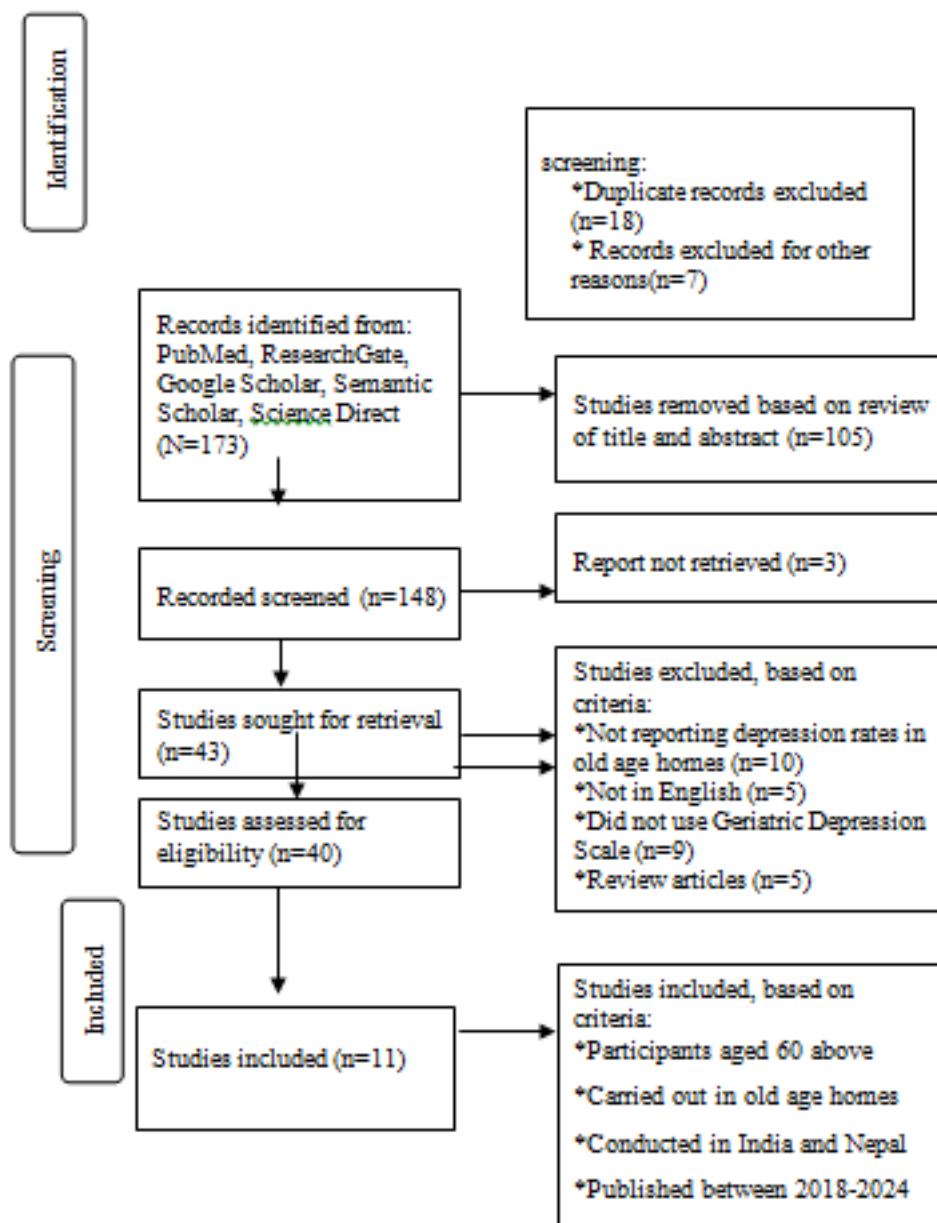


Figure 1: Flowchart for selection of studies

Results and Discussion

Table 1: Summary of results

| Author(s) and years | Country | Age | Sample Size (old age home) | Tools | Prevalence |
|--------------------------|---------|--------------------|----------------------------|--------|------------|
| Maharjan et al. (2024) | Nepal | 60 years and above | 142 | GDS-15 | 58.5% |
| Poudel et al. (2022) | Nepal | 60 years and above | 108 | GDS-15 | 36.2% |
| Pokharel & Sharma (2019) | Nepal | 60 years and above | 52 | GDS-30 | 69.2% |
| Mali et al. (2021) | Nepal | 60 years and above | 122 | GDS-15 | 74.6% |
| Roopa et al. (2018) | India | 60 years and above | 80 | GDS-30 | 62.16% |
| Karini et al. (2019) | India | 60 years and above | 50 | GDS-15 | 80% |

Cont....

| | | | | | |
|--------------------------|-------|--------------------|-----|--------|--------|
| Sapkota et al. (2019) | Nepal | 60 years and above | 62 | GDS-15 | 43.54% |
| Lamichhane et al. (2022) | Nepal | 60 years and above | 155 | GDS-15 | 82.6% |
| Kumar et al. (2021) | India | 60 years and above | 142 | GDS-15 | 47.8% |
| Chaudhari et al. (2022) | India | 60 years and above | 78 | GDS-15 | 41.1% |
| Singh et al.2022 | India | 60 years and above | 105 | GDS | 73.3% |

*GDS-Geriatric Depression Scale

This narrative review reveals a consistently high prevalence of depression in elderly populations in long-term care settings in South Asia, particularly in India and Nepal, with reported rates of up to 82.6%, 80%, 74.6%, and 73.3%¹²⁻¹⁵. **These results emphasize the immediate need for attention to mental health services in institutional care settings to address the growing concern of late-life depression.**

Many studies have identified age and gender as significant risk factors for depression. Older age groups and females, particularly widowed or illiterate females, are at high risk of developing depression¹⁴⁻¹⁹. The highest rate of depression among females is attributed to psychosocial stressors, dependency, and reduced social interaction, whereas widowhood further contributes to the state of loneliness and emotional distress. **This suggests the importance of developing target mental health interventions that are sensitive to both gender-based vulnerabilities and the influence of educational background among the elderly**

The process of institutionalization appears to be a major contributing factor in the exacerbation of depressive symptoms. Elderly individuals residing in care homes revealed consistently high rates of depression as compared to community settings. For instance, Pokharel & Sharma (2019) reported a prevalence rate of 69.2% in institutional settings versus 19.2% discovered in community settings, whereas Mali et al. (2021) found 74.6% in institutions versus 41.8% in the community. Similarly, another study also found higher rates of depression as compared to the community¹³. **These findings highlight the urgent need to improve the living environment, increase recreational and social engagement opportunities, and strengthen emotional support systems within institutional care homes.**

In contrast, studies from high-income countries report significantly lower rates of depression

among institutionalized elderly. Studies in Western nations show prevalence rates ranging from 21% to 44.33%²⁴, while studies from middle-income countries like Taiwan and Egypt report higher rates, that is, 58.3% and 62.0% respectively^{24,25}. Although institutionalization is a recognized risk factor for depression globally as a risk factor for depression, the severity of the issues in South Asia is magnified by conditions specific to low and middle-income countries, including inadequate mental health services, economic insecurity, social stigma, and a lack of trained mental health professionals²⁶⁻²⁸. **This comparison shows healthcare gaps between low- and middle-income countries and high-income countries, highlighting the need for country-specific mental health strategies.**

Other major contributors to depression, such as loneliness, lack of family support, poor social interaction, and negative attitudes towards life^{13-15,17}. A study conducted in Jabalpur city found that the elderly who had a lack of interaction with their family members had a greater chance of mental condition²⁰, which shows the importance of social connectedness as a protective factor against depression¹⁶. **These insights suggest the need for creating interventions that focus on enhancing family involvement and community connection.** Moreover, dissatisfaction with health care facilities among industrialized elderly is also linked to higher depression rates¹⁴, **which suggests that mental health services in homes for the age require substantial improvements.**

Elderly often experience emotional symptoms like feelings of emptiness and boredom, hopelessness, worthlessness, lack of interest, and hobbies²¹. These symptoms may act as early indicators for healthcare providers, policymakers, and other stakeholders to take effective control measures and carry out routine assessments for older adults. Unfortunately, during the early stage of depression, these symptoms

are frequently ignored due to social stigma, misinterpreted as a normal aging process, or lack of mental health awareness, which has a devastating consequence, significantly affecting well-being in late life. **Therefore, it is necessary to enhance awareness, early screening and stigma reduction to detect and address mental health concerns at early stages.**

Despite the high incidence of depression, protective factors such as religious and spiritual beliefs and active social engagement during leisure time have played a great role in reducing depression rates^{16,18}. **This insight supports need for interventions that promote religious or spiritual practices and social engagement into institutionalized care to improve psychological wellbeing.**

Furthermore, family history of psychiatric illness, chronic health conditions, and physical co-morbidities like asthma and smoking habits are significantly associated with depression^{14,15,17,22,23}. This shows that there is a bidirectional relationship between physical and mental health. **This suggests that a combination of physical and mental healthcare approaches may reduce the risk of developing depression and lead to better overall health outcomes among the elderly.**

Overall, studies emphasize the critical need for regular mental health assessment, early identification and detection of psychological issues, and implementation of psychosocial interventions for elderly individuals living in homes for the aged^{14,15,23}. Since the majority of the elderly participants in this review experienced some degree of depression, the highest percentage falls under mild, followed by moderate and severe categories^{14,22,23}. **This suggests that depression in seniors residing in elder care facilities is generally less severe and can be managed appropriately. So, timely preventive and therapeutic measures, including the development of appropriate coping strategies and engaging activities, need to be designed which is suitable for the institutionalized elderly, which can help to reduce the mental health burdens and improve quality of life.**

Key Takeaways and Insights

- 1. High Depression Rates in Institutional Settings:** Depression affects up to 82.6% in Nepal and 80% in India among elderly in care homes—far higher than in community settings. This confirms institutional living as a major risk factor, especially in low- and middle-income countries.
- 2. Sociodemographic Risk Factors:** Females, widows, the illiterate, and the oldest age groups are more vulnerable to depression, highlighting the need for targeted, culturally sensitive interventions.
- 3. Family Structure Shifts Fuel Isolation:** The move from extended to nuclear families, along with children's migration, is causing emotional detachment and loneliness, key contributors to elderly depression.
- 4. Community vs. Institutional Gap:** Depression rates are significantly higher in institutions (up to 82.6%) than in communities (as low as 19.2%), underscoring the need to improve mental health care and social engagement in elder homes.
- 5. Value of Protective Factors:** Religious faith, social activity, and family bonds reduce depression risk. Holistic care models that integrate mental, physical, and spiritual wellbeing are essential for improving elderly quality of life.

Comparative Perspective: South Asia vs. High-Income Countries

Depression among institutionalized elderly is significantly higher in India (80%) and Nepal (82.6%) compared to 21%–44.3% reported in high-income countries like the U.S., Canada, and parts of Europe. This disparity reflects systemic gaps in eldercare and mental health support in South Asia.

- **Mental Health Services:** High-income countries ensure routine screenings and access to trained professionals, unlike South Asia, where such resources remain limited.
- **Social Security:** Robust welfare systems abroad ease financial stress, whereas many Indian and Nepalese elders lack pensions or structured support.
- **Awareness & Stigma:** Mental health is more openly addressed in the West, while in South Asia, depression is often overlooked as normal aging.
- **Institutional Quality:** Care homes in wealthier nations emphasize autonomy, recreation, and psychosocial care; South Asian facilities often lack such provisions.

- **Community Engagement:** Western models promote active aging through volunteering and social integration, in contrast to the social isolation common in South Asian institutions.

These findings stress the need for context-sensitive reforms in India and Nepal, including enhanced mental health services, improved institutional environments, and greater community and family involvement.

Conclusion

Although depression is a common mental health issue among older adults, nearly half of the cases remain undetected. Depression is considered a major factor contributing to global disability and the burden of disease. Compared to other health services, evidence on depressive disorders in older adults is relatively scarce, which may result in inconsistent mental health services at the community level.

This narrative review emphasizes the elevated occurrence of depression among seniors in industrialized care facilities, compared to those living in the community. Key contributing factors for depression such as advanced age, female gender, widowhood, loneliness, lack of family and social interaction activities, chronic illness, and pessimistic perception of life.

From a public health point, there is a pressing need for comprehensive mental health strategies targeting older adults, particularly those residing in long-term care homes. The findings highlight the importance of regular mental health screenings, ongoing psychosocial assessment, and tailored psychosocial interventions. Encouraging social interaction, supporting spiritual wellbeing, and fostering family involvement can act as protective measures against depression.

The findings offer valuable information for anyone in the country, especially for the healthcare sector, such as healthcare providers, researchers, and policymakers, to develop effective public health and welfare programs aimed at preventing and managing depression in older populations. Addressing these issues could help to enhance the quality of life of seniors as well as help to reduce the impact on families, society, and the nation as a whole.

Funding sources: This study did not receive any grant from funding agencies.

Declaration of conflicts of interest: The authors declare no conflicts of interest

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Dementia in Developing countries: A Community-Focused Review of Prevalence, Risk Factors, and Public Health Priorities

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How to cite this article: Varalakshmi B, Suriya Kumar T, Prahankumar R. Dementia in Developing countries: A Community-Focused Review of Prevalence, Risk Factors, and Public Health Priorities. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Dementia is an emerging public health priority due to rapid population ageing, particularly in low- and middle-income countries (LMICs), where over 60% of affected individuals reside. In India, national estimates overlook substantial regional and rural–urban variation, and community-based evidence remains limited.

Objective: To review evidence on the prevalence, risk factors, methodological approaches, screening tools, and public health response to dementia, with emphasis on community-based studies from LMICs, especially India.

Methods: A narrative review of literature published between January 2000 and June 2024 was conducted using PubMed, Scopus, and Google Scholar. Community-based epidemiological studies, relevant reviews, and policy documents were included. Hospital-based studies and those focusing exclusively on pharmacological or molecular aspects were excluded. Thirty-seven articles were synthesized thematically.

Results: Global dementia prevalence is projected to increase from about 57 million in 2019 to over 150 million by 2050, with the fastest rise in LMICs. In India, prevalence among adults aged ≥60 years ranges from 4.5% to 11% across states, with higher burden influenced by education, lifestyle, and healthcare access. Nearly 45% of dementia cases are attributable to modifiable life-course risk factors. Community-based studies using culturally appropriate screening tools provide more accurate estimates, though methodological challenges persist.

Conclusion: Addressing dementia as a public health priority requires strengthening community-based research and integrating prevention, early detection, and care into existing health systems in LMICs.

Keywords: Dementia, Public Health, Prevalence, Community-based studies, India

Introduction

Dementia has traditionally been viewed as a clinical condition focused on accurate diagnosis,

symptomatic management, individualized care, and support for patients and caregivers, with the primary goal of maintaining quality of life and cognitive function. The WHO Global Action Plan on

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Submission date: November 12, 2025

Revision date: Jan 10, 2026

Published date: April 14, 2026

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the Public Health Response to Dementia (2017–2025)¹ recognizes dementia as a public health priority due to its widespread impact and complexity.

Over 55 million people currently live with dementia worldwide, with about 10 million new cases annually, and numbers are projected to reach 152 million by 2050, with over 60% of cases and the fastest growth occurring in low- and middle-income countries despite most evidence originating from high-income settings.

Regional data gaps remain a challenge in India, where national-level estimates conceal substantial state-wise variation, and certain regions lack any population-based prevalence estimates despite rapid demographic ageing. While national programs such as the National Program for Non-Communicable Diseases (NP-NCD) and National Program for Health Care of the Elderly (NPHCE) have made some progress in addressing aspects of dementia care, efforts remain insufficient. There is a **pressing need for a comprehensive national dementia policy** accompanied by a **dementia-specific program**, underscoring the urgency of integrating dementia care and prevention into the existing public health system.

Methods

This narrative review was conducted to synthesize published evidence on the prevalence, risk factors, and public health response to dementia, with a particular focus on community-based studies from low- and middle-income countries (LMICs), especially India. We conducted a literature search across the following electronic databases: **PubMed**, **Scopus**, and **Google Scholar**, covering the period from **January 2000 to June 2024**. The following search terms and their combinations were used: “dementia” OR “Alzheimer’s disease” AND “prevalence” OR “epidemiology” OR “burden” OR “risk factors” AND “developing countries” OR “low- and middle-income countries” OR “India” OR “community-based”. Boolean operators were applied appropriately. The search was limited to articles published in **English**. Additional articles were identified by screening the reference lists of key publications and relevant policy documents from organizations such as the **World Health Organization (WHO)**, **Alzheimer’s**

Disease International (ADI), and **Ministry of Health and Family Welfare**, India. We included original community-based epidemiological studies on dementia prevalence or risk factors, systematic or narrative reviews pertaining to Low- and Middle-Income countries, and policy documents and program reports from national and international public health agencies. Hospital-based studies, studies focused exclusively on pharmacological interventions or molecular/genetic mechanisms were excluded from the review. All titles and abstracts were screened for relevance, followed by full-text review of potentially eligible articles. A total of **37 articles** were included in the final synthesis. Data were extracted and summarized narratively under thematic headings: **I** Global and regional prevalence of dementia, **II** Understanding dementia in a public health perspective **III** Risk factors, Pathophysiology and Recent advances **IV** Methodological approaches in Dementia studies. **V**. Screening and Diagnostic Tools. Rather than pooling quantitative data, we focused on describing patterns, highlighting disparities, and identifying evidence gaps in LMIC contexts.

Results

I Global and regional prevalence of dementia

Overview of Global trends

Earlier projections estimated that the number of people with dementia would **increase from 57.4 million in 2019 to 152.8 million by 2050**.¹ Women are disproportionately affected, with a **female-to-male ratio of 1.69** in 2019. The **lowest increases in prevalence** are expected in **high-income Asia Pacific (53%)** and **Western Europe (74%)**, while the **highest rises** are projected in **North Africa and the Middle East (367%)** and **Eastern Sub-Saharan Africa (357%)**.² . This variation highlights that the **burden of dementia is not uniform across populations**, with **population aging and growth** being the major contributors to the observed trends.

The Burden of Dementia is not uniform across different populations

The global burden of dementia is substantial and expected to rise sharply in the coming decades. According to the Global Burden of Disease (GBD) Study 2021 by the Institute for Health Metrics and

Evaluation, an estimated **56.9 million people were living with dementia worldwide**, with a **higher preponderance among females (36.1 million cases)**.³ The age-standardized rate of dementia incidence increased minimally from 93.6 (80.1–106.7) per 100,000 in 1990 to 95.0 (81.6–107.9) in 2019.⁴ with the highest rise reported in East Asia (14.3%), Western Pacific Region (13.6%) and Asia Pacific (12.4%).⁴ A Systematic review⁵ on emerging trends in cognitive impairment and dementia among older populations in Asia has reported a diverse and varied prevalence of Dementia by region. Dementia prevalence shows marked variation across Asia, ranging from 87.1% in a Taiwanese study of 6,549 participants to 41.4% in urban Hong Kong (2023), 6.44% in a broad age-range study in Japan (20–97 years), and 9.11% in China (2022). Moreover, a 2020 Malaysian study reported an 8.5% prevalence and a 2023 Bangladeshi study recorded an 8.0% prevalence among individuals aged ≥ 60 years⁵.

National Trends and Regional Variations

According to a nationwide study by Lee et al.⁶ inadequately representing the national and state populations. \n\nMethods: \nFrom the Longitudinal Aging Study in India (LASI), the estimated dementia prevalence among individuals aged 60 and older in India is 7.4% (6.4–8.5), and age-standardized dementia prevalence is 8.0%. Cross-state variation in dementia prevalence in India shows lowest prevalence in Delhi at 4.5% and highest in Jammu and Kashmir at 11% (7.3 to 14.8). Southern states such as Tamilnadu, Kerala, Karnataka reported a prevalence of 6.1%, 8.27%, 7.61% respectively. Chandigarh, Daman & Diu, Dadra & Nagar Haveli, Goa, Lakshadweep, Puducherry, Andaman & Nicobar lacked the Population projection information as per Census of India 2011.⁷

Prevalence of dementia in urban and rural settings

Understanding rural-urban differences in dementia prevalence requires careful consideration of methodological approaches and comparative analysis of social, economic, and environmental factors to design targeted interventions.

Global level: According to a study conducted in Taiwan in 2022 with 10 432 participants aged 65 years and above, the prevalence of dementia in

rural, suburban, and urban areas among the elderly was 8.69% (95% CI, 8.68–8.69), 6.63% (95% CI, 6.62–6.63), and 4.46% (95% CI, 4.46–4.47), respectively with Urbanization an independent factor for dementia.⁸ 10,432 participants aged 65 years and more were selected through computerized random sampling from all administrative districts in Taiwan and were assessed using an in-person interview. We calculated the prevalence of MCI and dementia, with their risk factors examined using multivariable logistic regression. \nRESULTS: The prevalence of dementia in rural, suburban, and urban areas among the elderly was 8.69% (95% CI, 8.68–8.69) Belina et al. studied the prevalence of dementia in rural areas and urban populations from Northern Portugal and found the prevalence of dementia was 2.7% with a rural /urban Prevalence Ratio of 2:1.⁹ The study conducted by Nakamura et al.¹⁰ aimed to examine rural-urban differences in the prevalence of cognitive impairment in Japan. Cognitive impairment was found to be higher in the rural area with 8.4% and 2.0% in the rural areas.

India: Menesgere et al.¹¹ especially rural India, are sparse and therefore we aimed to assess risk factors in a rural cohort on aging and compare it with an urban cohort. Methods We are presenting baseline data on proportion of hypertension, diabetes, obesity, physical inactivity, and Cardiovascular Risk Factors, Aging, and Incidence of Dementia (CAIDE) evaluated the risk factors for Dementia in India and reported that the proportion of participants with hypertension, diabetes, and obesity was lower in the rural cohort, whereas physical inactivity was higher in comparison with the urban cohort. Shaji et al.¹² in “The dementia India report: prevalence, impact, costs and services for dementia. Alzheimer’s & Related Disorders Society of India (ARDSI), 2010” has reported the rural prevalence of dementia to be at 3.39% while in urban setting at 4.86%. Education, occupation, and healthcare access were protective factors, with urban residents showing better awareness and access to care, while many rural cases remained undiagnosed due to lower health-seeking behavior.

A study focused on differential distribution of Dementia¹³ among the Himalayan belt of Northern India reports a 1.6% prevalence among elderly individuals with female preponderance. This pattern

may be explained by differences in life expectancy, and the absence of cases in tribal populations has been attributed to dietary factors such as staple consumption of barley, wheat, and maize.

II Understanding dementia from a Global Public health perspective

Dementia needs to be addressed as a Public Health problem globally. The alignment with each individual criteria of a public health problem is discussed as follows:

High Prevalence: According to the World Health Organization (WHO), over 55 million people are living with dementia globally. There are 10 million new cases every year. This number is projected to increase to 152 million by the year 2050.¹⁴ Over 60 % of the global estimate of Dementia cases live in low- and middle-income countries.¹⁵

Significant Morbidity and Mortality: Dementia is currently the seventh leading cause of Death and one of the major causes of disability and dependency among older people worldwide.¹⁵

Economic Burden: Globally, the total cost of dementia was US\$ (1.3 trillion), with 50 % of the cost accounted by informal care in 2019 according to WHO.¹⁵ In 2020, Dementia cost rose substantially to 14513 billion international dollars. China INT\$2961 billion, USA INT\$2331 billion, Japan INT\$1758 billion face the largest absolute economic burden. The cost of informal care ranges from 60-97% in high income countries to 85-45% in lower-middle-income countries, and treatment and formal care costs range from 10-50% in lower-middle-income countries to 30-80% in high-income countries.¹⁶

Impact on Quality of life: Persons with Dementia had multiple health conditions and had experienced poor quality of life.^{17,18} Patients with Alzheimer's dementia experience worse Quality of life compared to those with Mild Cognitive impairment.¹⁷

Epidemic risk: Dementia remains one of the major problems of the elderly population, with increasing life expectancy across the globe. The number of cases is projected to reach 150 million by 2050, especially among developing countries.¹⁹

Preventability and Intervenability: Evidence has been generated for 14 modifiable risk factors in the prevention of Dementia since 2017 till date.^{14,20,21} Life cycle approach is implicated in the prevention or risk reduction of Dementia with different risk factors operating at different time points such as early, middle and later phases of life. The specific actions identified in reducing the risk factors^{21,22} are as follows: Good quality education, accessible hearing aids for people with hearing loss, treating depression, preventing head injuries by use of helmets and protection in contact sports, encouraging physical exercise, reducing smoking, prevention or reduction of hypertension (< 130mm Hg), maintaining healthy body weight, reducing social isolation, treating visual loss, and reducing exposure to air pollution.

Disparities and Vulnerable population: Low socioeconomic status, limited access to health care and lower education witness higher prevalence of Dementia, especially in low- and middle-income countries. Two thirds of persons with Dementia live in LMICs.²³ High prevalence of risk factors, poor dementia awareness, stigma and misconception about Dementia are the significant risk factors in Low- and Middle-income countries.²⁴ The majority of global dementia care costs occur in high-income countries (HICs)

Need for Public health intervention:

Dementia management requires a coordinated, multipronged approach integrating healthcare policies, community support services, and public awareness initiatives. One example of above-mentioned approach at Global level is that of WHO's Global Action Plan on the Public Health Response to Dementia (2017-2025).¹

Social and Behavioral influence: Evidence from Systematic review and meta-analyses of longitudinal studies²⁵ by Wang et al showed that strong social engagement and frequent social contact were positively associated with low prevalence of Dementia. Loneliness was significantly associated with an increased risk of Dementia.

III Risk factors, Pathophysiology and Recent advances

A report from the Lancet Commission²¹ on Dementia, 2024 recommends Life course approach

of modifiable risk factors. Forty-five percent of the dementia cases could be prevented or delayed if the risk factors were addressed efficiently.

Early Life (Green Zone): Less education accounts for 5% of dementia cases, highlighting the importance of cognitive reserve development in childhood.

Midlife (Yellow Zone): The largest contributors to dementia risk are hearing loss (7%) and high LDL cholesterol (7%). Other significant risk factors include depression (3%), traumatic brain injury (3%), physical inactivity (2%), diabetes (2%), smoking (2%), hypertension (2%), obesity (1%), and excessive alcohol use (1%).

Late Life (Blue Zone): Social isolation (5%), air pollution (3%), and visual loss (2%) are major contributors to dementia risk in older adults.

Dementia is characterized by primary pathophysiological mechanisms which include Amyloid-beta ($A\beta$) Plaque Accumulation, Tau Protein Hyperphosphorylation, Neuroinflammation, Oxidative Stress and Vascular dysfunction.²⁶ The Glymphatic system acts in a similar fashion as that of the regular lymphatics thereby ensuring homeostasis in the brain and removal of waste products like $A\beta$. Defective glymphatic system, low expression of AQP4, sleep disruptions lead to the inefficient removal and $A\beta$ plaques and thus increase the risk of neurodegenerative diseases.^{27,28} Microglial cells maintain brain function by clearing waste and supporting neurotransmission, but inappropriate activation can trigger inflammation and amyloid-beta ($A\beta$) accumulation. Consequently, therapies targeting microglial activation, particularly anti-inflammatory agents, are being explored as potential disease-modifying treatments. Aducanumab and Lecenemab are the two mAbs which have been approved by US FDA for treatment in early Alzheimer's disease with proven β -amyloid pathology.²⁹

IV Methodological Approaches in Dementia studies

Dementia is a complex disorder so that measurement of its prevalence across older populations require different study designs, each with its own merits and demerits. Various factors like gradual onset, delay in diagnosis, exponential increase with age, misclassification of other cognitive

syndromes (delirium, old age psychosis) are found to be misleading in estimating the prevalence of dementia.³⁰ Comorbid physical illnesses may impair functioning and be misattributed to cognitive decline, leading to misclassification of dementia. Additionally, obtaining informed consent from caregivers is challenging when individuals with severe cognitive impairment are included in surveys.

Overview of common study designs used in prevalence studies

A single study design is not appropriate to estimate the prevalence of Dementia. Few study designs are described below, which may be used in combinations to estimate the true prevalence.

Community prevalence studies use population-based sampling and face-to-face cognitive screening and are considered the most reliable for estimating true dementia prevalence by identifying early cases. However, they are limited by low response rates, selection bias, single-phase designs, and the need for caregiver input to assess functional decline.

Population-based cohorts allow long-term follow-up of older adults, enabling direct estimation of dementia incidence and detailed health assessment. However, advanced age at recruitment leads to high attrition and survival bias, while neurophysiological testing is often constrained by cost, limited mobility, comorbidities, and poor feasibility in severely affected individuals.

Non-population-based Cohorts are those cohorts specifically recruited for cognitive decline dementia and provide more specific neuroimaging and testing but have limited generalizability and small subgroup sample sizes.

Dementia registries derived from healthcare institutions providing routine care have low population coverage and require ongoing maintenance costs. They are also prone to selection bias, as they mainly include individuals who are educated, financially able, and well connected to health services.

Administrative datasets uses electronic health records from the national or state level with readily available data at low cost. It allows for inclusion of primary health care data with possibility of detecting early dementia.

Combination of study designs

The most relevant outcome of an appropriate study design would be estimation of age-specific prevalence of Dementia in a population and association with its determinants, such as social, economic, health related and lifestyle factors and so on. The estimates need to fulfill the following criteria:

- ✓ Generalizable to a population
- ✓ Address Recruitment bias and attrition
- ✓ Long term follow up to detect trends
- ✓ Based on statistically adequate large samples
- ✓ Inferred by resilient and long-lasting processes.

V Screening and diagnostic tools for Dementia

Assessment of Dementia shall be based on Cognitive domain and Functional domain. Screening for Cognitive impairment:

Hindi Mental State Examination (HMSE) - Indian adaptation of the MMSE, specifically designed for illiterate and rural elderly populations. It covers key cognitive domains and has shown a sensitivity of 81.3% and specificity of 60.2% at a cut-off score of ≤ 23 for cognitive impairment.³¹ Hindi Mental State Examination (HMSE) might be used to screen for dementia in both rural and urban areas. However, it might not be suited for detecting Dementia in people with higher education, especially in urban areas.

*Vellore Screening Instrument for Dementia*³² -combines informant-based and direct testing to provide a culturally appropriate tool for low-literacy populations in South India, showing good reliability and field utility (Charles et al., 2016).

*Rowlands Universal Dementia Assessment Scale*³³ - developed to reduce cultural and educational biases in cognitive screening. It evaluates multiple cognitive domains such as memory recall, praxis, and executive function, making it suitable for multicultural settings (Storey et al., 2004)

*Montreal Cognitive Assessment*³⁴ -globally accepted tool for detecting mild cognitive impairment, with a cut-off score of < 26 ; however, it is affected by education level, requiring adjustments for those with ≤ 12 years of education (Nasreddine et al., 2005).

Addenbrooke's Cognitive Examination (III) -detailed cognitive assessment tool that evaluates five domains—attention, memory, fluency, language, and visuospatial skills—allowing for differentiation of dementia subtypes (Hsieh et al., 2013).

Screening for Functional domain:

Functional ability is an essential domain in the assessment of elderly individuals, particularly in the context of cognitive impairment.

*The Katz Index of Activities of Daily Living (ADL)*³⁵ is widely used to evaluate basic self-care tasks such as bathing, dressing, toileting, transferring, continence, and feeding, helping to determine the level of dependence or independence in daily functioning (Katz et al., 1963).

For assessing more complex skills necessary for independent living, the *Lawton and Brody Instrumental Activities of Daily Living (IADL) Scale*³⁶ is often used; it includes domains such as handling finances, managing medication, using transportation, and preparing meals (Lawton & Brody, 1969).

*The Barthel Index*³⁷ is another validated tool that evaluates mobility and personal care, with scoring that reflects the degree of independence, making it useful for both clinical and community-based settings (Mahoney & Barthel, 1965).

Together, these tools provide a comprehensive understanding of functional status and are often used in conjunction with cognitive screening tools in geriatric assessments.

Conclusion

Community- Based studies on Dementia are essential for capturing the true burden of dementia among diverse populations. Data on specific communities with insights into regional variations are useful in understanding the local practices and helpful in line with designing culturally effective interventions. The locally available data can be utilized by the policy makers to allocate resources and planning of health care services according to the community needs. Studies suggest that individuals with more years of schooling might score within the normal range on screening tests, even if they have early signs of dementia in urban population. This

could lead to an underestimation of dementia cases in urban populations. Dietary influences, Impact of Air Pollution, Climate Change on Dementia are potential newer thrust areas for exploration and research. Research on Barriers to Dementia diagnosis and management can guide policies to improve early detection and care in underserved communities

Conflict of Interest: Nil

Source of Funding: Nil

Ethical Clearance: Approved by Institutional Human Ethics Committee, Mahatma Gandhi Medical College and Research Institute – MGMCRI/Res/01/2022/43/IHEC/15

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Hand Function among Persons with type 2 Diabetes Mellitus in Southern India: An Observational Study

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How to cite this article: Anila Paul, Aneena Alex, Kumari Indira K S et. al. Hand Function among Persons with type 2 Diabetes Mellitus in Southern India: An Observational Study. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Hand function is a crucial element in performing activities of daily living in persons with Diabetes Mellitus (DM). The functional utilization of hands varies across various socio-cultural contexts which may influence the functional impairments. The extent of functional impairments of hands among individuals with DM in southern India has not been extensively investigated.

AIM: This study aimed to explore the hand functions among persons with DM in southern India.

Methods: This observational study included 70 individuals with DM, and 70 age matched non-diabetic controls from both community dwelling and institutionalized population, selected based on specific inclusion and exclusion criteria. All participants were assessed for hand muscle grip and pinch strength, fine and gross dexterity and function using a hand grip dynamometer, pinch gauge, nine-hole peg test, box and block test and cochin hand function scale respectively. The statistical analysis of the results was conducted using SPSS Software (SPSS.20).

Results: This study identified a significant decline in dominant hand muscle grip strength ($p=0.02$), lateral pinch strength ($p=0.04$), tip to tip pinch strength ($p=0.04$), pad to pad pinch strength ($p=0.03$), hand fine dexterity ($p=0.03$), gross dexterity ($p=0.05$) among persons with DM using unpaired t test with significance level at $p\leq 0.05$. The evaluation of hand function ($p=0.32$) did not indicate significant variation.

Conclusion: This study underscores the necessity for screening diabetic hand function for early detection of functional impairments among persons with DM. Effective interventions should be implemented to prevent deterioration in hand function.

Keywords: Hand strength, pinch strength, hand function, diabetes complications, type 2 diabetes mellitus.

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Submission date: January 9, 2025

Revision date: November 11, 2025

Published date: April 14, 2026

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Introduction

Diabetes mellitus (DM), a chronic metabolic condition with elevated levels of blood glucose, has become a serious challenge to global health. Diabetes around the world in 2021 was about 537 million adults (20-79 years), which is one in ten populations. Over 3 in 4 adults with diabetes live in low- and middle-income countries⁽¹⁾. In South - East Asia, 1 in 11 adults (90 million) are living with DM. In India, people with DM are expected to reach 134 million by 2045. Kerala state, at the southern part of India, is the diabetes capital of the country, with a prevalence of diabetes as high as 20%, more than double the national average of 8%.⁽¹⁾

Risk factors such as ethnicity, family history of diabetes, previous gestational diabetes, aging, overweight, obesity, unhealthy diet, physical inactivity and smoking contribute to DM⁽²⁾. Clinical manifestations involving various systems of the body are exhibited as the DM progresses⁽³⁾. It is reported that DM leads to musculoskeletal disorders such as limited joint mobility, carpal tunnel syndrome, Charcot's joints, trigger finger etc. The pathophysiological and structural changes in the nervous and connective tissues could affect the motor and sensory functions of the distal extremities like hands⁽⁴⁾

Even though, there are sufficient literature on diabetic foot evaluation and screening for complications, there is scarcity of literature on functional impairments in diabetic hand. The functional impairments of hand may affect the activities of daily living in long run and thereby reducing the quality of life of persons with DM. Therefore, a comprehensive study to evaluate the hand muscle strength, dexterity and functional activities among persons with DM is required.

There are few research literature on functional limitations of diabetic hand reported from various countries across the globe⁽⁵⁻⁸⁾. The socio-cultural and anthropometric aspects are different in India, which has a wide diversity within the country. The prevalence of DM is reported to be highest in southern parts of India especially Kerala, where the urban population reported the highest prevalence in the country⁽⁹⁾. The awareness and knowledge about the complications and treatment of DM is

also reported as less among the rural population in Kerala, southern India⁽⁹⁾. Moreover, the screening and diagnosis of prediabetes and diabetes is poor, leading to many undiagnosed cases of DM in the community. In a developing country like India, cost effective screening and implementation of health care services and awareness programs are important to ensure early detection and prevention of complications⁽¹⁰⁾.

Diabetic foot syndromes have attained good attention among health care providers and conducting diabetic foot screening to some extent. However, lack of time and skill training among medical practitioners in primary health care settings is found to affect early detection of complications in diabetic foot⁽¹¹⁾. Hand complications are completely ignored and have not attained any attention among medical practitioners in India. The undetected functional impairments of hand can affect the activities of daily living of persons with DM as the duration increases⁽⁷⁾.

The use of hands in various day to day activities among Indian population is different from the countries in western part of the world. The eating habits using hands, self-care activities, washing clothes and dishes, making dough for rotis etc are daily practice of an average population in south India. With less use of machines for washing clothes and utensils, the hands are used for cleaning in most of the rural parts of southern India. This might have some positive influence on the functional level of hands in persons with DM. Therefore, this study was designed to explore the hand function among persons with DM in southern part of India, Kerala.

Methods

This observational case control study was conducted to evaluate hand function specifically focusing on hand muscle grip and pinch strength, gross and fine dexterity and functional activities in individuals with type 2 diabetes mellitus. Ethical approval was secured from the institutional ethics committee, and all participants were informed about the study's purpose and procedures, with informed consent obtained from each subject. The research adhered to the declaration of Helsinki, 1964.

Participants were recruited using a purposive sampling technique from both community dwelling

and institutionalized groups based on predefined inclusion and exclusion criteria. Subjects were assigned to either group A or group B, with group A comprising individuals clinically diagnosed with type 2 diabetes mellitus for a minimum duration of ten years and group B consisting of matched non-diabetic controls. Based on sample size estimation, seventy subjects were recruited for each group using convenience sampling. The inclusion criteria for group A included individuals of both genders, clinically diagnosed with diabetes mellitus for over ten years, with an HbA1c level greater than seven percent and a mini mental state examination score exceeding 24. The exclusion criteria encompassed individuals with neurological impairments affecting upper extremity, a history of upper extremity fractures within the past year, any surgical procedures performed on the upper extremity, soft tissue injuries affecting the upper extremities, and joint disorders including degenerative and rheumatoid conditions.

The subjects who are medically diagnosed with diabetes mellitus by medical practitioner were identified by the primary investigator from the community and institutionalized care homes and recruited for the study. Demographic details and anthropometric measurements such as height, weight and handedness were assessed and documented. The hand muscle grip and pinch strength, fine and gross dexterity and function were assessed by Hand Grip Dynamometer, Pinch Gauge, Nine Hole Peg Test, Box and Block Test and Cochin Hand Function Scale - Indian Version respectively.

Hand grip strength was assessed with KERN MAP 80K1S hand held dynamometer with maximum measuring range of 80 kg, which is reliable and valid tool. The participants were comfortably seated with shoulder adducted and elbow flexed to 90° with the forearm and wrist in neutral position. Subjects were instructed to squeeze the dynamometer with maximum strength for five seconds without pain and the reading was documented. With a rest period of ten seconds, three trials were conducted. The average was estimated for the analysis^(12,13)

Pinch strength was assessed with BASELINE hydraulic pinch gauge (50 lbs) for lateral pinch, tip to tip and pad to pad. Participants were instructed to sit comfortably in a chair with back support and fixed

arm rest. The shoulder was adducted, elbow flexed to 90 degrees and forearm in neutral position. For lateral pinch, subject was instructed to pinch thumb against the radial side of the index finger, for tip to tip pinch, to pinch thumb to opposite pad of the index finger, and for pad to pad pinch, to pinch thumb in opposition against the index and long finger^(14,15). Three trials were conducted and the average was considered for analysis.

Nine hole pegboard HPEE, (15x7 with 8 mm diameter pegs 9 nos) was used to measure fine hand dexterity which is an inexpensive test and can be implemented quickly^(16,17). The subjects were instructed to place nine pegs in the hole and then remove them and put back in the container, one at a time. The time taken in seconds were considered as the final score. The timer commenced when the subject touched the first peg and finished when the subject dropped last peg in the container^(17,18). Average of three trials was documented for further analysis.

The box and block test is an easy and inexpensive technique to assess gross hand dexterity, with a wooden box in specified dimensions with two compartments and 150 small blocks. The subject was seated in a chair in front of the box. After getting the instruction to start, the person took one block at a time from one compartment and deposited in the other compartment. After one minute, an instruction was provided to stop the test. The number of blocks transferred from one compartment to the other, in one minute was considered as the final score^(19,20)

The Cochin Hand Function Scale (CHFS), otherwise known as Duruoz Hand Index, is valid and reliable tool for evaluation of extend of functional disability in diabetes mellitus. The internal consistency is high with Cronbach's $\alpha=0.890$ and reliability $r=0.809$ ⁽²¹⁾. This questionnaire consists of 18 questions about common daily activities^(21,22). The culturally adapted version of Cochin hand function scale for Indian scenario is implemented in the current study⁽²³⁾. Permission was obtained from the authors for using the scale in this study.

Assessor blinding was employed to reduce the bias in functional assessments. Two trained physiotherapists who conducted the evaluations

were blinded to participants' glycemic levels and medical history. The dominant hand was determined through a standardized self-report questionnaire adapted from the Edinburgh handedness inventory, administered at enrollment. To minimize fatigue during testing, mandatory 2-5 minute breaks were inserted between assessments and participants were encouraged to signal discomfort.

The outcome measures were hand grip and pinch strengths, hand gross and fine dexterity and hand functions. The data was gathered from seventy medically diagnosed persons with type 2 diabetes mellitus and seventy age and gender matched healthy individuals. Statistical analysis was conducted using SPSS software (IBM Corp. Released 2011. IBM SPSS

Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp) with student 't' test. The statistical data analyst was blinded by labelling the groups as A & B.

Results

This study included seventy persons with diabetes mellitus from both community dwelling and institutionalized groups (group A) with mean age of 69.78 (± 5.6) years and seventy non-diabetic controls from both community dwelling and institutionalized groups (group B) with mean age of 70.62 (± 7.8) years. The mean duration of diabetes mellitus among group A subjects were 14.98 (± 6.53) years and hemoglobin A1C was 8.29 (± 1.41) %.

Table 1: Demographic details

| Groups | Age | | Gender | | BMI | |
|--------------------------|-------|------|--------|--------|-------|------|
| | Mean | SD | Male | Female | Mean | SD |
| Diabetic cases- A | 69.78 | 5.55 | 27 | 43 | 26.03 | 4.47 |
| Non-diabetic controls- B | 70.62 | 7.80 | 40 | 30 | 24.81 | 4.34 |

Both groups were compared for hand muscle strength, dexterity and function using unpaired t test with significance level of $p \leq 0.05$ on both dominant and non-dominant hands. The analysis of hand

muscle grip strength on dominant and non-dominant hands among both groups revealed significant difference with p value 0.02 and 0.01 respectively.

Table 2: Hand grip strength of the dominant and non-dominant hand

| Hand | Groups | Mean | SD | p value |
|-------------------|---------|-------|------|---------|
| Dominant Hand | Group A | 12.25 | 2.61 | 0.02 |
| | Group B | 13.28 | 2.42 | |
| Non-Dominant Hand | Group A | 12.11 | 2.80 | 0.01 |
| | Group B | 13.20 | 2.45 | |

The hand muscle pinch strength which included lateral pinch, tip to tip pinch and pad to pad pinch, was analyzed on dominant and non - dominant sides among both groups and revealed

p value 0.04, 0.04, 0.04, 0.04, 0.03, 0.04 respectively which pointed towards significant decline in hand muscle pinch strength among persons with diabetes mellitus.

Table 3: Hand pinch strength of the dominant and non-dominant hand

| | Hand | Groups | Mean | SD | p value |
|------------------------|-------------------|---------|------|------|---------|
| Lateral pinch strength | Dominant Hand | Group A | 6.36 | 1.72 | 0.04 |
| | | Group B | 6.96 | 1.77 | |
| | Non-Dominant Hand | Group A | 5.23 | 1.39 | 0.04 |
| | | Group B | 5.71 | 1.47 | |

Cont.....

| | | | | | |
|---------------------------|-------------------|---------|------|------|------|
| Tip-to-tip pinch strength | Dominant Hand | Group A | 3.95 | 1.0 | 0.04 |
| | | Group B | 4.35 | 1.33 | |
| | Non-Dominant Hand | Group A | 4.02 | 0.93 | 0.04 |
| | | Group B | 4.38 | 1.10 | |
| Pad-to-pad pinch strength | Dominant Hand | Group A | 5.22 | 1.40 | 0.03 |
| | | Group B | 5.79 | 1.72 | |
| | Non-Dominant Hand | Group A | 5.22 | 1.39 | 0.04 |
| | | Group B | 5.70 | 1.47 | |

The fine hand dexterity, gross dexterity in both dominant and non - dominant hands and hand function revealed p value 0.03, 0.02, 0.05, 0.08 and

0.32 respectively. The gross hand dexterity in non - dominant hand and hand function revealed p > 0.05

Table 4: Hand fine and gross dexterity of dominant and non-dominant hand & hand function

| | Hand | Groups | Mean | SD | p value |
|-----------------|-------------------|---------|-------|-------|---------|
| Fine dexterity | Dominant Hand | Group A | 35.27 | 8.72 | 0.03 |
| | | Group B | 32.56 | 8.74 | |
| | Non-Dominant Hand | Group A | 37.87 | 9.75 | 0.02 |
| | | Group B | 34.76 | 5.84 | |
| Gross dexterity | Dominant Hand | Group A | 59.16 | 11.94 | 0.05 |
| | | Group B | 54.69 | 14.71 | |
| | Non-Dominant Hand | Group A | 55.97 | 10.90 | 0.08 |
| | | Group B | 52.64 | 12.53 | |
| Hand function | Both hands | Group A | 2.11 | 3.0 | 0.32 |
| | | Group B | 1.63 | 2.80 | |

The results of this study revealed significant decline in hand muscle grip and pinch strength and gross and fine dexterity in both dominant and non-dominant hands among persons with DM. The hand functional status evaluated with ICHFS did not report significant decline in hand functions.

Discussion

The hand is a crucial component of the body for performing activities of daily living. Patho physiological alterations in neuro muscular system in individuals with DM may impact hand function. The scientific literature presents conflicting reports on the involvement of hand function in DM. This study compared hand grip and pinch strength, hand fine and gross dexterity and hand functional activities between individuals with DM and age and gender matched non-diabetic controls.

The evaluation demonstrated significant decline in hand muscle grip and pinch strength among individuals with DM compared to matched non-diabetic controls. This finding aligns with the reports by Cetinus, who indicated that the severity of stiffness in subcutaneous tissues and neuropathy can lead to decreased muscle strength. Severe neuropathy can result in distal upper extremity flexor muscle weakness and affect the motor activities of hands^(5,24). Prolonged hyperglycemia can lead to loss of skeletal muscle mass, resulting in muscle atrophy, which may contribute to a decrease in muscle strength^(5,25).

Hand fine and gross dexterity is essential for the smooth conduct of daily activities, work related tasks and recreational activities. Diminished hand skills directly affect hand function, particularly in object manipulation and indirectly lead to a reduction in daily life activities. SK Wani et al. reported that

decreased hand skills in prolonged DM could be attributed to structural changes in the connective tissues of the hands, increased stiffness in the small joints of the hands, and visual impairment due to diabetes^(6,26).

In the present study, no significant differences were observed in hand functional activities between individuals with DM and non-diabetic controls. The hand function may be influenced by confounding factors such as occupation, physical activity level, and hand manipulation skills. The activities listed in the I-CHFS were relatively simple and part of the daily routines of the study participants, potentially contributing to higher I-CHFS scores. The I-CHFS is a self-administered questionnaire and most participants responded based on their perception of dysfunction. It was noticed that participants' perceptions of their hand function were more favorable than the actual issues, possibly due to the gradual development of complications and adaptation to changes⁽²⁷⁾.

The findings of this study align with global research indicating a decline in hand muscle strength and dexterity among persons with type 2 DM^(5,7,28). However, research conducted in Turkey and Australia reported a decline in hand function which contrasts with the results of the current study conducted in southern India^(28,29). This discrepancy may be attributed to differences in the extent of hand use in basic and instrumental activities of daily living across these countries. In semi urban and rural parts of southern India, individuals frequently use their hands for kitchen activities such as making dough, washing utensils, rather than relying on machines. Factors such as skillful hand use, occupation, cultural variations and hand anthropometric differences may influence hand functional skills. The authors observed that community dwelling individuals exhibited better hand function compared to institutionalized individuals likely due to greater involvement in household activities. Further research is needed to explore these confounding factors that may affect hand function.

Several potential confounding factors like age, disease duration, and glycemic control levels could influence outcomes, as older participants and those with prolonged hyperglycemia may exhibit exacerbated neuropathy or reduced hand dexterity

independent of DM alone. Comorbidities such as hypertension, obesity or peripheral vascular disease might confound associations between T2DM and hand dysfunction. Occupational demands could further bias results, as repetitive strain might amplify perceived dysfunction. Socio economic status, affecting access to healthcare and nutrition is another potential confounding factor. Future studies should consider these confounding factors for better results.

There are conflicting reports on the impact of DM duration on hand function, with some literature suggesting that more than ten years of DM can impair hand joint mobility and function⁽³⁰⁾. The authors noted that some individuals with longstanding DM, yet leading active lives, maintained fair hand muscle strength, highlighting the importance of engaging in routine functional activities. Periodic evaluation of hand function is crucial for maintaining functional integrity and early detection of functional skill deterioration⁽³¹⁾. The limitations of the current study include the lack of separate consideration for different types of DM in assessing their impact on hand function. Participants were recruited from both community dwelling and institutionalized populations where environmental factors and physical activity levels may differ, potentially influencing the results. The assessment procedures for hand muscle strength, dexterity and functional activities were somewhat lengthy, which may have affected participants' performance. A key limitation lies in the reliance on self-reported assessments which are susceptible to recall bias and subjective interpretation. Language barriers and literacy levels could also introduce inaccuracies. Cultural and anthropometric variations further impact generalizability. Anthropometrically, the smaller average hand size and body mass index in south Indian populations could alter functional thresholds.

Conclusion

The findings of this observational study provide preliminary evidence on significant decline in hand function among individuals with DM. These functional impairments of hands can affect the activities of daily living. However, considering cross sectional study design, these results should be considered as initial findings which require

confirmation through larger, multi-center studies. Critically, there is an emerging need for longitudinal research to track the progression of hand dysfunction over time and to identify potential risk factors. Additionally, developing and evaluating targeted hand exercise programs could play a vital role in preventing deterioration of hand function and improving quality of life for individuals with DM. Early screening of hand function is necessary for timely management of these complications.

Acknowledgments: We thank the authors of Indian version of CHFS for their consent to use the questionnaire for this study. We appreciate the cooperation and support from the authorities of institutionalized care centers towards recruitment of subjects for the study.

Competing Interests: Nil

Ethical Approval: Approval from institutional ethics committee (Ref No.: MTH/MPT/EC/2892/21)

Funding: Nil

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Exploration of Symptoms of OCD and Anxiety in Association with Fear of Covid-19

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How to cite this article: Isha Rastogi. Exploration of Symptoms of OCD and Anxiety in Association with Fear of Covid-19. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

The COVID-19 pandemic has generated psychosocial distress which show far reaching and unprecedented effects on the population all around the world. The distress caused by the pandemic situation appears to have profound psychological consequences on all the individuals. One of the aspects of these effects is personal fear about the virus. Given the context of the pandemic as well as the nation's responses, the present study is undertaken to assess fear and predict the psychopathology of the coronavirus as well as show the association between fear of coronavirus with levels of anxiety and obsessive-compulsive disorder. The results observed that Asian Indian ethnicities across the world were most affected psychologically and expressed elevated levels of anxiety and OCD symptoms. Although the research lacks a positive link between fear of COVID-19, anxiety, and OCD, indicating this may stand for a general psychological pattern as opposed to being particular to COVID-19, it examines a substantial correlation between OCD and anxiety symptoms ($r = .598$, $p < .01$). These data illustrate the interaction of anxiety and OCD during the pandemic, emphasising the importance of focused mental health therapies.

Keywords: COVID-19, Pandemic, fear, psychological distress, anxiety, OCD (obsessive compulsive disorder)

Introduction

The novel Coronavirus (COVID-19) originated on the 31st of December 2019 in the city of Wuhan, China and was announced to the World Health Organization⁴⁶ becoming the "public health emergency of International Concern"¹⁷ leading to a surge of public anxieties as well as fear of COVID-19²⁷ recorded in many countries. As of today 16th July 2021, this novel virus has infected 188,332,972

individuals with 4,063,453 deaths globally. The two distinguishing features observed of this virus are high transmissibility and high pathogenicity²³ leading to the increasing high rates of both mortality and morbidity. This has called for behavioural changes at the individual as well as country/state level. From the rules such as social distancing wearing masks and regular hand hygiene, various public policies such as isolation and self-quarantine were issued by the government². Although substantial attention

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Submission date: Sep 13, 2024,

Revision date: Oct 22, 25

Published date: April 14, 2026

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has been provided to the people infected with coronavirus, identifying the mental health effected by the pandemic has been relatively neglected⁴⁷. It has been researched that severe psychological as well as physical consequences can be generated by excessive worry which could be triggered by macrolevel stressors such as natural disasters dramatic situations and pandemics¹⁷.

Massive disruption to the behaviour and psychological well-being of individuals in the population could be triggered by the waves of heightened anxiety and fear, a severe result of mass tragedies⁶. Links between pandemic-related anxiety and symptoms of suicidality and post-traumatic stress have been observed¹³. However, there is a significant research gap in identifying how COVID-19 fear causes anxiety and obsessive-compulsive disorder (OCD) symptoms, particularly across diverse groups. The present investigation fills the void by looking into these connections and emphasising the importance of specific mental health studies during pandemics¹⁸.

Obsessive-Compulsive Disorder

Considering the current distribution of coronavirus, the fear of unknown, irrational behaviours and paranoia brings different kinds of obsessions resulting in compulsive behaviours in individuals. The psychological distress that the COVID-19 pandemic has introduced the world to invokes people of all age groups. In response to the sense of fear of contracting the virus, Obsessions lead to pain or emotion as well as Compulsions, which describe the behaviours necessary to heighten or suppress their pain or feelings. Consistently unpleasant thoughts and behaviours relate to anxiety disorder, commonly known as obsessive compulsive disorder or (OCD)⁴⁵. As mentioned by the American Psychiatric Association and WHO, Obsessions and compulsions are time consuming, the pre-occupations and behaviours in this disorder not only take more than one hour per day but also cause the psychologically and clinically significant distress and adversely impact other areas of functioning⁴⁵. In the case of COVID-19, the shift from fear to anxiety frequently takes the form of "COVID anxiety syndrome," which is characterised by

maladaptive habits like compulsive cleaning and avoiding public places²⁰.

The World Health Organization⁴⁵ and the Centers for Disease Control and Prevention (CDC) have been recommending social distancing, hand and respiratory cleanliness as primary containment preventing tactics as global health authorities battle to find a solution in this pandemic. OCD symptoms such as repeated handwashing/antibacterial gel usage, avoiding possible pollutants, or social isolation might be replicated by strict adherence to UK government rules for reducing the risk of spreading COVID-19 to other observers. Obsessive-compulsive disorder (OCD) sufferers have been observed to wash their hands until they meet an "internally referenced criterion" such as "feeling comfortable" or "just right." This results in protracted and repetitive behaviour that which is likely to last longer than 20 seconds. In comparison, the individuals without obsessive compulsive disorder (OCD) are observed to be more prone to follow the government guidelines (i.e., thorough hand washing for 20 seconds). Rather than washing their hands at a time when it is essential, like as going home from a crowded place, they may wash their hands more regularly because of an obsession which includes intrusive thought, doubt or feeling, an idiosyncratic trigger (e.g., after a shower), or the anticipatory anxiety and fear of contracting COVID-19. Alternatively, they may have devised techniques for sterilizing things with anti-bacterial gel, using sanitiser spray bottles on the goods before getting them in the house. Sanitizers, soaps, and gloves are in high demand all over the world since hand washing is deemed one of the best safeguards against infection. Hygiene precautions, washing, and contamination avoidance are stressed by every media outlet. Individuals with obsessive-compulsive disorder (OCD) may find it difficult to adhere to this rule, even though it appears to be the easiest to follow. Other symptoms include heightened moral responsibility for the spread of COVID-19, as well as excessive checking of information on COVID-19 and a need for reassurance to settle their levels of anxiety. OCD symptoms have been overlooked amongst the COVID-19 pandemic's numerous psycho-social effects including panic, health anxiety, mass hysteria and loneliness of isolation. Worldwide, there have been reports of an upsurge in symptoms of anxiety,

and concern regarding this. There is still not much research done on the effect of COVID-19 Pandemic on specific mental health disorder such as obsessive-compulsive disorder (OCD). Henceforth, this study observes the prevalence of OCD symptoms in individuals in a non-clinical sample in association with fear of COVID-19.

Methodology

Participants

A cross-sectional, observational study carried out around the globe. As survey questionnaire was designed using Qualtrics with a consent form appended to it. The mode of recruitment of participants was done through social networking sites (LinkedIn, WhatsApp, Instagram, etc.) The participants were encouraged to share the word. A debrief followed by the consent form appeared on accessing the link to the survey. Data was collected from the participants of 18 years and above. The Nottingham Trent University School of Social Sciences Research Ethics Committee (SREC) authorised the data collecting process on April 27, 2021 (August 20, 2022; commencement of the project May 20, 2021), under the reference number NTU-SREC-2021-045. This follows the British Psychological Society (BPS) rule of ethical practice, assuring voluntary participation, informed consent, and data withdrawal options until July 10, 2021.

Materials

This online self-reported questionnaire contained 3 sections related to the Overall anxiety and impairment, Obsessions and Compulsions, and Fear of COVID-19 following the Likert scale format. Descriptive statistics have been used in the research to analyse the findings. Mean, Standard deviation, Correlations, Regression, and ANOVA has been used to estimate the results of the data collected. A quantitative research design is used along with 3 scales.

Overall Anxiety Severity and Impairment Scale (OASIS): - a 5 item self-report questionnaire assessing the impairments and anxiety severity (frequency and intensity of anxiety along with level of social avoidance and interference associated with the anxiety), The scoring is done based on 5-point Likert scale, where Item 1 (frequency of anxiety)

and 3 (avoidance behaviour) are rated from "None" to "All the time"; Items 2 (intensity of anxiety), 4 (impairment in daily life), and 5 (impairment in interpersonal relationships) are rated from "None" to "Extreme." ²⁹

Yale-Brown Obsessive-Compulsive scale (Y-BOCS): Yale Brown Obsessive Compulsive Scale) is a 10 item severity scale divided into obsession and compulsion subscales with five parallel items that assess frequency, interference, distress, resistance, and control over the symptoms in the past seven days on a 5-point Likert scale (no symptom to severe symptom) and evaluate the severity of the OCD symptoms ¹⁸.

The Fear of Coronavirus-19 Scale (FCV-19S); ¹ A seven item scale which assesses fear of COVID-19. (e.g., "It makes me uncomfortable to think about coronavirus-19"). Respondents were asked to rate their agreement with each item on a 5-point scale from "1 – Strongly Disagree" to "5 – Strongly Agree." Higher scores are therefore indicative of a greater level of fear of COVID-19.

Procedure

The data was collected from all over the world, predominantly India, between June 8th and August 9th, 2021, employing Qualtrics, an internet-based self-report survey and commercial survey sample and administration provider. The data collection procedure was approved by the Nottingham Trent University ethics committee (SREC) approved the data collection procedure on April 27, 2021 (August 20, 2022 ; project start May 20, 2021), with reference number NTU-SREC-2021-045, and all respondents provided their consent prior to the polling procedure commenced. and all respondents expressed their agreement before the survey commenced. Web panels were randomized for age, gender, ethnicity, employment, and marital status in order to achieve a representative sample of the general population by Qualtrics. Respondents with incomplete responses were extracted from the data applying filters. Demographic details followed by other relevant questions for the study were requested post consent of the participant. Yale Brown Obsessive Compulsive Scale) is a 10-item severity scale divided into obsession and compulsion subscales. Participants were asked

to identify their major symptoms (obsessions and compulsions) and submit to a series of questions after performing a standard checklist concerning their obsessions and compulsions. Obsessions and compulsions are independently measured on the scale, which is divided into two main subscales: A scale from 0 (no symptoms) to 4 (severe symptoms) is used to assess five elements of obsessive-compulsive pathology: frequency, interference, distress, resistance (more resistance is assigned lower scores), and perceived control over the condition. Scores on each subscale are added together to get a Y-BOCS score¹⁸.

SPSS software was used for the analysis of the data. Descriptive statistics were calculated along with the mean score as well as the overall mean score for responses and were compared and correlated based on the demographic information using Bivariate Correlations and Multiple Regression. Based on the main scores are calculated as low and elevated levels of fear. Scores less than or equal to the mean considered indicated elevated fear of the pandemic and in when kept continuous, the scores were correlated with

anxiety and OCD. Multiple regression analysis was carried out for comparison of low and higher levels of fear. Observed scores with the value $p > 0.05$ were rated to be statistically significant.

Results & Discussions

Descriptive Statistics and Correlations Between Variables

As indicated in the **Table 1: Descriptive Statistics and Standard Deviations**, means cause standard deviation for all measures are reported. The total sample consisted of 144 participants, ages ranging from 18 to 88 years of age (59 men, 79 women, **with 5 missing gender values**), participants in the sample originated from a diverse range of cultural backgrounds, with the majority being 97 Asian Indian, (67.4%), 19 Americans (13.2%), with a balance of 6 African origin (4.2%), and 15 British (10.4 %) while a score of 7 participants decided not to respond to the question. A significant proportion of participants (59.0 %) employed (6.3 %) were unemployed, (1.4 %) were retired, and (28.5 %) were students.

Table 1: Descriptive Statistics

| | N | Statistic | Minimum Statistic | Maximum Statistic | Mean statistic | Mean Std. Error | Std. Deviation | Variance |
|--------------------|-----|-----------|-------------------|-------------------|----------------|-----------------|----------------|----------|
| Age | 139 | | 18 | 88 | 33.14 | 1.106 | 13.045 | 170.18 |
| Employment Status | 137 | | 1 | 4 | 1.85 | 0.064 | 0.746 | 0.557 |
| Ethnicity | 137 | | 1 | 5 | 1.85 | 0.121 | 1.414 | 1.998 |
| Marital Status | 137 | | 1 | 4 | 2.05 | 0.078 | 0.91 | 0.828 |
| OVERALL_ANXIETY | 130 | | 6 | 21 | 13.308 | 0.2858 | 3.25611 | 10.602 |
| OVERALL_fear | 93 | | 7 | 28 | 15.484 | 0.5516 | 5.31939 | 28.296 |
| Overall_OCD | 96 | | 10 | 37 | 20.167 | 0.61939 | 6.31001 | 39.93 |
| Gender | 139 | | 1 | 3 | 1.58 | 0.043 | 0.509 | 0.259 |
| Valid N (listwise) | 91 | | - | - | - | - | - | - |

Pearson's correlation analysis was used to further analyze the characteristics of participant and the relationship between the predictor and the outcome variable of the regression model. The correlation between the two independent variables of survey Y-BOCS and OASIS (Overall OCD score, and overall Anxiety score) and FCV-19S (grouped into Overall Fear) score was performed. Significant

differences of Y-BOCS score, anxiety and fear were found among the groups ($P = < 0.1$). The criterion of $P = < 0.1$ was selected to discover patterns in a small sample size, despite conventional significance ($P < 0.05$) is recommended. This exploratory approach gives with the research's preliminary nature³⁶. There was no statistical significance found between the measures of fear of COVID-19 and anxiety along

with fear of COVID-19 and OCD. However according to Pearson’s correlation, the overall anxiety had a strong correlation with the overall score of obsessive-compulsive disorder (r=.598) as shown in Table 2.

Table 2: Correlations

| | | Overall_OCD | Overall_fear | Overall_Anxiety |
|-----------------|---------------------|-------------|--------------|-----------------|
| Overall_OCD | Pearson Correlation | 1 | 176 | 598 |
| | sig. (2-tailed) | | 0.092 | <.001 |
| | N | 96 | 93 | 96 |
| Overall_fear | Pearson Correlation | 0.176 | 1 | 202 |
| | sig. (2-tailed) | 0.092 | | 0.053 |
| | N | 93 | 93 | 93 |
| Overall_Anxiety | Pearson Correlation | .598** | 0.202 | 1 |
| | sig. (2-tailed) | <.001 | 0.053 | |
| | N | 96 | 93 | 130 |

** Correlation is significant at the 0.01 level (2-tailed)

Despite the fact that there is one significant correlation in the study, they are not so strong as to interfere with the regression because they were all below 0.8 As a result, the multicollinearity

assumption was met. The linear regression analysis was used in order to explore the relationship between the two predictors (overall OCD and overall anxiety) with the outcome variable (overall fear of COVID-19).

Table 3: Model Summary

| Model | R | R Square | Adjusted R Square | Std. Error of the Estimate | R Square Change | F Change | Change Statistics | | Sig. F Change |
|-------|-------|----------|-------------------|----------------------------|-----------------|----------|-------------------|-----|---------------|
| | | | | | | | df1 | df2 | |
| 1 | .202a | 0.041 | 0.03 | 5.23878 | 0.041 | 3.85 | 1 | 91 | 0.053 |
| 2 | .214b | 0.046 | 0.024 | 5.25412 | 0.005 | 0.47 | 1 | 90 | 0.495 |

a: Predictors: (Constant), OVERALL_ANXIETY

b: Predictors: (Constant), OVERALL_ANXIETY, Overall_OCD

c: Dependent Variable: OVERALL_fear

The regression indicated that the model was not significant, and the predictors do not significantly explain the fear of COVID-19. (F (2,90) =2.150, p < 0.1) with (R² = 0.46). The correlation coefficient between the overall fear, OCD and anxiety was .214 with (P=.122) as depicted in Table 3.

(B=.202, p=.053) and Overall OCD (B=.087, p=.495). The unstandardized coefficient does not show any correlation with the overall scores for fear of COVID-19. Since both the predictors were neither significantly correlated nor significant in the regression the research does not show any association of fear of COVID-19 with symptoms of obsessive-compulsive disorder and anxiety.

The regression model in the Table 4 shows the two significant predictors. Overall Anxiety

Table 4: Coefficients^a

| | | | | | | 95.0% CI for B | | Correlations | | | | Collin-earity Statistics | |
|-------|---------------------|--------------------------|------------------------------------|--------------------------------------|-------|----------------|----------------|----------------|-------------|---------|-------|--------------------------|-------|
| Model | | Unstan- dardized B | Coef- ficients Std. Error | Standardized Coefficients beta | t | Sig | Lower Bound | Upper Bound | 0- Order | Partial | Part | Tolerance | VIF |
| 1 | (Constant) | 11.300 | 2.199 | | 5.138 | <.001 | 6.931 | 15.669 | | | | | |
| | OVERALL_ ANXIETY | 0.315 | 0.160 | 0.202 | 1.963 | 0.053 | -0.004 | 0.633 | 0.202 | 0.202 | 0.202 | 1.000 | 1.000 |
| 2 | (Constant) | 10.867 | 2.295 | | 4.736 | <.001 | 6.309 | 15.426 | | | | | |
| | OVERALL_ ANXIETY | 0.235 | 0.199 | 0.150 | 1.179 | 0.242 | -0.161 | 0.630 | 0.202 | 0.123 | 0.121 | 0.653 | 1.531 |
| | OVERALL_ OCD | 0.074 | 0.109 | 0.087 | 0.685 | 0.495 | -0.141 | 0.290 | 0.176 | 0.072 | 0.071 | 0.653 | 1.531 |

a: Dependent Variable :OVERALL_fear

Discussion

The purpose of this study was to examine the relationship between COVID-19 fear and anxiety and obsessive-compulsive disorder (OCD) symptoms in an Indian sample beginning in 2021. Despite analysing OCD subscales (obsessions and compulsions), no significant link was found between fear of COVID-19 and anxiety or OCD symptoms²⁸. However, a strong association between anxiety and OCD symptoms ($r=.598$, $p<.01$) supports a general psychological pattern that is not specific to COVID-19²⁹. Rising instances, restricted supplies, and sensationalised media in 2020 increased panic, especially in India^{5,7}. In contrast to the study done by Satici, which connected fear to anxiety in 2020⁶, our 2021 data suggests reduced fear, possibly due to immunisations and improved knowledge⁴⁴. By October 2025, with the pandemic managed and mortality rates dropped, anxiety and fear gradually declined, but OCD symptoms persist, indicating long-term psychological consequences²⁸.

Individuals with pre-existing psychological issues experienced elevated unpleasant emotions, with maladaptive anxiety leading to reduced functioning and strained community resources¹⁷. Gender disparities in crises are consistent with women reporting higher levels of fear, anxiety, and OCD than men⁶. Subjective assessments revealed no statistical differences despite disproportionate effects on communities of colour, which may be an outcome of cultural reporting characteristics or urban bias⁵.

The aversion of uncertainty, which grew worse by the fear of the unknown, which was aggravated by asymptomatic cases and unclear fatality rates^{15,12}. However, our data imply the developing situation in 2021 decreased fear's role.

The severe cleaning and stockpiling that resulted from negative emotional reactions exacerbated OCD symptoms including loneliness and trouble sleeping^{11,31}. High levels of anxiety hinder rational reactions, according to the Fear of COVID-19 Scale (FCV-19S)¹, but no association with DSM-based measures was discovered, confirming the significance of the anxiety-OCD linkage⁹. The fear of contamination, which affects around 50% of OCD patients, could persist beyond the pandemic and increase the likelihood of germaphobia^{10,37}.

Limitations

While the findings of this research contribute to an expanding collection of evidence on the association between fear of COVID-19, anxiety and obsessive-compulsive disorder (OCD) outcomes on the global population, a few significant limitations have been found specifically in the Indian population

Firstly, A cross-sectional design prevents this research from examining how variations in the level of anxiety and OCD translate into the COVID-19 induced fear translate over time through causal modelling applying longitudinal data. There would have been a bidirectional link between the samples if the data included of individuals who are fearful of

the pandemic, which would make their symptoms of OCD and anxiety worse. Future research might focus on those who already suffer from anxiety and OCD to further illustrate the fear of the pandemic.

Secondly, it is important to emphasise that the data used in this study was collected during a pivotal time in 2021 with a sharp increase of COVID-19 cases worldwide, especially in India, and extensive media coverage and social media activity that stoked widespread concern and panic for more than three months. This stands in stark contrast to the current situation, where the worldwide pandemic has mostly abated as of October 2025 as a result of extensive vaccination efforts and better public health measures, lowering death rates from their 2020 high⁴⁴. With more social resilience and normalised living situations, the extreme anxiety and fear that prevailed in 2021 have subsided, but the recurrence of OCD symptoms points to a long-lasting psychological impact. This tendency is following forecasts that anxiety and fear would decrease as case numbers decreased and restrictions relaxed – trends that are now fully realised by 2025 – while OCD levels might persist because of ingrained behavioural patterns²⁸.

Indeed, self-reporting bias would exist, which might distort participants' subjective interpretations or underreporting of their levels of anxiety, OCD, and fear. Third, one of the study's major limitations is the ethnic behaviour pattern of Asian Indian males, which further contributes to gender bias. The prevailing belief among Asian males is that showing fear is a sign of weakness in the gender that is thought to be emotionally stronger. This view is heavily impacted by male-dominant social behaviour. To further exacerbate the bias in self-reported data, this cultural norm caused Indian male respondents to have abnormally low levels of fear of COVID-19²⁸.

Lastly, this research admit that online polls are biased in their selection and systematically exclude respondents with restricted availability to advanced technologies or a competent Internet access. Consequently, the data overrepresents urban internet users while underrepresenting low-income rural population.

Conclusions

Despite serious limitations, the findings of this study are crucial for several reasons. The physical and mental symptoms of the condition have increased for

over a year following the coronavirus outbreak. There were noticeable signs of worry, panic, and obsessive-compulsive behaviours. Some Asian ethnic groups, particularly India, showed more anxiety and fear related to the COVID-19 epidemic, perhaps because of insufficient medical facilities. Mental health is negatively impacted by psychological symptoms associated with coronaviruses in people of all ethnic backgrounds worldwide. These COVID-19-related variables prompted To address the immediate long-term potential risks of mental and public health catastrophe in the future correlated with the COVID-19 pandemic, a psychologically informed strategy solution must be designed that takes into account the fear associated with symptoms of anxiety and OCD (obsessive compulsive disorder).

Declaration

Funding: No grant was obtained for this study from any governmental, private, or nonprofit funding organisation. The author has disclosed no conflicts of interest.

APPENDICES

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DSM -IV TR diagnostic criteria for OCD

ICD-10 diagnostic criteria for Anxiety

ICD-10 diagnostic criteria for OCD

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Fear of Coronavirus-19 Scale

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Study Protocol: Development, Validation and Implementation of Pain Education Module in Patients With Chronic Knee Osteoarthritis: A Mixed Method Study

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How to cite this article: Jui V. Banc, Chhaya V. Verma. Study Protocol: Development, Validation and Implementation of Pain Education Module in Patients With Chronic Knee Osteoarthritis: A Mixed Method Study. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Knee osteoarthritis is the most prevalent musculoskeletal disorder globally, with pain being the most important feature. Pain management is the cornerstone of knee osteoarthritis treatment. This study aims to develop a validated, understandable, and actionable pain education module for patients with Chronic Knee Osteoarthritis in the form of a video in English, Hindi, and Marathi.

Methods: The study will be conducted in three phases. The first phase of the study will include the development of the video in English, Hindi and Marathi. Phase 2 of the study will include validation of the video by experts from different specialties, including physiotherapists, Orthopaedic surgeons, pain interventionists, and people from the general population, using rigorous and robust research methods. The validated English, Hindi and Marathi Pain education videos will then be incorporated into the treatment of patients with chronic knee Osteoarthritis in the third phase of the study. This part of the study will be conducted in the form of a randomized controlled trial, (RCT) in which 120 patients with Chronic Knee OA will be included. With 60 patients in each group, the patients in Group 1 will receive pain education via video and the standard plan of care. Patients in Group 2 will receive only the standard of care. The assessment of patients will be performed by an assessor who will be blinded to the treatment allocation groups before and after treatment. The total treatment duration will be 6 weeks. The additional benefit of using the pain education module will be studied at the end of this study.

Discussion: The pain education module developed, validated, and tested in this study, if found to be effective, can be used for pain education in patients with chronic knee osteoarthritis as a regular treatment protocol. The results of this study may help reduce pain intensity and kinesiophobia and improve function and perception of knee osteoarthritis.

Keywords: *Pain education, chronic knee osteoarthritis, chronic pain, Pain neuroscience education*

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Submission date: August 10, 2025,

Revision date: November 14, 2025

Published date: April 14, 2026

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Introduction

Osteoarthritis (OA) is the most prevalent musculoskeletal disorder globally and the leading cause of chronic pain and disability in adults.^[1,2] It imposes a substantial clinical and economic burden, which continues to rise with aging populations and increasing obesity rates.^[3-5] In India, OA cases rose from 23.46 million in 1990 to 62.35 million in 2019, with a 10% increase in knee OA incidence since 1990.^[6]

Pain is the predominant and disabling symptom of knee OA, affecting function and quality of life.^[7] It typically progresses to wider areas and may involve other lower limb joints.^[8] Consequently, patients often reduce physical activity, influenced by factors such as age, gender, symptom severity, and ethnicity.^[9] Psychosocial factors—including self-efficacy, anxiety, social support, kinesiophobia, helplessness, pain catastrophizing, and depression—also affect pain perception and physical function.^[10-14]

Pain in knee OA is complex and multifactorial, encompassing peripheral, psychological, and neurological mechanisms.^[15,16] It aligns with the biopsychosocial model of the ICF, emphasizing biological, psychological, and social influences on symptoms and suffering. However, both patients and clinicians often attribute knee OA symptoms solely to structural damage, reinforcing the misconception that surgery is the only effective treatment.^[17] Persistent pain after total knee replacement challenges this belief.^[18-20]

Clinical guidelines from ESCEO and OARSI (2019) recommend education, structured exercise, and weight loss as core components of non-surgical management.^[21-23] Patient education—especially pain education—aims to improve knowledge, modify behaviour, and foster positive pain beliefs.^[24,25] A 2022 systematic review demonstrated that education enhances pain, function, and the effectiveness of conservative therapies in knee and hip OA.^[26]

Although existing models like Pain Neuroscience Education, Explain Pain, and Pain-Informed Movement show promise, they are generalized, lack condition-specific and culturally tailored content, and are seldom validated rigorously.^[26-29] Delivery methods are inconsistent, often designed at high

literacy levels and within Western contexts, limiting accessibility for Indian patients.^[30-37]

Current gaps include: (1) Development – absence of an India-specific pain education module for knee OA addressing myths and literacy; (2) Validation – lack of systematic content validation for accuracy and clarity; and (3) Implementation – limited clinician training and feasibility in clinical settings.

To address these, the present study adopts a three-phase approach: (i) development of a multimedia pain education module through expert consensus, (ii) validation for clarity, readability, and cultural appropriateness, and (iii) implementation testing among patients with knee OA. This design aims to deliver an evidence-based, context-specific, and implementable pain education resource for the Indian population.

Material and Methods

The study was conducted in three phases.

Phase 1: To develop a pain education module for patients with chronic knee osteoarthritis (multimedia content) in English, Marathi, and Hindi.

Phase 2: To validate the Pain education module from experts and representatives of general population using the Delphi

Phase 3: To study the effect of using a Pain Education module on pain perception, catastrophization, kinesiophobia, patients' beliefs, and knee function in patients with chronic knee Osteoarthritis: A randomized controlled trial.

Aim:

1. To develop, validate and implement Pain education module for patients with chronic Knee OA
2. To study the effect of pain education module on pain perception, catastrophization, kinesiophobia, and knee function in patients with chronic knee OA.

Objectives for Phase 1:

1. To develop a Pain education module for patients with chronic knee osteoarthritis (multi-media content) in English Marathi and Hindi

Objectives for Phase 2:

1. To validate the Pain education module for chronic knee osteoarthritis from experts & representatives of general population using the Educational Content Validation Instrument in Health (ECVIH)
2. To assess the Pain education module for chronic knee osteoarthritis for understandability and actionability of the multimedia content from experts and representatives of general population using the Patient Education Materials Assessment Tool for Audiovisual materials questionnaire (PEMAT-A/V)

Objectives for Phase 3:

1. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on pain perception using the Numerical pain rating scale (NPRS) and Pain algometer
2. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on pain catastrophization using the Pain Catastrophization Scale
3. To study the effect of a pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on kinesiophobia using the Tampa Scale of Kinesiophobia.
4. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on Knee function using the Knee Osteoarthritis Outcome Score (KOOS) and Timed Up and Go test (TUGT)
5. To study the effect of Pain education module on patients with chronic knee osteoarthritis plus standard plan of care exercises on Patient's beliefs using the Knee Osteoarthritis Fears and Beliefs Questionnaire (KOFBeQ)
6. To compare the effect of pain education module plus standard plan of care vs the effect of only standard plan of care exercises on pain perception, catastrophizing, Kinesiophobia, patient's beliefs and knee function in patients with chronic knee osteoarthritis.

Ethical Considerations: The Ethics Committee for Academic Research Projects (ECARP) gave ethical approval for the conduct of the study. Approval no. ECARP/2024/148. The study is also registered in the Clinical Trials Registry CTRI/2025/02/081419.

Study Design

Phase 1: Development of Multimedia Pain Education Module

- a. Study Design: Descriptive
- b. Duration: Approximately 1 year
- c. Sampling Method: Convenient sampling

Research Team:

- 2 experts for script development
- 1 animation artist/video editor/Graphic designer
- 1 language expert (English, Hindi, Marathi)

Procedure:

The development of the multimedia pain education module was guided by conducting a **robust literature review** and expert consensus.

A structured protocol was prepared to ensure transparency and replicability. The protocol for the literature review include:

- **Research Question:** Clearly framed using the PICOT framework to ensure the question is answerable, clinically relevant, and feasible.

P (Population): Adults with chronic knee osteoarthritis

I (Intervention): Pain education interventions (including Explain Pain, Pain Neuroscience Education, Pain-Informed Movement, or other structured educational strategies delivered in any format)

C (Comparison): Usual care, standard education, or no education intervention

O (Outcomes): Improvement in pain knowledge, beliefs, attitudes, pain intensity, function, and self-management behaviours

T (Time): Short-term and long-term follow-up (if reported in included studies)

- **Search Strategy:** Comprehensive search across multiple electronic databases (e.g., PubMed, Scopus, Web of Science, Cochrane Library, CINAHL), using relevant keywords, Boolean operators, and Medical Subject Headings (MeSH).
- **Study Selection Criteria:** Inclusion and exclusion criteria (e.g., study type, population, language, publication timeframe) will be defined to ensure appropriate screening of studies.

The findings from the literature review, along with **expert consensus**, will guide the **script development**. Content will be structured around three key pain education frameworks:

1. Explain Pain
2. Pain Neuroscience Education (PNE)
3. Pain-Informed Movement

The script will also address **common myths and misconceptions about knee osteoarthritis (KOA)**, ensuring that culturally relevant patient beliefs are considered.

The initial draft of the script was developed in **English** for clarity and tested for readability and understandability. The educational module was then be converted into a **multimedia format** (animated/video-based) by a graphic designer and editor. Following this, the content was translated into **Hindi and Marathi**, ensuring semantic accuracy, cultural appropriateness, and linguistic clarity through expert language review.

The **feedback from subject experts and language reviewers** was incorporated to refine the content. And a final version of the module was then incorporated for the next phase, that is the validation of the multimedia content.

Phase 2: Validation of the Module via Delphi Study

- a. Study Design: Delphi Study
- b. Duration: ~6 months – 1 year
- c. Sampling Method: Convenient sampling
- d. Participants:

Expert Panel: Professionals with >10 years clinical experience managing chronic knee OA (orthopaedist, rheumatologist, interventional pain specialist, 2 physiotherapists)

General Population: Two representatives from the general population.

Validation Tools and Processes:

Educational Content Validation Instrument in Health (ECVIH):

Experts and laypersons rated the content. (Table 1)

- o CVI ≥ 0.83 (experts), ≥ 0.78 (general population) = Acceptable.^[38]

Patient Education Materials Assessment Tool for Audiovisual materials PEMAT-A/V: (Table 1) Measures of understandability and actionability. Cut-off score: $\geq 70\%$ ^[39]

Delphi Rounds: Was conducted until threshold scores were met.

Comments and suggestions were used to revise the video modules.

Medical experts with more than 10 years of experience in management of pain in chronic knee osteoarthritis were included in the study. There will be a total of 5 experts: 1 orthopaedic surgeon, 1 rheumatologist, 1 interventional pain medicine expert and 2 physiotherapists trained in pain neurophysiology. Other than the experts' 2 members of the general population were also included in the validation process who were fluent with English, Hindi and Marathi languages.

Data Analysis Plan (Phase 2):

- Content Validity Index (CVI):
 - o I-CVI = (# agreed items) / total reviewers
 - o S-CVI = Average of I-CVI values
- PEMAT-A/V Score Calculation:
 - o (Total agreed / Total possible) $\times 100 = \% \text{ score}$
 - o Cut-off: $\geq 70\%$ for both understandability and actionability

Phase 3: Implementation of Pain education module (RCT)

- a. Study Design: Randomized Controlled Trial
- b. Duration: Approximately 1 year
- c. Participants: Patients with chronic knee osteoarthritis

d. Setting: Musculoskeletal Physiotherapy OPD of The SIA College of Health Sciences, Dombivli

e. Sampling Method: Simple Random sampling

f. Sample Size: 120 (60 per group)

Sample Size Calculation:

- Based on:
 - o $\alpha = 0.05$, Power = 80%
 - o True difference = 0.7 units
 - o SD = 1.27 (Supe et al., 2023)
- Formula from Chow S et al., 2008
- Final size: $\sim 52 + 10\%$ attrition = 60 per group

Randomization:

- Using Excel-generated random number table.
- Participants select a chit with group allocation.

Participants with knee osteoarthritis fitting in the clinical American College of Rheumatology (ACR) criteria^[40] were included in the study. The participant with the age from 50-75 years, with pain lasting for more than 3 months, ^[41]pain on Numerical Pain Rating Scale (NPRS) more than or equal to 4-8 on 10, with grade 1 to 3 radiological severity of Osteoarthritis were included in the study. Participants with recent trauma, fracture or soft tissue injuries, history of knee surgery, known cognitive or neurological deficits were excluded. Those with other known rheumatological, systemic or infectious cause of knee pain were excluded from the study.

A written informed consent was taken from all the participants. They were assigned randomly to one of the 2 groups using a closed seal envelope. Participants of both the groups were assessed by a blinded assessor before the start of the intervention. The assessor was blinded to treatment allocation groups. (Table 2).

Participants in Group 1 received Pain education using the developed pain education module along with the standard plan of physiotherapy management for 6 weeks with 3 sessions/week.

Participants in Group 2 received only the standard plan of Physiotherapy management with 3 sessions/week for 6 weeks.

Both the groups were re-assessed at the end of 6 weeks by the same blinded assessor.

Interventions:

1. Pain Education Module Group:

- Weeks 0-6:
 - o Video 1: *Knee Osteoarthritis*
 - o Video 2: *Pain Education*
 - o Alternated weekly (e.g., Week 0: Video 1, Week 1: Video 2, and so on)
- Session Format:
 - o Videos shown in the OPD
 - o Q&A sessions after each visit
 - o Participants encouraged to reflect and review at home

2. Standard of Care Group:

- Frequency: 3 supervised sessions/week
- Content:
 - o Mobility exercises
 - o Strength training
 - o Balance/proprioceptive exercises
 - o Stretching
- Guidelines Referenced: Clinical guidelines by European Society for Clinical and economic aspects of Osteoporosis, Osteoarthritis and musculoskeletal diseases (ESCEO) and Osteoarthritis Research Society Initiative (OARSI 2019) ^[21-23].
- Pain Algometry: ^[42]
 - o Device perpendicular to medial joint line.
 - o Pressure increased at 2 kp/s.
 - o Average of 3 readings, 20 sec apart.
- Timed-Up-and-Go Test: ^[43]
 - o 3-meter walk from chair to cone and back.
 - o Stopwatch timing.
 - o One practice trial will be given.

Data Analysis Plan (Phase 3):

- Software: SPSS

- Normality Testing: Shapiro-Wilk or Kolmogorov-Smirnov test
- Descriptive Stats: Mean, SD, % frequency
- Between-Group Analysis:
 - o If normal: Independent t-test
 - o If non-normal: Mann-Whitney U test
- Within-Group Comparison:
 - o If normal: Paired t-test (2 points) or Repeated Measures ANOVA (>2 points)
 - o If distribution is not normal: Wilcoxon Signed Rank (2 points) or Friedman test (>2 points)
- Categorical Data: Chi-square test

- Significance Level: $p < 0.05$
- Power: 80%, Alpha: 0.05, Beta: 0.20

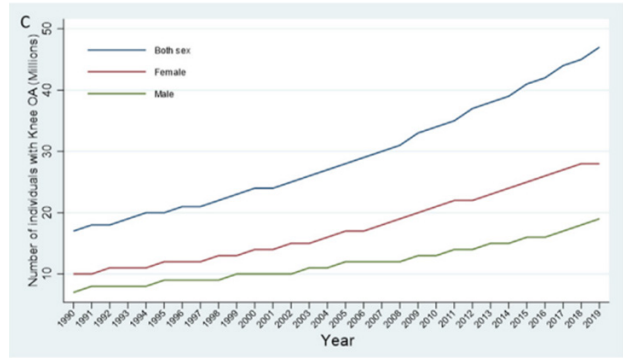


Fig 1: Graph showing trend of rising cases of Knee OA in India from 1990 to 2019

Table 1: Outcome Measures Used in Phase 2:

| Sr. No | Outcome Measure | Description | Psychometric Properties | Permission |
|--------|---|--|-------------------------|---------------|
| 1 | Educational Content Validation Instrument in Health (ECVIH) | Validates content in health education materials | ICC > 0.8 | Obtained |
| 2 | Patient Education Materials Assessment Tool for Audiovisual materials | Assesses understandability and actionability of AV materials | $\alpha = 0.71$ | Public domain |

Table 2: Outcome Measures used in Phase 3

| Tool | Description | Psychometric Properties | Permission/Source |
|------------------------------|---|---------------------------------------|----------------------------|
| NPRS | Numeric pain scale (at rest & during activity) | ICC = 0.95, SEM = 0.48, MDC = 1.3 | Public domain |
| Pain Algometry | Measures pressure pain threshold at medial joint line | ICC = 0.909-0.956 | Therapist assessed |
| Pain Catastrophizing Scale | Assesses negative thoughts about pain | $\alpha = 0.87-0.93$ | MAPI permission obtained |
| Tampa Scale of Kinesiophobia | Measures fear of movement | ICC = 0.887, Moderate validity | Author permission obtained |
| KOOS | Measures knee function (Hindi & Marathi validated) | ICC > 0.75 for all subscales | MAPI permission obtained |
| Timed-Up-and-Go (TUG) | Assesses function, gait and balance | ICC > 0.94, MDC = 3.4 s | Therapist administered |
| KOFBeQ | Assesses fears & beliefs in knee OA patients | Cronbach $\alpha = 0.85$, ICC = 0.81 | Permission request sent |

Results and Discussion

The study hypothesizes that the pain education module would be effective, understandable and actionable. It would help to address the myths and beliefs in the minds of the patients and their caregivers regarding knee osteoarthritis and pain associated with it. The module would be effective in reducing pain intensity, improving pain perception, reducing Kinesio phobia and improving knee function. The existing literature supports the use of pain education strategies in the management of chronic knee osteoarthritis. But the unavailability of a culture specific, understandable and actionable pain education module, prompted us to take up this study. The pain education module thus developed in this study will prove to be of help to address the myths and beliefs in the minds of the patients with chronic knee osteoarthritis.

The pain education module if found to be effective can be used for pain education in patients with chronic knee osteoarthritis as a regular treatment protocol. The Pain education in the form of the video would be easy to administer in the treatment protocol. A similar pain education module can be developed, targeted for other musculoskeletal problems presenting with chronic pain like Low back pain, fibromyalgia, Complex regional Pain syndrome, Rheumatoid arthritis, etc.

We understand that there might be certain limitations to the study.

The pain education module was developed and tested only in 3 languages. So, its applicability may be restricted. India being a diverse nation with a wide range of languages spoken across the country there might be limitations to the use of the pain education multimedia.

Conflict of Interest: There is no conflict of interest.

Source of Funding: None

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Investigating WASH (Water, Sanitation, and Hygiene) Practices and Related Health Risks Among Women in Communities of Dharavi, Mumbai

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How to cite this article: Jumana Boty, Kanchan S. Chitnis. Investigating WASH (Water, Sanitation, and Hygiene) Practices and Related Health Risks Among Women in Communities of Dharavi, Mumbai. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Access to sufficient water, sanitation, and hygiene (WASH) remains a persistent challenge in urban slum settlements thus, affecting women's health and well-being. This pilot study investigates WASH practices among women aged 15–45 in Dharavi, Mumbai—one of Asia's largest informal settlements—with a keen focus on menstrual hygiene management and the associated risk of Urinary Tract Infections (UTIs). A cross-sectional survey was conducted among 50 women aged 15–45 years using structured questionnaires. Data were analysed using descriptive statistics, Chi-square, and Fisher's Exact Test to evaluate associations between menstrual hygiene practices and UTI symptoms. Most women (78%) are still dependent on overcrowded community toilets, which lack basic facilities such as water and soap. Disposable sanitary pads were used by 74% of respondents, while 26% still relied on cloth. A significant association was observed between frequency of changing menstrual products and UTI symptoms ($\chi^2 = 14.3$, $p = 0.027$; Fisher's $p = 0.011$). Avoiding eating to reduce toilet visits was also associated with UTI symptoms ($\chi^2 = 4.37$, $p = 0.037$). Choice of menstrual product was linked to age ($p = 0.022$) and education level ($p = 0.006$) of the women. However, reduced water intake showed no significant association ($p = 0.155$). The study highlights the urgent need for raising awareness programs in managing reproductive infections in Dharavi. Affordable sanitary products, safe disposal facilities, and gender-sensitive sanitation policies are critical to reducing health risks and promoting dignity in menstrual hygiene management. Comparative analysis with previous slum-based studies further revealed that women in Dharavi exhibit higher adoption of sanitary pads across all education levels and age groups but problems such as sanitation insecurity, behavioural restrictions, and unsafe disposal practices still persist which highlights incompetent WASH conditions in low-resource urban environments.

Keywords: Menstrual Hygiene, WASH Practices, UTI, Dharavi, Women's Health.

Introduction

The World Health Organization (WHO) has placed water, sanitation, and hygiene (WASH) practices to be the most basic needs for universal development.

One of the 2030 agendas called the "WASH initiative" and Goal 6 of the Sustainable Developmental Goals (SDGs), was framed with the aim "to ensure availability and sustainable management of water

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Submission date: September 9, 2025

Revision date: October 22, 2025

Published date: April 14, 2026

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and sanitation for all" by 2030^{1,2}. Slum settlements have become an inevitable feature in urban areas, often seen as residence with inadequate housing, overcrowding, and a lack of basic amenities such as clean water, sanitation, and secure living conditions³. Inadequate and poor quality sanitation infrastructure is the major concern for developing country such as India⁴. Data related to individual characteristics of women, housing condition, access to sanitation facilities, behaviors adopted by the women that could lead to UTI and an episode of symptomatic UTI in the previous one month were recorded through structured questionnaire. Logistic regression analysis was performed to find out risk factors for UTI among women. Results: The prevalence of UTI was found to be 19.6%. The prevalence was higher among young women aged upto 30 years (23.2%). The gap in access to safe WASH services in Indian slums is expected to expand as the rate of growth in urban population is 2–3% per year, whereas the slum populations are increasing at an alarming rate (6–8% per year)⁵. In the slums of Mumbai, around 81 to 243 people share one toilet. This is the world's highest number, and India ranks among the first 12 countries practising open defecation which is a major public health concern⁶.

Women are especially vulnerable as the lack of adequate and safe WASH affects their overall livelihood⁵. Besides privacy, women need to spend more time in the toilet because they must always sit or squat^{7,8}. Women need to be physically safe when they use outside or in public toilets; be it at school, marketplace, or workplace. If WASH facilities in schools, workplaces, market spaces, and public areas are poorly maintained, dirty, and unsafe, it will have a cascading effect on women's health. Health risks of women and adolescent girls exacerbate especially

when they menstruate if there are no facilities for changing and disposing sanitary materials safely. The issue of toilets is more serious in urban slum areas as compared to the rural slum because spaces are cramped and open space is deficient. A study conducted by Srivastava et al.⁹ in slums of Lucknow aimed to examine the health and sanitation practices among women living in these settlements. Poor menstrual hygiene practices placed them at an increased risk of infections, including urinary tract infections and sexually transmitted diseases.

An astonishing 355 million women and girls are still waiting for a toilet. Unavailability of either an individual or shared toilet forces them to use poorly maintained and overcrowded community toilet blocks or practice open defecation¹⁰. Often, in densely populated areas of urban slums it is a challenge for women to find privacy. This can lead them to avoid urinating and defecating for many hours which may cause urinary tract infections (UTI) in them¹¹. Such behaviour causes persistent constipation, diarrhoea, increased rates of maternal mortality, and worsened menstrual and pregnancy symptoms¹². UTI is the most common non-intestinal infection among women worldwide. More than half of all women experience at least one urinary tract infection (UTI) during their lifetime.¹³ This study aims to examine the water, sanitation, and hygiene practices of women living in Mumbai's slums, particularly in Dharavi, and assess the health risks linked to inadequate sanitation and hygiene. The pilot study conducted through this research might aid in providing various factors that might provide new link to UTI and poor sanitation practices and would also bridge the gap for further research.

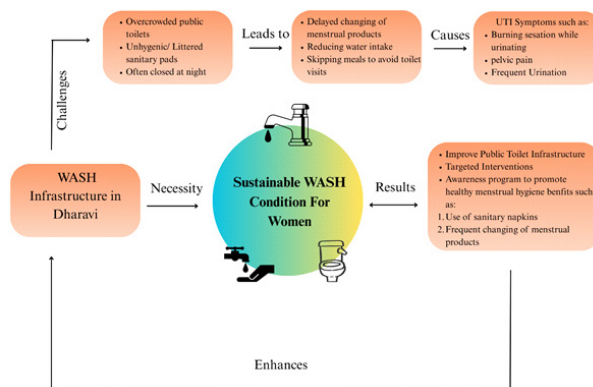


Figure 1: Infographic depicting factors affecting WASH Infrastructure access and required improvements

Methodology

Study Design and Area

This study is a cross-sectional pilot survey conducted to explore the association between WASH (Water, Sanitation, and Hygiene) practices and related health risks among women residing in the slum areas of Dharavi, Mumbai.

Study Population

The target population for this study included women between the ages of 15 and 45 years, who are residents of slum localities within the Dharavi region. This age group was selected to specifically understand menstrual hygiene management practices and the occurrence of urinary tract infections (UTIs) among women in their reproductive years.

Sample Size and Sampling Technique

The total sample size for this pilot study was 50 respondents. The sample size of 50 was based on the availability and willingness of respondents during the study period. Participants were selected through purposive and convenient sampling techniques. This approach was adopted due to the limitations in time and accessibility to participants, which restricted the ability to conduct random sampling.

Data Collection Tool and Procedure

Data were collected through interviews based on a self-constructed, structured questionnaire designed to gather information on sanitation practices, usage of community toilets, hygiene strategies, challenges during menstruation, and symptoms related to UTIs. Offline collection was carried via direct one-on-one interaction.

Variables Selected

The following variables were assessed through the questionnaire:

Section 1: Demographic Information

Section 2: Sanitation and Toilet Usage

Section 3: Water Access & Usage

Section 4: Menstrual Hygiene Practices (For menstruating women)

Section 5: Coping strategies and health seeking behaviour

Results:

1. Demographic Information

Table 1.1 Age of the respondents

| Age Group | Number of Respondents | Percentage |
|-----------|-----------------------|------------|
| 15-25 | 20 | 40% |
| 26-35 | 12 | 24% |
| 36-45 | 18 | 36% |

Table 1.2. Education Level of the respondents

| Education Level | Number of Respondents | Percentage |
|---------------------|-----------------------|------------|
| No Formal Education | 12 | 24% |
| Primary | 13 | 26% |
| Secondary | 11 | 22% |
| Higher Secondary | 8 | 16% |
| Graduation | 6 | 12% |

Table 1.3. Occupation of the respondents

| Occupation | Number of Respondents | Percentage |
|-------------------|-----------------------|------------|
| Housewife | 25 | 50% |
| Unemployed | 9 | 18% |
| Daily Wage Worker | 6 | 12% |
| Private Job | 5 | 10% |
| Student | 5 | 10% |

Table 1.4. Type of Residence

| Type of House | Number of Respondents | Percentage |
|---------------|-----------------------|------------|
| Semi-Pucca | 36 | 72% |
| Pucca | 14 | 28% |

The above section depicts the age of the respondents, where 40% of the sample was of age 15-25, which was majority of the population, and the education level depicted that most of the women (26%) had received education till primary level. However, 50% of the women were housewives and majority of the population (72%) resided in semi-pucca houses in Dharavi region.

2. Sanitation and Toilet Usage

Table 2.1 Type of Toilet Used

| Type | Number of Respondents | Percentage |
|-----------|-----------------------|------------|
| Community | 39 | 78.0% |
| Household | 11 | 22.0% |

Table 2.2. Frequency of using household/community toilet

| Frequency | Number of Respondents | Percentage |
|-------------------|-----------------------|------------|
| 1-2 times | 26 | 52.0% |
| 3-4 times | 20 | 40.0% |
| More than 4 times | 4 | 8.0% |

Table 2.3. Waiting time to use the community/household toilet

| Waiting Time | Number of Respondents | Percentage |
|-------------------|-----------------------|------------|
| Less than 5 mins | 33 | 66.0% |
| 5-10 minutes | 13 | 26.0% |
| More than 10 mins | 4 | 8.0% |

Table 2.4. Availability if water in household/community toilet

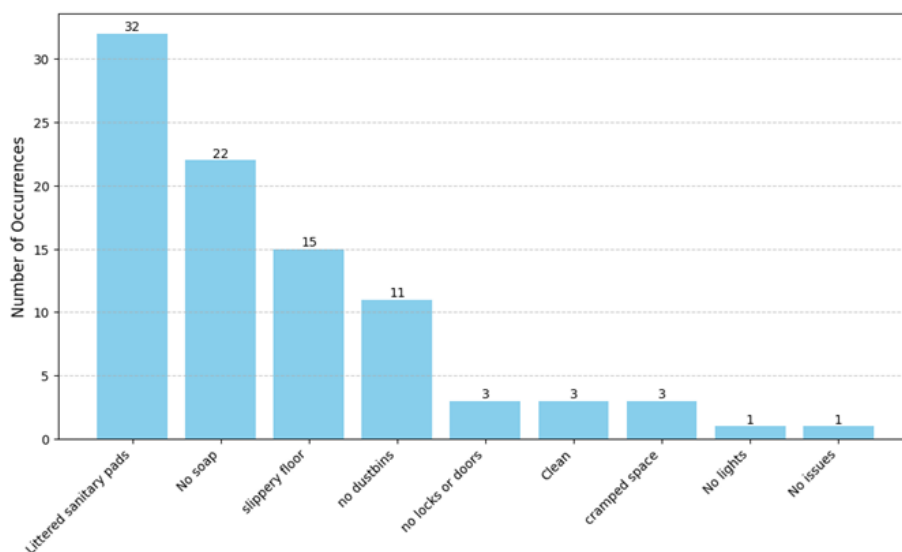
| Availability | Number of Respondents | Percentage |
|---------------------|-----------------------|------------|
| Always available | 36 | 72.0% |
| Sometimes available | 14 | 28.0% |

Table 2.5. Condition of the community toilet

| Condition | Number of Respondents | Percentage |
|---------------------------|-----------------------|------------|
| Clean and well-maintained | 10 | 20.0% |
| Partially clean | 24 | 48.0% |
| Dirty and unhygienic | 14 | 28.0% |
| Not applicable | 2 | 4.0% |

Table 2.6. Handwashing practices after using the toilet:

| Practice | Number of Respondents | Percentage |
|---------------------------------|-----------------------|------------|
| With soap and water | 37 | 74.0% |
| Just water | 10 | 20.0% |
| With water only (sink not used) | 1 | 2.0% |
| No handwashing sink | 1 | 2.0% |
| No handwashing | 1 | 2.0% |



Graph 2.7. Toilet infrastructure issue faced:

(78%) of women use community toilet and (50%) of women use them at least 1-2 times daily, thus

maintaining them is crucial. 68% women have to at least wait for 5 minutes to use these community toilets. 40% of

women claimed that while the community toilets were partially clean, many (26%) also complained that there were used sanitation pads thrown on the ground or stuck in between the windows of the toilets that caused odor and flies in the toilet, making them uncomfortable and hesitant to use them. No soap, no dustbins and slippery floors were other major issues that women faced while using community toilets.

3. Water Access & Usage

Table 3.1. Access to safe drinking water at home

| Source | Number of Respondents | Percentage |
|-------------|-----------------------|------------|
| Piped water | 50 | 100.0% |

Table 3.2. Daily water intake (glasses per day)

| Intake Level | Number of Respondents | Percentage |
|--------------|-----------------------|------------|
| Less than 3 | 11 | 22.0% |
| 3-5 | 22 | 44.0% |
| More than 5 | 17 | 34.0% |

Table 3.3. Difficulty in accessing water daily

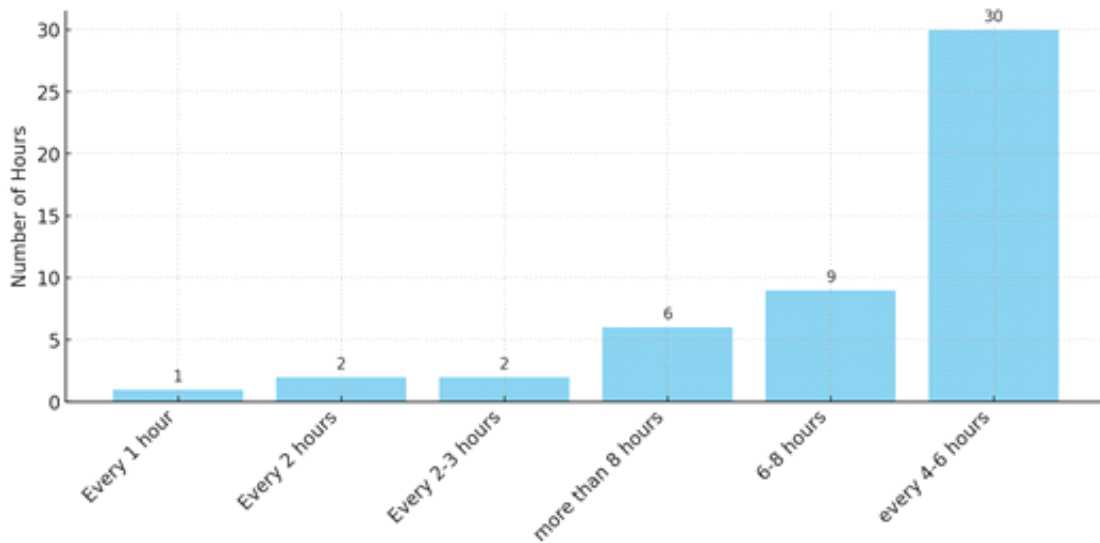
| Response | Number of Respondents | Percentage |
|-----------|-----------------------|------------|
| Yes | 10 | 20.0% |
| Sometimes | 8 | 16.0% |
| No | 32 | 64.0% |

Everyone in the region received piped water on a daily basis. This is a positive indication on water facility in the colonies of Dharavi. However, varied results were obtained for water intake, where 44% of the women only consumed 3-5 glasses of water daily. For healthy individuals, the average daily water for men is about 15.5 cups and for women about 11.5 cups. That might mean that at least four to six cups of plain water, is mandatory when depending on other fluid sources such as coffee, tea, juice, fruits, and vegetables. While majority of women had no issues in accessing water daily, rest 80% women did face some issues that could potentially limit their water intake as well.

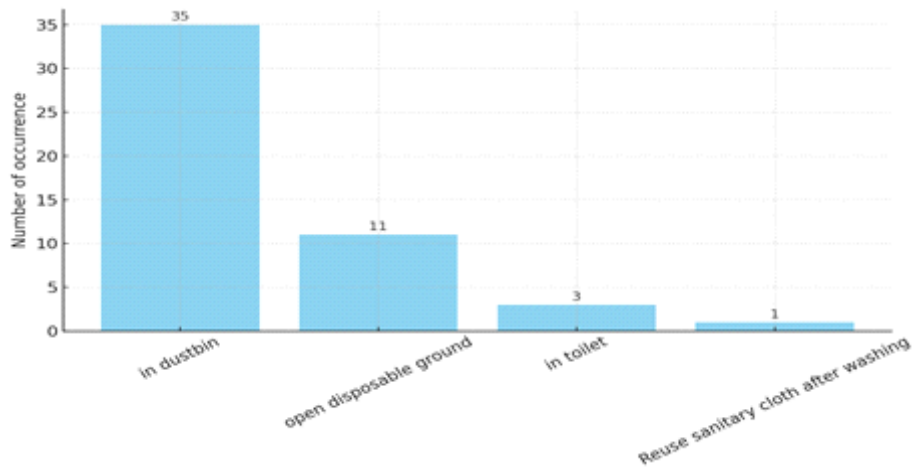
4. Menstrual Hygiene Practices (For menstruating women)

Table 4.1. Type of menstrual product used:

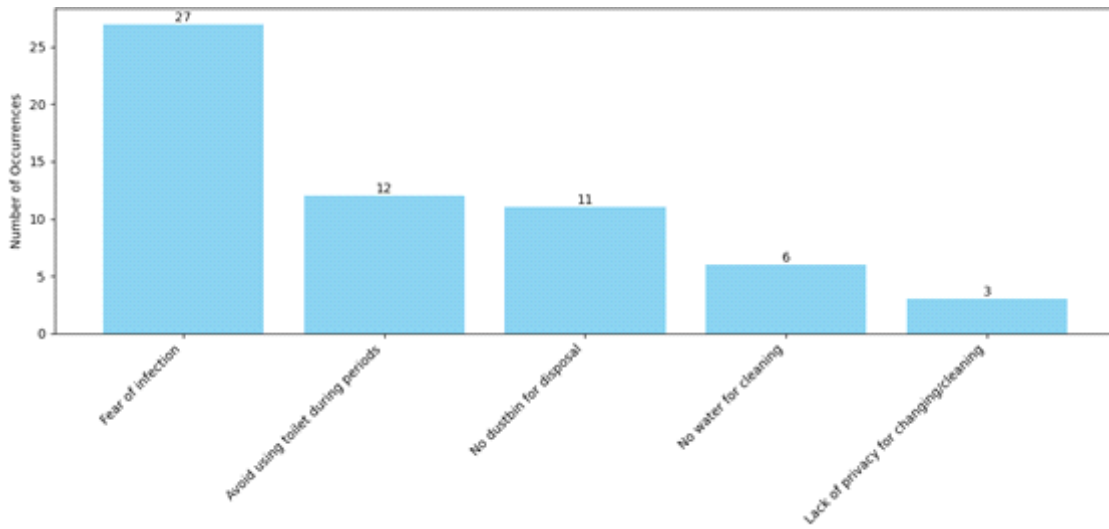
| Menstrual Product | Percentage | Number of Respondents |
|--------------------------|------------|-----------------------|
| Disposable sanitary pads | 74.0% | 37 |
| Cloth | 26.0% | 13 |



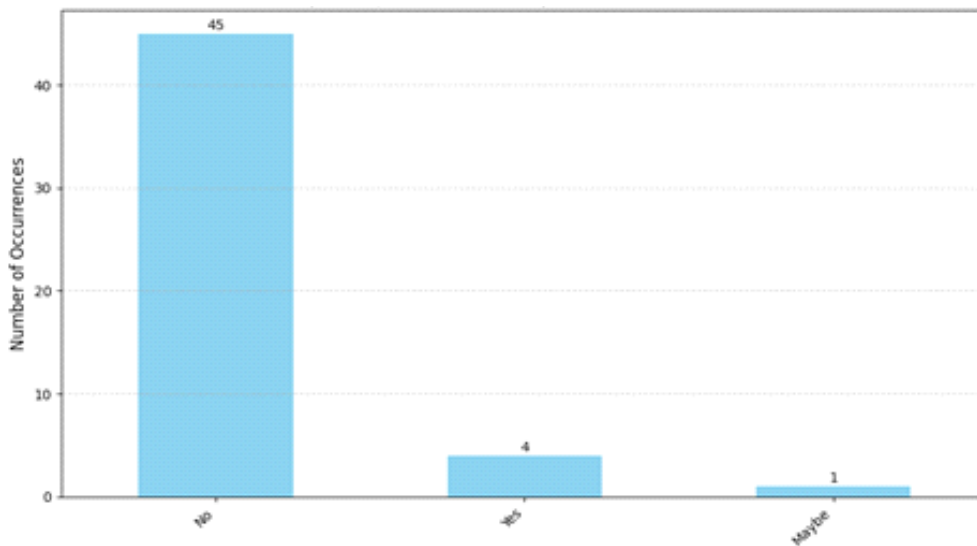
Graph 4.2. Frequency of changing menstrual product:



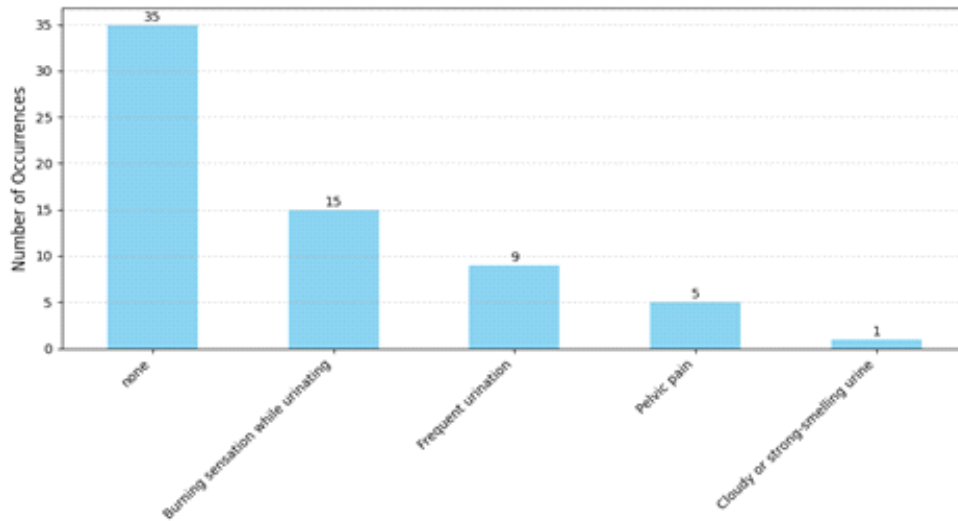
Graph 4.3. Disposal Method of Used Menstrual Product:



Graph 4.4. Challenges Faced During Menstruation While Using Community Toilets:



Graph 4.5. Have you experienced Urinary Tract Infections (UTIs)?



Graph 4.6. Have you experienced following symptoms of UTI?

Around 74% of women use disposable sanitary pads, and most women tend to change their menstrual product in every 4-6 hours and thus maintaining a healthy menstrual hygiene. 26% of the respondents rely on using cloth, and many tend to reuse them after washing. Additionally, a significant amount of women disposed their used menstrual product in open disposable ground due to lack of a dustbin nearby. Fear of getting infection, avoiding using community toilets during menstruation, lack of disposable bins were few key challenges faced by majority of the women interviewed. Although (90%) of women claimed that they don't have UTI, large percentage of women did experience the symptoms of UTI, such as burning sensation while urinating, pelvic pain and frequent urination. This is particularly concerning as it suggests that many women lack the knowledge of whether they suffer from UTI thus

making diagnosis of the infection even more difficult.

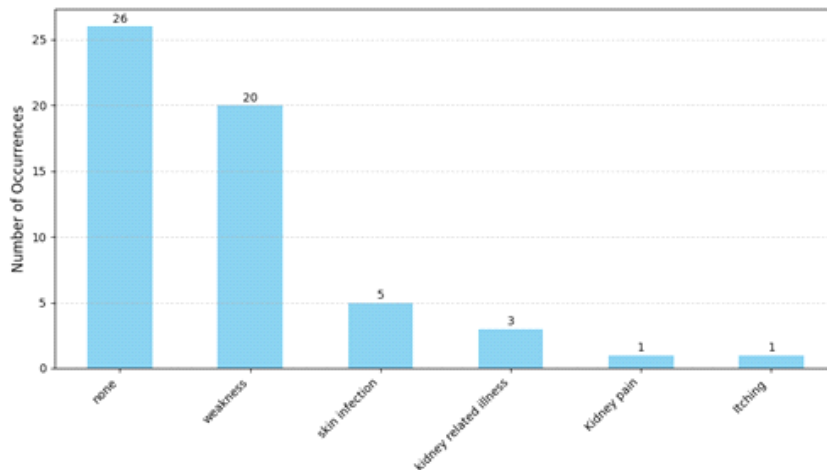
5. Coping strategies and health seeking behaviour

Table 5.1 Have you ever reduced water intake to avoid using community toilets?

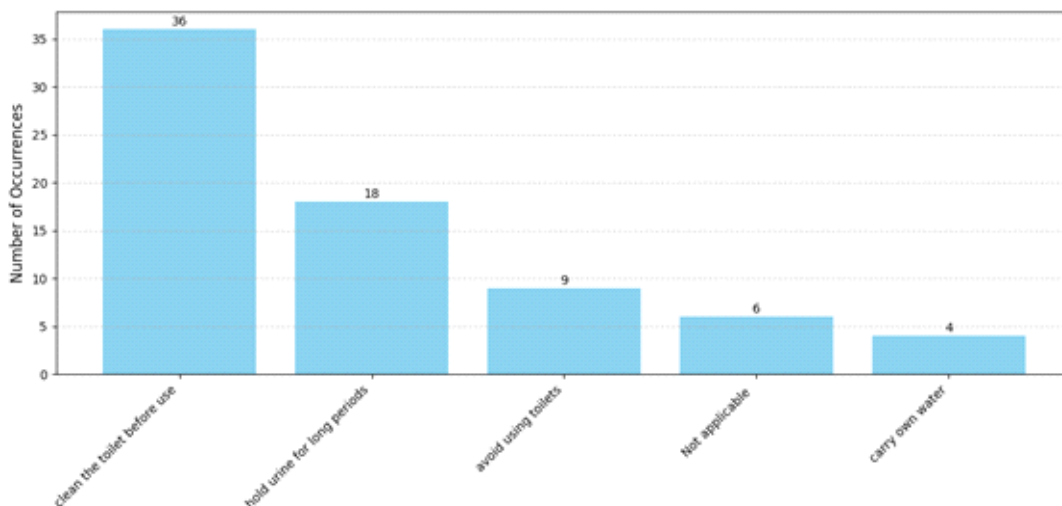
| Response | Number of Respondents | Percentage |
|----------------|-----------------------|------------|
| No | 34 | 68.0% |
| Sometimes | 15 | 30.0% |
| Yes, regularly | 1 | 2.0% |

Table 5.2 Have you ever avoided eating to reduce toilet visits?

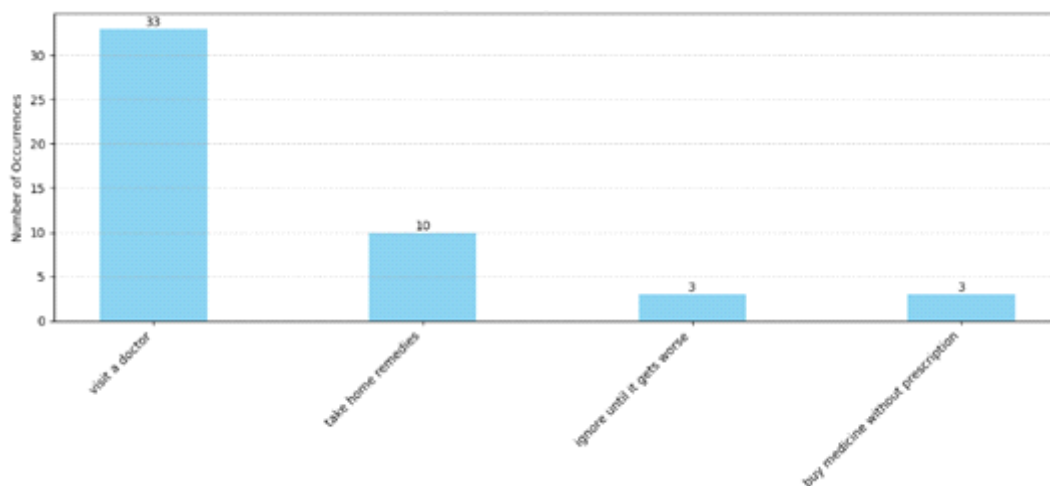
| Response | Number of Respondents | Percentage |
|----------|-----------------------|------------|
| No | 44 | 88.0% |
| Yes | 6 | 12.0% |



Graph 5.3. Have You Experienced Any of the Following Due to Poor WASH Conditions?



Graph 5.4. What Strategies Do You Use to Manage Hygiene in Poor Toilet Conditions?



Graph 5.5. What do you do when you have health problems:

While not observed commonly, a few women might tend to avoid eating or drinking to minimise toilet visits when the community toilets were closed, especially during the night. Weakness, and skin infections were observed in women who were interviewed. Poor hygiene conditions and avoidance towards hygiene of toilets could potentially cause these conditions.

STATISTICAL ANALYSIS

CHI SQUARE TEST AND FISCHER'S EXACT TEST BETWEEN FREQUENCY OF CHANGING MENSTRUAL PRODUCT AND UTI OCCURENCE

Null Hypothesis (H₀):

There is no association between the frequency of changing menstrual products and the occurrence of UTI symptoms.

Alternative Hypothesis (H₁):

There is a significant association between the frequency of changing menstrual products and the occurrence of UTI symptoms.

| | Experienced Any UTI Symptoms (True/False) | | Total |
|---|---|------|-------|
| | False | True | |
| frequency of changing menstrual product | | | |
| 5-10 hours | 1 | 0 | 1 |
| 6-8 hours | 4 | 4 | 8 |
| Every 1 hour | 1 | 0 | 1 |
| Every 2 hours | 0 | 2 | 2 |
| Every 2-3 hours | 0 | 2 | 2 |
| every 4-6 hours | 25 | 5 | 30 |
| more than 8 hours | 4 | 2 | 6 |

| frequency of changing menstrual product | Experienced Any UTI Symptoms (True/False) | | Total |
|---|---|------|-------|
| | False | True | |
| Total | 35 | 15 | 50 |

| χ^2 Tests | | | |
|---------------------|-------|----|-------|
| | Value | df | p |
| χ^2 | 14.3 | 6 | 0.027 |
| Fisher's exact test | | | 0.011 |
| N | 50 | | |

Since the **p-value (0.027) < 0.05**, we reject the null hypothesis.

Thus, there is a **statistically significant association** between the frequency of changing menstrual products and the occurrence of UTI symptoms.

CHI SQUARE TEST AND FISCHER'S EXACT TEST BETWEEN AVOIDING EATING TO REDUCE TOILET VISITS AND UTI OCCURENCE

Null Hypothesis (H₀):

There is no association between avoiding eating to reduce toilet visits and the occurrence of UTI symptoms.

Alternative Hypothesis (H₁):

There is a significant association between avoiding eating to reduce toilet visits and the occurrence of UTI symptoms.

| Have You Ever Avoided Eating to Reduce Toilet Visits? | Experienced Any UTI Symptoms (True/False) | | Total |
|---|---|------|-------|
| | False | True | |
| no | 33 | 11 | 44 |
| yes | 2 | 4 | 6 |
| Total | 35 | 15 | 50 |

| χ^2 Tests | | | |
|---------------------|-------|----|-------|
| | Value | df | p |
| χ^2 | 4.37 | 1 | 0.037 |
| Fisher's exact test | | | 0.058 |
| N | 50 | | |

Since the **p-value (0.037) < 0.05**, we reject the null hypothesis.

Thus, there is a **statistically significant association** between avoiding eating to reduce toilet visits and the occurrence of UTI symptoms.

CHI SQUARE TEST AND FISCHER'S EXACT TEST BETWEEN REDUCING WATER INTAKE TO AVOID USING COMMUNITY TOILET AND UTI OCCURENCE

Null Hypothesis (H₀):

There is no association between reducing water intake to avoid using community toilets and the occurrence of UTI symptoms.

Alternative Hypothesis (H₁):

There is a significant association between reducing water intake to avoid using community toilets and the occurrence of UTI symptoms

| Experienced Any UTI Symptoms (True/False) | Have You Ever Reduced Water Intake to Avoid Using Community Toilets? | | | Total |
|---|--|-----------|----------------|-------|
| | no | sometimes | yes, regularly | |
| False | 26 | 9 | 0 | 35 |
| True | 8 | 6 | 1 | 15 |
| Total | 34 | 15 | 1 | 50 |

| χ^2 Tests | | | |
|---------------------|-------|----|-------|
| | Value | df | p |
| χ^2 | 3.73 | 2 | 0.155 |
| Fisher's exact test | | | 0.122 |
| N | 50 | | |

Since the **p-value (0.155) > 0.05**, we fail to reject the null hypothesis.

Thus, there is no **statistically significant association** between reducing water intake to avoid using community toilets and the occurrence of UTI symptoms.

CHI SQUARE TEST AND FISCHER'S EXACT TEST BETWEEN THE TYPE OF MENSTRUAL PRODUCT USED AND THE AGE OF THE RESPONDENTS

Null Hypothesis (H₀):

There is no association between the type of menstrual product used and the age of the respondents

Alternative Hypothesis (H₁):

There is a significant association between the type of menstrual product used and the age of the respondents

| Contingency Tables | | | |
|--------------------|--------------------------------|--------------------------|-------|
| | type of menstrual product used | | |
| Age | cloth | disposable sanitary pads | Total |
| 15-25 | 1 | 19 | 20 |
| 26-35 | 5 | 7 | 12 |
| 36-45 | 7 | 11 | 18 |
| Total | 13 | 37 | 50 |

| χ ² Tests | | | |
|----------------------|-------|----|-------|
| | Value | df | p |
| χ ² | 7.67 | 2 | 0.022 |
| Fisher's exact test | | | 0.012 |
| N | 50 | | |

Since the **p-value (0.022) < 0.05**, we reject the null hypothesis.

Thus, there is a **statistically significant association** between the type of menstrual product used and the age of the respondents

CHI SQUARE TEST AND FISCHER'S EXACT TEST BETWEEN THE TYPE OF MENSTRUAL PRODUCT USED AND THE EDUCATION LEVEL OF THE RESPONDENTS

| Contingency Tables | | | |
|---------------------|--------------------------------|--------------------------|-------|
| | type of menstrual product used | | |
| Education level | cloth | disposable sanitary pads | Total |
| Graduation | 0 | 6 | 6 |
| Higher Secondary | 1 | 7 | 8 |
| No formal education | 8 | 4 | 12 |

| Contingency Tables | | | |
|--------------------|--------------------------------|--------------------------|-------|
| | type of menstrual product used | | |
| Education level | cloth | disposable sanitary pads | Total |
| Primary | 2 | 11 | 13 |
| Secondary | 2 | 9 | 11 |
| Total | 13 | 37 | 50 |

| χ ² Tests | | | |
|----------------------|-------|----|-------|
| | Value | df | p |
| χ ² | 14.3 | 4 | 0.006 |
| Fisher's exact test | | | 0.010 |
| N | 50 | | |

Since the **p-value (0.006) < 0.05**, we reject the null hypothesis.

Thus, there is a **statistically significant association** between the type of menstrual product used and the education level of the respondents.

Discussion

This exploratory study sheds light on WASH-related challenges faced by women in Dharavi and their association with urinary tract infections (UTIs). In comparison to the study by Kawade et al.⁴ and our present studies indicate heavy dependence on shared sanitation facilities where, 78% of women in Dharavi relied on community toilets compared to complete absence of individual toilets in Kawade et al.'s⁴ sample, though 93.2% of their respondents had access to a semi-private bathroom structure for urination. In contrast, only 22% of women in Dharavi reported household toilet access, reflecting continued infrastructural inadequacy in Mumbai's largest slum.

Our current data reflects that 32% women reported deliberately reducing or delaying fluid intake to avoid community toilet which is comparatively higher than the 12.15% as reported by the findings of Devane et al.(2024)¹⁴ and merely 12% of the current participants in our study avoided eating to reduce toilet visits as compared with 24.9% in Devane et al.(2024)¹⁴ study, suggesting lack of sanitation security within the Dharavi community. With respect to these behavioural patterns, the prevalence of UTI symptoms in our study has been reported at 34% which was nearly threefold higher than in

the pre-intervention phase of studies undertaken by Devane et al. (2024)¹⁴ (12.8%). Together, these comparisons reinforce that limited access to safe sanitation facilities drives unhealthy behavioural adaptations particularly, reduced food and water intake that increases susceptibility to urinary-tract symptoms (UTIs).

Additionally, our current study's finding states that approximately 30% of women who delayed changing menstrual products beyond 4–6 hours exhibited a statistically significant association with UTI symptoms ($\chi^2 = 14.3$, $p = 0.027$; Fisher's $p = 0.011$) which closely aligns with the results of Torondel B. et al.(2018)¹⁵, who reported that 30.1% of women changing menstrual absorbents once daily had a higher prevalence of Bacterial Vaginosis ($p = 0.001$). Both studies reflect that infrequent absorbent changing pattern is a consistent behavioural determinant of urogenital infections such as UTI, BV (Bacterial Vaginosis) in low-resource settings.

Compared with the study conducted by Kejriwal et al. (2021)¹⁶, the present study showed consistently higher adoption of sanitary pads across all education levels with 74 % overall usage versus 58.4 %. Among women with no formal education, 40 % of women in our study used pads compared with 28 % in theirs, and among graduates, the difference was particularly striking (90 % versus 7.4 %). These results suggest better awareness and accessibility initiatives in community of Dharavi despite similar socio-economic constraints, while education remains a strong determinant of product choice in both populations. When age-wise patterns were compared, both, our present study and Kejriwal et al. (2021)¹⁶ studies revealed that younger women were more likely to use sanitary pads, while older age groups still relied on cloth. The sanitary pad usage in our current study was 90% among women aged 15–20 years which gradually declined to 50 % among those aged 41–45 years, whereas Kejriwal et al. (2021)¹⁶ reported 78.3% and 32.1%, respectively, for the same age groups. Despite substantial disposable pad use in our study, unsafe disposal practices such as open dumping of used pads (22%) and in toilets itself (6%), shows an inevitable gap between product usage and safe disposal infrastructure.

Conclusion

This study helps to understand how inadequate WASH infrastructure in Dharavi significantly compromises women's health, particularly by increasing vulnerability to urinary tract infections (UTIs). Key findings demonstrate that delaying the change of menstrual products beyond recommended intervals and behavioural adaptations such as skipping meals to avoid unsafe toilets were significantly associated with UTI symptoms. Younger and more educated women were more likely to use disposable sanitary pads compared to older or less-educated counterparts.

The contribution of this study lies in linking specific coping behaviours—such as avoiding food intake due to unsafe sanitation facilities—to UTI occurrence, a rarely documented pathway in slum health research. These findings are consistent with previous studies on poor menstrual hygiene practices but expand understanding by showing how women's strategies to overcome use of unsafe toilets themselves become health risks.

However, being a pilot study with a modest sample size and purposive sampling method, generalizability is limited. Larger-scale studies are needed to explore larger sample size that will provide a comprehensive data and thus evaluate targeted interventions. Despite these limitations, the implications are clear: policymakers, community medicine professionals, and social workers must prioritize gender-sensitive WASH infrastructure, affordable sanitary products, safe disposal mechanisms, and awareness campaigns. Addressing these gaps is not only a matter of infection prevention but also a question of equity, dignity, and empowerment for women living in urban slums.

Funding Sources: This research did not require any grant from any funding agency.

Statement of Ethics: This study involved primary data collection only through voluntary participation. Informed verbal and written consent were obtained from all participants prior to their inclusion in the study. The research by no means involved any sensitive medical records, clinical procedures, or interventions. No human trials were conducted, and no personally identifiable information was collected that could compromise participant privacy. As the

study was observational in nature and did not pose any physical, psychological, or social risk to the participants, it did not require ethical clearance from an Institutional Ethics Committee.

Declaration of conflicts of interest: The authors declare that there are no conflicts of interest related to this study.

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Nutritional Status in Relation to Food Habits and Lifestyles among Adolescent Boys and Girls of Sombaria Village, West Sikkim

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How to cite this article: Maibam Samson Singh. Nutritional Status in Relation to Food Habits and Lifestyles among Adolescent Boys and Girls of Sombaria Village, West Sikkim. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Nutritional status is the health status of an individual resulting from the intake and utilisation of nutrients. Adolescence is a nutritionally vulnerable developmental stage, and insufficient dietary intake can lead to delayed sexual maturation and growth.

Objective: The present study was conducted to assess the nutritional status in relation to food habits and lifestyles among adolescent boys and girls of Sombaria village, West Sikkim.

Methods: Cross-sectional data on 100 adolescent boys and 100 adolescent girls were collected through a random sampling method from Sombaria village. An anthropometric rod and a weighing scale were used to measure height and weight respectively, following the standard technique of Lohman et al. Data on different food habits, exercise, sleeping hours and television time were collected from each subject. The prevalence of underweight and overweight was calculated by using z-scores for BMI for age and sex recommended by the WHO.

Results: The present study shows that the prevalence of underweight was found the same between adolescent boys (4.00%) and girls (4.00%). However, the prevalence of overweight/obesity was slightly higher among adolescent boys (13.00%) than girls (11.00%). The study reported the higher prevalence of overweight/obesity in both boys (15.76%) and girls (15.68%) who preferred restaurant foods.

Conclusion: Prevalence of overweight/obesity was higher than underweight in both sexes in the present study. Underweight was found to be more or less the same in both vegetarian and non-vegetarian adolescent boys and girls. However, the prevalence of overweight/obesity was higher in both sexes who preferred restaurant foods over home-cooked foods.

Keywords: Underweight, overweight, food habits, lifestyles, adolescent

Introduction

Adolescence is the transition phase from childhood to adulthood aged ranging from

10-19 years.¹ It is a nutritionally vulnerable developmental stage characterized by rapid growth and development in biological, psychological and

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Submission date: Dec 5, 2025

Revision date: Jan 4, 2026

Published date: April 14, 2026

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social changes.² During this period, they gain up to 20 percent of adult stature, 40 percent of adult skeleton mass and 50 percent of adult weight.³ However, insufficient dietary intake can result in delayed onset of sexual maturation and growth.^{4,5} Malnutrition is the major health problem, which causes at least half of all childhood deaths, and one-third of child deaths are due to undernutrition only.⁶ The double burden of malnutrition is more prevalent in low and middle-income countries where nutrition transition is rapidly underway.^{7,8,9} It is especially prevalent in sub-Saharan Africa, South-East Asia, and the Pacific.⁹ Approximately 90 percent of the world's adolescents reside in low and middle-income countries.¹⁰ According to the National Family Health Survey (NFHS-4), 41.9 percent of adolescent girls and 44.8 percent of adolescent boys had a BMI less than 18.5 kg/m².¹¹ However, the same study reported the low prevalence of overweight/obesity as compared to underweight in both adolescent boys (4.8%) and adolescent girls (4%). Undernutrition during the adolescent period leads to delayed and stunted growth, impaired development, an increased risk for infectious diseases, and adverse pregnancy outcomes.^{10,12,13} On the other hand, overweight adolescent has many immediate and long-term risks, including type 2-diabetes, high blood pressure, and adult obesity.^{14,15}

Under this backdrop, the present study was conducted to assess the nutritional status of adolescent boys and girls of Sombaria village of West Sikkim and the associated food habits and lifestyle factors.

Materials and Methods

The data for the present study were collected from both adolescent boys and girls aged 12 to 19 years from Sombaria village of West Sikkim. Sombaria is a small village with a mixed population of Limboo, Lepcha, Bhutia, and other Nepali communities located at a distance of 112 km from Gangtok, the capital of Sikkim. Each community in Sombaria village has their own distinct culture, tradition and beliefs. The economy of Sombaria village is mostly based on agriculture, dairy and poultry farming. A cross-sectional data

of 200 participants (100 adolescent boys and 100 adolescent girls) was collected through a random sampling method for the present study. Data were collected randomly so that participants had an equal chance of selection. An Anthropometric rod and a weighing scale to the nearest 0.1cm and 0.5 kg respectively, were used to measure height and weight following the standard technique of Lohman et al.¹⁶ The prevalence of underweight and overweight was evaluated by using z-scores for BMI for age and sex.¹⁷ According to this, BMI z-score $>+2SD$ is considered as obese, BMI z-score $>+1SD$ is considered as overweight, and BMI z-score $<-2SD$ is considered as underweight.

Information on lifestyle factors and food habits was collected from each subject following a recall method of one week period. Data on regular exercise and activities while eating were collected from each subject. Television watching time was divided into two categories: less than/equal to two hours per day and three/more than three hours per day. Data on sleeping hours was divided as less than/equal to eight hours per day and nine/more than nine hours per day. Data on food consumption were classified into two categories, namely vegetarian and non-vegetarian. Intake of non-vegetable items was divided as one-two times per week and three/more than three times per week. The data on the consumption of meals was divided into two times per day and three times per day. Data on main meals of the day, such as breakfast, lunch and dinner were also collected from each subject. The present study also collected data on preferred foods such as home-cooked foods and restaurant foods.

The data were analyzed using MS-Excel software. The parameters taken were analyzed statistically to find out mean and standard deviation for the anthropometric measurements. Overweight and obesity were grouped together as the prevalence of obesity in both adolescent boys and girls was found to be very less in the present study. Prevalence of underweight and overweight/obesity was calculated in relation to different food habits and lifestyle factors. In order to test the level of significance, both the t-test and chi-square test have been used in the present study.

Results

Table 1. Basic data on mean height, weight, BMI, underweight and overweight among adolescent boys and girls of Sombaria village

| Sex | N | Mean Height (cm) ± SD | Mean Weight (kg) ± SD | Mean BMI ± SD | Underweight | Overweight/obese |
|-------|-----|------------------------|------------------------|------------------------|-------------------------------|------------------|
| Boys | 100 | 156.78±10.98 | 48.14±12.21 | 19.28±3.00 | 4 (4.00%) | 13 (13.00%) |
| Girls | 100 | 150.01±6.64 | 46.40 ± 8.87 | 20.50 ± 3.14 | 4 (4.00%) | 11 (11.00%) |
| | | t=4.824; df=98; p<0.05 | t=0.993; df=98; p>0.05 | t=2.840; df=98; p<0.05 | $\chi^2=0.190$; df=2; p>0.05 | |

Mean height was significantly ($p<0.05$) higher among adolescent boys (156.78±10.98) than adolescent girls (150.01±6.64) in the present study (table 1). The mean weight was also higher among adolescent boys (48.14±12.21) than adolescent girls (46.40±8.87). However, mean BMI was significantly ($p<0.05$) higher

among adolescent girls (20.50±3.14) than adolescent boys (19.28±3.00). The frequency of underweight was found the same between adolescent boys (4.00%) and adolescent girls (4.00%). But, the frequency of overweight/obesity was found higher among adolescent boys (13.00%) than adolescent girls (11.00%).

Table 2. Distribution of different BMI values in relation to food consumption, non-veg intake and activities while eating among adolescent boys and girls of Sombaria village

| Category | Boys | Underweight | Overweight/obesity | Girls | Underweight | Overweight/obesity |
|-----------------------------|------|-------------------------------|--------------------|-------|-------------------------------|--------------------|
| Vegetarian | 23 | 1 (4.35%) | 3 (13.04%) | 25 | 1 (4.00%) | 3 (12.00%) |
| Non-veg. | 77 | 3 (3.89%) | 10 (12.98%) | 75 | 3 (4.00%) | 8 (10.67%) |
| | | $\chi^2=0.009$; df=2; p>0.05 | | | $\chi^2=0.034$; df=2; p>0.05 | |
| Intake of non-veg. per week | | | | | | |
| 1-2 times | 38 | 2(5.26%) | 6(15.79%) | 63 | 3(4.76%) | 7(11.11%) |
| 3+ times | 39 | 1(2.56%) | 4 (10.25%) | 12 | 1(8.33%) | 2(16.67%) |
| | | $\chi^2=0.970$, df=2; p>0.05 | | | $\chi^2=0.601$; df=2; p>0.05 | |
| Activities while eating | | | | | | |
| Yes | 53 | 0(0.00%) | 8(15.09%) | 38 | 1(2.63%) | 1(2.63%) |
| No | 47 | 4(8.51%) | 5(10.64%) | 62 | 3(4.84%) | 10(16.13%) |
| | | $\chi^2=4.940$, df=2; p>0.05 | | | $\chi^2=4.872$, df=2; p>0.05 | |

Table 2 shows that the frequency of underweight was found to be more or less the same between vegetarians (4.35%) and non-vegetarians (3.89%) adolescent boys. Similarly, the prevalence of overweight/obesity was also found to be more or less the same between vegetarians (13.04%) and non-vegetarians (12.98%) adolescent boys. The frequency of underweight (4.00%) was found the same among adolescent girls who are vegetarians and non-vegetarians. However, the frequency of overweight/obesity was slightly higher among adolescent girls who are vegetarians (12.00%) than non-vegetarians (10.67%). The higher frequency of underweight (5.25%) and overweight/obesity (15.79%) was found among adolescent boys who

eat non-vegetable items one to two times per week. However, the frequency of underweight (8.33%) and overweight/obesity (16.67%) was found higher among adolescent girls who eat non-vegetable items more than three times per week. The frequency of underweight (8.51%) was higher among adolescent boys who didn't do any activities while eating. Whereas, the frequency of overweight/obesity (15.09%) was higher among adolescent boys who engaged in activities like watching television and playing games on their mobile phone while eating. The frequency of both underweight (4.84%) and overweight/obesity (16.13%) was higher among adolescent girls who didn't do any activities while eating.

Table 3. Distribution of different BMI values in relation to the number of meals, main meal and preferred food among adolescent boys and girls of Sombaria village

| Category | Boys | Underweight | Overweight/ obesity | Girls | Underweight | Overweight/ obesity |
|----------------------|------|--------------------------------|------------------------|-------|--------------------------------|------------------------|
| Number of meals/day | | | | | | |
| 2 times | 11 | 1(9.09%) | 2(18.18%) | 24 | 2(8.33%) | 3(12.50%) |
| 3 times | 89 | 3(3.37%) | 11(12.35%) | 76 | 2(2.63%) | 8(10.52%) |
| | | $\chi^2=1.213$; df=2; p>0.05 | | | $\chi^2=1.673$; df=2; p>0.05 | |
| Main meal of the day | | | | | | |
| Breakfast | 24 | 1(4.17%) | 1(4.17%) | 22 | 0(0.00%) | 4(18.18%) |
| Lunch | 22 | 0 (0.00%) | 3(13.64%) | 17 | 0(0.00%) | 1(5.88%) |
| Dinner | 54 | 3(5.55%) | 9(16.67%) | 61 | 4(6.56%) | 6(9.83%) |
| | | $\chi^2=3.638$; df=4; p>0.05 | | | $\chi^2=4.275$; df=4; P>0.05 | |
| Food preference | | | | | | |
| Home-cooked | 68 | 4(6.25%) | 8(11.76%) | 49 | 3(6.12%) | 3(6.12%) |
| Restaurant | 32 | 0(0.00%) | 5(15.62%) | 51 | 1(1.96%) | 8(15.68%) |
| | | $\chi^2= 2.142$; df=2; p>0.05 | | | $\chi^2= 3.245$; df=2; p>0.05 | |

Table 3 shows that the frequency of underweight (9.09%) and overweight/obesity (18.18%) was higher among adolescent boys who eat meals twice a day. Similarly, the frequency of underweight (8.33%) and overweight/obesity (12.50%) was higher among adolescent girls who eat meals twice a day. The higher frequency of underweight (5.55%) and overweight/obesity (16.67%) was found among adolescent boys whose main meal of the day is dinner. Among adolescent girls, the higher frequency of underweight

(6.56%) and overweight/obesity (18.18%) was found in those whose main meals of the day are dinner and breakfast, respectively. The higher frequency of underweight was found among adolescent boys (6.25%) and girls (6.12%) who preferred home-cooked foods. However, the frequency of overweight/obesity was found higher among adolescent boys (15.62%) and girls (15.68%) who preferred restaurant foods.

Table 4. Distribution of different BMI values in relation to exercise, television watching and sleeping hours among adolescent boys and girls of Sombaria village

| Category | Boys | Underweight | Overweight/ obese | Girls | Underweight | Overweight/ obesity |
|---------------------|------|-------------------------------|----------------------|-------|-------------------------------|------------------------|
| Exercise | | | | | | |
| Yes | 58 | 0(0.00%) | 7(12.07%) | 38 | 1(2.63%) | 6(15.79%) |
| No | 42 | 4(9.52%) | 6(14.28%) | 62 | 3(4.84%) | 5(8.04%) |
| | | $\chi^2=6.020$, df=2; p<0.05 | | | $\chi^2=1.649$, df=2; p>0.05 | |
| Television watching | | | | | | |
| ≤2hours | 69 | 3(4.35%) | 6(8.69%) | 64 | 3(4.69%) | 8(12.50%) |
| 3hours+ | 31 | 1(3.22%) | 7(22.58%) | 36 | 1(2.78%) | 3(8.33%) |
| | | $\chi^2=3.659$; df=2; p>0.05 | | | $\chi^2=0.673$; df=2; p>0.05 | |
| Sleeping hours | | | | | | |
| ≤8 hours | 33 | 0(0.00%) | 6(18.18%) | 30 | 1(3.33%) | 3(10.00%) |
| 9hours+ | 67 | 4(5.97%) | 7(10.45%) | 70 | 3(4.28%) | 8(11.43%) |
| | | $\chi^2=2.995$, df=2; p>0.05 | | | $\chi^2=1.503$; df=2; P>0.05 | |

Table 4 shows that the frequency of underweight (9.52%) and overweight/obesity (14.28%) was found to be higher among adolescent boys who didn't exercise. The prevalence of underweight (4.84%) and overweight/obesity (15.79%) was higher among adolescent girls who didn't exercise and who exercised, respectively. The frequency of underweight (4.35%) and overweight/obesity (22.58%) was found higher among adolescent boys who watched television for less than/equal to two hours per day and more than three hours per day, respectively. Among adolescent girls, the frequency of underweight (4.69%) and overweight/obesity (12.50%) was found higher in those who watched television less than/equal to two hours per day. The higher frequency of underweight (5.97%) and overweight/obesity (18.18%) was found among adolescent boys who slept for more than nine hours and eight hours per day, respectively. Among adolescent girls, the higher frequency of underweight (4.28%) and overweight/obesity (11.43%) was found in those who slept over nine hours per day.

Discussion

Adolescence is an important period in which nutritional needs increase for the growth of bone, muscle and development.¹⁸ The health behaviours related to diet and physical activities shaped during this time persist into adulthood.¹⁹ The present study shows that the frequency of underweight (4.0%) was found the same in both adolescent boys and girls. However, overweight/obesity was slightly higher among adolescent boys (13.0%) than girls (11.0%). The prevalence of overweight/obesity was higher than underweight in both sexes in the present study. A study in rural West Bengal shows the prevalence of underweight (boys-31.1%; girls-21.1%) and overweight/obesity (boys-4.1%; girls 5.2%) among adolescents.²⁰ Another study by Panda et al. shows the prevalence of underweight (boys-15.8%; girls-8.8%) and overweight (boys-7.5%; girls-10.3%) among adolescents in Sikkim.²¹ The economic status of households is an important indicator of access to adequate food supplies and good health care facilities. An increase in westernization and globalization has led to a nutritional transition in low and middle-income countries which characterized the coexistence of undernutrition and overnutrition.²²

Adolescence is a time when individuals experience increasing control over their food choices.²³ The present study shows that the prevalence of underweight and overweight/obesity was more or less the same in both vegetarian and non-vegetarian adolescent boys and girls. The prevalence of both underweight and overweight/obesity was higher among adolescent girls who eat non-vegetable items more than three times a week in the present study. It was higher among adolescent boys who eat non-vegetable items one-two times a week. The differences in the prevalence of underweight and overweight/obesity in relation to the intake of non-vegetable items were statistically insignificant in the present study. Breakfast is considered the most important meal of the day to stay healthy, yet breakfast is more commonly missed than any other meal.²⁴ It is estimated that children consume approximately 20 percent of their daily energy intake at breakfast.²⁵ In the present study, the prevalence of underweight was higher in both sexes who considered dinner as their main meal of the day. The study further shows the higher frequency of overweight/obesity among adolescent boys and girls who considered dinner and breakfast respectively as the main meals of the day. The prevalence of nutritional status in relation to the main meals of the day was statistically insignificant in the present study. Many studies have reported that people who missed breakfast had lower energy and macronutrient intake compared with those who usually consumed breakfast.^{26,27} Adolescents consume a larger percent of energy intake at fast food and other restaurants,²⁸ which often leads to weight gain by accumulating excess fat. The present study shows a higher prevalence of overweight/obesity in both sexes who prefer restaurant foods, and underweight was higher in both sexes who preferred home-cooked foods.

Several studies reported the negative association between the level of physical activity and overweight in children.²⁹ The prevalence of underweight was higher in both sexes who didn't exercise in the present study. However, overweight/obesity was higher in adolescent boys and girls who didn't exercise, and those who did exercise, respectively. An increasing level of physical activity can contribute to weight management.³⁰ Many studies have shown an association between television time and obesity.³¹

Eating while viewing television increases energy intake in children.³² The present study shows that overweight/obesity was higher among adolescent boys who played mobile games and watched television while eating. It was found the opposite in case adolescent girls. However, underweight was higher in both sexes who didn't play mobile games and watched television while eating. These differences were statistically insignificant. Children who spend more time on television consume more energy-dense foods and drinks resulting in higher energy intake.^{33,34} The present study shows a higher prevalence of overweight/obesity among boys who slept for eight hours or less per day. However, it was slightly higher among girls who slept for more than nine hours per day. The underweight was higher in both sexes who slept over nine hours per day. The prevalence of both underweight and overweight/obesity in relation to sleeping duration was found statistically insignificant in the present study. Short sleep duration may produce hormonal changes associated with weight and nutrition.³⁵ It may also contribute to physical inactivity and decreased energy expenditure.^{36,37}

Conclusion

The prevalence of overweight/obesity shows higher than underweight in both sexes in the present study. Prevalence of both underweight and overweight in relation to consumption of non-vegetable items shows fluctuation in both sexes. However, the prevalence of overweight/obesity shows a positive relation in both sexes who prefer restaurant foods. The underweight was higher in both sexes who considered dinner as their main meal of the day. The prevalence of nutritional status shows differences in relation to lifestyle factors such as exercise, television time, activities while eating, and sleeping hours. Therefore, awareness and proper education on health should be provided to identify the factors influencing nutritional status and its health consequences.

Informed Consent: Data were collected during mandatory Anthropological fieldwork by my students for their master's dissertations under my guidance. During the fieldwork, written informed consent was not taken from the participants. However, the nature and

purpose of the research work were clearly explained to the participants verbally before the data collection. Participants were also informed the measurements involved, such as height and weight, as well as some of the questions on lifestyles and food habits. Participants were involved in data collection voluntarily.

Ethical Clearance: no

Source of Funding: Nil

Conflict of Interest: No

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A Survey of Allied Health Students' Knowledge and Awareness of Radiation Hazards and Protection in a Private University in Guwahati

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How to cite this article: Mayuri Ojah, Meghna Guha, Priyanka Kumari. A Survey of Allied Health Students' Knowledge and Awareness of Radiation Hazards and Protection in a Private University in Guwahati. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Radiation exposure, particularly in healthcare settings, poses significant risks if not managed properly. Understanding the hazards associated with radiation and adhering to protection protocols are essential, especially for allied health students who are likely to encounter radiological procedures in their professional careers. This study assessed the awareness and knowledge levels regarding radiation protection and hazards among students from various allied health departments at a private university in Guwahati.

Methods: A cross-sectional study was conducted with 435 participants of allied health students at The Assam Royal Global University selected through non-probability convenience sampling. The study was conducted between June and August 2024. It was made up of 17 close-ended questions assessing their awareness about radiation and related radiation hazards. Data were collected via a self-administered online questionnaire distributed through Google Forms. Participants were also questioned about their willingness to learn more about radiation safety measures and need of awareness programs on radiation safety. Descriptive statistics, t-tests, and ANOVA were used for data analysis.

Results: The majority of respondents (96.5%) were aware of radiation hazards, and 93.5% expressed willingness to attend a radiation awareness program. There was no significant difference in knowledge or awareness between male and female students ($p = 0.758$ and $p = 0.991$, respectively). However, a significant difference was observed across departments in both knowledge ($p = 0.0001$) and awareness ($p = 0.0003$), with Radiography students scoring the highest. The mean age of participants was 21.02 years, with a balanced gender distribution (52% male, 48% female), and most were undergraduate students (91.26%).

Conclusion: While overall awareness of radiation hazards among allied health students was high, knowledge levels varied significantly by department. These findings highlight the need for targeted educational interventions to ensure all healthcare students receive adequate training in radiation safety, especially those in non-radiology fields.

Keywords: radiation hazard, radiation protection, allied health students, awareness and knowledge, guwahati

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Submission date: August 6, 2025

Revision date: October 6, 2025

Published date: April 14, 2026

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What is already known on this subject:

1. Exposure to ionizing radiation provides significant occupational hazard in healthcare settings.
2. There is a lack of awareness and knowledge of radiation safety among medical and allied health students.
3. Previous studies suggest gaps in radiation protection knowledge among non-radiology students.

What this paper adds:

1. It provides a comparative analysis of awareness and knowledge across various allied health departments.
2. It highlights significant differences in radiation knowledge between Radiography and other health programs.
3. It emphasizes the need for curriculum-wide integration of radiation safety training.

Introduction

Radiation plays a critical role in modern healthcare, particularly in diagnostic imaging and therapeutic procedures. While the benefits of radiation in medicine are undeniable, it also poses significant hazards if not properly managed. Healthcare professionals, including allied health workers, must be knowledgeable about radiation safety and protection protocols to minimize the risks of exposure to themselves, patients, and the broader public¹. Radiation exposure can lead to both immediate and long-term health consequences, including tissue damage, radiation sickness, and an increased risk of cancer². Therefore, a strong understanding of radiation hazards and the implementation of protective measures is crucial in clinical practice. Despite this, previous studies have indicated that knowledge and awareness of radiation protection among healthcare students, including those in allied health disciplines, may be inadequate³. This inadequacy could result in unsafe practices and heightened risk of exposure in clinical settings⁴.

Allied health professionals, who often work closely with radiological procedures, need to be well-versed in radiation safety. Given the growing reliance on diagnostic imaging and other radiation-based techniques in modern healthcare, there is an urgent

need to assess the level of knowledge and awareness among students in this field⁵. Identifying gaps in their understanding can inform educational reforms and ensure that future healthcare workers are equipped to handle radiation safely and effectively.

Research Gap

Several studies have been conducted worldwide where the researchers have evaluated medical and allied health students' knowledge and awareness of radiation hazards; however, data is limited in the Indian subcontinent and especially in the North-Eastern region. All those studies mentioned earlier have included medical students or students or trainees from the Radiology department and have not taken into consideration the awareness and understanding of the other allied health disciplines like physiotherapy, optometry and nutrition and dietetics. This creates a vacuum in our understanding of how awareness and knowledge differ throughout departments that could come into indirect contact with radiation in clinical practice.

Need for the study

It is crucial that all allied health workers, not just radiography or radiology trainees, have sufficient understanding of radiation risks and safety measures due to the growing dependence on radiation-intensive treatment procedures and diagnostic imaging. Universities can create focused training programs, curriculum changes, and awareness campaigns by identifying current knowledge and awareness gaps. In Guwahati, where a number of allied health programs coexist in a private university context, this study is especially significant since it provides a chance to compare knowledge levels across disciplines and identify areas that need educational reinforcement. The students from allied departments will, in the future, be working around a Radiology department and as such it becomes crucial that they are aware about the harmful effects of ionizing radiation as well as the precautionary measures available at the departmental and individual level.

This study aims to assess the knowledge and awareness of radiation hazards and protection among allied health students at a private university in Guwahati, Assam, India. By evaluating their current understanding, we hope to identify areas where

improvements are needed and recommend strategies for enhancing radiation safety education within the allied health curriculum.

Materials & Methods

A cross-sectional study was conducted with 435 participants of allied health students at The Assam Royal Global University selected through non-probability convenience sampling. The study was conducted between June and August 2024. It was made up of 17 close-ended questions assessing knowledge and methods of radiation safety measures and data were collected via a self-administered online questionnaire distributed through Google Forms. Participants were also questioned about their willingness to learn more about radiation safety measures and need of awareness programs on radiation safety.

Study Population: The study population consisted of allied health course students enrolled in four programs at The Assam Royal Global University, which are those from departments of Radiography, Physiotherapy, Optometry and Nutrition and Dietetics. A total of 450 students were invited to participate in the survey.

Sampling Technique: A convenience sampling method was employed to recruit participants for this study. Students who met the inclusion criteria and were willing to participate in the survey were selected. The inclusion criteria were allied health students currently enrolled in any of the medical allied science programs and students who gave informed consent to participate. The exclusion criteria were students who did not provide consent and students who had previously completed radiation protection courses or training outside their academic curriculum.

No formal power analysis was done before data collection. With 435 participants and a high response rate, the sample was large enough for descriptive estimates and for detecting moderate group differences, but no exact calculation for specific effect sizes was performed.

Data Collection Tool: A structured questionnaire was developed based on previously validated tools and adapted to the local context. The questionnaire comprised seventeen questions. The questionnaire was distributed in online format using Google Forms to accommodate students' preferences. Participation

in the survey was voluntary, and consent was obtained from the head of the departments before proceeding. Students were informed that their responses would be anonymous and confidential. Questions included age, sex, program in which they are enrolled, familiarity about radiation and its harmful effects, protective devices of minimizing radiation and other such related questions. Students were also asked about their willingness to improve their knowledge about radiation safety.

Statistical Analysis: The collected data were entered into Microsoft Excel for statistical analysis.

Result

There were 450 questionnaires distributed to the allied health students, radiography (n= 162), physiotherapy (n=171), optometry (n= 69) and nutrition and dietetics (n=33). There were 435 respondents (response rate of 96%), of which 52.7% (n=225) were males and 48.3% (n=210) were females (Table 1). Out of the 435 respondents, 92.26% (n=397) were undergraduate and 8.73% (n=38) were postgraduate students. The mean age of the respondents is 21.02 years, with a standard deviation (SD) of 2.004, indicating that most participants are young adults, in the undergraduate or early postgraduate age range, with minor variation in age. Out of 435 respondents, 225 (52%) were male and 210 (48%) were female. The distribution is a balanced one, suggesting no significant gender skew in participation. A vast majority, 397 respondents (91.26%), are pursuing undergraduate (UG) education. Only 38 participants (8.73%) are at the postgraduate (PG) level, implying that the findings mainly reflect the knowledge and awareness levels of undergraduate students. [Table 1].

Table 1: Demographic information on the respondents

| Characteristics | Mean | SD |
|------------------------|---------------|----------|
| Age | 21.02 | 2.004 |
| Sex | Number | % |
| Male | 225 | 52% |
| Female | 210 | 48% |
| Education level | Number | % |
| UG | 397 | 91.26 |
| PG | 38 | 8.73 |

Cont....

| Department | Number | % |
|------------------|--------|-------|
| Radiography | 162 | 37.24 |
| Physiotherapy | 171 | 39.31 |
| Optometry | 69 | 15.8 |
| Food & Nutrition | 33 | 7.5 |

Table 2: Awareness frequency of the respondents

| Awareness | Frequency | % |
|-----------|-----------|------|
| Yes | 420 | 96.5 |
| No | 15 | 3.4 |

Table 2 presents the demographic distribution of awareness regarding radiation hazards. A significant majority (96.5%) of respondents reported being aware of radiation hazards, while only 3.4% indicated a lack of awareness.

Table 3 shows the awareness frequency disaggregated by sex. The mean knowledge score on radiation protection was slightly higher among females (12.38%, SD = 3.20%) compared to males (12.29%, SD = 2.74%). Similarly, the mean awareness score was nearly identical between females (96.55%, SD = 18.26%) and males (96.53%, SD = 18.3%). The p-values for both knowledge (p = 0.758) and awareness (p = 0.991) indicate no statistically significant difference between male and female respondents.

Table 4 provides a department-wise comparison of knowledge and awareness. Radiography students had the highest mean knowledge (14.27%, SD = 1.74%) and full awareness (100%) of radiation protection. This was followed by Physiotherapy, Food & Nutrition, and Optometry students. The p-values for both knowledge (p = 0.0001) and awareness (p = 0.0003) suggest statistically significant differences among departments.

Table 3: Knowledge on radiation protection and awareness of hazard between males and females

| Sex | Knowledge of radiation protection Mean (SD) | Awareness of radiation hazards Mean (SD) |
|---------|---|--|
| Males | 12.29% (2.74%) | 96.53% (18.3%) |
| Females | 12.38% (3.20%) | 96.55% (18.26%) |
| P value | 0.758 | 0.991 |

Table 4: Knowledge on radiation protection and awareness of hazard among different departments

| Department | Knowledge of radiation protection Mean (SD) | Awareness of radiation protection Mean (SD) |
|------------------|---|---|
| Radiography | 14.27% (1.74%) | 100% |
| Physiotherapy | 12.53% (2.91%) | 96.49% |
| Optometry | 10.88% (3.89%) | 91.30% |
| Food & Nutrition | 11.39% (3.12%) | 93.93% |
| p value | 0.0001 | 0.0003 |

Table 5: Willingness of the respondents to attend a radiation awareness program

| Willingness | Frequency | % |
|-------------|-----------|------|
| Yes | 407 | 93.5 |
| No | 28 | 6.4 |

Table 5 highlights respondents' willingness to attend a radiation awareness program. A large proportion (93.5%) expressed interest in participating, while only 6.4% were not willing. Overall, the results indicate high levels of awareness and willingness to learn more about radiation hazards, though notable differences in knowledge exist across academic departments.

Discussion

A research by Shafiq et al evaluated medical students' understanding of radiation dangers and protection. According to their research, pupils who had no formal radiography education had a typically poor comprehension of these subjects. Nonetheless, the students who had taken a brief radiography course or workshop had a markedly improved comprehension of ionizing radiation, its origins, possible health hazards, and preventative actions. The study emphasizes how awareness can be raised with even short educational interventions. This research bolsters the case for including brief, targeted training sessions on radioactive safety in medical curricula, particularly for students pursuing fields outside than radiography or radiology⁶.

In Palestine, Awadghanem et al conducted a study on medical students' understanding of radiation dosages and related hazards. The findings

revealed a serious lack of knowledge among students, especially with regard to the radiation exposures connected to routine diagnostic procedures including CT scans, X-rays, and nuclear medicine imaging. Numerous participants understated the dangers of ionizing radiation, indicating that misunderstandings and ignorance may be a factor in risky behaviors or inadequate patient communication. In order to meet the needs of undergraduate medical students, this study highlighted the critical need for structured teaching modules that cover radiation dosimetry and the biological effects of radiation exposure⁷.

In another study, O'Sullivan et al looked into how students' understanding of radiation exposure was affected by clinical radiology exposure in the curriculum. According to the study, students who were enrolled in a structured program that covered clinical radiology issues showed a progressive rise in understanding as their years of school rose. Higher-year students showed a greater understanding of dosage estimation, imaging appropriateness, and radiation safety principles. This implies that a more thorough comprehension and more knowledgeable future practitioners may result from early and regular exposure to radiology instruction during medical training. According to the study, radiology education should be integrated longitudinally, starting in medical school and continuing through clinical rotations⁸.

Our study, which built on this all-encompassing approach, sought to identify the comparative knowledge gaps between students from other allied health fields, including physiotherapy, nursing, laboratory technology, and optometry, and radiology students, who are expected to have formal exposure to radiation-related topics. All medical practitioners, regardless of specialty, are likely to come into direct or indirect contact with radiation-based procedures during clinical practice, which is the justification for this inclusion.

Conclusion

The radiography students demonstrated a fair understanding of ionizing radiation, but the knowledge among students from other courses were lacking. This is concerning, as it is essential for all students to have awareness of radiation, especially

considering that they will eventually be working in a hospital environment where radiation-related procedures are common. Additionally, the presence of a radiation facility on the university premises further underscores the importance of understanding radiation safety and its potential risks. These findings are new and highlights that allied health programs differs widely in their understanding of radiation safety even within the same organisation. Many students expressed a willingness to improve their knowledge in this area and showed interest in participating in awareness programs that would help them gain a better understanding of ionizing radiation. Putting together interactive training sessions, seminars, and workshops on radiation safety could greatly close the knowledge gap among students who are not studying radiography. All allied health schools should include basic radiation awareness in their curricula to guarantee that all students, regardless of specialization, have a basic understanding of radiation sources, possible health hazards, and safety procedures. Furthermore, cooperation across departments like public health, medical physics, and radiology can help create multidisciplinary modules that emphasize the significance of radiation safety in all areas of healthcare. Frequent evaluations and feedback systems could be used to track the success of these programs and pinpoint areas in need of more development.

Implications of the study

There are a few important implications from the findings of this study for public health and allied health professionals. In the near future, many of these students will eventually be working in hospitals and clinical setting where ionizing radiation based procedures will be common. Knowledge inadequacy will result in unsafe practices and increase in occupational hazards. Since radiation can neither be seen nor felt, it becomes a very difficult task to monitor how much a person is irradiated without proper protocols. Therefore, including radiation safety courses in all allied health curricula will undoubtedly improve future healthcare providers' readiness and foster a safer workplace for both employees and patients.

Limitations of the study

There are several limitations on this study. Convenience sampling from a single private university may have limited the results' generalization, and no formal sample-size calculation was done. Additionally, smaller subgroup sizes (e.g., Nutrition & Dietetics) have reduced the precision of department-level comparisons. Future research should include bigger, more representative samples and formal power calculations as well as examine radiation awareness and knowledge among allied health students across various institutions and geographical areas.

Declaration by Authors: This study involved an anonymous, voluntary survey of university students and did not collect any sensitive personal or health-related information. As per institutional practice, such student-based surveys were considered exempt from formal ethics committee review. Informed consent was obtained from all participants prior to data collection, and confidentiality of responses was maintained throughout the study.

Source of Funding: None

Conflict of Interest: The authors declare no conflict of interest.

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Relationship Between Depression and Quality of Life Among Bipolar Affective Disorder (BPAD) Patients at a Tertiary Care Hospital, West Bengal, India.

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How to cite this article: Mita Mandal Basak, Aparna Ray, Gautam Bandyopadhyay. Relationship Between Depression and Quality of Life Among Bipolar Affective Disorder (BPAD) Patients at a Tertiary Care Hospital, West Bengal, India. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Introduction: Bipolar Affective Disorder (BPAD) is a serious and long-lasting mental illness marked by episodes of mania and depression. Even when patients are in remission, depressive symptoms often persist and can greatly reduce their quality of life (QOL). Understanding this relationship is important for improving overall patient care and outcomes.

Materials and Methods: This cross-sectional study was conducted in the Psychiatry Department of MCH, Kolkata, from April to December 2024. A total of 180 BPAD patients aged 18–65 years, all in remission, were selected through simple random sampling technique. Data were collected using a socio-demographic questionnaire, WHOQOL-BREF (26 items), and Hamilton Depression Rating Scale (17 items). Analysis was performed using SPSS (2016 version).

Results: Residual depression was common: 51% of patients had mild depression, 47.7% moderate, and 1.11% severe. Quality of life scores showed 16.11% with poor QOL, 81.11% with average QOL, and only 2.77% with good QOL. A moderate negative correlation was found between depression and QOL, indicating that greater depression was linked to poorer life quality. Religion, residence, occupation, and medication discontinuation were significantly associated with depression, while age, gender, and occupation influenced QOL.

Conclusion: Even during remission, many BPAD patients experience depression that impacts daily living and overall wellbeing. Addressing socio-demographic factors and ensuring treatment adherence are crucial for improving their quality of life.

Keywords: Bipolar Affective disorder, Quality of Life, Depression.

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Submission date: October 4, 2025

Revision date: Nov 20, 2025

Published date: April 14, 2026

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Introduction

Bipolar Affective disorder (BPAD) is a chronic, severe, and disabling mood disorder characterized by alternating episodes of mania and depression. It significantly impairs daily functioning, cognition, and overall quality of life (QOL). In India, the lifetime prevalence of BPAD is about 0.5%, with a slightly higher rate in males (0.6%) than females (0.4%)¹

The depressive phase is particularly common in both Bipolar I and II disorders and is marked by persistent low mood, loss of energy, lack of interest, poor sleep and appetite, low self-esteem, and feelings of guilt or worthlessness. BPAD is recognized as one of the leading global causes of disability, affecting work, family, and social life²⁻⁴

Quality of life (QoL) reflects an individual's perception of physical, psychological, and social well-being.⁵ Enhancing QoL in BPA Dpatients is crucial, as it indicates overall functioning and well-being^{6,7} Research consistently shows that depressive symptoms are strongly linked to reduced QoL in BPAD⁸⁻¹⁰

Globally, BPAD affects around 1% of the population and is associated with premature mortality, increased suicide risk, and higher rates of comorbid anxiety and substance use disorders. Patients often remain symptomatic for nearly half their lives, with depressive episodes being particularly disabling and long-lasting¹¹. Even during symptom-free periods, individuals with BPAD experience lower QOL compared to healthy individuals, with impairments in mood regulation, cognition, sleep, social functioning, and occupational performance¹²

Overall, Bipolar Affective disorder profoundly impacts multiple aspects of life, emphasizing the need for comprehensive management strategies aimed at improving both symptom control and quality of life.

WHOQOL-BREF is a globally validated and cross-culturally applicable holistic instrument to assess QoL¹⁷. It is organized into four domains regarding specific aspects of QoL related to: I) physical health; II) psychological health; III) social relationships; and IV) environment.

Although broad and highly subjective, recent evidence in mental health points to QoL as an

important indicator of patients' well-being¹⁹; thus, its assessment could be of great value to better understanding the patients' health and decide among possible treatments¹³.

Patients with bipolar disorder spend approximately half their life-time symptomatic¹¹, with syndrome or sub-syndrome symptoms, greatly affecting their quality of life². Depressive symptoms are particularly disabling and long-lasting, making patients unable to act properly in home and workplace for approximately 30% of their lives¹⁶. These also have a significant effect on severity and prognosis of the disease. Presence of Depressive symptoms also cause a significant impact on the quality of life (QOL) of patients with BPAD, and predict even worse outcomes in a variety of prognostic and severity indicators.

Operational Definition: Remission was defined as the absence of clinically significant symptoms of both mania and depression for at least two months. For assessment, a Young Mania Rating Scale (YMRS) score of ≤ 12 was used to indicate minimal or no manic symptoms, and a Hamilton Depression Rating Scale (HAM-D17) score of ≤ 7 was used to indicate minimal or no depressive symptoms

Materials and Methods

- Study Participants
- The study included patients diagnosed with Bipolar Affective Disorder (BPAD) attending a tertiary care hospital from April 2024 to December 2024, recruited using a random sampling technique.

Inclusion Criteria:

- Diagnosed with BPAD for at least one year
- Age 18–65 years
- Able to understand Bengali, Hindi, or English
- Willing to participate and provide informed consent
- Exclusion Criteria:
- Pregnant women
- Newly diagnosed cases
- Presence of severe medical comorbidities

Study Instrument:

Data were collected using three instruments: a semi-structured sociodemographic questionnaire, the WHOQOL-BREF (26 items) for assessing quality of life, and the Hamilton Depression Rating Scale (HDRS, 17 items) for evaluating depression in BPAD patients.

The sociodemographic questionnaire was divided into two parts:

Part I: Personal and social information, including age, sex, religion, education, marital status, occupation, monthly family income, and residence.

Part II: Clinical information, including duration of illness, family history of mood disorders, number of recurrences, type of medication, history of substance use, prior hospitalizations, and treatment adherence (yes/no).

Bengali versions of the WHOQOL-BREF and HDRS were adopted from previously validated published literature.

Data Collection:

Ethical Approval: Ethics committee approval was taken from MCH, Kolkata Ref No MC/KOL/IEC/NON-SPON/657/03/2020 DATED 12/03/2020.

Informed Consent was taken from the subjects by informing the nature and purpose of the study, and the participants did not get financial benefits from this study. The present study posed a very low risk to the participants.

Study Design and Population

This study was conducted as part of a PhD research project and included patients diagnosed with Bipolar Affective Disorder (BPAD) who were currently in remission. Patients attending the clinic and meeting the inclusion criteria on each clinic day were invited to participate. The purpose and nature of the study were explained, and written informed consent was obtained from all participants.

Data Collection Procedure

Data collection began with participants completing a sociodemographic questionnaire

and the WHOQOL-BREF to assess quality of life. Subsequently, the Hamilton Depression Rating Scale (HDRS) was administered by the investigator to evaluate the severity of depressive symptoms. This approach ensured the systematic collection of both self-reported and clinically assessed data.

Statistical Analysis

Sociodemographic data were analyzed using descriptive statistics. Multiple logistic regression analyses were performed to examine associations between the severity of depression and sociodemographic variables. Additionally, domain-wise quality of life (QOL) scores were compared with depression scores. The level of statistical significance was set at $p < 0.05$.

Result & Analysis

Table I: Demographics and clinical characteristics of Bipolar Affective Disorder patients n=180

| Sl no | characteristics | Variables | n(%) |
|-------|-------------------|---------------|------------|
| 1. | Age | • 18-25 yrs | 22(12.22) |
| | | • 25-35 yrs | 44(24.44) |
| | | • 35-45 yrs | 56(31.11) |
| | | • 45-55yrs | 37(20.55) |
| | | • 55-65 yrs | 21(11.66) |
| 2. | Sex | Male | 91(50.55) |
| | | Female | 89(49.44) |
| 3. | Religion | Muslim | 108(60) |
| | | Hindu | 72(40) |
| 4. | Marital Status | Married | 128(71.11) |
| | | Single | 39(21.66) |
| | | Widow | 9(5) |
| | | Divorce | 4(2.22) |
| 5. | Residence | Urban | 62(34.44) |
| | | Rural | 98(54.44) |
| | | Semi urban | 20(11.11) |
| 5. | Occupation | Home maker | 75(41.66) |
| | | Labor | 61(33.88) |
| | | Self Employed | 05(2.77) |
| | | Business | 15(8.33) |
| | | Unemployed | 24(13.33) |
| 6. | per capita income | <3000 | 84(46.66) |
| | | 3001-5000 | 75(41.66) |
| | | 5001-10000 | 21(11.66) |

Cont...

| | | | |
|-----|---------------------------------|-------------|------------|
| 7. | Duration of illness | 1-3 yrs | 28(15.55) |
| | | 4-6 yrs | 67(37.22) |
| | | 7-10 yrs | 29(16.11) |
| | | <10 yrs | 56(31.11) |
| 8. | Diagnosis | BPADI | 130(71) |
| | | BPADII | 50(27.77) |
| 9. | H/O discontinuation of medicine | yes | 132(73.33) |
| | | no | 48(26.66) |
| 10. | previously hospitalized | yes | 48(26.66) |
| | | no | 132(73.33) |
| 11. | No of recurrence/relapse | 1 time | 43(23.88) |
| | | 2 times | 75(41.66) |
| | | 3 times | 39(21.66) |
| | | 4 times | 13(7.22) |
| | | 5 and above | 10(5.55) |
| 12. | Family H/O BPAD | No | 64(35.55) |
| | | yes | 116(64.44) |
| 13. | Medication regimen | Sodium | 68 |
| | | valproate | 52 |
| | | Lithium | 29 |
| | | Tab | |
| | | Clonazepam | 90 |
| | | Tab | |
| | Olanzapine | 37 | |
| | Tab AMT | | |

Table no 1 presents the sociodemographic and clinical profile of the study sample. Among patients with BPAD, 50.55% were male and 49.44% female. The largest age group was 35–45 years (31%), followed by 25–35 years (24%), 18–25 years (12%), and 55–65 years (11%). Most were married (71.11%), with 21.66% single and 5% widowed. By religion, 60% were Muslim and 40% Hindu. In terms of habitat, 54.44% lived in rural areas, 34% urban, and 11% semi-urban. Among females, 41.66% were homemakers, while among males, the main occupations were labor (33.88%), unemployed (13%), and business (8%). Nearly half (46.66%) had a per capita income of less than ₹3000. Regarding clinical characteristics, 37.22% had illness duration of 4–6 years. BPAD-I was diagnosed in 71%, and 73.33% had a history of medication non-compliance. 41.66% had two recurrences, and 64.44% had a family history of BPAD. Treatment regimens included Sodium Valproate (68 patients), Lithium (52), Olanzapine (90), and Amitriptyline (37).

Table 2. Level of Depression and Quality of Life among Patients with Bipolar Disorder n = 180

| Variable | Category | n | % |
|-----------------------|----------|-----|-------|
| Depression Level | Mild | 92 | 51.11 |
| | Moderate | 86 | 47.77 |
| | Severe | 2 | 1.11 |
| Quality of Life (QOL) | Poor | 29 | 16.11 |
| | Average | 146 | 81.11 |
| | Good | 5 | 2.77 |
| Overall QOL Mean | — | — | 58.20 |

Table no 2 represents level of depression among Bipolar Disorder patients. Mild depression 92(51.11%), Moderate depression 86(47.77%), Severe depression 2(1.11%)

This table showed Average QOL(81.11 %), poor quality of life. 16.11(%), good QOL (2.77%). overall QOL mean is 58.20.

Table 3: Domain wise Mean and SD of QOL Score: n=180

| Sl no | Domain Name | Mean± SD |
|-------|---------------|--------------|
| | psychological | 62.05 ±16.66 |
| | Social | 58.33± 0 |
| | physical | 53.57±14.28 |
| | Environmental | 40.62± 6.25 |

Table no 3 represents domain wise Quality of life of the BPAD patients. 1. Psychological domain mean± SD (62.05 ±16.66) followed by 2. Social domain 58.33± 0 3. Physical domain (53.57±14.28)& 4. Environmental domain 40.62± 6.25

Table 4: Findings related to correlation between depression and Quality of life of Bipolar Disorder patients:

| Correlations | | | |
|-----------------|---------------------|-------------|-----------------|
| | | Depression | Quality of life |
| Depression | Pearson Correlation | 1 | -.465(.060) |
| | Sig(2-tailed) | | |
| | N | 180 | 180 |
| Quality of life | Pearson Correlation | -.465(.060) | 1 |
| | Sig(2-tailed) | | |
| | N | 180 | 180 |

Table no 4 depicts moderately negative correlation between depression and Quality of life

of bipolar Disorder patients: Can also be termed as significant negative correlation at 0.05 level.

Table 5. Association between Quality of Life and Sociodemographic Profile of BPAD Patients (Multiple Logistic Regression) n=180

| Variable | B | SE | df | Sig (p-value) | Interpretation |
|----------------|--------|-------|----|---------------|---|
| Age | -0.38 | 0.023 | 1 | 0.096 | Not statistically significant |
| Gender | -1.222 | 0.703 | 1 | 0.082 | Trend toward females having better QOL |
| Marital Status | 0.246 | 0.622 | 1 | 0.692 | Not significant |
| Occupation | | | | | |
| Homemaker | 1.331 | 1.031 | 1 | 0.970 | Not significant |
| Labor | 2.109 | 0.844 | 1 | 0.012 | Significant; better QOL than homemakers |
| Business | 0.904 | 0.690 | 1 | 0.190 | Not significant |

Model fitness: The model explained 31% of the variability in QOL (Nagelkerke $R^2 = 0.31$).

Table 5: Multiple logistic regression analysis examined the association between QOL and sociodemographic factors among BPAD patients. The model explained 31% of the variability in QOL (Nagelkerke $R^2 = 0.31$). Among the predictors, occupation was significantly associated with QOL. Specifically, laborers reported significantly better

QOL than homemakers ($p = 0.012$). Age, gender, marital status, and business occupation were not statistically significant, although there was a trend suggesting that female patients and older age groups may have slightly better QOL. These findings indicate that occupational status plays a key role in the perceived quality of life in patients with BPAD, while other sociodemographic factors have a weaker influence.

Table no 6: Association between Depression and Sociodemographic Profile of BPAD Patients (Multiple Logistic Regression) n=180

| Variable | B | SE | df | Sig (p-value) | Interpretation |
|---------------------------------------|-------|-------|----|---------------|---|
| Religion | 4.012 | 1.446 | 1 | 0.006 | Significant; Hindu patients less depressed than Muslim patients |
| Residence | 3.424 | 1.240 | 1 | 0.006 | Significant; Rural patients less depressed than urban patients |
| Occupation | | | | | |
| Business | 0.335 | 2.428 | 1 | 0.890 | Not significant |
| Homemaker | 2.773 | 3.161 | 1 | 0.380 | Not significant (trend toward higher depression) |
| Labor | 0.106 | 1.857 | 1 | 0.955 | Not significant |
| History of Medication Discontinuation | 18.73 | 47.68 | 1 | 0.977 | Not significant (trend toward higher depression) |

Model Fitness: The model explained 59% of the variability in depression (Nagelkerke $R^2 = 0.59$).

Table 6: Multiple Logistic Regressions (predictor of Depression): presents predictors of depression. Religion (Hindu), residence (rural), occupation (homemaker), and history of medication discontinuation were associated with depression levels. The model explained 59% of depression variability (Nagelkerke $R^2 = 0.59$).

Discussion

In the present study, 92 (51.11%) patients with bipolar disorder had mild depression, 86 (47.77%) had moderate depression, and 2 (1.11%) had severe depression. A moderate negative correlation was found between depression and quality of life (QOL), indicating that greater depressive symptoms were associated with poorer QOL. Depression levels were significantly associated with religion, habitat, occupation, and medication discontinuation. Similar findings were reported by Chakraborty S., who observed that nearly half of bipolar patients were non-adherent to treatment¹³, and by Tamene et al. in Ethiopia, who identified medication non-adherence as a key predictor of poor outcomes¹⁴.

The overall mean QOL score was 58.20; 81.11% of participants reported average QOL, 16.11% poor QOL, and 2.77% good QOL. QOL was significantly associated with age, gender, and occupation. Consistent with previous studies, patients with bipolar disorder demonstrated an overall poor QOL^{15,16,17} with females showing lower QOL than males. Age and occupation were also significant predictors, aligning with findings by Boyban et al. and Simon et al.^{18,19}

Our results support earlier evidence that depressive symptom severity and sociodemographic factors adversely affect QOL and functioning in bipolar disorder²⁰. Similarly, systematic reviews by Morton et al. and Michalak et al. found that depressive symptoms were moderately and negatively correlated with QOL^{21,22} while Brieger et al. reported reduced QOL across all domains in both unipolar and bipolar groups²³. Longitudinal findings by Khafif et al. also confirmed that depressive episodes consistently impair QOL over time²⁴.

Limitation: The present study has certain limitations. Data were collected from a single tertiary

care centre, which may not represent all individuals with bipolar disorder. The restricted inclusion and exclusion criteria may limit the generalizability of the findings. As participants were recruited from a medical college hospital, replication in community settings is recommended. Moreover, the cross-sectional design precludes establishing causal relationships between predictor and outcome variables.

Conclusion

This study's conclusion emphasizes the significant relationship between depression and quality of life (QOL) in patients with Bipolar Affective Disorder (BPAD). The research found a moderately negative correlation between depression and QOL, indicating that as depressive symptoms increase, a patient's QOL tends to decline. A large majority of the studied BPAD patients were found to have depressive symptoms, with over half having mild depression and nearly half having moderate depression. The findings highlight that key factors like age, gender, occupation, and medication adherence are significantly associated with a patient's QOL and depression levels. The study's methodology, which uses validated scales to measure depression and QOL, can be applied in other settings to further explore this relationship. The results provide a crucial foundation for developing targeted interventions to manage depressive symptoms and improve the well-being of BPAD patients.

Acknowledgements: The authors would like to acknowledge all the patients and their family members of department of psychiatry who are participated in the study for their support.

Declaration of conflict of interests: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

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Water, Sanitation and Hygiene Practices: A Cross-sectional Study on Rural Women from West Bengal in India

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How to cite this article: Nivedita Som. Water, Sanitation and Hygiene Practices: A Cross-sectional Study on Rural Women from West Bengal in India. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Sustainable Development Goal targeted equitable access to safe water, sanitation and hygiene (WaSH) in women's life. However, utilization in WaSH still does not reach optimal level in rural sector of India despite huge promotion of policies.

Objective: To understand water, sanitation and hygiene practices of rural women from the state of West Bengal.

Methods: The present cross-sectional study involved 252 women [88 from caste (PC women), 53 from tribal (PT women) group of rural part of Purulia; 111 from caste (HC women) group of rural part of Howrah] following purposive sampling technique. A pre-tested schedule was canvassed for collecting data on socio-demographic characteristics, water facilities, usage and associated issues, urination and defecation practices, menstrual health management. Descriptive statistics were performed. A sub-section of the participants was involved in group discussion.

Results: PC women reported scarcity of drinking water (89.7%), open site urination and defecation practice (97.9%), used clothes as menstrual absorbents (61.1%). PT women reported use of sanitary napkins (90%), could get access of household toilets (99.9%), nearby drinking water source (66.6%); however, 83.7% reported open site urination and defecation practice. HC women used household toilets (42.8%), nearby drinking water source (71.4%); reported habit of washing hands (89.5%) and private parts during menstruation (63.4%) along with frequent changing of menstrual absorbent (52.4%); however, unhygienic disposal of menstrual absorbent was practiced by HC women.

Conclusion: The study suggests that intervention programs could impart education for uprising knowledge and attitude towards adoption of healthy WaSH practices among rural women.

Key words: WaSH practices, rural women, Purulia, Howrah, India

Introduction

A comprehensive understanding of Water, Sanitation and Hygiene (WaSH) became an

interesting domain of research as a multidimensional and culturally embedded phenomenon. Inadequate WaSH emerges global health challenge, affecting health and well-being of one-third population.¹

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Submission date: August 7, 2025

Revision date: October 6, 2025

Published date: April 14, 2026

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Worldwide, 2.1 billion people do not have access to safe drinking water at home, 2.3 billion do not have access to basic sanitation, 1 billion practice open defecation.² Women are the most vulnerable because they receive a limited access to WaSH services while they have greater need for privacy during defecation and bathing compared to men.³ The Sustainable Development Goal (SDG) 6 (universal access to safe water and sanitation) jointly with the SDG 5 (Women and girls often manage water, and access to water reduces gender inequality) has been highlighting on access to equitable sanitation and hygiene for women during menstruation, pregnancy and postpartum.⁴

During the last few decades, Government of India implemented policies with the aim to improve WaSH facilities throughout India. In spite of huge promotion of these programs, rural people mostly remained unaware about adopting improved WaSH services,⁵⁻¹⁰ thereby utilization of WaSH still does not reach optimal level.¹¹ In West Bengal, so far, a very few studies demonstrated the scenario of WaSH practices among people living in rural sector. Thus, the present study aimed to understand water, sanitation and hygiene practices of rural women from the state of West Bengal.

Materials and Methods

Study area

The present study was conducted in rural areas of Purulia and Howrah district of West Bengal. In Purulia, the study was conducted in two villages namely 'Bareriya' and 'Bhupatipally' of the Baghmundi community development CD block of Jhalda sub-division and four villages namely 'Anara', 'Loyara', 'Jhapra', 'Jabarra' of the Para CD block of Raghunathpur subdivision. In Howrah district, the study was conducted in one village 'Narit' of Amta II CD block and in two villages namely 'Chak Thakurani' and 'Paliara' of Udaynarayanpur CD block of Uluberia sub-division. The study areas were chosen following operational convenience.

Justification for selection of the study areas

Following the record of Ministry of Drinking Water and Sanitation, despite the successful coverage of Swachh Bharat Mission throughout India, West Bengal showed a little decline in open

defecation free (ODF) coverage and Household toilet (HHT) coverage [West Bengal: ODF- 95.61%, HHT- 99.78%].¹² Furthermore, about 95% sanitation coverage was reported in rural sector of most of the districts (including Howrah) in West Bengal. However, Purulia district solely showed a low sanitation coverage (<65%).¹³ Thus, there remained a definite need to involve both districts of West Bengal in order to depict a comparative approach with respect to WaSH practices.

Study participants

Initially, 736 women [(155 from Para CD block, 99 from Baghmundi CD block, and 482 from both Amta II and Udaynarayanpur CD block)] aged 20 to 45 years were enlisted following the electoral roll. The study used purposive sampling technique to finally recruit 252 women from the rural areas of Purulia and Howrah district following the selection criteria: the participants, who were married, aged between 20 and 45 years old, remained in child bearing age, had at least one surviving child. Out of 252 participants, 88 (PC women) from caste (Bauri) group, 53 (PT women) from tribal (Birhor) group were selected from 'Para' and 'Baghmundi' CD block of Purulia respectively; 111 (HC women) from caste (Mahisya, Bagdi, Tili) group were selected from Amta II and Udaynarayanpur CD block of Howrah. Women, who attained both natural and surgical menopause (n=193), remained reluctant to voluntarily participate in survey (n=231) and remained unavailable (n=60) were excluded from study. The survey was conducted in Purulia between the month of December, 2019 and March, 2020; and in Howrah between the month of September, 2021 and November, 2021. The response rate for participation at survey was 55% and 23% in Purulia and Howrah respectively. A low response rate in Howrah district was associated with the fact that a large proportion of women expressed hesitant to take part in survey amid pandemic situation. A written informed letter was submitted to office of the Block Development Officer of each CD block. The verbal consent was obtained from each study participant.

Data types

Data on socio-demographic characteristics, water facilities, usage and associated issues, urination and defecation practices, menstrual health management

were collected using a pre-tested schedule. The schedule was developed in English language, translated into vernacular language and further back translated to English language to check validity of the questions. Each participant was interviewed in private. A sub-section of the participants was involved in group discussion.

Statistical analyses

Descriptive statistics (Frequency and percentage) was performed to understand the distribution of socio-demographic characteristics, water facilities, usage and associated issues, urination and defecation practices, menstrual health management for three distinct groups of the study participants using SPSS 26.0. Here, narratives of a few study participants during group discussion were presented as the excerpts.

Results

Socio-demographic profile

It is found that median value of age of the participants of PC, PT and HC group were 31 years, 29 years and 37 years respectively. Majority of the participants and the spouse belonging to PC and PT group were non-literate while a large proportion of HC participants and spouse reported attainment of school education up to primary and secondary levels. The participants of all three groups were exclusively home makers, while majority of spouse were engaged as the daily labour. (Table 1)

Table 1 Socio-demographic profile of study participants (n=252)

| Socio-demographic characteristics | PC women (n=88) | PT women (n=53) | HC women (n=111) |
|--|-----------------|-----------------|------------------|
| | % | % | % |
| Age of the participants (completed years) (median value) | 31 | 29 | 37 |
| Educational levels of the participants | | | |
| Non-literate | 72.2 | 87.0 | 43.3 |
| Primary | 24.2 | 13.0 | 33.3 |
| Secondary | 3.4 | - | 17.3 |
| Graduate | - | - | 6.0 |

Cont....

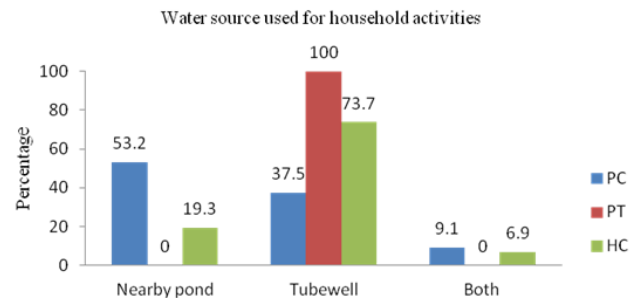
| | | | |
|---|------|------|------|
| Occupational status of the participants | | | |
| Exclusive homemakers | 91.0 | 69.5 | 53.3 |
| Daily labours | - | 23.0 | 33.3 |
| Others* | 9.0 | 7.4 | 13.2 |
| Educational levels of the spouse | | | |
| Non-literate | 54.5 | 77.0 | - |
| Primary | 27.3 | 13.0 | 55.5 |
| Secondary | 15.2 | 10.0 | 33.3 |
| Graduate | 3.0 | - | 11.2 |
| Occupational status of the spouse | | | |
| Daily labours | 82.0 | 91.3 | 56.6 |
| Service | 4.5 | - | 30.1 |
| Small scale business | 13.6 | 8.7 | 13.2 |

PC= caste group of Purulia, PT= tribal group of Purulia, HC= caste group of Howrah

*others= engaged in small scale business, house-maid

Water facilities, usage and associated issues

About 49.6% of PC women and all HC women used water from tube well for drinking and cooking, 53.2% of PC women used water from pond for other household activities. All PT women used water for drinking and household activities from tube well. None of the water filtration method was used by PT and PC group; only 13.9% HC women reported the practice of water filtration. 89.7% PC women reported scarcity of drinking water in the locale. (Figure 1)



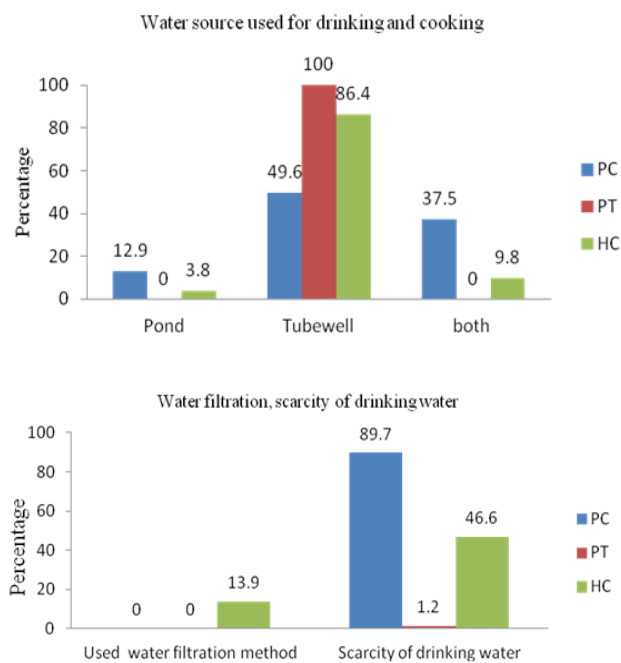


Figure 1: Water facilities, usages and associated issues reported by study participants

Urination and defecation practices

About 97.9% of PC women reported urination and defecation practices at open site, 1/4th of them reported presence of HHT. While almost all PT women reported presence of HHT, 66.6% of PT women reported presence of water source nearby HHT; however, only a few (19.8%) used HHT, 83.7% practiced open site urination and defecation. About 82% and 42.8% of HC women had HHT and water source nearby respectively; 39.8% of them practiced open site defecation and urination.

Moreover, PT women reported cleaning of places after defecation (60.8%), washing private parts after urination (78.2%) and hands with soap (39.6%) after defecation. About 13.8% and 33.3% of PC women respectively reported washing private parts after urination and washing hands with soap after defecation. While 50.8% of HC women reported washing places and private parts after urination; 89.5% of them used soap for hand washing after defecation. (Figure 2)

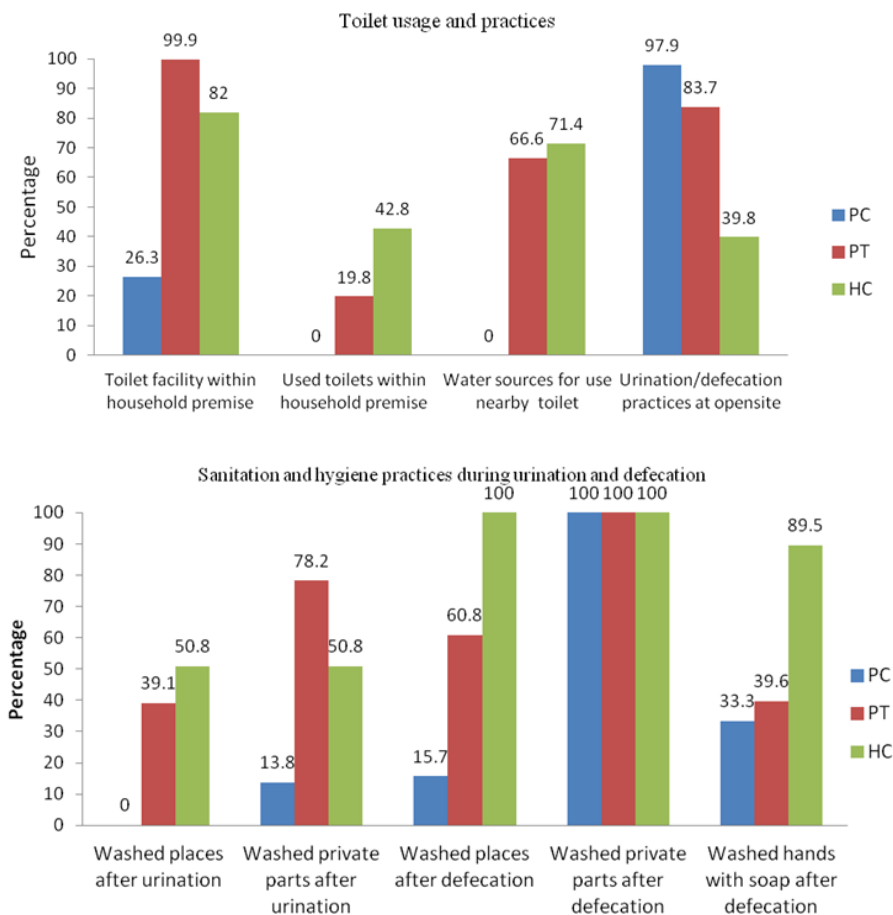


Figure 2: Urination and defecation practices reported by study participants

Menstrual health management

About 90% and 82.5% of PT and HC women respectively reported use of sanitary napkins, 61.1% of PC women reported use of clothes as menstrual absorbent. PT (65%) and PC (55.5%) women reported change of menstrual absorbents once in a day. HC women reported cleaning of private parts once in a day and used soap during menstrual days more compared to PC and PT women. PC women washed used clothes (58.4%) and disposed menstrual absorbents into pond or nearby places (44.5%). PT women burnt sanitary napkins (55%) and sometime disposed under-ground (33.6%). HC women reported disposal of absorbents into pond or nearby places (67.3%). (Figure 3)

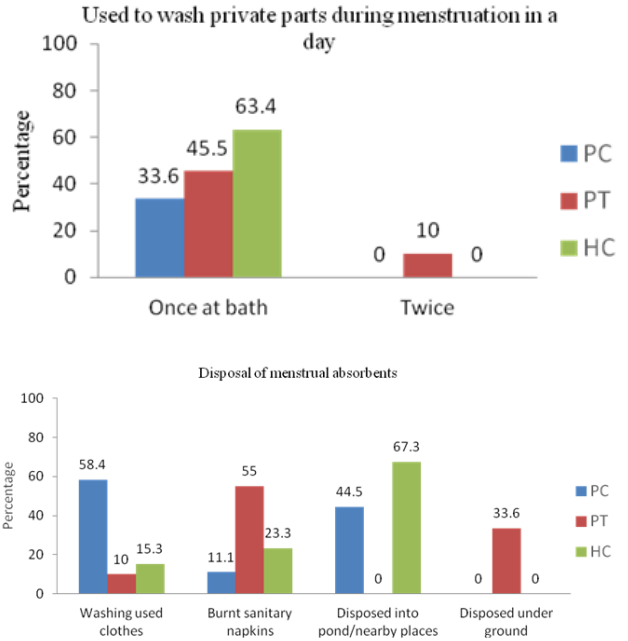
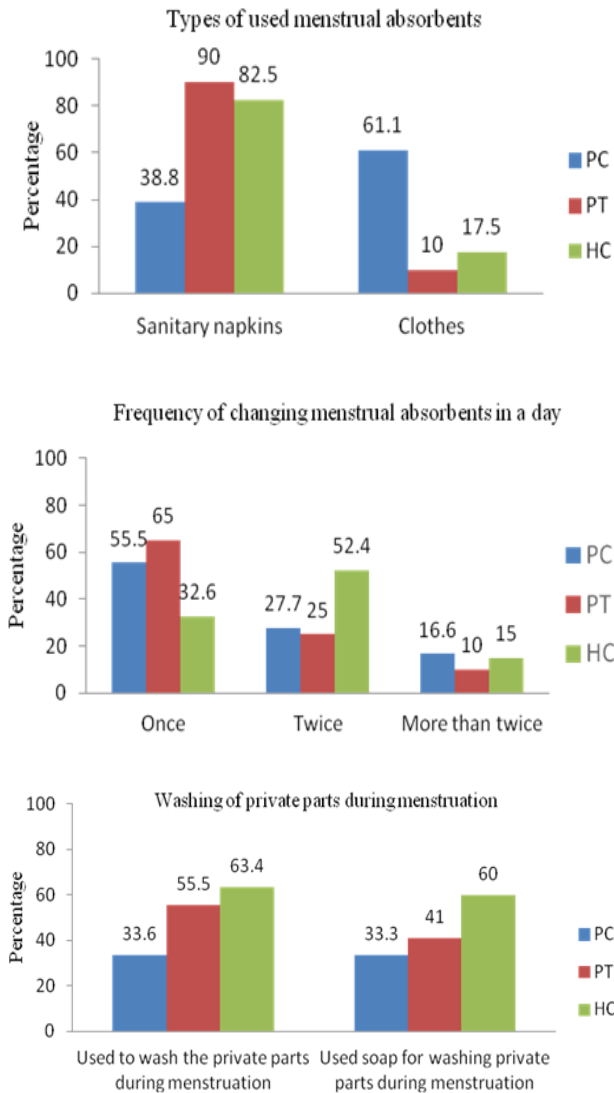


Figure 3: Menstrual health management reported by study participants

Excerpts from PC group

One participant (36 years old) said, “We have HHT, but it has been in the condition of no use due to its substandard construction. There is no water supply nearby the toilet. We need to carry water from pond, prefer to go open site defecation and urination nearby pond.”

Another participant (37 years old) said, “We do not have tube well nearby. I have to carry water for drinking and cooking from a distance. I use water from nearby pond for other household chores.”

Another participant (41 years old) said, “The water from tube well proximal to household contains dirt and soil. I regularly fetch water from tube well of neighborhood village. Drinking water shortage at summer remains high in this region.”

A participant (33 years old) said, “Our family members do not use HHT because of its location beside living room. We go for open site urination and defecation. I use clothes as menstrual absorbent. I do not want to spend money for buying sanitary pads, but my two daughters use sanitary pads. I usually wash the clothes (used as menstrual absorbents) at the nearby pond. My two daughters also disposed sanitary pads nearby pond.”

Excerpts from PT group

One participant (24 years old) said, "There are HHT attached with tube well. Family members use both HHT and tube well."

Another participant (43 years old) said, "In spite of having HHT attached with tube well, I prefer open site urination and defecation as I am used to with this practice since my childhood. Only my daughter-in-laws use HHT because of young age."

One participant (26 years old) said, "I use water for drinking and household chores from tube well nearby. I use sanitary pads and buy those from nearby health centre at low cost; often receive those from non-governmental organizations who frequently visit our village. I usually dispose of used sanitary pads under-ground."

Excerpts from HC group

One participant (29 years old) said, "HHT is being used by all family members. Water supply is sufficient because of presence of tube well proximal to my house. Family members use water for drinking and household chores from nearby tube well, but during monsoon, here due to the flood in each year, we need to use water from pond."

Another participant (41 years old) said, "I use water from nearby pond for household chores, use water for drinking from nearby tube well. I use clothes as menstrual absorbents. I wash private part once during menstrual days. I usually wash the used clothes (menstrual absorbents) nearby pond."

Another participant (25 years old) said, "I use sanitary pads and change it more than twice a day. I wash private part daily during menstruation. I usually dispose used sanitary pads nearby places."

Discussion

The present study aimed to understand WaSH practices of rural women from the state of West Bengal. The study involved women of both caste and tribal groups from rural part of Purulia and women of caste group from rural part of Howrah. Therefore, a comparative approach was reflected on these three groups of women living in distinct locales of West Bengal.

The study revealed that PC women could not be able to access safe water, mostly expended their

energy to carry water from a distance, and reported scarcity of drinking water, particularly at summer. The urination and defecation at open site was largely practiced by them because of the substandard construction of HHT and/or the position of toilet beside living room. The attitude and practices towards menstrual hygiene remained unsatisfactory probably because of their paucity of knowledge regarding menstrual health management. Studies suggest that Purulia is considered to be the worst-performing district in terms of WaSH services in West Bengal.^{14, 15} It was found that about 86% of rural people in Purulia still followed open site defecation and urination and reported complaint against substandard construction of the Government aided HHT; thus they used HHT as the alternative of other ancillary purposes.¹⁶ On the other hand, Purulia being a drought-prone area, rural women commonly used to collect water by walking miles after miles with earthen pots, particularly at summer. Because of their hard struggle for water they remained aware of the importance of water conservation.¹⁷ However, in the present study, PC women did not report any sort of water conservation practice despite their enormous grievance towards water quality and scarcity at summer.

PT women, from Birhor community could get access of toilets and had drinking water source within household premise. However, most of them never used HHT, preferred open site urination and/or defecation practices because of their long day's old habit. Despite the long-term struggle with cultural and religious identity, recently the Birhors in West Bengal tend to interact with mainstream society and participate slowly in various non-governmental and government-sponsored developmental programs¹⁸ that probably develop positive attitude towards adoption of good menstrual health management among women as found in the present study. The reports of both NFHS 4 (2015-2016) and NFHS 5 (2019-2021) documented that tribal groups across different states of India showed a steady development in terms of decline in open defecation practice, acceptance of HHT facilities, and accessibility to drinking water source within premise and adoption of good habit like washing hand with soap before meals.¹⁹ However, a study on Malayalee tribal group living at Jawadhi hills, TamilNadu demonstrated that WaSH practices remained significantly poor in association with low

per capita income of household.²⁰ Similarly, rural mothers belonging to both caste and tribal groups of Odisha were found failing to follow adequate WaSH practices, consequently that raised potential risk of getting infected with water borne diseases among their children of age under five years old.²¹ In rural areas, several domestic and personal exposure (such as washing the cooking utensils, bathing, washing mouth, cooking, and drinking) into nearby pond could contaminate water source and caused to the outbreak of water born diseases,²² that might have shown significant association with poor nutritional status of local people.²³

HC women in the present study mostly reported use of HHT and drinking water source within premise. However, several preferred for open site defecation. A good habit of washing hand and private parts along with frequent changing of menstrual absorbent were also reported by them. But, the practice of unhygienic disposal of menstrual absorbents indicates their paucity of knowledge and ignorant attitude towards menstrual health management. Bera and Adhikari²⁴ showed that rural Bengalee Hindu women could not afford to maintain hygiene during menstruation because of their lower socio-economic standard, though they had a satisfactory level of knowledge and attitude towards menstrual health management. Studies from Odisha, Bihar and Chattisgarh found that rural women reported open site defecation practice despite having HHT, used clothes as menstrual absorbents and adopted the practice of unhygienic disposal of menstrual absorbents.^{23,25} Several factors like non Hindu household, resource poor condition of the family, distant location of drinking water source, non acceptance of primary health centre visit, and non attendance in Government aided intervention programs were responsible to develop such attitude towards unhealthy WaSH practices among rural women.²³

Like other studies,^{5,7} the present study epitomized that despite the promotion of WaSH related policies, a gap still prevails in understanding towards the availability and utilization of WaSH services among rural women. Apart from this, unequal access to WaSH services as found in distinct groups of rural women living in same province also determines a large difference in WaSH utilization. Because of having inadequate knowledge on WaSH,

rural women during their childbearing age are likely to be more susceptible to urinary infectious disease that may cause impaired menstrual health, declined fertility, adverse pregnancy outcome, and maternal and infant mortality²⁶.

Policy implication of the study

The present study findings would help the policy makers to recognize the notion regarding overall improvement in WaSH related quality of life of women in rural setting. Subsequently, it is imperative to focus on the investment for developing more advanced WaSH infrastructure, promotion of the district-wise awareness-generation campaign for imparting education on WaSH acceptance, proper utilization and the relevance of shifting social stigma and traditional cultural norms associated with unhealthy WaSH practices.

Strength and limitation

One of the major limitations of the study included a small sample size. Inclusion of both adolescent girls and menopausal women in this study could satisfactorily portray overall scenario of rural women, irrespective of age.

Studying issues associated with menstrual health management was the major strength. Inclusion of Birhor women also remained strength of the study.

Conclusion

The study showed a conspicuous difference in WaSH practices among rural women living in distinct locales of West Bengal. Intervention programs could impart education for uprising knowledge and attitude towards adoption of healthy WaSH practices among rural women. Furthermore, a multi-collaborator approach including efforts of both government and non-governmental organizations, local bodies and community engagement is required to increase accessibility and utilization of WaSH services in rural sector with a sustained commitment to achieving public health goals.

Acknowledgements: Author would like to express gratitude to the study participants who voluntarily participated in the study. Author expresses a sincere gratitude to Indian Council of Social Science Research for funding this study.

Funding Sources: The fund was provided by the Indian Council of Social Science Research (Grant reference: F. No. 02/92/2019-2020/MN/ICSSR/RP dated 31 October, 2019).

Ethical Clearance: The objectives and methods of the study was reviewed and approved by the Research Ethics Committee of the Indian Council of Social Science Research (F. No. 02/92/2019-2020/MN/ICSSR/RP dated 31 October, 2019).

Conflicts of interest: not applicable

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Doctors Suggest Mandatory Screening Policy, Increase in IEC Programs can Control Rise in Breast Cancer

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How to cite this article: P. Bhattacharya, Varalakshmi K. N., P. Mathur. Doctors Suggest Mandatory Screening Policy, Increase in IEC Programs can Control Rise in Breast Cancer. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: A qualitative study was carried out among doctors in Karnataka to understand their perceptions about breast cancer, its rapid rise and control measures.

Methods: 67 doctors from allopathic as well as AYUSH fields answered a qualitative questionnaire related to screening policy in breast cancer, uptake, control measures, treatment costs and health insurance cover.

The questionnaires were sent as links to Google Forms. About 300 doctors were contacted but only about 67 doctors answered the questions. Answers were recorded from Google Forms into Excel sheets and subjected to statistical analysis by SPSS program.

Results: Among all the participating doctors, 66% of participants suggested making screening of breast cancer a mandatory procedure in the form of clinical breast exams (CBE), self-breast exams (SBE) and mammography.

Conclusion: Most doctors feel that screening policies could be made mandatory. They recommend breast cancer to be treated as a public health emergency.

Key words: Breast cancer; awareness; screening policy; IEC; NCD; stigma

Introduction

The Global Breast Cancer Initiative (GBCI) Implementation Framework Executive Summary released in 2023 observes that breast cancer (BC) is the most common cancer among women and the second most common cancer in 23 countries.^{28, 29}

Current studies estimate that by 2030 the worldwide number of new cases diagnosed will reach 2.7 million annually, while the number of deaths will reach 0.87 million. In 2020, India's cancer cases were estimated at 1.32 million⁹ and were predicted to double by 2040.^{25,26}

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Submission date: August 9, 2025

Revision date: September 30, 2025

Published date: April 14, 2026

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There is no single national policy specifically focused only on breast cancer in India, it is covered under multiple national frameworks and guidelines. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was launched in 2010 by the Ministry of Health and Family Welfare (MoHFW). It provides Breast cancer coverage by promoting early detection and screening of common cancers (breast, cervical, oral). Health and wellness centres under Ayushman Bharat are being used for community-level screening. ASHA workers and frontline health staff are trained to detect symptoms and refer women for further diagnosis.

ASHAs and ANMs are being trained for community-level detection of early signs of cancer, including clinical breast examination. Some states (e.g., Tamil Nadu, Kerala, Punjab, Kashmir) report better early detection rates due to effective implementation of screening protocols.²⁸ NPCDCS has helped integrate cancer prevention and early detection into primary healthcare, rather than leaving it to tertiary hospitals.⁸ Operational Guidelines have been issued for Screening of Common Cancers (2016, updated versions later) the MoHFW under NPCDCS. Recommends clinical breast examination (CBE) for women aged 30 years and above, to be conducted every 5 years. Provides a step-by-step protocol for primary, secondary, and tertiary-level management of breast cancer cases.

The Indian government launched a National Cancer Screening Programme in November 2016.^{3,7} It suggested that there will be mandatory screening for oral, throat, breast and cervical cancer in people over the age of 30 in 100 districts of India before the programme expands to other areas.

The National Health Policy (2017) emphasizes preventive healthcare and universal screening for major NCDs, including breast cancer and encourages integration of cancer services into primary health care systems. The Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PM-JAY) provides financial protection for secondary and tertiary care, including treatment for breast cancer such as surgery, chemotherapy, and radiotherapy. Covers vulnerable populations through government-funded insurance. The National Cancer Registries were formed in 1960.

12 A study^{19,20} about the National Cancer Grid formed in August 2012 to create uniform standards of care and treatment/ research in cancer has shown advantages of group negotiation in procuring pooled drugs easily. It is a network of over 300 cancer centres across India aiming to standardize cancer care, including breast cancer, across the country. It promotes evidence-based guidelines, training, and research collaborations.

Some states have launched their own cancer control programs, such as Tamil Nadu and Kerala offer mobile screening units for breast cancer. Delhi State Cancer Control Program as well as Maharashtra and Karnataka have implemented population-based screening programs with a focus on early detection.

There are very few studies on awareness of screening in Breast Cancer. We do not have national studies on the need for screening breast cancer in India or a study on all policies with special emphasis on screening.

As doctors play an important role in creating public awareness, a study was conducted in order to understand their perception towards screening and opinions on breast cancer with the help of questionnaires. Results would help in finding measures to prevent and decrease breast cancer cases.

Methods

Design:

The team consisted of only the first author. A qualitative study was designed with a questionnaire (QA) that gave us an insight into the minds of doctors regarding breast cancer. The questionnaire was developed based on existing literature and experts' opinions. A study^{16,21} was used as a model to create question sets. A pilot study with ten participants was conducted in an online setting and relevance, validity, timing and types of questions were checked.

The doctors were from various institutions in Karnataka such as Ramaiah Hospital in Bangalore, Shimoga Institute of Medical Sciences, other government hospitals, some PHC clinics in Sagar District, and from private hospitals and practice.

Participants

About 200 physicians were contacted out of which 67 doctors answered the questions. The

inclusion criteria were that they were graduates or postgraduates in allopathic medicine or alternative medicine such as AYUSH streams. The participants were in the age group of 22 years to 61 years. Among the participants, 21% were graduates, while 78% were post graduates. 82% were employed while the rest were retired or self-employed. Among them 77 % had attended breast cancer awareness lectures or programs and read or worked with breast cancer. All the participants were trained physicians. There was only one breast cancer specialist in the sample as we wanted a standard model for comparison, too. The exclusion criteria was that they must be non - specialists because we were looking at a general opinion across all disciplines. As this was an exploratory study, a power analysis was not conducted.

Ethical guidelines of ICMR were followed throughout the study and Ethical Clearance cancer was obtained from the Institutional Ethical Committee of JAIN University (Re. No. JU-EC-/021/HHS/PPG/PhD-JUL2023).

Data collection

A descriptive type of questionnaire was developed with the help of previous studies and colleagues involved in similar studies.

It had 15 open ended questions about an opinion on women's attitudes to screening in breast cancer, low uptake of screening, perceived causes, ideas on increasing screening uptake, awareness of the screening policy of 2016, reasons for rising numbers of cases and how they could be controlled. The doctors were asked about their awareness on breast cancer, screening, costs of screening and treatment, measures to increase screening uptake, identify causes of probable low uptake and suggest measures to decrease cases of breast cancer.

Background information was requested at the beginning of the questionnaire. The questions were tested on five doctors orally before it was shared with the participants. The results showed that the questionnaire was adequate.

Procedure

The participants were given the questionnaire as hard printed copies or on Google Forms sent on

email/ WhatsApp messenger. The interviews were face to face or through emails. The recorded answers were saved as data and the answers were analysed.

Data analysis

The data from the interviews were subjected to qualitative content analysis. The transcripts were read and reread to make notes. The analysis began by highlighting meaningful phrases in the answers. Then in the second step, the meanings were condensed and labelled with codes. In the third step, codes were compared for similarities and differences in each answer.

In the fourth step, each code was developed as a category or group under which a certain similar sounding responses were grouped. Peer checking and disagreements were discussed. Each category was given a certain number and converted to data in excel sheets. Thus, doctors who responded in category 1 and 2 in a certain question were coded as 1 and 2. The data was analysed using SPSS software.

Results and Discussion

Low uptake of Screening Policy

There is an organised population-level national cancer screening program from 2016 for breast, cervix and oral cancers for women.³ There are studies that say breast cancer is the topmost cancer in India and there is a low uptake of screening.^{5, 22; 13, 17} Fear and stigma are an important component of the reluctance of women to get screened, say studies.¹⁶

Table 1: Doctors give reasons for low uptake of screening policy

| Opinion of doctors | Percentage of doctors giving the reason |
|---|---|
| Ignorance about the program and lack of awareness | 67 |
| Women feel shy to go for screening | 19 |
| Not reaching the rural population | 14 |
| Fear and stigma of disease | 11 |
| Policy not advertised | 8 |
| Govt program not implemented effectively | 8 |

Cont.....

| | |
|--|---|
| Economic reasons among rural women if they miss day work, pay is cut | 8 |
| Lack of motivation unless symptoms appear | 5 |
| Less importance to early diagnoses and treatment | 3 |
| Covid havoc for two years | 2 |
| Low budget and lack of resources | 2 |
| Expensive tests | 2 |
| No idea | 2 |
| No time | 2 |

Source: Data collected and analysed by researcher

The answers regarding our question on low uptake of screening indicate that doctors perceived a low uptake. (Table 1). A majority of respondents (67%) attributed this to limited awareness and personal barriers, such as embarrassment or reluctance related to physical breast examinations, the latter noted by 19% of participating physicians. In our study, some physicians (41%) felt that most women are aware of early-stage detection and increased survival rates associated with early detection.

Approximately 8% of the doctors suggested that the involvement of female healthcare personnel in both screening and patient communication could enhance participation rates. An additional 10% cited sociocultural barriers as contributing factors, while 2% specifically highlighted a lack of resources. Economic constraints were also noted, with 8% of physicians indicating that rural women, particularly those engaged in daily wage labour such as farm or agricultural work, may forego screening due to potential income loss. A further 2% reported time constraints as a significant deterrent.

Furthermore, 8% of the respondents felt that the national screening policy had not been effectively communicated to the target population. An equal proportion emphasised deficiencies in the dissemination of government screening initiatives, suggesting that community-based outreach, such as day camps, may be more effective in promoting awareness and participation.

Ways of increasing breast cancer screening among women

Studies suggest that targeted screening in India may be more cost effective as other screening methods may not be reliable in the Indian scenario.

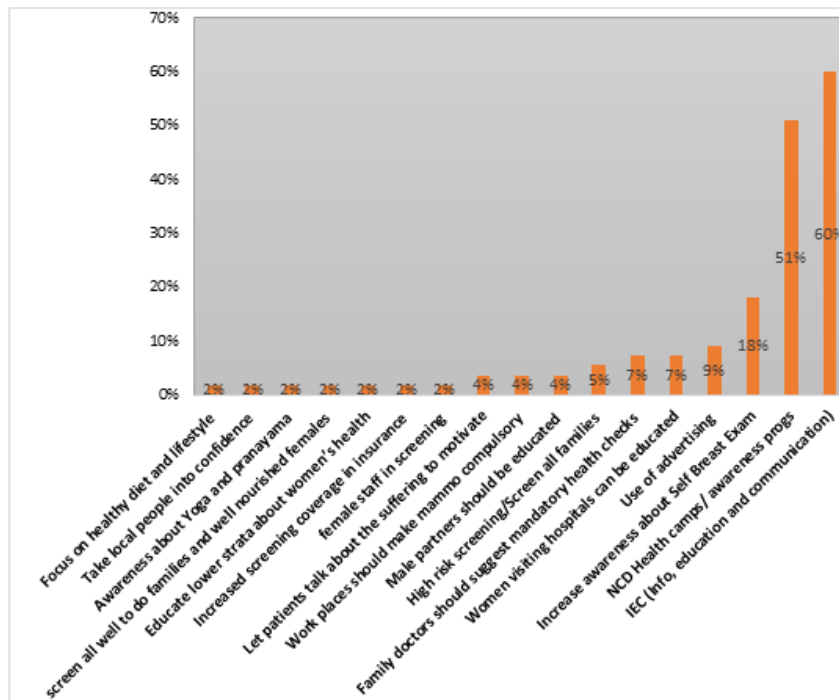


Figure 1: Doctors give their solutions to increase screening

Increasing participation of women in screening can be challenging as it involves various factors that are associated with the local scenario such as the socioeconomic status of women and cultural factors.¹³ Similar studies in North India and America among doctors suggest that doctors feel that social barriers may be a hindrance to screening.^{22; 23}

In response to our question that asked doctors to suggest solutions to increase screening, participating doctors suggested regular health checks and Non-Communicable Disease Camps for better surveillance of Breast cancer (**Figure 1**). About 60% suggest IEC (Information, education and communication) programs and mass education through presentations, newspapers, include celebrities to communicate social messages on screening, arrange talks, create awareness on social media, TV and online media.

Among the rest, 51% advocated for the implementation of Non-Communicable Disease (NCD) health camps at the primary healthcare level, coordinated by the government, as a strategy to

enhance breast cancer screening uptake. Additionally, 18% recommended the promotion of Breast Self-Examination (BSE) practices, particularly among women affiliated with anganwadis, self-help groups, and among college-aged females.

A smaller proportion of respondents (7%) emphasized the importance of opportunistic health education, suggesting that every hospital visit should be utilized to educate women about breast cancer. Furthermore, 4% of the physicians proposed the inclusion of male partners in breast cancer awareness initiatives to foster supportive environments for screening and early detection. There were other less frequently cited recommendations that included mandating mammography in workplaces (4%), using patient testimonials to emotionally sensitize women to the impact of breast cancer (4%) etc.

Rise of breast cancer cases in urban areas

The pattern of thinking among the doctors in our study sample is based on the Indian population.

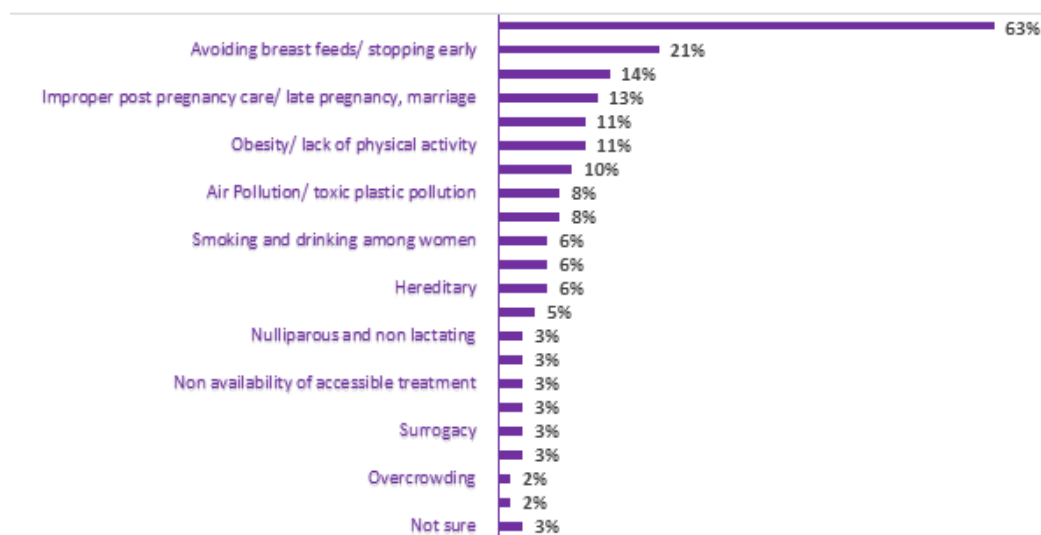


Figure 2: Cause of the rise in breast cancer cases as suggested by doctors

As seen in **Figure 2**, most doctors felt that the rise of breast cancer was mainly because of a sedentary lifestyle among women (63%) and stopping breast feeds early or avoiding breast feeding (21%).

They also thought that stress (14% of doctors), late pregnancy (13%) obesity (11% of doctors), Hormone Replacement Therapy, multivitamin supplements

(10% of doctors), air pollution (8% of doctors) and cosmetics (8% of doctors) could also cause breast cancer. Some doctors (6%) suggested that smoking and drinking among women could cause breast cancer. Others felt that lack of awareness (6%) and heredity (6%) could cause the disease, while 5% felt that early menses in women or late menopause could be the reason.

A smaller fraction of physicians suggested nulliparous women/ non - lactation (3%), existing conditions such as Diabetes/blood pressure (3%), non-availability of treatment (3%), late detection of the disease (3%), surrogacy (3%) as well as lack of adequate sleep could be contributing to rise in breast cancer among women. Some felt that overcrowding (2%) or synthetic/ padded bras (2%) could also be the culprit.

The above findings are supported by earlier studies^{1,4,5, 6,22, 14, 15, 17,18,24}

Reluctance among women to get screened for breast cancer

The Covid vaccination drive in India extended throughout the country and was one of the largest vaccination programs in the world in which three doses of the vaccine were given to the population.²⁷ Women from all sections of the society were not hesitant to get vaccinated against Covid. Our participating physicians were asked about most women who took the Covid Vaccine, would they as easily get screened for breast cancer?

Though most women got vaccinated against Covid, they may not agree to breast cancer screening so easily was an emerging consensus among the doctors (44%). They gave reasons to explain the reluctance among women to screen (Figure 3). They range from ignorance (45%); cultural taboos (17%); a gap between policy and its implementation (12%); stigma (12%) against the disease to lack of motivation (10%). Some participants (10%) have suggested that Covid vaccination involves a single prick of a needle whereas breast cancer screening is complicated and may not always involve female staff.

Other doctors (7%) felt that media has not highlighted the importance of screening, so most women do not find it necessary, another group (2%) felt that screening was pharma industry driven and not care based, some think (2%) that costs of screening could be a deterrent while others (7%) did not know. A fraction (5%) felt that there was no intervention at the grass root levels. The above findings suggest that doctors feel that screening is uncomfortable to most women.

Table 2: Reasons for reluctance to screen among women as suggested by doctors

| | |
|--|-----|
| Policy is Pharma driven not care based | 2% |
| Cost | 2% |
| No intervention at grassroots level | 5% |
| Don't know | 7% |
| Media does not highlight the need for screening | 7% |
| BC screening is not a single prick but complicated | 10% |
| Lack of motivation | 10% |
| Stigma | 12% |
| Gap between Govt. policy and its implementation | 12% |
| Hesitancy/ shame/ cultural taboos | 17% |
| Lack of awareness | 45% |

Doctors suggest mandatory screening will play an important role

Among all the participating doctors, 66% of participants suggested making screening of breast cancer a mandatory procedure in the form of clinical breast exams (CBE), self-breast exams (SBE) and mammography.

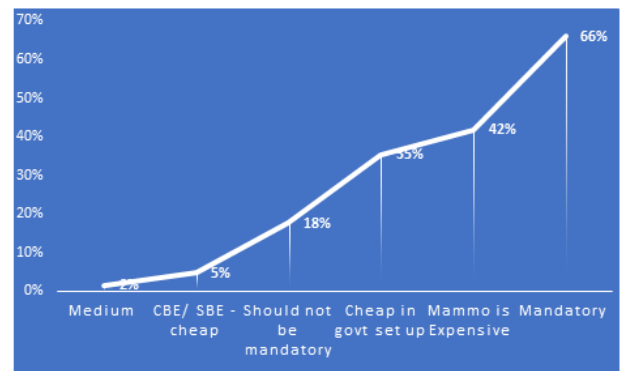


Figure 5: Doctors' suggest screening should be mandatory

Screening can be expensive in corporate hospitals but cheaper in government set ups, say 35% of the participating doctors. Early screening and detection can play an important role in bringing down cases of breast cancer, feel doctors (Figure 5).

Measures to bring down cases of breast cancer

As shown in Table 2, of the participating doctors, 48% cited awareness, screening (38%) and

early detection with management (28%) can combat breast cancer and control rise in cases. Some doctors (23%) feel that a better diet, lifestyle, limiting use of chemicals in cosmetics and being careful about Hormone Replacement Therapy can control rise in breast cancer cases while others (17%) feel Breast Self-Exam (BSE) and breast feeding children is an important preventive measure. Other doctors (8%) suggest that women can undergo a Clinical Breast Examination when they visit a hospital while a few (8%) suggest that preventive policy implementation by the government⁸ is necessary, especially in rural areas - such as PHC buildings can display charts about Breast Cancer, experts could be available while NGOs can pitch in. More doctors (6%) suggest identifying risk factors and others (3%) suggest counselling as ways to prevent breast cancer and reducing stress (2%) through yoga and meditation. Government has a mechanism to track female children which can be extended suggested another 2% of doctors.

Genetic screening was advocated by only 2% of participants. A view that emerged was that costs of detection and treatment are cheaper in government set ups (Table 2).

BSE along with awareness of causes and work on the need for population based genetic testing^{4, 10, 11} will help in bringing down the cases of breast cancer, suggest studies. Some earlier studies reported the need for population testing.¹¹

Polio was eradicated from India in 2014 and the Pulse Polio publicity campaign played a large role in sensitizing the public to vaccinate children against polio.²⁵ The wide vaccination drive against Covid in India launched by the Government of India achieved mass vaccination in a relatively short time.^{2, 27} The participants feel that Breast Cancer has developed into a public health situation such as Covid and demands the same urgent attention.

Conclusion

Most of the participating doctors feel that screening of breast cancer could be made mandatory along with better communication about screening policies through Non-Communicable Disease camps and the public could be informed by awareness campaigns through media, famous personalities,

advertising etc. They feel clinical breast exams (CBE), self-breast exams (SBE) and mammography would help. Doctors acknowledge the rise in cases and the fact that they are not detected early because of a low uptake of screening while treatment is expensive in non-governmental setups and mortality is high. They also feel that there is a stigma associated with the disease and that women are hesitant about screening and screening policies have not been implemented well, leading to a lower awareness about screening. Not many studies have suggested mandatory screening to decrease breast cancer cases.

Table 3: Doctors suggest methods to bring down number of BC cases

| Methods | Number of doctors (per cent) |
|---|------------------------------|
| Awareness | 48 |
| Screening | 38 |
| Early detection and management | 28 |
| Stress free, healthy diet as well as lifestyle/ Avoid chemicals/ careful about Hormone Replacement Therapy | 23 |
| Breast Self - Exam and breast feeding is important | 17 |
| There ought to be preventive policy implementation by the Government especially in rural areas/ Primary Health Centre buildings can display charts about BC/easily available experts/ NGOs can help | 8 |
| Every woman who attends hospital can undergo a Clinical Breast Exam | 8 |
| Identify risk factors | 6 |
| Counselling | 3 |
| Genetic screening | 2 |
| Govt has a mechanism to track female children, these can be extended | 2 |
| Reduce stress through yoga and meditation | 2 |

Declaration of Interest Statement: None declared.

Limitations: Fig 2 also suggests bias/subjective beliefs in subjects. This could be a limitation of our study as studies on the effects of cosmetics, chemical effects, multivitamins on cancer are few.

Funding Sources: None

Ethical Clearance: University Ethical Committee , JAIN (Deemed-to-be University)

319, 25th Main. 17th Cross , J.P. Nagar 6t Phase Bengaluru - 560 078 Date: 17th July 2023

Number: JU-EC-/021- HHS/PPG/PhD - JUL2023

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Lifestyle Choices Influence the Susceptibility towards Essential Hypertension

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How to cite this article: Poonam, Basant Kumar, Shashi Chaudhary. Lifestyle Choices Influence the Susceptibility towards Essential Hypertension. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Despite provisions of anti-hypertensives and WHO measures, prevalence of hypertension is increasing worldwide, especially in low- & middle-income countries. This indicates a common issue, probably non-affordability of medicines and non-availability of proper health care facilities to larger section of population. This provided two important objectives to the study, first to investigate the basic health parameters of hypertensive and normotensive individuals and second to correlate their lifestyle choices with health parameters to understand the cause and effect.

Methods: The cross-sectional study was conducted through a consecutive sampling of 110 individuals, including hypertensive (n=60) and normotensive (n=50) individuals between January to September 2024 at Advanced Cardiac Centre, PGIMER. Data regarding participants lifestyle habits and biochemical parameters were collected using case record forms. Statistical analysis, including intergroup and intragroup comparisons, was performed using Chi-square test, unpaired t-test (Mann-Whitney test), descriptive analysis. A p-value <0.05 was considered statistically significant. Additionally, logistic regression analysis was conducted to evaluate the association between biochemical parameters and hypertension as predictive variables.

Results: A higher proportion of individuals with a sedentary lifestyle were observed in the hypertensive group. Further analysis of normotensive individuals with sedentary lifestyles revealed that 78.5% were vegetarians and only a small fraction reported with alcohol consumption. In contrast, hypertensives with a sedentary habit exhibited higher rates of non-vegetarian food intake (76.2%) and alcohol consumption (71.4%).

Conclusion: This study underscores lifestyle modifications as the primary strategy to improve the overall health parameters, to reduce the increasing prevalence of hypertension, as well as reduce drug dependence.

Keywords: Hypertension, lifestyle, biochemical parameters, blood pressure.

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Submission date: August 28, 2025

Revision date: Oct 6, 2025

Published date: April 14, 2026

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Introduction

Hypertension increases the risk for cardiovascular diseases by keeping the blood pressure (BP) above the standard read of 120/80mm Hg. Essential/Primary hypertension is more common, polygenic, and a complex condition where several factors like age, gender, stress, sedentary lifestyle, genetics, and epigenetics play an important role. Worldwide, the estimates for hypertensive individuals in the age group of 30-79 years is 1.28 billion, among which two-third belongs to low- and middle-income countries. Secondary hypertension is when BP elevates due to a known cause. It is less common, but present more among younger age group (18-40 years) and therefore, alarming⁽¹⁻³⁾. Primary aldosteronism and renovascular hypertension are two representative examples of secondary hypertension. As per 2017 guidelines from the American College of Cardiology (ACC)/American Heart Association (AHA), BP measurement of 120/80mm Hg is the standard whereas stage 1 hypertension is when systolic blood pressure (SBP) is within 130-139 mm Hg, and stage 2, when SBP is above 140 mmHg. Although fluctuations in BP could be attributed to enormous lifestyle as well as heritable factors, former could have a strong effect regardless of genetic background. Studies on different populations report effective reduction in BP after incorporating healthy practices such as physical activity, non-westernized diet and proper sleep-wake cycle^(4,5). As per the European Society of Cardiology (ESC)/European Society of Hypertension (ESH), lifestyle changes must be considered as the primary line of treatment for hypertension in first 3-6 months, and the pharmacological treatment to be suggested only when uncontrolled BP persists despite lifestyle changes. Also, the lifestyle factors act independent of pharmacological treatment, as evident through DASH (Dietary Approaches to Stop Hypertension) diets, which are equally successful in the reduction of BP in patients with or without pharmacological treatment^(1,6-7).

As per meta-analysis, individuals with less physical activity bear a 6% lower risk of hypertension in comparison to individuals with a sedentary lifestyle. Recommended physical activity in patients with pharmacological treatment led to the withdrawal of anti-hypertensive drugs. The remarkable benefits

have also been observed in patients with resistant hypertension who incorporated physical exercise in their routines⁽⁸⁾. Smoking is another well-known habit as well a risk factor for increasing hypertension. Besides other toxic chemicals present in cigarettes, Nicotine is a known adrenergic agonist, which impacts both systemic and local catecholamine release. Also, smoking elevates oxidative stress and impairs cardiac remodelling, bioavailability of nitric oxide, endothelial function, and arterial flexibility. As per one of the Iranian studies, when the impact of cigarette smoke on BP was investigated among elementary school children, the outcome depicts increased systolic and diastolic BP among exposed group in comparison to non-exposed group. Regardless of public awareness about the risks of smoking, millions of individuals continue to smoke worldwide. Hence, alternate strategies are suggested by physicians to enhance smoking cessation, such as nicotine replacement therapy and behaviour modification⁽⁹⁻¹²⁾. Third risk factor is high body fat mass commonly known as overweight⁽¹³⁻¹⁵⁾. The World Health Organization recommended Body-mass index (BMI) of 18.5-24.9kg/m² as normal, 25-25.9kg/m² as overweight and above 30kg/m² as obese. Study on individuals from India (Gujrat) reported a positive association of high BMI among males and females with the occurrence of hypertension⁽¹⁶⁾. Several epidemiological studies from different populations have also repeatedly reported an increased risk of hypertension due to alcohol consumption. As per some studies, reduction in alcohol consumption among heavy drinkers significantly reduced the systolic and diastolic BP, but the exact mechanism remains elusive⁽¹⁷⁻²⁰⁾. Additionally, stress due to any reason, including disturbed sleep, is another factor known to influence sympathetic and adrenergic activation. As per psychological counsellors, the relaxation techniques should be incorporated into practices for better sleep and stress management⁽²¹⁻²³⁾. Considering the above-mentioned information, the primary objective of the study was to examine if any difference occurs between hypertensive and normotensive individuals with respect to lifestyle choices. The second objective was to investigate how specific lifestyle choices, such as physical activity, dietary habits, alcohol and smoking consumption, and sleep patterns, influence

the risk of developing essential hypertension. Both objectives together direct us towards potential targets for preventive strategies and improved management of essential hypertension.

The current study is unique as it offers a dual approach to assess the comprehensive correlation of lifestyle choices as well as biochemical profiles with respect to essential hypertension within a target group. As per available literature almost negligible data was found on this correlation from Indian studies.

Materials and Methods

Recruitment and Diagnosis

As per the JNC report 8, hypertension was diagnosed if the individual had systolic and diastolic BP above 130/80mm Hg with or without anti-hypertensive treatment. The baseline BP was recorded using an electronic apparatus and validated by a sphygmomanometer, when seated with straight posture on a chair comfortably, with both feet on the ground. All the consecutive patients diagnosed with essential hypertension (hypertensive, n=60) and healthy individuals (normotensive, n=50) were recruited using consecutive sampling method, from the Advanced Cardiac Centre, PGIMER, Chandigarh, between January-September, 2024. All the participants were conversant with the study, and provided written informed consent. All the patients, either newly diagnosed or visiting for follow-up, within the age range of 20-65 years were recruited, whereas individuals with secondary hypertension and pregnant women were excluded. Expert phlebotomist collected 2-3ml blood sample from each participant for biochemical analysis such as lipid profile (HDL-C, LDL-C, Total Cholesterol, Triglycerides), Total Protein, Urea, Uric Acid, Creatinine, Sodium, Potassium, Chloride and CRP. The Institutional Ethics Committee of PGIMER, Chandigarh (IEC-12/2023-2968), and Panjab University, Chandigarh (240822-II-160) provided the ethical approval to the study.

Assessment of Lifestyle factors

Hypertension was divided into four stages: Pre-hypertensive stage [SBP 120-139mm Hg, diastolic blood pressure (DBP) 80-89mm Hg] Stage1 (SBP 140-159mm Hg and DBP 90-99mm Hg), Stage2 (SBP>160mm Hg and DBP>100mm Hg) and Stage3 (SBP \geq 180 or DBP \geq 110mm Hg). The structured questionnaires in the Case record form of each

participant documented various parameters (age, gender, height, weight) including lifestyle choices [consumption of alcohol and cigarette smoking (each with rough quantification), sedentary or active occupation/lifestyle, additional physical activity, dietary history (portion of meals, junk, fried or healthy food), and sleep-wake patterns].

For analytical purpose cigarette smoking was marked as present smoker, former smoker or never smoker, whereas alcohol consumption was classified as present drinkers, former drinkers and never drinkers. BMI was measured as per WHO recommendations and physical activity was determined as sedentary (if occupation with no physical work and complete absence of walk/exercise) or active (if occupation with physical work or regular walk/exercise assessed in minutes). The sleep patterns were identified as per quality and quantity of sleep (as told by participant), whereas dietary patterns were measured as Vegetarian/non-vegetarian, and consumption of junk food (with less nutrition, high calories). Analysis for junk food was excluded later, as most of the participants in this study were non-frequent consumers.

Statistical analysis

The association of BP with lifestyle choices was analysed using the Chi-square test and with other clinical evaluation of biochemical parameters by the unpaired t-test (Mann-Whitney test) and descriptive statistical analysis. Logistic regression was used to analyze the rate of change in susceptibility towards hypertension due to particular biochemical parameter as predictors. All the statistical analysis were performed using Prism8 and SPSS Statistics 27.0.1 and p-value <0.05 was considered statistically significant.

Results

Demographic details

A total of 110 individuals were enrolled from outpatient department of Advanced Cardiac Centre, PGIMER, and Bhai Ghanaiya Ji Institute of Health, Panjab University, Chandigarh, including hypertensive (n=60) and normotensive (n=50) individuals. As per demographic characteristics (Table1), all the participants in case and control groups, were of similar age but female participants were fewer among controls than cases. The Odds ratio for the association of gender and age with hypertension 0.2356 (0.1075 to 0.5476), indicating more risk association with higher age and male gender.

Table 1. Age and gender distribution among cases and controls groups.

| Characterstics | HTN (n=60) | NTN (n=50) | p-value |
|----------------|---------------|---------------|---------|
| Age (in years) | 45.00±11.81 | 44.54±9.603 | 0.8213 |
| Gender | | | |
| Male | 58.33% (n=35) | 80.00% (n=40) | 0.0231* |
| Female | 41.67% (n=25) | 20.00% (n=10) | |

Note- **p-value*<0.05

Association of lifestyle factors and blood pressure

Overweight individuals were significantly more among hypertensive group (*p* value <0.0001), clearly indicating higher possibility of hypertension among weight gainers (Table2). A positive family history of hypertension mostly correlates with early onset of hypertension, however, current study showed equal percentage of early- as well late-onset individuals within positive family history individuals. Additionally, high percentage of late onset (81.25% vs 18.75%), were seen with negative family history, indicating predominance of sporadic hypertension than familial type. The correlation of negative family history with late onset of hypertension when analysed

by Fisher's exact test, showed statistical significance with *p-value* of 0.0142 and the Odds ratio was 4.333 (1.414 to 13.94). Lifestyle choices like sedentary versus active (*p-value* 0.4325), smoking (*p-value* 0.3769), and alcohol consumption versus non-alcoholic individuals (*p-value* 0.8739) did not show much difference. On the contrary, dietary habits did show significant (*p-value* 0.0036) difference between two groups. Another significant association was found with sleeping pattern (*p-value* <0.0001), where the Odds ratio was 0.1098 (95% CI:0.04818 to 0.2796). All the notable findings are mentioned in Table 2 and represented in Figures 1a and 1b.

Table 2. Distribution of lifestyle parameters among Normotensive (NTN) and Hypertensive (HTN) individuals.

| Lifestyle parameters | Categories | NTN (n=50) | HTN (n=60) | p value |
|--------------------------|---------------------|----------------|---------------|-------------|
| Age | 20-45 years | 67.50% (n=27) | 32.50% (n=13) | 0.0007*** |
| | 46-65 years | 32.86% (n= 23) | 67.14% (n=47) | |
| BMI(Kg/ m ²) | Normal weight | 66.67% (n=38) | 33.33% (n=19) | <0.0001**** |
| | Overweight | 22.64% (n=12) | 77.36% (n=41) | |
| Physical activity | Active lifestyle | 48.00% (n=36) | 52.00% (n=39) | 0.4325 |
| | Sedentary lifestyle | 40.00% (n=14) | 60.00% (n=21) | |
| Dietary pattern | Vegetarian | 29.17% (n=14) | 70.83% (n=34) | 0.0036** |
| | Non-vegetarian | 58.06% (n=36) | 41.94% (n=26) | |
| Sleep pattern | Regular sleep | 67.21% (n=41) | 32.79% (n=20) | <0.0001**** |
| | Irregular sleep | 18.37% (n=9) | 81.63% (n=40) | |
| Smoking | Smokers | 33.33% (n=3) | 66.67% (n=6) | 0.3769 |
| | Former | 75.00% (n=43) | 25.00% (n=1) | |
| | Non-smokers | 44.79% (n=4) | 55.21% (n=53) | |
| Alcohol | Drinkers | 48.00% (n=12) | 52.00% (n=13) | 0.8739 |
| | Former | 37.50% (n=3) | 62.50% (n=5) | |
| | Non-drinkers | 45.45% (n=35) | 54.55% (n=42) | |

Note- *degree of statistical significance

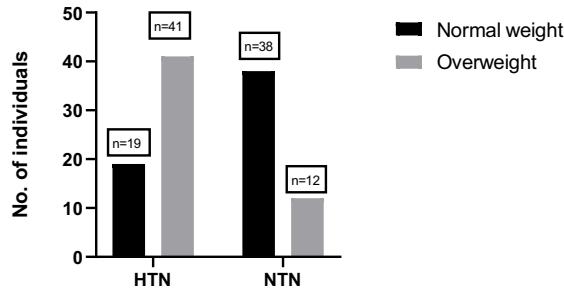


Figure1a. The prevalence of hypertension according to different BMI orders.

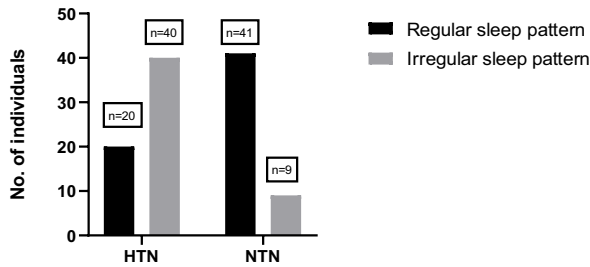


Figure1b. The prevalence of hypertension according to different sleep patterns.

Evaluation of Biochemical parameters

The biochemical parameters included HDL-C, LDL-C, total cholesterol, triglycerides, glucose, creatinine, total protein, electrolytes (such as sodium, potassium and chloride), urea, uric acid and CRP. Notable differences were observed between hypertensive and normotensive individuals as evident from Table 3. Additionally, logistic regression was performed to assess the risk of hypertension with one-unit change in biochemical parameters. The predictors, such as age, gender, creatinine, HDL-C,

LDL-C, total cholesterol, triglycerides and CRP, fit best in the models for logistic regression (Table 4). The general form of the model used is as follows

$$\log\left(\frac{P}{1-P}\right) = \beta_0 + \beta_1X_1 + \beta_2X_2 + \dots + \beta_kX_k$$

where,

P=probability of event occurring

β_0 = intercept (constant)

β_1 = coefficient of predictor X_i

$$\log\left(\frac{P}{1-P}\right) = \log \text{odds of outcome}$$

The logistic regression model for hypertension in our study is as follows:

$$\log\left(\frac{P}{1-P}\right) = -18.264 + 0.088 (\text{Age}) + 2.969 (\text{Sex}) + 0.042 (\text{Total cholesterol}) + 0.286 (\text{HDL-C}) + 0.060 (\text{LDL-C}) + 0.014 (\text{Triglycerides})$$

The model performs well with 84% accuracy, depicting older individuals to be more susceptible to hypertension, whereas males were 19.5 times more likely to have hypertension. As per data, increase in levels of LDL-C and triglyceride increases the risk of HTN by 6% and 1.4% risk per unit, respectively and total cholesterol also shows slight effect on BP. Though HDL-C is a positive factor for health but after a certain level, increase in HDL-C increases risk of high blood pressure and other cardiovascular conditions (24). Surprisingly in this study, creatinine, glucose and CRP emerged as weak predictors for hypertension.

Table 3. Comparative assessment of biochemical parameters among HTN and NTN individuals.

| Parameters | Controls NTN(n=50) | Cases HTN(n=60) | p-value |
|---------------------------|--------------------|-----------------|-------------|
| Glucose(mg/dl) | 98.53±26.67 | 113.2±58.3 | 0.0794 |
| Creatinine(mg/dl) | 0.69±0.09 | 0.85±0.19 | <0.0001**** |
| HDL-C (mg/dl) | 42.89±1.49 | 48.95±10.82 | <0.0001**** |
| LDL-C (mg/dl) | 87.29±27.42 | 113.5±36.68 | <0.0001**** |
| Total cholesterol (mg/dl) | 162.5±35.30 | 188.6±47.03 | 0.0036** |
| Triglycerides (mg/dl) | 134.6±42.44 | 164.8±69.41 | 0.0235* |
| CRP (mg/L) | 3.05±3.79 | 5.15±6.48 | 0.0249* |
| Sodium (mmol/L) | 140.1±2.07 | 138.9±4.71 | 0.4736 |
| Potassium (mmol/L) | 4.208±0.31 | 4.36±0.47 | 0.0293* |

Cont.....

| | | | |
|-------------------|--------------|------------|-------------|
| Chloride (mmol/L) | 100.7±1.71 | 102.5±2.30 | <0.0001**** |
| Urea (mg/dl) | 23.35±4.51 | 27.22±7.98 | 0.0077** |
| Uric acid (mg/dl) | 4.386±0.5397 | 5.10±1.46 | 0.0382* |
| Protein (g/dl) | 6.911±0.3381 | 7.32±0.67 | <0.0001**** |

Note- The continuous variables are shown as Mean ± Standard deviation. BMI Body mass index, HDL-C High-density lipoprotein cholesterol, LDL-C low-density lipoprotein cholesterol, CRP C-reactive protein.*Degree of statistical significance.

Table 4. Logistic regression describes the association between biochemical parameters and hypertension with 95% confidence interval.

| Variables | B | S.E. | p-value | Exp(B) | 95% C.I. for EXP(B) | |
|-------------------|---------|-------|---------|--------|---------------------|---------|
| | | | | | Lower | Upper |
| Age | 0.088 | 0.034 | 0.009 | 1.092 | 1.023 | 1.167 |
| Gender | 2.969 | 0.974 | 0.002 | 19.468 | 2.887 | 131.274 |
| Glucose | -0.002 | 0.010 | 0.821 | 0.998 | 0.978 | 1.018 |
| Creatinine | -0.047 | 0.125 | 0.708 | 0.954 | 0.746 | 1.220 |
| Total Cholesterol | 0.042 | 0.016 | 0.011 | 0.959 | 0.929 | 0.991 |
| HDL Cholesterol | 0.286 | 0.083 | <0.001 | 1.331 | 1.132 | 1.565 |
| LDL Cholesterol | 0.060 | 0.018 | 0.001 | 1.062 | 1.024 | 1.100 |
| Triglycerides | 0.014 | 0.006 | 0.014 | 1.014 | 1.003 | 1.025 |
| CRP | 0.099 | 0.072 | 0.171 | 1.104 | 0.958 | 1.272 |
| Constant | -18.264 | 4.468 | <0.001 | 0.000 | | |

Note- Variables: age, gender, glucose, creatinine, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides and CRP. Interpretation coefficient (B) represents the average change in the log-odds of hypertension per one-unit increase in a predictor, adjusting for all other variables. Weak ($p > 0.05$) & Strong Predictors ($p < 0.05$).

Discussion

Present day automation and advanced technology brought major changes in the economy as well as the living conditions especially in developing regions. Individuals in the middle- and low-income class tend to imitate a carefree and luxurious lifestyle, which majorly includes an automation-led sedentary lifestyle, higher intake of alcohol, cigarette smoking, and inappropriate sleep and diet patterns. As per literature, all the above-mentioned factors have a tendency to increase the prevalence of hypertension and cardiovascular conditions (25). Age is considered one of the major risk factors for hypertension due to the physiological changes that occur during ageing process and thereby, higher prevalence of hypertension was found among higher age (46-65 years) than the lower age (20-45 years) group. Most of the studies on hypertension have reported higher prevalence among men than women, and our data

also indicates the same. This could probably be due to the cardioprotective role of estrogen found among women (26-28) but authors do acknowledge the lesser number of women in the current study. Higher BMI among HTNs than NTN in this study mirrors the previous findings, where overweight individuals probably exhibited dysregulation of Renin Angiotensin Aldosterone System (RAAS) and vascular alteration due to particular cytokines such as IL-1, MCP-1, TNF- α , IL-6 which are known to regulate inflammation and oxidative stress, thereby, increasing the susceptibility towards hypertension (29). As per this study, consumption of non-vegetarian diet was comparatively more among the normotensives but since consumption was not very high, it might represent the protein supplements provided as in DASH diet (Dietary Approaches to Stop Hypertension- includes mild non-veg diet) which helps prevent BP elevation (30-32). In one of the previous

studies, prevalence of hypertension was reported high among cases with positive family history⁽³³⁾, but as per present study, non-significant differences were observed between positive family history and prevalence of hypertension. Comparatively, a higher proportion of hypertensive individuals were found with negative family history in comparison to those with positive family history (55% vs 45%) indicating more sporadic than familial cases. An active lifestyle which includes physical activities such as brisk walk, run and additional exercises is known to reduce BP, but as per current study, such association was not clear (Table 2). However, individuals with sedentary lifestyle were more among hypertension group than the other (60% vs 40%). A good sleep pattern mediated through circadian rhythm, but any factor leading to sleep deprivation could increase the risk for high BP. As per few reports, sleep deprivation reduces parasympathetic tone, increase sympathetic activity, and induce heart rate variability⁽³⁴⁻³⁶⁾. Similarly in this study, a higher proportion of sleep-deprived individuals were found among hypertensive (81.63% vs 18.37%) group, whereas individuals with regular sleep were found more among normotensives (67.21% vs 32.79%).

Further, this study found no correlation of smoking, alcohol consumption with hypertension which could be attributed to lesser number of individuals with such preferences. The current study also analysed, if biochemistry profiles due to lifestyle choices show any significant differences between the two groups. The data from this study revealed a higher range of values for lipid profiles such as HDL-C, LDL-C, triglycerides and total cholesterol among HTNs than NTN. Similar findings were reported among Chinese adults, where increased LDL-C and total cholesterol showed a strong association with the incidence of hypertension, whereas a positive relationship was seen between HDL-C and systolic blood pressure⁽³⁷⁾. In the current study, glucose, creatinine, potassium, chloride, uric acid, and protein were though within the reference range, but were slightly higher among hypertensive individuals. As per earlier studies, CRP stimulates monocytes, elevates LDL uptake, expression of adhesion and proliferative molecules, and decreases the vasodilatory molecules⁽³⁸⁾. Increased levels of CRP were also reported among

hypertensive subjects⁽³⁹⁻⁴⁰⁾ and unhealthy lifestyle choices were associated with high inflammation as determined by circulatory inflammatory factors, i.e., C-reactive protein (CRP)^(4,16). The present study also found significant differences ($p=0.0249$) of CRP inflammatory factor between HTN and NTN individuals [Table 1]. As per WHO-International Society of Hypertension guidelines and Joint National Committee VI, the increased level of creatinine and protein are predictors for stratification of cardiovascular risk. Therefore, long-term elevation of BP and the extreme range of the above-mentioned biochemical parameters probably indicate towards other complications associated with hypertension such as vascular stiffness and end organ damage.

Conclusion

The present study although represents pilot investigation on the correlation of lifestyle choices on susceptibility towards hypertension, it illustrates a significantly higher risk for hypertension among individuals with sedentary lifestyle, disturbed sleep patterns and high BMI. The knowledge about increased risk of hypertension would motivate individuals to modify their lifestyle choices and lead a more sensible healthy life at no additional cost. More individuals with sedentary lifestyles were found among hypertensive group (60%) and further analysis on normotensives with sedentary lifestyle, showed 78.5% individuals to be vegetarian and miniscule (7.1%) proportion were alcohol consumers. In contrast, hypertensives with sedentary lifestyle showed a higher consumption of non-vegetarian diet (76.2%) and alcohol (71.4%), which indicates, sedentary lifestyle along with alcohol and non-veg diet increases the susceptibility for hypertension. Consequently, hypertensive individuals with sedentary lifestyle showed disturbed lipid profile with high proportion of LDL (71.5%), total cholesterol (71.5%), triglycerides (76.2%), whereas lower percentage of individuals with disturbed lipid profile (14.2% for LDL and 7.1% for triglycerides) were seen among normotensives with sedentary lifestyle. Though the sample size analysed is small in this study but it depicts a trend of improving lifestyle choices to lower the risk of hypertension. This might further reduce the overall risk and incidences of cardiovascular diseases. Authors do accept small size

as a limitation of this study but the strength of the study lies in the selection of lifestyle choices which are prevalent across populations, and also correlating them with the biochemistry of participants, which represents the overall health conditions.

Acknowledgement: We highly appreciate and acknowledge all the participants' willingness for the study. We are also thankful to phlebotomists from PGIMER and Panjab University for the collection of samples from participants recruited for the study.

Funding Sources: The fellowship is provided by UGC with ID: 201920-19J6107081 to P.

Ethical Clearance: The study was designed and implemented following the Declaration of Helsinki, and the protocol was reviewed and approved by the Institutional Ethics Committees of Panjab University (240822-11-160) and PGIMER (IEC-12/2023-2968), Chandigarh.

Declarations of conflicting interests: The author(s) declared no conflicts of interest concerning this article's research, authorship, and/or publication.

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Perceived Stress, Loneliness, and Quality of Life Among Transgenders in South India: A Cross-Sectional Study

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How to cite this article: Prasanna Kumar Markapudi, Daniel Finney Sankuru, Phanindra Dulipala. Perceived Stress, Loneliness, and Quality of Life Among Transgenders in South India: A Cross-Sectional Study. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Transgender individuals face widespread stigma, discrimination, and social exclusion, contributing to elevated levels of psychological stress, loneliness, and reduced quality of life (QOL). These challenges are particularly pronounced in South India, where culturally contextualized data on the psychosocial well-being of transgender populations remain limited. Understanding the interplay between stress, loneliness, and QOL is essential to inform inclusive, rights-based mental health and public health interventions. Additionally, complex intra-community dynamics and lack of emotional maturity may further compound psychological distress despite the presence of social contacts.

Methods: A cross-sectional study was conducted among 50 self-identified transgender individuals aged 18–45 years residing in the urban field practice area of Katuri Medical College and Hospital, Guntur, Andhra Pradesh. Participants were recruited using purposive sampling with the support of community leaders and NGOs to ensure diverse representation (trans women, trans men, non-binary individuals). Data were collected using validated instruments—the Perceived Stress Scale (PSS-14), UCLA Loneliness Scale (Version 3), and WHOQOL-BREF—translated and culturally adapted into Telugu. Face-to-face interviews were conducted in private settings, with the option for anonymous self-administered responses. Descriptive statistics and Pearson correlation analyses were performed using SPSS version 20.0 to examine relationships between perceived stress, loneliness, and QOL across physical, psychological, social, and environmental domains.

Conclusion: A high prevalence of perceived stress was observed: 76% reported moderate stress and 24% high stress. None had low stress levels. Perceived stress and loneliness were significantly and negatively correlated with overall QOL ($r = -0.643$ and $r = -0.421$; $p < 0.001$). Stress had the strongest negative association with social relationships ($r = -0.748$), while loneliness showed the strongest inverse correlation with mental health ($r = -0.684$). An unexpected positive correlation was noted between loneliness and social relationships ($r = 0.645$), suggesting that quantity of social interactions may not equate to quality or emotional connectedness. These findings highlight

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Submission date: July 11, 2025

Revision date: August 27, 2025

Published date: April 14, 2026

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the urgent need for gender-affirmative mental health services, emotionally supportive community frameworks, and inclusive public health policies tailored to transgender populations in South India.

Keywords: Transgender health; Perceived stress; Loneliness; Quality of life; Urban South India; Mental health disparities

Introduction

Transgender individuals in India, often identified as hijra, aravani, or other regional identities, face profound social, economic, and health disparities that contribute to elevated perceived stress, loneliness, and reduced quality of life (QOL).¹⁻⁴ These challenges are rooted in societal stigma and historical marginalization, exemplified by Section 377 of the Indian Penal Code, repealed in 2018, which criminalized non-normative gender and sexual identities, perpetuating discrimination in public and private spheres.⁵ This marginalization manifests as family rejection, workplace exclusion, and structural violence, such as police harassment, leading to psychological distress and social isolation, particularly among kothi-identified individuals in South India.⁶ The lack of resilience-building frameworks and anti-discrimination policies exacerbates these issues, limiting access to mental health support and community belonging.⁷

Economically, transgender individuals encounter significant barriers. A study in Andhra Pradesh reported a 43.1% illiteracy rate and high unemployment, with many resorting to informal economies like sex work or begging due to exclusion from formal sectors.⁸ In contrast, India's overall unemployment rate was 7.2% in the October-December 2022 quarter, highlighting the disproportionate economic marginalization of transgender populations.⁹ Perceived stress, a response to such external pressures, adversely impacts mental and physical health, increasing risks of depression and anxiety.^{11, 12} Social support systems, crucial for mitigating stress, are often absent, as family rejection forces reliance on chosen families within transgender communities, which may lack emotional or financial stability due to internal hierarchies.¹⁰ Loneliness, driven by social isolation and rejection, further compounds these challenges, with studies showing it predicts negative health outcomes in marginalized gender minorities.^{10, 13}

Access to transgender-affirming healthcare is severely limited, with few public facilities offering gender-affirming care like hormone therapy or surgeries, and discrimination by providers discourages care-seeking, exacerbating health disparities.^{3,5} These barriers contribute to poorer QOL across physical, psychological, social, and environmental domains, as measured by tools like the WHOQOL-BREF.^{15, 16} Emotional maturity and social support can mitigate these effects, but urban South India's rapid modernization and social stratification introduce unique stressors, such as heightened visibility and scrutiny, compared to rural settings.^{10, 17} The Perceived Stress Scale and UCLA Loneliness Scale, validated tools with high reliability (Cronbach's $\alpha \approx 0.85$ and $0.90-0.94$, respectively), are critical for assessing these psychosocial challenges.^{12,14} Despite legal advancements like the Transgender Persons (Protection of Rights) Act, 2019, implementation gaps leave psychosocial health needs unaddressed.⁷

Research on transgender psychosocial well-being in South India is scarce, with most studies focusing on HIV/STI prevalence or legal rights, leaving a critical gap in understanding the interplay of perceived stress, loneliness, and QOL.^{5,6} This study addresses this gap by examining these factors among transgender individuals in urban South India, using validated tools to inform culturally sensitive mental health interventions and inclusive public health policies to enhance their well-being.

Objectives

1. To assess the perceived stress, loneliness, quality of life, among transgender individuals residing in south India
2. To estimate the correlation between perceived stress, loneliness, quality of life among transgender individuals residing in South India.

Materials and Methods

Study Design

A cross-sectional study was conducted to assess perceived stress, loneliness, and quality of life (QOL) among transgender individuals.

Study Setting

The study was conducted in the urban field practice area of Katuri Medical College and Hospital, a tertiary care teaching hospital in Guntur, Andhra Pradesh, South India.

Study Population

Self-identified transgender individuals aged 18-45 residing in the study area for at least one year.

Study Period

August 1 to August 28, 2024.

Sampling Technique

Purposive sampling was employed to recruit transgender individuals. Community leaders and local NGOs facilitated participant identification to ensure diverse representation (e.g., trans women, trans men, non-binary).

Sample Size

A sample of 50 participants was selected based on a power analysis conducted to detect a moderate correlation ($r = 0.4$) between perceived stress and quality of life (QOL), with 80% power and a significance level of 0.05 (two-tailed). The power analysis indicated a minimum sample size of 46 participants. A sample size of 50 was chosen to account for potential incomplete responses or data quality issues, ensuring robust analysis.

Inclusion Criteria

- Self-identified transgender individuals aged 18-45.
- Residing in the study area for at least one year.
- Willing to provide informed consent.

Exclusion Criteria

- Individuals with severe psychiatric disorders impairing informed consent, assessed via self-report and community health worker consultation.
- Those undergoing major medical treatments (e.g., chemotherapy, major surgery) significantly affecting study variables.

Study Tools

Data were collected using a structured questionnaire incorporating three validated scales:

- **Perceived Stress Scale (PSS)**¹²: A 14-item scale (5-point rating, 0=never to 4=very often) assessing perceived stress. Scores range from 0-56, with higher scores indicating greater stress. Developed by Cohen et al. in 1983, it has high reliability (Cronbach's $\alpha \approx 0.85$).
- **UCLA Loneliness Scale (Version 3)**¹⁴: A 20-item scale (4-point rating, 1=never to 4=always) measuring subjective loneliness and social isolation. Scores range from 20-80, with higher scores indicating greater loneliness. Developed by Russell in 1996, it has excellent reliability (Cronbach's $\alpha \approx 0.90-0.94$).
- **WHO Quality of Life-BREF (WHOQOL-BREF)**¹⁶: A 26-item scale (5-point Likert scale) assessing QOL across four domains: physical health, psychological well-being, social relationships, and environment. Scores are transformed to 0-100, with higher scores indicating better QOL. Developed by WHO in 1995, it has good reliability (Cronbach's $\alpha \approx 0.70-0.90$).

Scales were translated into Telugu, back-translated, and pilot-tested ($n=10$) to ensure cultural and linguistic validity.

Data Collection

Data were collected via face-to-face interviews and the participants could opt for anonymous paper-based questionnaires also in private settings. Interviews occurred in community centers or private spaces, conducted in Telugu.

Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee of Katuri Medical College and Hospital. Written informed consent was secured in participants' preferred language, ensuring confidentiality through anonymized data and secure storage. Participants could withdraw at any time.

Data Analysis

The collected data were entered into a Microsoft Excel spreadsheet and analyzed

using SPSS software version 20.0. Descriptive statistics summarized demographic data and key variables: perceived stress (PSS), loneliness (UCLA Loneliness Scale), and quality of life (WHOQOL-BREF). Chi-square tests and Pearson correlation coefficients were used to assess the relationships between perceived stress, loneliness, quality of life, and emotional maturity.

Results and Discussion

➤ Age Distribution of Participants (n = 50)

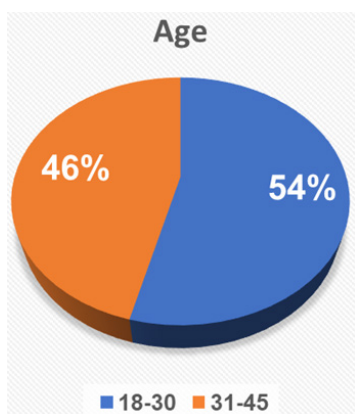


Fig 1: Age distribution of the participants (n=50)

Among the 50 transgender individuals studied, 27 participants (54%) were between 18 and 30 years old, while 23 (46%) were in the 31 to 45 years age group (Fig. 1).

➤ Educational Status of Participants

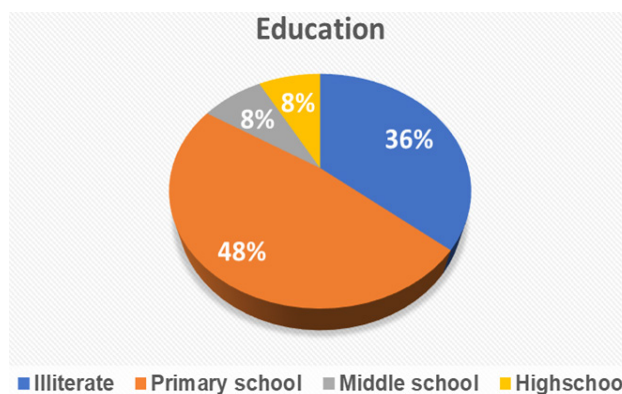


Fig 2: Educational status of the participants (n=50)

Out of 50 participants, 24 (48%) had completed primary school education. A smaller proportion had studied up to high school (4 participants, 8%) and middle school (4 participants, 8%). Notably, 18 individuals (36%) were illiterate (Fig. 2).

➤ Perceived Stress Levels Among Participants

Table 1: Stress levels of the participants:

| Stress | Frequency | Percentage |
|-----------------------|-----------|------------|
| Low Stress | 0 | 0% |
| Moderate Stress | 38 | 76% |
| High perceived Stress | 12 | 24% |
| Total | 50 | 100% |

None of the participants reported low levels of stress. The majority, 38 out of 50 (76%), experienced moderate levels of perceived stress, while 12 (24%) reported high stress levels (Table 1).

➤ Association of Perceived Stress and Loneliness with Quality-of-Life Domains

Table 2: The correlation analysis between perceived stress, loneliness, and various domains of quality of life (QOL) among the transgender individuals

| | Physical Health | Mental Health | Social Relationship | Environment |
|------------|----------------------|-----------------------|-----------------------|---------------------|
| Stress | r= -0.452 p<0.001 | r= -0.652 p<0.0001 | r= -0.748 p<0.0001 | r= -0.356 p<0.01 |
| Loneliness | r= -0.546 p<0.001 | r= -0.684 p<0.001 | r= 0.645 p<0.001 | r= -0.278 p<0.03 |

➤ Stress and Quality of Life Domains

- **Physical Health:** Higher stress was associated with lower perceived physical health scores (r = -0.452; p< 0.001).
- **Mental Health:** A strong inverse relationship was noted (r = -0.652; p< 0.0001).

- **Social Relationships:** The strongest negative association was with social relationships (r = -0.748; p< 0.0001).
- **Environmental Conditions:** A moderate negative association was observed (r = -0.356; p< 0.01).

➤ **Loneliness and Quality of Life Domains**

- **Physical Health:** Loneliness showed a negative association with physical health ($r = -0.546; p < 0.001$).
- **Mental Health:** Similar to stress, loneliness strongly correlated with poorer mental health ($r = -0.684; p < 0.001$).
- **Social Relationships:** A notable finding was a positive correlation ($r = 0.645; p < 0.001$), suggesting complex social dynamics that may require qualitative exploration.
- **Environmental Conditions:** A weak but significant inverse association was noted ($r = -0.278; p < 0.03$) (Table 2).

➤ **Overall Quality of Life (QOL) and its Association with Stress and Loneliness**

Table 3: Quality of Life (QOL) Correlation Analysis:

| QOL | r - value | P - value |
|------------|-----------|-----------|
| Stress | -0.643 | <0.001 |
| Loneliness | -0.421 | <0.001 |

- **Perceived Stress:** There was a strong inverse relationship between overall quality of life and stress levels ($r = -0.643; p < 0.001$), indicating that higher stress is linked with reduced well-being.
- **Loneliness:** Similarly, loneliness negatively correlated with overall QOL ($r = -0.421; p < 0.001$), suggesting that social disconnection significantly undermines life satisfaction among transgender individuals (Table 3).

Discussion

This study offers critical insights into the psychosocial health of transgender individuals in urban South India, highlighting high levels of perceived stress (76% moderate, 24% high, 0% low), loneliness, and reduced quality of life (QOL) across physical, mental, social, and environmental domains. These findings align with prior research, such as Budge et al., who reported a 48% prevalence of clinical depression and 39% prevalence of anxiety among transgender individuals, linked to low social support and personal loss.¹ Similarly, our study found strong negative correlations between perceived stress and mental health ($r = -0.652, p < 0.0001$) and loneliness and mental health ($r = -0.684, p < 0.001$),

underscoring the psychological burden in the absence of robust support systems.² Bockting et al. reported comparable rates of depressive symptoms (47.2%) and anxiety (41.9%) among transgender individuals in the U.S., primarily due to stigma and lack of community belonging.² Our study’s strongest negative association was between stress and social relationships ($r = -0.748, p < 0.0001$), reinforcing the notion that unsupportive social environments severely impair relational and emotional health.

Meyer’s Minority Stress Model suggests that chronic exposure to stigma and discrimination elevates mental health risks in sexual and gender minorities.¹³ Our data align with this framework, as persistent societal stigma likely contributed to the moderate-to-high stress levels observed. Reisner et al. reviewed global data, noting higher rates of depression (44%), anxiety (39%), and suicidal ideation (48%) among transgender individuals compared to cisgender peers.³ Similarly, our study found stress significantly correlated with reduced physical health ($r = -0.452, p < 0.001$) and environmental QOL ($r = -0.356, p < 0.01$), indicating multidimensional health deterioration due to psychosocial stressors. Chakrapani et al. documented structural violence, police abuse, and social rejection among kothi-identified men who have sex with men in Chennai, contributing to internalized stigma and emotional distress.⁶ These experiences likely parallel those of our participants, further explaining elevated stress and reduced QOL.

A particularly striking and unexpected finding was the positive correlation between loneliness and social relationships ($r = 0.645, p < 0.001$). Contrary to expectations that social relationships reduce loneliness, this result suggests that transgender individuals in urban South India may experience greater loneliness despite having more social connections. This finding diverges from prior research, such as Yousuf et al., who reported a negative correlation ($r = -0.87, p < 0.01$) between loneliness and social relations .QOL among transgender individuals in Pakistan, indicating that stronger social relationships typically reduce loneliness.⁸ Similarly, Grupp et al. found high loneliness prevalence (83.3%) among transgender individuals in Germany but did not report a positive correlation with social

relationships.⁹ This unexpected result may stem from the cultural context of urban South India, where social interactions within transgender communities, such as hijra gharanas, may be hierarchical or non-affirming, failing to provide emotional support. The emotional intelligence model by Salovey and Mayer supports this, suggesting that superficial or non-affirming interactions can exacerbate emotional isolation, a phenomenon termed “loneliness despite contact”.¹⁷

Several factors may explain this novel finding. First, the quality of social relationships may be critical. Transgender individuals may engage in social networks that lack genuine affirmation or include stigmatizing interactions, increasing feelings of loneliness.¹⁰ Second, the WHOQOL-BREF social relationships domain, used in our study, may capture different aspects of social interactions compared to other measures, such as the Lubben Social Network Scale used in other studies.^{15, 16} Third, unmeasured variables, such as the degree of gender affirmation or internalized stigma within social settings, may confound this relationship.⁵ This finding highlights the complexity of social dynamics for transgender individuals and underscores the need for nuanced interventions that prioritize meaningful, supportive connections over mere social contact.

Our findings also align with Fredriksen-Goldsen et al., who found that transgender older adults in the U.S. scored lower on physical and mental health domains compared to heterosexual peers.⁴ In our sample, overall QOL was inversely associated with perceived stress ($r = -0.643$, $p < 0.001$) and loneliness ($r = -0.421$, $p < 0.001$), reinforcing the profound impact of psychosocial stressors. Veeram et al.’s study in Kakinada, Andhra Pradesh, reported a 43.1% illiteracy rate, closely matching our 36%, and a 57.5% rate of gender reassignment surgery, nearly identical to our 57%, suggesting consistent patterns of educational disparities and access to gender-affirming care.⁸ Their findings of 100% lifetime STI prevalence and 11.9% past-year STD prevalence reflect psychosocial vulnerabilities and poor health-seeking behaviors, paralleling our cohort’s challenges.⁸ Additionally, 23.1% of their participants had at least one non-communicable disease (NCD), supporting our observed negative association between stress and physical health ($r = -0.452$, $p < 0.001$).

The methodological strength of this study lies in the use of validated tools—Perceived Stress Scale (PSS),¹² UCLA Loneliness Scale,¹⁴ and WHOQOL-BREF^{15, 16}—ensuring reliable and comparable findings. However, limitations include the small sample size ($n = 50$) and cross-sectional design, which restrict generalizability and causal inference. Intersectional factors such as income, caste, and rural-urban healthcare access were not fully explored, potentially influencing outcomes.⁷

These findings are significant for public health experts, community medicine professionals, mental health workers, and policymakers. They emphasize the need for tailored interventions that reduce stigma, enhance resilience, and foster affirming social support, as advocated by McCann and Brown.⁷ Future research should employ longitudinal and mixed-method designs to explore evolving stressors and coping mechanisms, particularly the unexpected positive correlation between loneliness and social relationships, to inform inclusive, rights-based health policies.

Conclusion

This study reveals high perceived stress (76% moderate, 24% high) and loneliness among transgender individuals in urban South India, significantly linked to reduced quality of life across physical, mental, social, and environmental domains. These findings underscore the urgent need for targeted mental health interventions and inclusive policies to enhance well-being. Self-reporting measures may introduce bias. Future research should use larger, diverse samples, longitudinal designs, and qualitative methods to explore evolving stressors and coping mechanisms, particularly the unexpected positive correlation between loneliness and social relationships ($r = 0.645$, $p < 0.001$). Comparative and intervention studies are needed to inform rights-based health policies.

Funding Sources : NIL

Ethical Clearance: F.No IEC/KMCH/2024/G-13 from Institutional Ethics Committee, Katuri Medical College and Hospital, Guntur, AP Date: 6/6/24

Declaration of conflicts of interest statement: NIL

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Imagery and Insight: A Qualitative Visual Analysis of Paediatric Cancer Patients' Drawings on Clinical Research Using the DRAWEP Framework

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How to cite this article: Rhea Aggarwal, Adarsh Keshari, Khushboo Sharma et. al. Imagery and Insight: A Qualitative Visual Analysis of Paediatric Cancer Patients' Drawings on Clinical Research Using the DRAWEP Framework. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Paediatric assent and engagement in clinical research pose ethical and developmental challenges, particularly when research concepts are communicated primarily through verbal explanations. Visual methods such as drawing offer an alternative pathway to capture children's thinking and to better understand their unspoken perspectives.

Objective: To explore how paediatric cancer patients conceptualize clinical research and clinical trials through hand-drawn posters, using the Drawing-Based Emotional Processing (DRAWEP) framework supported by AI-assisted qualitative analysis.

Methods: This qualitative exploratory study involved secondary analysis of hand-drawn posters created by children during an International Clinical Trials Day (ICTD 2025) awareness activity conducted by a national paediatric oncology non-governmental organization. Posters were anonymized, digitized, and analyzed using the Drawing-Based Emotional Processing (DRAWEP) framework. AI-assisted tools were used to support structured thematic organization, with all interpretations reviewed and validated by human researchers.

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Submission date: January 1, 2026

Revision date: January 27, 2026

Published date: April 14, 2026

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The DRAWEP framework guided interpretation across the following domains: Description (what is drawn), Reflect (feelings or ideas evoked by the artwork), Analyze (insights into the child's understanding of research), Wonder (questions arising from the artwork), Evaluate (effectiveness of communication), and Present (summary insight).

Results: Six thematic domains emerged, reflecting emotional, relational, and symbolic representations of clinical research. Common themes included hope, trust, process awareness, and compassion. Several posters also revealed misconceptions, particularly the equating of research with a guaranteed cure (therapeutic misconception) and the conflation of clinician and researcher roles.

Conclusion: Visual expression through drawing provides a developmentally appropriate window into children's ethical and emotional perceptions of clinical research. Identifying both understanding and misconceptions through such methods may help inform the development of age-appropriate communication strategies in paediatric research settings.

Introduction

While clinical trials stand as the cornerstone of progress in paediatric oncology, having dramatically improved survival rates and quality of life [1], securing true assent from children remains a complex challenge to researchers. Additionally, understanding of clinical research among child participants remains variable and often shaped by external factors such as the opinions of their parents & friends.

Paediatric assent is the agreement of a child to participate in research, requires developmentally appropriate understanding concepts, including risks, side effects, and the distinction between research and clinical care, yet children's internal understanding of research concepts is rarely explored directly. [2].

Current communication methods often rely on simplified verbal explanations which frequently fail to achieve true conceptual understanding in children, especially concerning the uncertainty of experimental treatment [1, 3]. A critical barrier to informed assent is the difficulty children face in articulating abstract concepts and communicating their opinion verbally. [4].

Visual expression, such as drawing, is a methodology that bypasses verbal barriers, allowing children to communicate much more easily [5]. Art-based methods have proven effective in health settings by offering a critical window into children's perspectives [6]. Drawings capture perceptions and meanings rather than factual knowledge and should be interpreted as expressive representations rather than indicators of cognitive mastery.

We employ the Drawing Based emotional processing (DRAWEP) framework combined with

the objective, scalable quantification provided by AI-assisted image analysis.

This study sought to address the following questions:

1. How do paediatric cancer patients visually conceptualize clinical research and clinical trials on international clinical trials day?
2. What emotional, ethical, and relational meanings are reflected in their drawings?
3. What misconceptions or gaps in understanding are revealed through visual expression?

Methods

Study Design and Setting

This was a qualitative, exploratory visual study using secondary analysis of children's artwork, utilizing a single dataset of original artwork for analysis using the DRAWEP tool with the help of AI. The study utilized posters created during an ICTD 2025 awareness activity organized by an Indian paediatric oncology NGO. Participants represented multiple Indian states based on their current location.

Participants and Ethical Compliance

The data comprised hand-drawn posters collected from paediatric cancer patients aged 8–18 years during an International Clinical Trials Day (ICTD 2025) awareness event. The final dataset for analysis consists of posters received during the event- the posters were anonymized (all identifiers removed).

Participant Recruitment:

Participation in the poster activity was voluntary. No sampling or selection was performed. Participation in a clinical trial was not required.

Exposure to Clinical Research

Children were not required to have prior enrolment in clinical trials. Their representations may reflect indirect exposure through clinicians, caregivers, hospital environments, or awareness activities. The study therefore explores perceived understanding rather than verified knowledge.

Inclusion Criteria:

- Posters created by children aged 8–18 years who participated in the ICTD 2025 drawing activity. The broad age range was intentionally retained to capture developmental variation in visual expression.

Exclusion Criteria:

- Posters containing unremovable identifying information (faces, names, unique landmarks)
- Posters with image quality issues that prevent reliable analysis (e.g., extremely low resolution, damage, very light, illegible text) and cannot be recaptured.

Ethical Compliance

The poster-making activity was conducted as an awareness initiative. For research purposes, all posters were anonymized prior to analysis, with removal of any identifiable information. The study involved non-interventional, secondary analysis of visual data and posed minimal risk; participation was voluntary. No clinical or personal data were collected directly from participants. Demographic and clinical details reported in the results were taken from de-identified records to describe the study population.

The study protocol was reviewed, and a waiver of ethical approval and written informed consent was granted by the CanKids Institutional Ethics Committee (Reference No. IEC-CK-2025-07, dated 28 August 2025).

Data Collection Procedures and Drawing Prompt

The data consisted of digitized images of posters created on paper using any drawing materials (crayons, markers, pencil) during International Clinical Trials Day 2025. Children were not provided with formal teaching or structured explanation about clinical trials prior to drawing. The intention was to capture their existing opinions as a snapshot.

Drawing Session Setup

Children were introduced to the activity by the staff of the paediatric cancer NGO. The single prompt provided was: “International Clinical Trials Day” Children were offered the choice to draw anything, and given the time of up to 1 hour.

Anonymization & Digitization

Prior to scanning/photographing, any visible names or identifiers were cropped or blurred. Each poster was digitized uploaded on to a secure password protected google drive folder

Analytic Framework: AI and DRAWEP Triangulation

Posters were analysed using the Drawing based Emotional Processing (DRAWEP) framework analysing the key themes, misconceptions, insights and poster highlights of posters in batches of 10 with the help of an AI-assisted analytic support using customized GPT.

The analytic prompt presented in the Appendix reflects the original protocol developed for the full dataset. Following application of inclusion and exclusion criteria, only 56 posters were included in the final analysis.

AI-assisted outputs were used to organize initial themes, which were reviewed by human researchers. Differences were resolved through discussion and consensus.

The DRAWEP tool guided interpretation includes- Description (what is drawn), Reflect (feelings/ideas that the artwork evokes), Analyse (Insights into the child’s understanding of research), Wonder (questions arising from the artwork), Evaluate (effectiveness of communication), Present (a summary insight).

AI tools were trained on the DRAWEP framework, as elaborated above. AI outputs served to maintain consistency in interpretation, the thematic conclusions were reviewed, by human researchers before finalizing to reduce bias.

Data Management and Storage

All anonymized digital images were stored on a password protected Google Drive folder, accessible only to study leads.

Results

A total of 96 childhood cancer patients participated in the poster competition held during ICTD 2025. Their demographic and clinical profiles are summarized in Table 1. The mean age was 14.4 ± 2.95 years, median 14 (12–17), with a slight female predominance (54.2% girls). Older adolescents more frequently included textual or procedural elements, whereas younger children relied predominantly on symbolic imagery, showing the expected developmental variation in clinical trial representation.

Among the participants, acute lymphoblastic leukaemia (ALL) was the most common diagnosis (46.9%), followed by acute myeloid leukaemia (5.2%), Hodgkin's lymphoma (8.3%), and osteosarcoma (8.3%). Most participants (66.7%) were on active treatment, while 17.7% had completed therapy and 14.6% were in maintenance or survivorship phases.

Participants represented 16 Indian states and Nepal, with the highest numbers from Uttar Pradesh (25.0%), Delhi (16.7%), and Bihar (13.5%), reflecting broad geographic engagement.

After applying inclusion and exclusion criteria, 56 posters were included for final DRAWEP analysis.

The analysis, guided by the Drawing based Emotional Processing (DRAWEP) framework, confirmed that paediatric oncology patients conceptualize clinical research across six major interconnected themes, with a small number of drawings showed confusion or oversimplification, such as depicting research as an automatic cure (therapeutic misconception).

Thematic Conceptualization and Synthesis (Table 2)

Children's posters offered a unique lens into their understanding of complex scientific processes, ethics, and human experiences associated with clinical trials. The analysis revealed six major thematic categories:

- **Hope and Healing:** This theme dominated the visual narratives, using metaphors like rainbows, sunrise ("New Hope"), and bridges to health. Research was often viewed optimistically as a path to recovery.
- **Partnership and Trust:** Children strongly emphasized the relational aspects of trials.

Research was visualized as a doctor-patient handshake ("Partnership") or a collaborative puzzle ("CURE"), highlighting a value for teamwork

- **Ethics and Fairness:** A surprising level of symbolic representation was evident. Posters conveyed concepts of risk-benefit evaluation ("Side Effects vs. Benefits"), fairness (doctor with scales), and consent (e.g., "I say yes!").
- **Structured Process:** Children demonstrated an awareness of the procedural nature of trials, including representations of trial stages.
- **Compassion in Science:** This theme showed the depiction emotional care. Examples included a microscope lens shaped like a heart ("Care in Science") and the written concept of "Science with love".
- **Symbolism and Metaphors:** Abstract concepts were communicated via powerful symbolism, including research as a Treasure hunt ("Discovery!"), a Tree of science, or a Light bulb representing innovation.

Emerging Awareness

The visual narratives were indicative that the children often correlated research with cure, which may indicate that they did not fully understand the risks involved. (therapeutic misconception). Additionally, the clinician and the researcher were often one and the same in the posters, which may not always be the case.

Consistencies (Emotional and Relational)

Optimism and hope dominated the visual narratives. Children consistently associated research with new cures, innovation, and progress, and trust in doctors and researchers was portrayed positively.

Divergences and Agency

The artwork showed a split in knowledge depth: some posters reflected trial knowledge using terms like phases of a clinical trial, while others relied on simplified metaphors such as rainbow syringes, which is likely due to the wide age range.

Importantly, the themes consistently highlighted children's depictions of themselves asking questions, imagining themselves as researchers, which indicates a preference for partnership rather than passive roles.

Role of Art in Communication

The use of art successfully demonstrated simplification, making abstract ideas graspable. Furthermore, the posters conveyed significant emotional depth and reached symbolic representation (weighing risks vs. benefits) that may be missed in purely verbal assessments. Direct quotes such as "I am part of a trial!" and "Partnership" highlight children's direct voices.

Overtly negative depictions of clinical research, such as fear or refusal, were uncommon. This may reflect the supportive context of the awareness event, and influence of parents/ caregivers and should not be interpreted as absence of concern.

Table 1: Profile of Childhood Cancer Patients Participating in the Poster Activity

| Parameters | n | % |
|-------------------------------------|--------------|------|
| Gender | | |
| Boys | 44 | 45.8 |
| Girls | 52 | 54.2 |
| Age | | |
| 09-11 yrs | 24 | 25.0 |
| 12 - 15 yrs | 29 | 30.2 |
| more than 15 yrs | 43 | 44.8 |
| Mean \pm SD | 14.40 + 2.95 | |
| Median (IQR) | 14 (12 - 17) | |
| Types of cancer | | |
| Acute Lymphoblastic Leukaemia (ALL) | 45 | 46.9 |
| Acute Myeloid Leukaemia (AML/APML) | 5 | 5.2 |
| Leukaemia (other/unspecified) | 9 | 9.4 |
| Hodgkin's Lymphoma (HL) | 8 | 8.3 |

Cont....

| | | |
|---------------------------------|----|------|
| Osteosarcoma (OS) | 8 | 8.3 |
| Ewing Sarcoma / PNET | 4 | 4.2 |
| Soft Tissue Sarcomas (STS) | 3 | 3.1 |
| Other Carcinomas | 5 | 5.2 |
| CML (Chronic Myeloid Leukaemia) | 1 | 1.0 |
| CNS (Central Nervous System) | 1 | 1.0 |
| GCT (Germ Cell Tumour) | 1 | 1.0 |
| NHL (Non-Hodgkin's Lymphoma) | 1 | 1.0 |
| RB (Retinoblastoma) | 2 | 2.1 |
| Treatment Status | | |
| Completed | 17 | 17.7 |
| Maintenance / Survivor | 14 | 14.6 |
| On treatment | 64 | 66.7 |
| Relapse | 1 | 1.0 |
| States | | |
| Delhi | 16 | 16.7 |
| Bihar | 13 | 13.5 |
| Gujarat | 5 | 5.2 |
| J&K | 1 | 1.0 |
| Jharkhand | 1 | 1.0 |
| Madhya Pradesh | 3 | 3.1 |
| Maharashtra | 8 | 8.3 |
| Nepal | 1 | 1.0 |
| North East | 2 | 2.1 |
| Odisha | 1 | 1.0 |
| Punjab | 1 | 1.0 |
| Rajasthan | 2 | 2.1 |
| Tamil Nadu | 2 | 2.1 |
| UP | 24 | 25.0 |
| Uttarakhand | 2 | 2.1 |
| West Bengal | 7 | 7.3 |

Table 2: Summary of Children's Conceptualizations and Emerging Themes

| Batch | Key Themes | Broad Understanding | Surprising Insights | Notable Quotes / Poster Highlights |
|-------|---|---|--|--|
| 1 | Hope, Healing, Support, Scientific Curiosity, Empowerment | Trials always cure; roles of doctor vs. researcher | Timeline of trial process, Graphs | "I am part of a trial!", "Trust", "How we know it works" |
| 2 | Procedures, Consent, Ethics, Fairness, Teamwork | Trials = universal cures; Research = hospital stay; Scientists as superheroes | Consent form, Pie chart, Poetic microscope-heart | "Consent Form", "Look inside", "New medicine for all children" |

Cont.....

| | | | | |
|---|---|---|--|---|
| 3 | Process flow, Protection, Consent agency, Ethical balance, Compassion in science | Trials as guaranteed protection; Kids as researchers; Medicine always wins | Risk-benefit scale, Child consent voice, "Science with love" | "I say yes!", "Science with love", "Which works better?" |
| 4 | Structure, Data, Metaphors (bridge, tree, treasure), Curiosity, Learning | Research = guaranteed health; Discovery = guaranteed cure; Race = medicine always wins | Comparison of trial vs. standard, Data/tech, Tree of science | "Data matters", "Why?", "Research is the bridge" |
| 5 | Trial phases, Monitoring, Risk- benefit ethics, Global unity, Partnership | Trials = guaranteed cure; Kids as researchers | Phases of trials, Risk-benefit scale, Partnership handshake | "Phase 1-3 clock", "Side Effects vs. Benefits", "Partnership" |
| 6 | Hope, Future, Ethics, Compassion, Teamwork, Innovation | Trials always succeed; Cure as puzzle solved easily | Doctor balancing fairness, Microscope- heart, Future door | "Care in Science", "Future", "CURE", "New Hope" |

Discussion

Integrating AI for Visual Analysis (Appendix)

The methodological innovation of this study lies in the integration of a customized GPT-based artificial intelligence (AI) model within the DRAWEP framework to support interpretation of children's visual narratives. By combining natural language and image-based reasoning, this approach facilitated structured and transparent organization of themes and enables a structured, replicable analysis of children's perceptions of clinical research.

AI-assisted visual analytics is an emerging frontier in qualitative research, enabling pattern recognition, emotion inference, and thematic clustering at scale (8-10). Current frameworks emphasize AI output verified by humans AI, ensuring that AI outputs remain transparent, accurate and consistent (8, 11). Such hybrid models where AI augments but does not replace human judgment offer a pathway toward standardized, scalable visual communication assessment in paediatric research literacy studies.

Therapeutic Misconception in Paediatric Research Perceptions

The dominant theme of *Hope and Healing* across children's posters reflects emotional resilience

as well as a potential therapeutic misconception, wherein participation in research is *perceived* as ensuring direct personal medical benefit (7, 12). This perception *appears to arise from* a conflation of clinical care and research roles, as seen in posters that depict the doctor, researcher, and scientist interchangeably. While expressions of optimism are developmentally understandable in paediatric oncology setting, it underscores a persistent ethical challenge in paediatric research communication.

Similar findings have been described in paediatric bioethics literature, where hope and trust often shape children's and families' understanding of research participation (7, 12). Addressing this requires developmentally sensitive communication that balances hope with honesty about uncertainty and experimental nature.

Educational interventions and materials should incorporate developmentally sensitive communication approaches- such as clearer role differentiation, balanced messaging around uncertainty, and age-appropriate visual explanations- all of which may help reduce therapeutic misconception:

1. Differentiate the roles of clinician and researcher clearly and repeatedly in both verbal and visual formats.

2. Balance optimism with transparency, preserving optimism while gently communicating that research may not guarantee cure.
3. Use child-friendly visual aids, metaphors, or illustrations distinguishing “experimental treatment” from “gold standard treatment.”
4. Include comprehension checks, such as drawing or explaining back concepts, to identify and correct misperceptions early.

Broader Implications

This study demonstrates that AI-mediated visual interpretation, when guided by an evidence-based framework like DRAWEP, can uncover nuanced insights into how children conceptualize clinical research insights often inaccessible through verbal or survey-based approaches. Children’s drawings revealed both ethical awareness (risk-benefit balance, fairness, consent) and misunderstanding (equating research with cure), offering valuable direction for findings highlight areas where communication may require clarification.

However, interpretive bias remains possible in both AI and human qualitative analysis, especially when evaluating culturally embedded or metaphorical imagery. Future studies should expand dataset diversity, and assess how visual-based educational interventions influence children’s understanding longitudinally.

While it is well established that children often adopt the views of their caregivers or family members regarding research participation, it remains important to actively engage paediatric participants in discussions about clinical trials. Efforts should be made to communicate study aims and procedures in an age-appropriate manner and to involve children as meaningful partners in their own healthcare. Promoting such engagement, with due consideration of developmental capacity, supports respect for bodily autonomy and constitutes an ethical imperative in paediatric research.

Limitations:

Interpretations are based on secondary analysis of artwork created in a non-research setting. The wide distribution serves to achieve a broader

understanding but may also muddy the results. The absence of standardized instruction, verification of research exposure, and the exclusion of some posters may limit generalizability. Findings should be interpreted as exploratory and descriptive.

In neutral or clinical contexts, children’s visual narratives may include greater expressions of fear, uncertainty, or ambivalence. Future studies should explore visual representations elicited in routine clinical settings to capture a broader emotional spectrum.

Conclusion

Children’s drawings provide valuable insight into how paediatric patients emotionally and symbolically perceive clinical research. Visual methods can complement traditional communication approaches by revealing both understanding and misconceptions, informing more developmentally sensitive discussions in paediatric research contexts.

Acknowledgment: “The authors sincerely thank all participating paediatric cancer patients and their caregivers of CanKids KidsCan for their enthusiastic involvement in this initiative. The authors also gratefully acknowledge the support and collaboration of the CanKids Education Team and Team PACER-India for their guidance, coordination, and contribution throughout the project.

Funding Sources: This study was undertaken as part of the PACER Initiative (Patient Advocates for ClinicalResearch) jointly implemented by APAR Health and CanKids KidsCan, commemorating *International Clinical Trials Day (ICTD) 2025*. No external funding was received.

Ethical Clearance: All procedures followed were in accordance with the ethical standards of the institutional and/or national research committees and with the Helsinki Declaration and the ICMR National Ethical Guidelines for Biomedical and Health Research.

Ethics Approval: The study protocol was reviewed, and a waiver of ethical approval was granted by the CanKids Institutional Ethics Committee (Ref no. [IEC-CK-2025-07], dated [28th August 2025]).

Declaration of conflicts of interest statement: Authors declare no conflict of interests.

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Investigating the Knowledge, Attitudes, Practices, and Growth Outcomes of Breastfeeding Among Indian Mother-Infant Dyads

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How to cite this article: Ruthika Matapathi, Pavan Kumar. Investigating the Knowledge, Attitudes, Practices, and Growth Outcomes of Breastfeeding Among Indian Mother-Infant Dyads. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Objective: To assess breastfeeding knowledge, attitudes, and practices (KAP) among Indian suburban mothers and evaluate their correlation with infant anthropometric outcomes, identifying socioeconomic and behavioral factors associated with growth faltering.

Methods: Cross-sectional study of 60 mother-infant dyads in Zahreeabad, Telangana. Data included structured questionnaires on demographics and KAP metrics, plus objective anthropometric measurements compared against age-sex-matched WHO standards. Descriptive and correlational analyses examined associations between maternal factors and infant growth.

Results: Mean maternal age was 27.47±4.24 years; 75% were homemakers (n=45), 60% held Bachelor's degrees or higher (n=36). Early breastfeeding initiation (≤ 1 hour) occurred in 65% (n=39), with universally positive attitudes. Maternal education strongly correlated with breastfeeding knowledge ($r_s(58) = .82, p < .001, 95\% \text{ CI } [.71, .89]$). Early complementary feeding significantly predicted length deficits ($B=-2.71, p=0.042, 95\% \text{ CI } [-5.32, -0.10]$). C-section infants showed 2.28 cm greater mean length deficits than vaginal births (Cohen's $d=0.48, 95\% \text{ CI } [-2.12, 4.68], p=0.32$). Despite 85% of infants exhibiting stunting and 55% showing weight deficits, 85% of mothers rated growth as "Average" or "Above Average," revealing a critical perception-reality gap.

Conclusions: High breastfeeding knowledge and positive attitudes don't prevent growth faltering, with 85% of infants stunted despite strong maternal awareness. Structural barriers – particularly C-sections (85% of delayed initiations) and early complementary feeding ($p=0.042$) – critically impair outcomes. A profound perception gap exists: 85% of mothers rated stunted growth as "Average" or above. The limited sample ($N=60$) constrains statistical power for some analyses but provides validated findings on feeding timing-growth relationships and identifies critical intervention targets. Effective interventions must address clinical barriers and maternal perceptual frameworks, not just knowledge dissemination.

Keywords: Breastfeeding, Knowledge-Attitude-Practice (KAP), Exclusive Breastfeeding, Infant Growth, Stunting, India, Maternal Education

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Submission date: December 30, 2025

Revision date: February 2, 2026

Published date: April 14, 2026

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Introduction

Breastfeeding is essential for optimal infant and maternal health, providing superior nutrition, neurodevelopmental support, and immunological defense¹. The WHO and UNICEF recommend Exclusive Breastfeeding (EBF) for six months, followed by continued breastfeeding with complementary foods up to two years or longer². EBF (Exclusively breastfeeding) provides only human milk without additional liquids, water, or solids³. Despite strong evidence, adherence to timely initiation and six-month exclusivity remains sub-optimal globally, representing a preventable public health challenge requiring targeted research on localized barriers⁴.

The KAP Framework: The Knowledge, Attitude, and Practice (KAP) model is an epidemiological tool assessing maternal feeding choices⁵. It evaluates Knowledge of best practices, underlying Attitudes and beliefs, and actual Practice (timing, duration, exclusivity), identifying barriers from misinformation, socio-cultural norms, lack of support, or clinical challenges like perceived insufficient milk supply (PIMS). Cultural discomfort with public breastfeeding also impacts on-demand feeding.

Rationale and Objective Breastfeeding benefits depend on timely initiation, full exclusivity, and adequate duration⁶. While knowledge may be high, obstacles like Caesarean sections or work constraints often cause deviations from optimal practice⁷. This study provides systematic, localized data evaluating knowledge, attitudes, and practices among postnatal mothers.

Methodology

Study Design: Cross-sectional, observational study of 60 mother-infant dyads in Zahreeabad, Telangana, India. Infants ranged from 0.36 to 18 months.

Data Collection: Face-to-face interviews using structured questionnaires covered: (1) Demographics (maternal age, education, occupation, income, family structure), (2) Knowledge and Attitudes (IYCF standards, comfort, beliefs; scored on 5-point scale), (3) Practices and Barriers (initiation timing, EBF duration, early complementary feeding reasons, challenges), (4) Infant Growth (anthropometric

data compared against WHO standards to calculate growth deficits).

Statistical Analysis: Descriptive statistics summarized demographics and KAP findings. Effect sizes (Cohen's d , R^2) and 95% CIs reported alongside p-values. Analyses included: Spearman's Rho (education vs. knowledge), unpaired t-tests (knowledge vs. complementary feeding reasons), logistic regression (complementary feeding vs. public comfort), Pearson's correlation (income vs. comfort/length deficit/EBF status), multi-linear regression (education, income, knowledge interactions; infant age, deficits, complementary feeding status), Welch's t-tests (C-section vs. deficits), Pearson's test (deficits vs. milestones). Cross-sectional design limits findings to associations; no causal inferences made. **Ethics:** Informed verbal consent obtained in local language. Responses anonymized (ID 1-60).

Results

Demographics (N=60): Mean maternal age 27.47±4.24 years; 75% homemakers (n=45); 60% bachelor's degree or higher (n=36); 80% joint families; 100% post-birth caregiver support. **Maternal Knowledge and Attitudes:** 100% strongly agreed breastfeeding is best; mean knowledge scores 4.2/5 (infant benefits), 4.5/5 (maternal benefits); 100% would recommend breastfeeding.

Table 1: Education Level and EBF Knowledge

| Education Level | Correct EBF Duration (6 months) |
|------------------------------|---------------------------------|
| Low/Middle School (5-10 yrs) | 50% |
| Bachelor's Degree (16 yrs) | 87.5% |
| Master's Degree (18 yrs) | 100% |

Public Comfort: 75% comfortable (65% very comfortable, 10% comfortable); 10% neutral; 15% very uncomfortable. The 15% "Very Uncomfortable" had higher knowledge scores (4.67 vs. 4.45 average). 3 mother reported belief that colostrum is unhealthy.

Practices and Barriers: Early initiation (≤ 1 hour): 65% (n=39); late initiation (> 24 hrs): 20% due to C-section (n=9) or maternal health (n=3). Early complementary feeding (< 6 months): 25% (n=15);

reasons: work constraints (n=3), perceived health issues/infant hunger (n=12). Common difficulties: sore nipples (n=12), PIMS (n=9).

Infant Health: 100% initiated breastfeeding and completed vaccinations. Mean infant age: 9.6 months. Minimal health issues (n=3 pneumonia). 90% achieved age-appropriate developmental milestones; 10% showed delays.

Growth Outcomes: 85% (n=51) exhibited length deficits (stunting); 55% (n=33) showed weight deficits. Despite 85% stunting prevalence, 85% of mothers rated growth as "Average" or "Above Average." Only mothers with severe deficits (-8.8 to -9 cm) perceived growth as "Below Average." Infants with weight deficits: median feeding frequency 1.0 hour.

Inferential Statistical Results

1. Multiple Linear Regression: CF Status and Infant Age vs. Length Deficit

- CF status: $B=-2.71$, $p=0.042$, 95% CI [-5.32, -0.10]
- Infant age: $B=0.05$, $p=0.567$, 95% CI [-0.13, 0.23]
- Overall: $F(2,57)=2.75$, $p=0.104$, $R^2=0.088$, Adjusted $R^2=0.044$

2. Spearman's Rho: Education vs. Knowledge

- Table 1 : $r_s=0.824$, $p<0.001$, $R^2=0.679$, 95% CI [.71, .89]

3. Multiple Linear Regression: Income and Education vs. Knowledge

- Overall: $F(2,57)=22.46$, $p<0.001$, $R^2=0.441$, Adjusted $R^2=0.422$
- Income: $\beta=0.0002$, $p<0.001$, 95% CI [0.0001, 0.0003]
- Education: $B=-0.85$, $p=0.0009$, 95% CI [-1.33, -0.37]

4. Binary Logistic Regression: Public Comfort vs. EBF Cessation

- $\chi^2(1)=0.012$, $p=0.914$, OR=0.98, 95% CI [0.68, 1.23], Nagelkerke $R^2<0.001$

5. Welch's t-Test: C-Section vs. Growth Deficits

- Length deficit: C-section $M=6.47$ cm (SD=5.12) vs. Natural $M=4.19$ cm (SD=4.58);

difference=2.28 cm, Cohen's $d=0.48$, 95% CI [-2.12, 4.68], $t(28.5)=1.01$, $p=0.32$

- Weight deficit: C-section $M=0.92$ kg (SD=0.71) vs. Natural $M=0.98$ kg (SD=0.62); difference=-0.06 kg, Cohen's $d=0.09$, 95% CI [-0.45, 0.33], $t(26.9)=-0.19$, $p=0.85$

Exploratory Descriptive Analyses (N=60 limits power):

6. Pearson's Correlations: Income and Outcomes

- Income vs. public comfort: $r=0.183$, $p=0.15$, $R^2=0.033$, 95% CI [-0.07, 0.41]
- Income vs. length deficit: $r=0.10$, $p=0.40$, $R^2=0.01$, 95% CI [-0.15, 0.35]
- Income vs. EBF status: $r=0.19$, $p=0.13$, $R^2=0.036$, 95% CI [-0.06, 0.42]

Descriptive observation: While income predicted knowledge (Test #3), it showed no relationship with comfort or growth outcomes, suggesting knowledge alone may not translate to behavioral improvements without addressing structural barriers. Larger samples (N=200-300) needed to validate patterns.

7. Pearson's Correlations: Growth Deficits vs. Milestones (n=39)

- Length deficit vs. crawling age: $r=-0.192$, $p=0.141$, $R^2=0.037$, 95% CI [-0.43, 0.07]
- Weight deficit vs. crawling age: $r=0.022$, $p=0.88$, $R^2=0.0005$, 95% CI [-0.29, 0.33]

Descriptive observation: Lack of significant relationships may reflect developmental resilience to moderate nutritional deficits, protective factors, or limited sample size obscuring longitudinal relationships. Prospective studies tracking growth and developmental trajectories needed.

Discussion

This study examined relationships between maternal KAP and infant health outcomes among 60 postnatal mothers in urban India, revealing a critical paradox: high maternal knowledge coexists with 85% infant stunting.

Hypotheses H1: Knowledge is positively associated with breastfeeding initiation and duration H2: Positive attitudes correlate with higher EBF rates and longer duration H3: Socioeconomic factors

significantly influence knowledge, attitudes, and practices H4: Optimal practices positively impact infant growth and development H5: Barriers associated with suboptimal practices and poorer outcomes

Hypotheses Evaluation:

H1(Knowledge-Practice Link): Strongly Supported. While 65% achieved timely initiation, 35% delayed due to C-sections (n=9) or maternal health (n=3)—structural barriers, not knowledge deficits. Education strongly correlated with knowledge ($r_s=0.824$, $p<0.001$, $R^2=0.679$). Income and education predicted knowledge ($F(2,57)=22.46$, $p<0.001$, $R^2=0.441$), with income as primary driver ($p<0.001$) and education showing negative relationship when controlling for income ($B=-0.85$, $p=0.0009$), suggesting financial resources/healthcare access may outweigh formal schooling. Knowledge is necessary but insufficient—structural barriers override awareness.

H2 (Attitude-Exclusivity Link): Partially Supported. Despite positive attitudes, 15% were “Very Uncomfortable” with public breastfeeding. Public comfort didn’t predict EBF cessation ($\chi^2(1)=0.012$, $p=0.914$, $OR=0.98$). Cessation driven by physical/structural barriers (C-sections, health complications, PIMS) rather than social stigma. Income predicted knowledge but not comfort ($r=0.183$, $p=0.15$), indicating cultural barriers operate independently of socioeconomic resources.

H3 (Socioeconomic Influence): Partially Supported. Income and education significantly predicted knowledge ($R^2=0.441$), but Pearson’s correlations showed weak, non-significant relationships between income and other outcomes ($r=0.10-0.19$, $p>0.05$). Socioeconomic status drives knowledge acquisition, but broader influences require larger-cohort investigation.

H4 (Practice-Growth Impact): Supported. 85% stunting prevalence aligns with suboptimal practices. CF status significantly predicted length deficits ($B=-2.71$, $p=0.042$), with infants starting solids before six months showing 2.71 cm greater deficits. C-section infants showed 2.28 cm greater mean length deficit (Cohen’s $d=0.48$, $p=0.32$)—clinically meaningful pattern despite non-significance. Mothers maintaining shortest EBF duration (1 month) exhibited most severe stunting (-9.0 cm), illustrating dose-response.

H5(Barriers-Outcomes): Strongly Supported. 85% of delayed initiations resulted from C-sections. Critical finding: despite 85% exhibiting stunting, 85% of mothers rated growth as “Average” or “Above Average.” Only mothers with severe deficits (-8.8 to -9.0 cm) reported “Below Average” growth—abnormally high thresholds mask widespread sub-optimal growth. Infants with weight deficits showed median feeding frequency 1.0 hour, indicating mothers responded to hunger cues, yet this was insufficient to overcome caloric deficits.

Key Points: While 65% achieved timely initiation, 35% delayed due to C-sections/maternal health, not knowledge deficits—birthing center structure is primary limiting factor[8]. The 85% stunting-85% perception disconnect constitutes a major intervention barrier.

While sample size ($N=60$) limits power for some analyses (particularly Tests #6-7), validated core findings on education-knowledge links ($R^2=0.679$), feeding timing-growth relationships ($p=0.042$), and perception-reality gap provide immediate clinical value. Descriptive patterns in less-powered analyses (C-section Cohen’s $d=0.48$, income-outcome relationships) serve as hypothesis-generating foundations for future investigations.

Limitations: Modest sample ($N=60$) limits statistical power. Cross-sectional design precludes causal relationships; prospective designs with 200+ participants would enable stronger inference. Self-reported practices introduce bias. Unmeasured confounders (formula marketing, workplace policies) not assessed.

Conclusion

High maternal knowledge and positive attitudes coexist with 85% infant stunting. Income and education explain 44.1% of knowledge variance ($F(2,57)=22.46$, $p<0.001$, $R^2=0.441$), yet are insufficient to ensure optimal growth. While 65% achieved timely initiation, structural barriers—particularly C-sections (85% of delayed initiations)—hindered adherence. A profound perception gap exists: 85% of mothers perceived stunted growth as “Average” or above. Early complementary feeding significantly predicted length deficits ($B=-2.71$, $p=0.042$, 95% CI [-5.32, -0.10]).

H1, H4, and H5 received strong support; H2 was not supported; H3 was partially supported. Limited sample (N=60) constrains power for exploratory analyses but provides validated findings demonstrating interventions must address clinical environments, structural barriers, and maternal perceptual frameworks—not just knowledge dissemination. Future studies should employ longitudinal designs to validate patterns and examine mechanisms linking delivery methods to growth outcomes.

Recommendations

Mandate immediate skin-to-skin contact and breastfeeding within one hour for all deliveries, including C-sections⁸. Link KAP counseling with objective growth metrics to resolve the 85% perception gap⁹. Address cultural discomfort through community campaigns, legislative advocacy, and “Breastfeeding Welcome” certification programs¹⁰. Target affluent mothers with PIMS counseling, train private pediatricians in evidence-based lactation support, and regulate formula marketing¹¹. **Future Research:** Employ larger, longitudinal designs (N=200+) beginning during pregnancy through 24 months postpartum to validate observed patterns and examine unmeasured confounders.

Conflict of Interest: None

Source of Funding: None

Ethical Clearance: MNR Medical University Ethics committee reference number [MNR EC-BHR-67/24] Date cleared : 06.12.2024

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Study of Breast Cytology Smears Using the International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology

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How to cite this article: Shezan Rasool, Rajnish Kumar, Alok Mohan et. al. Study of Breast Cytology Smears Using the International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Breast cancer is a major global health burden, especially in low- and middle-income regions where fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) remains a widely used diagnostic tool. The International Academy of Cytology (IAC) Yokohama System provides a standardized, evidence-based framework to improve diagnostic consistency in breast cytology.

Objective: To evaluate the diagnostic utility, accuracy, and risk of malignancy (ROM) of the IAC Yokohama System in categorizing breast FNAC/FINE NEEDLE ASPIRATION CYTOLOGY samples in a tertiary care setting.

Methods: A prospective study of 128 FNAC/FINE NEEDLE ASPIRATION CYTOLOGY samples from 120 patients was conducted and categorized according to the IAC Yokohama System. Cyto-histopathological correlation was available for 26 cases. Diagnostic performance indices were calculated using MedCalc.

Results: The distribution of cases was: Category 2 (Benign), 78.1%; Category 3 (Atypical), 3.3%; Category 4 (Suspicious), 3.3%; and Category 5 (Malignant), 15.6%. No Category 1 cases were recorded. Fibroadenoma was the most common benign lesion (38.2%). Overall cyto-histopathological concordance was 84.6%. ROM was 0% (Category 2), 66.7% (Category 3), and 100% for Categories 4 and 5. Diagnostic performance showed sensitivity 40.0%, specificity 95.2%, positive predictive value 66.7%, negative predictive value 87.0%, and overall accuracy 84.6%.

Conclusion: The IAC Yokohama System enhances the diagnostic reliability of FNAC/FINE NEEDLE ASPIRATION CYTOLOGY for distinguishing benign and malignant breast lesions. However, indeterminate categories (3 and 4) continue to require histopathological confirmation. The system offers significant value in resource-constrained settings, though larger multicentric studies are warranted to refine ROM estimates and strengthen generalizability.

Keywords: IAC Yokohama System; Breast cytopathology; FNAC/FINE NEEDLE ASPIRATION CYTOLOGY; Risk of malignancy; Breast cancer

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Submission date: November 6, 2025

Revision date: December 4, 2025

Published date: April 14, 2026

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Introduction

Breast cancer remains the most common malignancy among women worldwide and is a significant contributor to cancer-related morbidity and mortality^[1]. According to GLOBOCAN 2022, female breast cancer accounts for 11.6% of all cancers globally, with approximately 2.3 million new cases annually. In India, breast cancer is the leading cancer among women, with 216,108 new cases and 98,337 deaths reported in 2022. Early and accurate diagnosis is therefore crucial, particularly in low- and middle-income countries where resource limitations may restrict access to advanced diagnostic modalities.^[2]

Fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) continues to play a central role in the evaluation of palpable breast lesions due to its minimally invasive nature, low cost, rapid turnaround time, and high patient acceptability. However, diagnostic variability arising from subjective interpretation has historically been a challenge, potentially leading to inconsistent reporting and suboptimal clinical decision-making.^[3]

To address this, the International Academy of Cytology (IAC) introduced the Yokohama System in 2019, a standardized reporting framework that categorizes breast cytology into five diagnostic groups: Category 1 (Insufficient), Category 2 (Benign), Category 3 (Atypical), Category 4 (Suspicious for Malignancy), and Category 5 (Malignant). This structured system aims to improve diagnostic reproducibility, enhance communication between clinicians and cytopathologists, and facilitate evidence-based patient management.^[4]

Given the high burden of breast disease in India and the reliance on FNAC/FINE NEEDLE ASPIRATION CYTOLOGY as a frontline diagnostic tool, applying a standardized system such as the IAC Yokohama System becomes particularly relevant. The present study was conducted to evaluate the diagnostic utility, accuracy, and risk of malignancy associated with each category of the Yokohama System in a tertiary care setting.^[5]

Materials and Methods

Study Design and Setting

This hospital-based prospective observational study was conducted in the Department of Pathology,

Muzaffarnagar Medical College, Uttar Pradesh, over a period of 18 months. A total of 128 fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) samples were obtained from 120 patients presenting with palpable breast lumps. Bilateral breast involvement was noted in eight patients.

Inclusion and Exclusion Criteria

Inclusion criteria:

- Patients presenting with palpable breast swellings.
- Patients undergoing ultrasound- or CT-guided FNAC/FINE NEEDLE ASPIRATION CYTOLOGY for non-palpable lesions.

Exclusion criteria:

- Uncooperative patients.
- Patients with bleeding disorders or contraindications to FNAC/FINE NEEDLE ASPIRATION CYTOLOGY.

Procedure

FNAC/FINE NEEDLE ASPIRATION CYTOLOGY was performed using a 21G or 23G needle attached to a 10 mL syringe under strict aseptic precautions. Aspirated material was smeared onto clean glass slides and stained using:

- May-Grünwald-Giemsa (MGG) stain
- Papanicolaou stain

Cytological smears were categorized according to the International Academy of Cytology (IAC) Yokohama System for Reporting Breast FNAC/FINE NEEDLE ASPIRATION CYTOLOGY, which classifies cases into:

1. **Category 1 - Insufficient / Inadequate:** scant cellularity, poor preservation, or non-representative material
2. **Category 2 - Benign:** cytomorphology consistent with non-neoplastic benign lesions
3. **Category 3 - Atypical:** cytological features more than benign but insufficient for malignancy
4. **Category 4 - Suspicious for malignancy:** significant atypia but not fully diagnostic
5. **Category 5 - Malignant:** definitive cytological evidence of malignancy

Biopsy specimens were available for 26 patients and were processed routinely. Formalin-fixed tissue was embedded in paraffin, sectioned, and stained with hematoxylin and eosin (H&E) for histopathological correlation.^[6]

Statistical Analysis

Data analysis was performed using MedCalc software (version 22.020). Diagnostic performance parameters were calculated for FNAC/FINE NEEDLE ASPIRATION CYTOLOGY:

- Sensitivity
- Specificity
- Positive predictive value (PPV)
- Negative predictive value (NPV)
- Diagnostic accuracy

Risk of malignancy (ROM) was calculated for each Yokohama category using corresponding histopathological outcomes.^[7]

Results

This prospective study analyzed 128 fine needle aspiration cytology (FNAC) samples from 120 patients presenting with palpable breast lumps at Muzaffarnagar Medical College and Hospital over a period of 18 months. The cytological findings were systematically categorized according to the International Academy of Cytology (IAC) Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology. The study aimed to assess the spectrum of breast lesions, their distribution across these categories, and their cytohistopathological correlation.

The study examined the clinical characteristics of breast lumps, several key findings were observed. Laterality analysis revealed a predominance of right-sided breast lumps, accounting for 54.1% (n=69) of cases, followed by left-sided lumps at 39.1% (n=50), and bilateral involvement in 6.6% (n=8).

The majority of breast lumps (92.1%) measured between 2 and 5 cm, with a mean size of 2.94 cm and a range spanning from 1.5 to 5.5 cm. Larger lumps exceeding 5 cm constituted 5.4% of the cases. In terms of mobility and consistency, 81.6% of the breast lumps were mobile, while 18.3% were fixed. Specifically, within Category 2 lesions, 75% were mobile, whereas in Category 5, 12.5% were fixed. Hard consistency was observed in 17.8% of cases.

The age distribution of patients ranged from 11 to 80 years, with a mean age of 31 years. More than half (52.5%) presented in their third and fourth decades of life, and 91.6% were under the age of 50. Non-lactating females comprised 96.6% of the cases, while lactating females accounted for 3.3%, primarily presenting with lactational changes or mastitis.

These findings underscore the importance of laterality, size, mobility, consistency, age, and lactational status in the clinical evaluation of breast lumps, as they can provide valuable insights into the nature of the lesion and guide appropriate management strategies.

Of the 128 FNAC samples the distribution across the International Academy of Cytology (IAC) Yokohama System categories was as follows: Category 1 (Insufficient/Inadequate) had no reported cases (0%), which can be attributed to the use of repeat or image-guided FNAC for initially inadequate samples, ensuring sufficient cellular material for diagnosis. Category 2 (Benign) was the most prevalent, comprising 100 cases (78.1%), reflecting the predominance of non-malignant breast conditions in the study population. Category 3 (Atypical) included four cases (3.3%) that exhibited cytological features suggestive of neoplasia but did not fulfill the criteria for malignancy. Similarly, four cases (3.3%) were categorized as Category 4 (Suspicious for Malignancy), where the cytological features strongly indicated malignancy but lacked definitive diagnostic criteria of malignancy. Lastly, Category 5 (Malignant) encompassed twenty cases (15.6%) that were diagnosed as malignant, confirming the presence of breast carcinoma based on definitive cytomorphological findings.

Table 1: Distribution of cases as per various types of cytological categories of breast lumps (As per The International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology) (N=128)

| CATEGORY | NO. OF CASES | PERCENTAGE (%) |
|-------------------------------|--------------|----------------|
| 2 (Benign) | 100 | 78.1 |
| 3 Atypical) | 4 | 3.2 |
| 4 (Suspicious for malignancy) | 4 | 3.2 |
| 5 (Malignant) | 20 | 15.5 |
| Total | 128 | 100 |

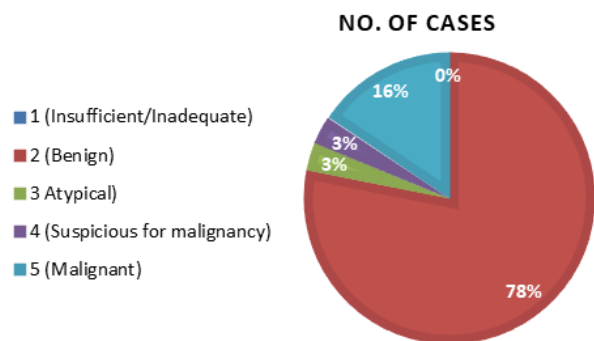


Figure 1: Pie diagram showing category wise distribution of breast lesions on FNAC (N=128)

The predominance of Category 2 cases aligns with global trends, where benign breast lesions are more common, particularly in younger populations. The malignant cases (Category 5) constituted a significant proportion, underscoring the burden of breast cancer in the study setting.

The spectrum of breast lesions identified in this study revealed a predominance of benign lesions among the 100 cases classified under Category 2 of the IAC Yokohama System. Within this category, benign neoplastic lesions comprised 53% (38.2% of total cases). Among these, fibroadenoma was the most frequent, accounting for 92.4% of benign neoplasms (49 cases, 38.2% of total), typically presenting as well-circumscribed, mobile masses in younger women and showing large, cohesive epithelial fragments, stromal fragments, and numerous bare bipolar nuclei on cytology. Benign phyllodes tumors represented 5.6% (3 cases) of this subgroup, with hypercellular smears, bonsai-like epithelial clusters, and distinct stromal cellularity. One benign lipomatous lesion (1.8%) was identified, characterized by smears with mature adipocytes and scant stroma. Inflammatory lesions made up 18% of Category 2 cases, including 12 cases (66.6%) of mastitis with neutrophil-rich smears and necrotic debris, and 6 cases (33.3%) of granulomatous mastitis, which displayed granulomas with epithelioid histiocytes and multinucleated giant cells. Cystic lesions accounted for 15% of Category 2 cases, primarily fibrocystic change (14 cases, 93.3%) showing foamy histiocytes, apocrine cells, and proteinaceous background, while one benign cystic lesion (6.6%) lacked apocrine epithelium. Epithelial hyperplasia was seen in 8% of Category 2 cases,

with smears demonstrating large ductal epithelial fragments, myoepithelial cells, and mild nuclear enlargement. Lactational changes were observed in 3 cases (3%), characterized by vacuolated epithelial cells and neutrophils. Additionally, galactocele was identified in 2 cases (2%) by milky aspirates and benign epithelial cells, and fat necrosis was noted in 1 case (1%), presenting with adipocytes, inflammation, and necrotic debris.

Among the 20 malignant cases (Category 5), invasive carcinoma of no special type (NST) was the most common, diagnosed in 18 cases (14% of total), featuring discohesive cells, marked nuclear atypia, irregular chromatin, and prominent nucleoli. One case of bilateral lobular carcinoma was also identified, distinguished by small, uniform cells with intracytoplasmic lumina and minimal pleomorphism. In the atypical (Category 3) and suspicious (Category 4) categories, each comprised four cases. Category 3 lesions showed mild nuclear enlargement and pleomorphism, not typical of benign processes, necessitating further assessment. Category 4 cases displayed increased cellularity and nuclear atypia, highly suggestive of malignancy but without definitive diagnostic criteria.

Cytohistopathological correlation was available for 26 cases. All 20 Category 2 cases with follow-up showed 100% concordance, confirming the diagnostic accuracy of FNAC for benign lesions. In Category 3, histopathological follow-up was available for three cases, of which two were confirmed malignant (ductal carcinoma in situ and invasive carcinoma NST), underscoring the intermediate risk associated with this category. The single Category 4 case with histopathology was confirmed malignant, reflecting the high-risk nature of this category. Both malignant cases with histopathological correlation, including the bilateral lobular carcinoma, showed complete agreement, validating FNAC's reliability in diagnosing malignancy. Overall, 22 out of 26 cases (84.6%) showed concordance between cytological and histopathological findings, while 4 cases (15.4%) were discordant, mainly within Categories 3 and 4.

The types of histopathological procedures included excisional biopsy (18 cases), core needle biopsy (5 cases), and modified radical mastectomy (3 cases, including 2 bilateral cases).

Table 2: Cyto-histopathological correlation of available biopsies.

| S.no | Cyto Category (IAC) | No. Of Cases | Cyto Diagnosis | Histopathological Diagnosis | No of cases (n) |
|------|---|---|---------------------------|-----------------------------|-----------------|
| 1 | 2 (n=20) | 13 | Fibroadenoma | Fibroadenoma | 9 |
| | | | | Fibrocystic disease | 1 |
| | | | | Breast hamartoma | 2 |
| | | | | Tubular adenoma | 1 |
| | | 2 | Acute Mastitis | Fibroadenoma | 1 |
| | | | | Lobular Mastitis | 1 |
| | | 2 | Epithelial Hyperplasia | Fibroadenoma | 2 |
| | | 1 | Idiopathic Gran. Mastitis | Neutrophilic gran mastitis | 1 |
| 1 | Tubercular Mastitis | Tubercular Mastitis | 1 | | |
| 1 | Fibrocystic change with collagenous spherulosis | Fibrocystic Change with collagenous spherulosis | 1 | | |
| 2 | 3 (n=3) | 3 | Atypical | Fibroadenoma | 1 |
| | | | | Invasive ductal carcinoma | 1 |
| | | | | Invasive ductal carcinoma | 1 |
| 3 | 4 (n=1) | 1 | Suspicious of malignancy | Invasive ductal carcinoma | 1 |
| 4 | 5 (n=2) | 2 | Lobular carcinoma | Lobular carcinoma | 2 |

The Risk of Malignancy (ROM) was assessed based on histopathological confirmation. In Category 1, classified as insufficient, there were no cases, rendering the ROM inapplicable. For Category 2, (Benign), the ROM was 0%, as none of the 20 cases with histopathological follow-up were found to be malignant. In Category 3, (Atypical), 3 out of 4 cytology cases had follow-up, with 2 confirmed as malignant, resulting in a ROM of 66.7%. Category 4, (Suspicious for malignancy), included 4 cytology cases as well, with 1 case undergoing follow-up and confirmed as malignant, leading to a ROM of 100%. Finally, in Category 5, (Malignant), among the 20 cytology cases, 1 case with a bilateral presentation had follow-up, which was confirmed malignant, also yielding a ROM of 100%.

Statistical Parameters, the diagnostic performance of fine needle aspiration cytology (FNAC) was assessed using several statistical parameters. The sensitivity was found to be 40%, suggesting a moderate capacity to detect malignant cases, which may be attributed to the limited number of histopathological correlations available. In contrast, the specificity was

notably high at 95.2%, showcasing FNAC’s strong accuracy in identifying benign cases. The positive predictive value (PPV) stood at 66.6%, indicating that a significant proportion of positive cytology results were confirmed as malignant. Additionally, the negative predictive value (NPV) recorded at 86.9% highlighted the reliability of negative cytology results in effectively ruling out malignancy. Overall, the diagnostic accuracy of FNAC was recorded at 84.6%, reflecting its general effectiveness in correctly classifying breast lesions.

Table 3: Cytohistological correlation (N=26)

| Cytology | | Histopathology | |
|--------------|--------------|----------------|--------------|
| IAC Category | No. of cases | Consistent | Inconsistent |
| 2 | 20 | 20 | 0 |
| 3 | 3 | 0 | 3 |
| 4 | 1 | 0 | 1 |
| 5 | 2 | 2 | 0 |
| Total | 26 | 22 | 4 |

* One case each in category 2 and category 5 was bilateral.

Discussion

This prospective study reinforces the continued value of fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) as a rapid, minimally invasive, and cost-effective diagnostic modality for evaluating breast lesions, especially in resource-limited settings where advanced imaging and core biopsies may not be readily accessible. Breast cancer remains the most common malignancy among women in India, and therefore early, reliable diagnostic triage is crucial for improving outcomes.^[8]

Application of the IAC Yokohama System provided a structured and evidence-based framework for FNAC/FINE NEEDLE ASPIRATION CYTOLOGY reporting, reducing subjectivity and improving communication between cytopathologists and clinicians. The predominance of benign cases (78.1%), especially fibroadenomas in younger women, parallels global findings. Similar proportions have been reported by Montezuma et al.^[9] (73.3%) and Apuroopa et al.^[10], although institutional and demographic differences may account for slight variation.

The proportion of malignant cases (15.6%), predominantly invasive carcinoma of no special type (NST), is consistent with studies by Agrawal et al.^[11] and Ahuja et al.^[12], supporting the reproducibility of the Yokohama System across diverse patient populations. The system's utility is particularly evident in Category 5, which showed a risk of malignancy (ROM) of 100% with complete concordance on histopathology. This underscores the system's reliability in guiding immediate and definitive management.

The higher ROM observed in Category 3 (66.7%) compared with prior studies, such as Ahuja et al.^[12] (17.4%) and Kamatar et al.^[13] (16%), suggests institutional variation, sampling differences, and borderline cytological features contributing to atypical cases. Category 4 (Suspicious) also demonstrated a ROM of 100%, consistent with its inherently high-risk nature. These findings highlight the need for mandatory histopathological evaluation of Categories 3 and 4, as recommended by the Yokohama guidelines.

The absence of insufficient samples (Category 1) reflects effective sampling techniques, including the selective use of repeat aspiration and image-guided FNAC/FINE NEEDLE ASPIRATION CYTOLOGY. Such practices align with evidence from Wong et al.^[14], who emphasized the role of rapid on-site evaluation (ROSE) in minimizing inadequate samples.

Diagnostic performance showed high specificity (95.2%) and overall accuracy (84.6%), comparable to earlier studies by De Rosa et al.^[15] and Oosthuizen et al.^[16] However, the sensitivity (40%) was lower, likely due to the limited number of cases with available histopathology (n=26), than Kamatar et al.^[13] (97%) or Verma et al.^[17] (100%). This limitation affects the stability of sensitivity estimates and signifies the need for larger cohorts to achieve more robust diagnostic indices.

Clinical characteristics, such as right-sided predominance (54.16%) and mobility (81.6%), align with Sigmani et al.^[18] and Bal et al.^[19], reinforcing typical presentations of benign lesions. The mean lump size (2.94 cm) and hard consistency (17.8%) in malignant cases provide valuable clinical correlates for diagnosis.

Limitations include the small histopathological cohort, potentially skewing ROM and sensitivity estimates, and the single-institution setting, which may limit generalizability. Future studies should incorporate larger, multicenter cohorts and standardized ROSE protocols to further validate the Yokohama System's utility.

In conclusion, FNAC, guided by the IAC Yokohama System, is a reliable preoperative diagnostic tool for breast lesions, with high concordance for benign and malignant categories.^[20] Its challenges in atypical and suspicious categories highlight the complementary role of histopathology, ensuring optimal patient management in breast cancer carcinoma.

Limitations

The main limitations of this study include:

1. Small number of cases with histopathological follow-up, limiting sensitivity estimates and ROM precision.
2. Single-center design, which may restrict generalizability.

Implications for Future Research

To strengthen the evidence supporting the Yokohama System, larger multicentric studies with standardized sampling practices and increased histopathological correlation are recommended. Such studies will help refine ROM estimates, improve diagnostic confidence, and enhance the system’s applicability in diverse clinical environments.

Conclusion

The International Academy of Cytology (IAC) Yokohama System provides a clear, structured, and reliable framework for reporting breast FNAC/FINE NEEDLE ASPIRATION CYTOLOGY, significantly enhancing diagnostic consistency and clinical communication. In this study, FNAC/FINE NEEDLE ASPIRATION CYTOLOGY demonstrated high

accuracy and specificity for distinguishing benign from malignant breast lesions, with complete concordance in clearly benign (Category 2) and malignant (Category 5) categories. Indeterminate categories (3 and 4), however, continue to require histopathological confirmation due to their higher risk of malignancy.

Given its simplicity, low cost, and strong diagnostic performance, the Yokohama System is particularly valuable in resource-limited settings where FNAC/FINE NEEDLE ASPIRATION CYTOLOGY remains a frontline diagnostic tool. Nevertheless, the limited number of histopathological correlations in this study highlights the need for larger, multicentric investigations to refine the risk of malignancy estimates and further validate the system’s applicability across diverse populations.

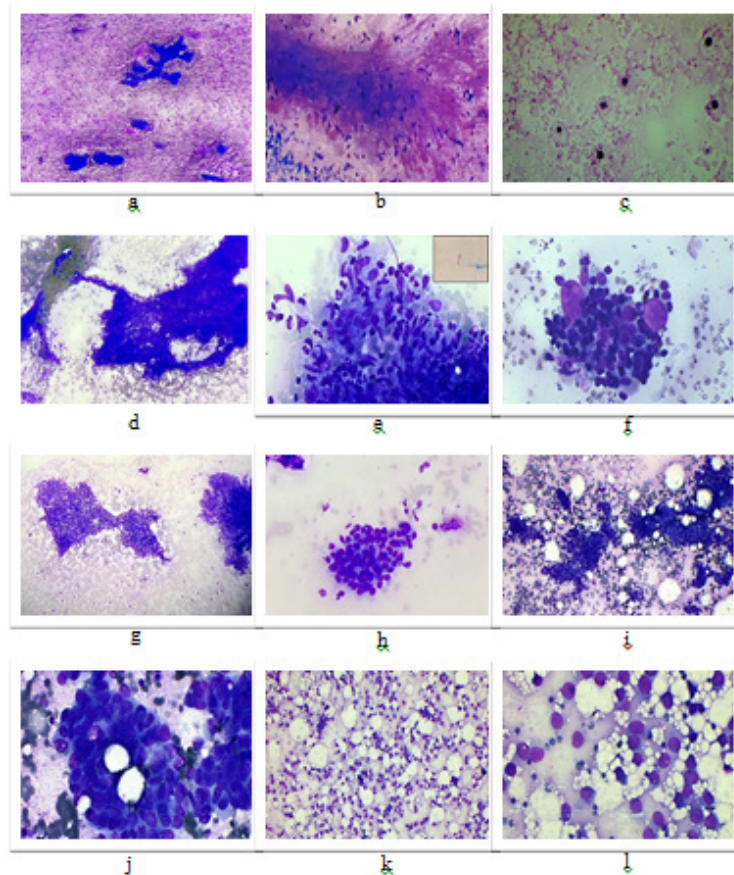


Figure 2: (a) Fibroadenoma (b) Benign phyllodes tumor (c) Galactocele (d) Epithelial hyperplasia (e) Tb mastitis (f) Fibrocystic change with collagenous spherulosis (g) Category 3 : Atypical (h) Category 3 : Atypical (i) Malignant : Invasive Carcinoma NST (j) Malignant : Invasive Carcinoma NST (k,l) Invasive lobular carcinoma.

Conflict of Interest: The authors declare that there is no conflict of interest regarding the publication of this paper.

Source of Funding: Self-funded.

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Morbidity Pattern and Knowledge on Medication among Elderly Population at Suraram, India

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How to cite this article: Suguna Dumpala¹, Padmavathi Vutukuru. Morbidity Pattern and Knowledge on Medication among Elderly Population at Suraram, India. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Ageing of the Population is a great human success story. Longevity leads to more numbers of older persons, eventually leading to a continuously growing share of older persons in the population mix. Preparing for the economic and social shifts associated with this sector of population is essential to ensure the achievement of the Sustainable Development Goals (SDGs) by 2030.

Objectives: To assess the magnitude and pattern of morbidity among the elder population and to assess the knowledge on medication among them

Materials and Methods: A facility-based cross-sectional study was conducted at the Community Health Centre (CHC), a field practice area of the Department of Community Medicine, Malla Reddy Medical College for Women (MRMCW), located in Medchal-Malkajgiri district, Telangana. Data were analysed using the Statistical Package for the Social Sciences (SPSS; IBM Corp., Chicago, IL, version 22). Descriptive and inferential statistical analyses were performed, with a p-value < 0.05 considered statistically significant. Results are presented as absolute numbers and percentages in tabular form.

Results: Of the participants, 149 (75%) reported having at least one chronic disease. Demographic variables such as age, religion, and caste showed a statistically significant association with morbidity ($p < 0.05$). Among participants with comorbidities, only 98 (49%) reported taking medications as prescribed by their physicians. When experiencing illness or adverse effects related to medication, the majority—53 (54%)—did not inform anyone, while 45 (46%) consulted their physician.

Conclusion: The high morbidity load among elderly in the present study stress the efforts to provide better health care services and ensure that they remain active members of the society. This would help policymakers to strengthen health care services to the elderly population at state and national level to achieve Sustained Development Goals by 2020. This special group should be well informed about the medicines by the attending Physicians/ Pharmacists.

Key Words: Elderly, Chronic Disease, Comorbidities

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Submission date: Sep 5, 2025

Revision date: Dec 16, 2025

Published date: April 14, 2026

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Introduction

Ageing of the Population is a great human success story.¹ Longevity leads to more numbers of older persons, a continuously growing share of older persons in the population pyramid. Preparing for the economic and social shifts associated with this sector of population is essential to ensure the achievement of the Sustainable Development Goals (SDGs) by 2030.² Most of the countries now face major challenges to ensure their health and social systems ready to face this demographic shift. By 2050, 80% of older people will be living in low- and middle-income countries. The pace of ageing of population is much faster than in the past. In 2020, the number of people aged 60 years and above outnumbered children less than 5 years old. Between 2015 and 2050, the proportion of over 60 yrs population will nearly double from 12% to 22% at Global level.³ Globally, there were 703 million aged 65 or over in 2019. Eastern and South-Eastern Asia had the largest number of the world's older population (260 million), followed by Europe and Northern America over 200 million.^{4,5} In India, ageing of the population is inevitable with socio-economic development. A person aged 60 years and above are considered as elderly in India.⁶ Declining fertility and increasing survival has resulted in more of older people in general population within a relatively short period of time. The country recorded a significant improvement in life expectancy at birth, which was 47 years in 1969, to 60 years in 1994 and 69 years in 2019. The share of population of elderly of 153 million, making India the second largest and is expected to reach a staggering 347 million by 2050² with an increase to 19%.^{7,8} They are prone for chronic physical, emotional and mental health disorders.⁹ A distinctive characteristic of this population in India is that the majority (80%) reside in rural areas, posing significant challenges to service delivery. Women constitute 51% of this group, there is a growing proportion of individuals aged 80 years and above, and approximately 30% live below the poverty line.¹⁰ There is a lack of data on morbidity pattern and knowledge on medication among elderly population in rural areas which is essential to address the important issues and provide primary health care services in India. This study, therefore explored the magnitude, pattern of morbidity and knowledge on medication among elder population living in the

rural area of Medchal-Malkajgiri district, Telangana, India.

Objectives:

1. To assess the magnitude and pattern of morbidity among the elder population
2. To assess the knowledge on medication among them

Materials and Methods

A facility-based, cross-sectional study was conducted at the Community Health Centre (CHC), a field practice area of the Department of Community Medicine, Malla Reddy Medical College for Women (MRMCW), Medchal-Malkajgiri district, Telangana state, which is in the southern part of India. The CHC, is the third tier of the network of rural health care institution, a referral centre, caters to a population of 1,20,000 for the neighboring 4 PHCs in the district especially for the patients requiring specialized health care services. It is 30 bedded hospital with four specialists in the area of Medicine, Surgery, Paediatrics and Gynaecology, has an operation theatre, labour room, X-ray machine, pathological laboratory, standby generator along with supportive medical and para-medical staff. **Inclusion criteria: Persons aged 60yrs and above, who availed health care services at the out-patient (O.P) department of the study area, willing to participate in the study. Those who were below 60 years of age, hospitalized and those not willing to participate in the study were excluded.** Ethical clearance was obtained from the institutional ethical review committee of Malla Reddy Medical College for Women, **Medchal on 02.03.2019 (Roc.AS/10/IEC/MMCW/2019-IEC No-1212).** It started in March 2019 but due to Covid-19, it was stopped and again **conducted from March to August 2020. The study subjects were briefed about the study and informed consent was taken.** A pre-tested Structured Questionnaire was administered to those who volunteered and gave the consent to participate in the study. The trained interns of MRMCW interviewed the study subjects in local languages (Telugu and Hindi) followed by a clinical history and examination. They also checked medical records if available with the participants. Responses from surrogates were not allowed. The sample size was all those study subjects who attended the study

area during the study period. **A convenient sample size was 200. All the study subjects who** attended the O.P department during the study participated in the study. The operational definition of morbidity used in the study was “Morbidity refers to having a disease or a symptom of disease, or a condition within a population”¹¹ Data on Socioeconomic and Demographic parameters pertaining to age, gender, religion, caste, education, socio-economic status as per B.G. Prasad social class classification, type of family, self-reported health problems were collected. The social class of caste was assessed as per the Social Welfare Department, Government of Telangana.¹² They were categorized as Open category (O.C), Backward class (B.C), Scheduled caste (S.C) and Scheduled tribe (S.T). Occupations were classified as Professionals, Skilled, Un-skilled workers, Dependents as per National Classification of Occupations, New Delhi, India. House-wives were included under dependents.¹³ Educational level was classified as illiterate and literate. All the statistical analysis were performed using Statistical Package for Social Sciences (SPSS, Inc., Chicago, IL; version 22.0) Descriptive statistics (frequencies, means) was used to characterize the study subjects. Primary outcome was morbidity, measured in numbers, percentages. The outcome was estimated with 95% confidence interval. Association between demographic variables and morbidities was assessed with Chi-square test at a significance level of 0.05.

Results

Table-1 shows the Demographic, Socio-economic Characteristics and their association with Morbidities of the Study Population. Most of the study subjects were between 60-69 yrs (83%). The mean age of the sample was 65 yrs (SD±4.86), minimum and maximum age was 60 yrs and 95 yrs. There were 120

(60%) females, who outnumbered the males. A large number of them, 120 (60%) were illiterate, followed by 26 (13%) completed primary school, 22 (11%) of them have done intermediate and the least were professionals only 2(1%). Hindus dominated. Most of them 101 (51%), belonged to B.C, followed by 54 (27%) O.C and 45 (23%) S.C and S.T together. Coming to economic status, 111 (56%) were dependent on children and remaining were self-sufficient. Married and living with their spouse were 131 (66%) and others included single, widows and widowers. Nuclear families were 114 (57%). Coming to health problems, 149 (75%) had reported to have a chronic disease. Coming to the morbidity pattern, 51 (26%) had no comorbidities. Maximum, 61 (31%) had only hypertension, 41 (21%) had both hypertension and diabetes, 36 (18%) had only diabetes. Demographic Correlation between morbidities and risk factors like age, religion, and caste were statistically significant at 0.05 level. Out of those with morbidity pattern, 28 (14%) were hospitalized. Family history of diabetes and hypertension together and only hypertension was reported among 17 (8.5%) each, followed by, history of diabetes in 12 (6%) families. Alcohol was consumed by 70 (35%) and 36 (18%) smoked. Those with comorbidities, only 98 (49%) take medicines prescribed by their doctors. The number of pills ranged from one to three per day. Among these subjects, 18 (9%) reported adverse events with prescribed medicines for their morbidities. It was mainly self-administration 112 (56%) and 25 (13%) were assisted by one of the family members to take the medicines. During their travel, 146 (73%) carry enough number of pills which has positive impact on the disease. When they fell sick with the pills, most of them, 53 (54%) do not inform anyone, 45 (46%) approach their physician.

Table 1: Demographic, Socio-economic Characteristics and their association with Morbidities of the Study Population

| Parameters | | No Morbidities | | One Morbidity | | Two or more than two Morbidities | | Total | | χ ² value | p-value |
|------------|--------|----------------|----|---------------|----|----------------------------------|----|-------|-----|----------------------|---------|
| | | No. | % | No. | % | No. | % | No. | % | | |
| Age (Y) | 60-69 | 45 | 23 | 086 | 44 | 34 | 17 | 164 | 83 | 6.178 | 0.046* |
| | ≥70-79 | 06 | 03 | 015 | 08 | 14 | 07 | 036 | 17 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |

Cont.....

| | | | | | | | | | | | |
|---------------------|--------------------------------|----|----|-----|----|----|----|-----|-----|--------|--------|
| Gender | Males | 24 | 12 | 039 | 19 | 17 | 07 | 080 | 40 | 1.56 | 0.458 |
| | Females | 27 | 13 | 062 | 32 | 31 | 15 | 120 | 60 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Religion | Hindus | 46 | 23 | 079 | 40 | 37 | 18 | 164 | 82 | 6.839 | 0.033* |
| | Others | 05 | 02 | 022 | 11 | 11 | 05 | 36 | 18 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Caste | OC | 10 | 05 | 037 | 19 | 07 | 03 | 054 | 27 | 11.755 | 0.019* |
| | BC | 28 | 14 | 045 | 23 | 28 | 14 | 101 | 51 | | |
| | SC, ST | 13 | 06 | 019 | 09 | 13 | 07 | 045 | 22 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Marital Status | Married and living with spouse | 37 | 18 | 068 | 34 | 26 | 13 | 131 | 65 | 3.999 | 0.135 |
| | Others | 14 | 07 | 033 | 17 | 22 | 11 | 069 | 35 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Type of Family | Nuclear | 26 | 13 | 066 | 33 | 26 | 13 | 118 | 59 | 2.704 | 0.259 |
| | Extended | 25 | 12 | 035 | 18 | 22 | 11 | 082 | 41 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Economic status | Self sufficient | 27 | 13 | 044 | 22 | 16 | 08 | 087 | 43 | 3.868 | 0.145 |
| | Dependent on family members | 24 | 12 | 057 | 29 | 32 | 16 | 113 | 57 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Alcohol consumption | Yes | 20 | 10 | 033 | 17 | 17 | 08 | 070 | 35 | 0.642 | 0.725 |
| | No | 31 | 15 | 068 | 34 | 31 | 16 | 130 | 65 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |
| Tobacco use | Yes | 05 | 02 | 018 | 09 | 13 | 06 | 036 | 18 | 5.006 | 0.082 |
| | No | 46 | 23 | 083 | 42 | 35 | 18 | 164 | 82 | | |
| | Total | 51 | 25 | 101 | 51 | 48 | 24 | 200 | 100 | | |

Discussion

Often, studies focused on genetics and morbidities that play a role in ageing but this study is on morbidity and knowledge on medication among them. The determinants of healthy ageing depend on various factors, age, gender, religion, culture, etc.,¹⁴ Study population shows high rate of illiteracy 60%, which is slightly more than as per census data of 56% of 2011.¹⁵ Those who are economically dependent partially or fully on others are 56% which is lower than 65% for day to day maintenance as per National Sample Survey.¹⁶ The most prevalent morbidity was hypertension 31%, followed by hypertension and diabetes together

21% and only diabetes 18% which are lower when compared to other studies (ranged from 57 to 59%).¹⁵ Those with comorbidities, 49% are on Polypharmacy, who should be evaluated regularly as mentioned in the study conducted by Ki S et al.,¹⁷ The hospitalized were 14%, which is stressful and a high risk of losing autonomy among them as mentioned in the study conducted by Rossi AP et al.,¹⁸ Hospitalization in elderly is found to be lower in the present study when compared to other studies.¹⁹⁻²² The knowledge on medication that they should approach the physician when they fall sick with pills is lagging in 22% of them, which has a deleterious effect on health of an individual.

IMPLICATIONS AND RECOMMENDATIONS:

The high burden of morbidity underscores the need to establish dedicated geriatric clinics at Primary Health Centres, with integrated use of modern medicine and traditional Indian systems of medicine. Evidence suggests that polypharmacy is associated with adverse drug reactions, highlighting the importance of improved medication management through patient education by medical practitioners and pharmacists. In addition, the development of age-friendly urban environments that promote physical activity and social interaction is essential.

Further research is recommended to evaluate community-based mental health programmes aimed at improving psychological well-being and reducing social isolation among older adults. Collectively, these interventions have the potential to enhance overall health, life satisfaction, and quality of life among India's ageing population.

Conclusion

The high morbidity load among elderly in the present study stress the efforts to provide better health care services to them and ensure that they remain active members of the society. This would help policymakers to strengthen health care services to the elderly population at state and national level to achieve Sustained Development Goals by 2020. This special group should be well informed about the medicines by the attending Physicians/ Pharmacists.

Acknowledgements: The authors would sincerely thank the VI Semester medical students who have given their time and participated in this study. A big thank you to the staff of Community Health Centre, who helped the medical students of MRMCW in this study. Lastly, we would like to acknowledge the study participants who generously gave their time and cooperated with the students.

Source of Funding: None

Conflict of Interest: None

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Association between CTG Parameters One Hour before Delivery and Neonatal Asphyxia

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How to cite this article: Sarah Muhammed Yaseen, Suha Abdul Jaleel Wadi. Association between CTG Parameters One Hour before Delivery and Neonatal Asphyxia. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Cardiotocography (CTG) is a vital tool in obstetric practice for real-time fetal monitoring. However, its predictive value in identifying neonatal asphyxia remains underexplored, particularly in the critical hour before delivery.

Aim of the Study: This study investigates the association between CTG monitoring in the last hour before delivery and neonatal asphyxia, aiming to evaluate its predictive value.

Patients and Methods: This study is a descriptive retrospective cohort study conducted at Al-Elwiya Maternity Teaching Hospital between January 2024 and January 2025. The study included 250 pregnant women presented with labour condition to the mentioned hospital, CTG monitoring was applied continuously. After delivery (whether by vaginal delivery or caesarean section) CTG of last hour before delivery was compared for the neonates who had asphyxia and those without asphyxia. Inclusion criteria were: Term months, no history of taking drug, before delivery that affects the heart rate of the foetus (as magnesium sulphate, narcotics and pain killers), no history of fever, no history of drugs, addition, not smoker, not alcoholic, babies without congenital anomalies. Exclusion criteria: Preterms, mothers with medical disease like diabetes mellitus and hypertension, addiction to smoking and alcohol, mothers taking drugs that affect the heart rate of the fetus like (magnesium sulphate, narcotics and pain killers, maternal fever, neonates with congenital anomaly, extremes of reproductive age group and extremes of BMI (<18.5 or ≥ 25 kg/m²).

Results: Pathological CTG patterns were observed in 70% of the asphyxia group, compared to 1.6% in the non-asphyxia group. Late decelerations, absent variability, and accelerations were significantly associated with asphyxia. Caesarean delivery was more common in the asphyxia group. The need of NICU admissions further emphasized the poor neonatal outcomes.

Conclusion: CTG monitoring in the last hour before delivery shows significant predictive potential for neonatal asphyxia. Specific CTG patterns can guide timely obstetric interventions, which can lead to improve neonatal outcomes.

Keywords: Cardiotocography, Neonatal asphyxia, Fetal monitoring, CTG patterns, Obstetric outcomes.

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Submission date: May 8, 2025

Revision date: Sept 18, 2025

Published date: April 14, 2026

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Introduction

Cardiotocography (CTG) is a technique used to monitor the fetal heartbeat and uterine contractions during pregnancy and labor. The machine used to perform the monitoring is called a cardiotocograph. It aids early fetal distress detection^(1, 2). Recent studies suggest that specific CTG pattern, like recurrent late deceleration and reduced variability, may indicate fetal distress, potentially leading to neonatal asphyxia if not addressed promptly⁽³⁾.

The physiology of fetal heart rate (FHR) is a complex process governed by the autonomic and somatic components of the central nervous system, essential for maintaining fetal well-being during gestation and particularly through the stress of labor. The autonomic nervous system, comprised of the sympathetic and parasympathetic systems, plays a pivotal role in modulating the FHR. The sympathetic system is responsible for increasing heart rate, preparing the body for 'fight or flight' responses, while the parasympathetic system, through mechanisms such as the action of baroreceptors and chemoreceptors, seeks to decrease the heart rate, promoting rest and digest activities. This dynamic balance between the two systems establishes the baseline FHR and its variability, observed in clinical settings as fluctuations on the cardiotocography⁽⁴⁾. A normal CTG trace is pivotal in assessing fetal well-being, providing insights into the fetal heart rate and its regulation by the autonomic and somatic nervous systems during pregnancy and labor⁽⁵⁾. Neonatal asphyxia is the medical condition resulting from deprivation of oxygen to a newborn infant during the birth process leading to physical harm to the brain, causing immediate neurological deficits and long term (for living babies). It is a major cause of neonatal morbidity and mortality worldwide, emphasizing the need for effective preventive strategies⁽⁶⁾. The incidence of perinatal asphyxia is 2-10 per 1000 births in developed countries, but the rate rises up to (10) times higher in developing countries where there may be limited access to maternal and neonatal care. Of these affected infants, 15-20% die in the neonatal period, and up to 25% of survivors are left with permanent neurological deficits⁽⁷⁾. Perinatal asphyxia can occur due to maternal events (hemorrhage, amniotic fluid embolism, hemodynamic collapse),

placental events (acute abruption), uterine events (rupture), cord events (tight nuchal cord, cord prolapse/avulsion) and intrapartum infection (maternal fever in labor)⁽⁸⁾. The asphyxia can occur prior to the birth (50% prepartum, during birth 40%, and immediately postpartum 10%)⁽⁹⁾. Categorization of CTG according to NICE guideline including the 4 features of the CTG (contractions, baseline FHR, variability, decelerations) as white, amber and red (red indicates increasing levels of concern). Alongside consideration of the presence of accelerations to classify the overall CTG trace⁽¹⁰⁾. FIGO classification of categorize CTG pattern into: normal, suspicious and pathological also using the 4 feature of CTG (contractions, baseline FHR, variability, decelerations)⁽¹¹⁾.

Health care professional should consider the entire clinical picture, including maternal observations, contraction frequency, and labor progression together with fetal heart assessment using CTG categorizations mentioned above to make informed care decisions and ensure timely interventions according to the results⁽¹¹⁾.

The aim of this study was to predict the association between abnormal CTG patterns one hour before delivery and the occurrence neonatal asphyxia outcomes. The predictive value of pre-delivery CTG monitoring for neonatal asphyxia has been a subject of extensive research and clinical debate. CTG monitoring is a standard practice in obstetrics, aiming to identify fetuses at risk of asphyxia by assessing the FHR patterns and uterine contractions and providing invaluable insights into fetal wellbeing during labor. The primary goal is to predict asphyxia and intervene before it causes irreversible harm⁽¹²⁾.

There is a gap in understanding the correlation between CTG patterns observed an hour before delivery and neonatal asphyxia outcomes, with some researchers advocating for continuous monitoring⁽¹³⁾.

Patients and Methods

Study Design

This was a descriptive retrospective cohort study, carried out in the Department of Obstetrics and Gynecology, Department of Neonatal Intensive Care Unit at Al-Elwiya Teaching Hospital, Baghdad, Iraq during a period of one year from 15th of January

2024, till 15th of January 2025. The study protocol was approved by Scientific Counseling of Obstetrics and Gynecology. All patients informed about the nature of study and verbal consent was taken from them.

Sample size and date collection

250, term, pregnant women were included in the study. They were presented with labour condition in the labour room of the mentioned hospital above. Questionnaire was arranged for each patient including: age, parity, gravidity, LMP, time of quickening, pregnancy test if available or early ultrasound and calculation of the gestational age was done accordingly. Height and weight was measured followed by calculation of BMI (weight in kilograms divided by the height in squared meters). Previous medical, drug, social and obstetrical history was taken. All should have anomaly scan done during their antenatal period.

Inclusion criteria

Term, no history of taking drugs that affect the fetal heart like magnesium sulphate, narcotics, and pain killers before delivery. No history of fever, no history of drug addiction, smoking or alcohol consumption. Neonates without congenital anomalies.

Exclusion criteria

Preterms, Medical diseases like diabetes mellitus and hypertension. Addiction to drugs, alcohol and smoker. Mothers taking drugs that affect the heart rate of the fetus like magnesium sulphate, narcotics,

pain killers, and maternal fever. Congenital anomalies of the baby. Extremes of reproductive age groups. Extremes of BMI (<18.5 or ≥ 25 kg/m²).

CTG data and labour details

All patients included in the study were monitored continuously by CTG which was performed by obstetricians or other healthcare professionals. Labour details, type of delivery (vaginal or cesarean section) were recorded in the patient form.

Diagnosis of neonatal asphyxia

Usually done by senior pediatrician in the neonatal resuscitation room in the labour or theater or NCU. Asphyxia was diagnosed based on a combination of clinical and biochemical criteria. Clinically, neonates with an Apgar score of less than 7 at 5 minutes were considered. Biochemical criteria included arterial blood gas pH less than 7.1 or base deficit greater than 12 mmol/L. Information on any neurological sequelae was also included to assess the long-term impact of asphyxia.

CTG assessment

Expert obstetricians interpret each CTG trace for each patient retrospectively after delivery. The CTG parameter included in the study were those in the last hour baby delivery for both asphyxia and no-asphyxia neonates. CTG parameters as defined by FIGO classification was evaluated for each CTG trace and then blinded to the neonatal outcome, to compare CTG parameters between asphyxia and no-asphyxia neonates (blinded CTG).

Table (1): FIGO classification of CTG (1).

| Category | Criteria | Interpretation |
|--------------|---|--|
| Normal | - Baseline FHR: 110-160 bpm - Variability: 5-25 bpm - No repetitive decelerations | - No hypoxia or acidosis - No intervention required |
| Suspicious | - Missing one or more features of normal but without pathological features | - Low probability of hypoxia or acidosis - Requires action to correct reversible causes or close monitoring |
| Pathological | - Baseline FHR: <100 bpm - Reduced, increased variability, or sinusoidal pattern - Repetitive late/prolonged decelerations (>30 min or >20 min if reduced variability) - Deceleration lasting >5 min | - High probability of hypoxia or acidosis - Immediate action needed, including possible expedited delivery |

Statistical analysis

The data analyzed using Statistical Package for Social Sciences (SPSS) version 26. The data presented as mean, standard deviation and ranges. Categorical data presented by frequencies and percentages. Independent t-test (two tailed) was used to compare the continuous variables accordingly. A level of p-value less than 0.05 was considered significant

Results

During study period 6892 women were delivered,

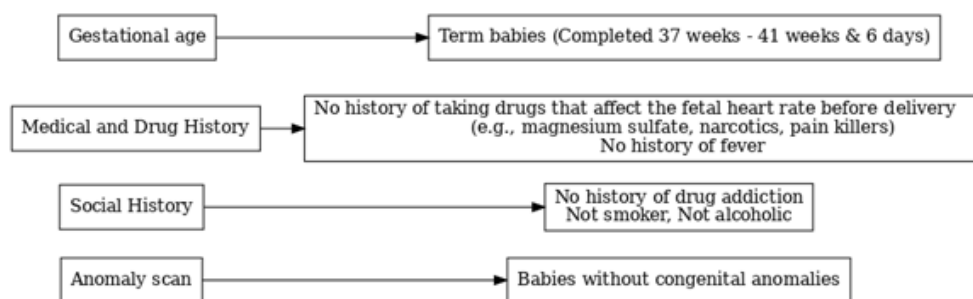


Figure (1): Flowchart of the study inclusions

- Maternal age was similar between the asphyxia group (28.26±6.17 years) and the no-asphyxia group (28.99±5.79 years), with no significant difference (P = 0.425). Gravidity and parity also showed no statistically significant differences between the two groups, with mean values of 5.23±2.22 and 3.28 ± 1.54 in the asphyxia group compared to 5.67 ± 2.37 and 3.67 ± 1.81 in the no-asphyxia group (P = 0.237 and P = 0.204, respectively).

Similarly, the number of previous miscarriages was comparable, with mean values of 0.96 ± 0.91 in the asphyxia group and 1 ± 0.84 in the no-asphyxia group (P = 0.755). Maternal BMI did not differ significantly between the two groups, with values of 27.07 ± 2.35 in the asphyxia group and 27.24 ± 2.44 in the no-asphyxia group (P = 0.641) (Table 2).

Table (2): Distribution of patients' demographics according to the groups.

| Variables | Asphyxia | No-asphyxia | P value |
|-------------|-------------|-------------|---------|
| | Mean ±SD | Mean ±SD | |
| Age | 28.26 ±6.17 | 28.99 ±5.79 | 0.425 |
| Gravidity | 5.23 ±2.22 | 5.67 ±2.37 | 0.237 |
| Parity | 3.28 ±1.54 | 3.67 ±1.81 | 0.204 |
| Miscarriage | 0.96 ±0.91 | 1 ±0.84 | 0.755 |
| BMI | 27.07 ±2.35 | 27.24 ±2.44 | 0.641 |

- Induction of labor was not significantly associated with neonatal asphyxia, occurring in 60% of the asphyxia group and 61.7% of the no-asphyxia group (P=0.556).

Mode of delivery showed a significant association with neonatal asphyxia

(P < 0.001). Caesarean section (C/S) was more common in neonates with asphyxia (90%) compared to those without asphyxia (47.9%). Conversely, vaginal delivery was significantly less frequent in the asphyxia group (10%) compared to the no-asphyxia group (52.1%) (Table 3).

Table (3): Induction of labor and mode of delivery according to study groups.

| Variables | | Asphyxia | No-asphyxia | P value |
|--------------------|---------------------|----------|-------------|---------|
| | | No. (%) | No. (%) | |
| Induction of Labor | Yes | 6 (60) | 148 (61.7) | 0.556 |
| | No | 4 (40) | 92 (38.3) | |
| Mode of delivery | Vaginal | 1 (10) | 125 (52.1) | <0.001 |
| | C/S | 9 (90) | 115 (47.9) | |
| Causes of C/S | Fetal distress | 7 (77.8) | 36 (31.3) | <0.001 |
| | Failure to progress | 2 (22.2) | 68.7) | |

- **CTG Variables:** CTG parameters demonstrated significant differences between the asphyxia and no-asphyxia groups:

Variability: Absence of variability was observed in 70% of the asphyxia group, compared to none in the no-asphyxia group (P<0.001). Variability was present in all neonates without asphyxia (100%) but only in 30% of those with asphyxia.

Accelerations: Absence of accelerations was significantly more common in the asphyxia group (80%) compared to the no-asphyxia group (11.3%) (P<0.001).

Decelerations: Decelerations were observed

in 40% of the asphyxia group and 91.1% of the no-asphyxia group (P < 0.001).

Type of Deceleration: Late decelerations were exclusive to the asphyxia group (75%), while early decelerations were observed only in the no-asphyxia group (74.9%) (P < 0.001). Variable decelerations were similar in frequency in both groups (25% vs. 25.1%).

Baseline Fetal Heart Rate (FHR): The mean baseline FHR was significantly lower in the asphyxia group (98.11 ± 4.34 bpm) compared to the no-asphyxia group (134.13 ± 13.33 bpm) (P < 0.001)(Table 4).

Table (4): CTG Variables according to study groups.

| Variables | | Asphyxia | No-asphyxia | P value |
|----------------------|----------|-------------|---------------|---------|
| | | No. (%) | No. (%) | |
| Variability | Absent | 7 (70) | 0 (0) | <0.001 |
| | Present | 3 (30) | 240 (100) | |
| Acceleration | Absent | 8 (80) | 27 (11.3) | <0.001 |
| | Present | 2 (20) | 213 (88.7) | |
| Deceleration | Absent | 6 (60) | 21 (8.9) | <0.001 |
| | Present | 4 (40) | 219 (91.1) | |
| Type of deceleration | Early | 0 (0) | 164 (74.9) | <0.001 |
| | Variable | 1 (25) | 55 (25.1) | |
| | Late | 3 (75) | 0 (0) | |
| Baseline FHR | Mean ±SD | 98.11 ±4.34 | 134.13 ±13.33 | <0.001 |

- CTG categorization showed a strong association with neonatal asphyxia (P < 0.001). In the asphyxia group, 80% of cases were classified as pathological,

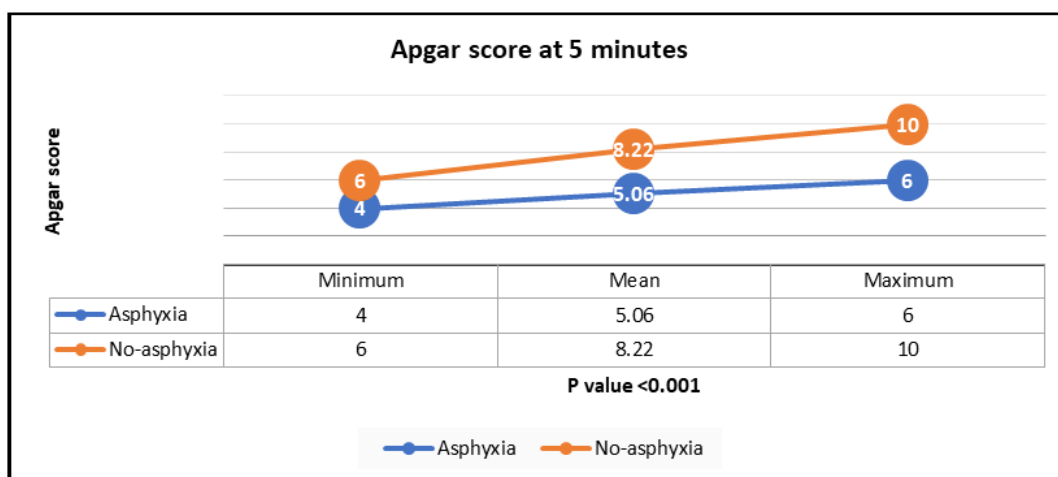
compared to only 1.6% in the no-asphyxia group. Normal CTG patterns were observed in 10% of the asphyxia group and 81.3% of the no-asphyxia group (Table 5).

Table (5): CTG categorization according to study groups.

| Category | Asphyxia | No- asphyxia | P value |
|--------------|----------|--------------|---------|
| | No. (%) | No. (%) | |
| Normal | 1 (10) | 195 (81.3) | <0.001 |
| Suspicious | 1 (10) | 41 (17.1) | |
| Pathological | 8 (80) | 4 (1.6) | |

- The Apgar scores at 5 minutes were significantly lower in the asphyxia group compared to the no-asphyxia group ($P < 0.001$). The minimum, mean, and maximum Apgar scores in the asphyxia

group were 4, 5.06, and 6, respectively, while in the no-asphyxia group, they were 6, 8.22, and 10. These findings highlight the reduced neonatal condition in cases of asphyxia (Figure 2).

**Figure (2): Apgar score according to study group.**

- NICU admission was required for all neonates in the asphyxia group (100%), while only 12.1% of neonates in the no-asphyxia group required NICU admission. None of the neonates in the asphyxia group avoided NICU care, whereas 87.9% of neonates in the

no-asphyxia group did not require NICU admission. This stark difference highlights the strong association between neonatal asphyxia and the need for NICU admission (Table 6).

Table (6): NICU admission rate.

| NICU | Asphyxia | No-asphyxia | P value |
|------|----------|-------------|---------|
| | No. (%) | No. (%) | |
| Yes | 10 (100) | 29 (12.1) | N/A |
| No | 0 (0) | 211 (87.9) | |

N/A: not applicable.

Discussion

The current study, there was a significant association between pathological CTG (absence of fetal heart accelerations, reduced variability, late decelerations and bradycardia seen in the last hour

before delivery and neonatal asphyxia ($p < 0.001$). In addition this study showed that suspicious CTG patterns were observed more often in the no-asphyxia group (17.2%) than in the asphyxia group (10%). Normal CTG patterns were more frequent in the no-asphyxia group (81.3%) than in asphyxia group (10%).

As compared to other studies, they found that pathological CTG patterns, are indicative of potential fetal hypoxia and associated with adverse neonatal outcomes⁽¹⁴⁾.

In the current study, the absence of FHR accelerations was significantly more common in the asphyxia group (80%) compared to no-asphyxia group (11.3%) and ($p < 0.001$). This finding underscores the importance of FHR accelerations as indicators of fetal well-being.

FHR accelerations are typically associated with fetal movements and reflect an intact central nervous system and adequate oxygenation, they are indicator of fetal well-being, as compared with other studies, they found that their absence during labor was associated with an increased risk of fetal hypoxia, neonatal acidemia and adverse outcomes⁽¹⁵⁾.

The current study showed that all neonates without asphyxia exhibited variability and there is significant association between absence of variability and neonatal asphyxia ($p < 0.001$).

FHR variability, is the fluctuation in the time intervals between adjacent heartbeats, it indicates healthy neurocardiac function and is generated by heart- brain interactions and dynamic non-linear autonomic nervous system processes⁽¹⁶⁾.

As compared with the studies, they found that reduced or absent FH variability was a strong indicator of fetal hypoxia, potential asphyxia and newborn acidemia⁽¹⁷⁾.

Decelerations in FHR are common during labour. The pattern of deceleration is more indicative of development of fetal hypoxia and later on neonatal asphyxia. Early decelerations are caused by the compression of the baby's head during uterine contractions. The compression causes vagal stimulation which slows the fetal heart rate. Late decelerations are caused by decreased blood flow to the placenta and can signify an impending fetal acidemia, the usual cause of this type is uteroplacental insufficiency. Variable decelerations are caused by direct umbilical cord compression, which lead to decelerations in the FHR. FHR accelerations or increase in heart rate is a sign that the baby is doing well. Early decelerations happen during contractions

and are also considered normal. However late decelerations may indicate that there is a decrease in blood flow from the placenta. A variable deceleration can happen when the umbilical cord is temporarily compressed and can be a sign that the baby isn't getting enough oxygen⁽¹⁸⁾.

In the current study, early decelerations were observed only in the no-asphyxia group ($p < 0.001$). Late decelerations were exclusive to the asphyxia group. Variable decelerations were similar in frequency in both groups (about 25%).

As compared with other studies, they found that certain patterns of decelerations, such as recurrent late decelerations with minimal or absent variability, are more concerning for fetal acidemia and hypoxia⁽¹⁹⁾.

In the current study, neonates in the asphyxia group had significantly lower 5 minute Apgar scores compared to those in the no-asphyxia group ($p < 0.001$) and all neonates in the asphyxia group required NICU admission, whereas only 12% of those in the no asphyxia group did.

As compared with other studies in their systematic review and meta-analysis, they found that cases of neonatal asphyxia were associated with poor neonatal outcomes, low Apgar score, and higher NICU admission rates⁽²⁰⁾.

Neonatal asphyxia, characterised by impaired gas exchange leading to hypoxemia and hypercapnia, often necessitates advanced supportive measures available in NICUs to manage potential complications such as respiratory distress, metabolic acidosis and organ dysfunction.

In the current study showed that maternal age, gravidity, parity, BMI, labor induction for any cause showed no significant association with neonatal asphyxia.

In comparison with other studies, they found that age less than 20 years had increase in the risk of birth asphyxia. This difference because current study patients were matched regarding their age to eliminate the demographic bias⁽²¹⁾.

Regarding gravidity some studies showed the same as current study⁽²²⁾ while other studies showed that primigravida is a significant risk factor for the

development of birth asphyxia^(23, 24). Regarding BMI, current study showed no significant association between BMI and birth asphyxia.

In comparison with other studies, they showed that obesity was associated with higher rate of birth asphyxia compared to normal weight mothers^(25, 26). This difference between studies because the current study selected cases with matched BMI (avoidance of extremes of weight).

In the current study showed no significant association with the labor induction.

In comparison with other studies, they found the same non significance between induction of labor and birth asphyxia. This other study stated that although induction of labor is associated with uterine contractions and possibility of changes in fetal heart rate but the rate of neonatal asphyxia is not elevated providing the proper management of labor and judicious use of uteritonic agent⁽²⁷⁾.

In current study, mode of delivery was significantly associated with neonatal asphyxia ($p < 0.001$). Caesarean section was more prevalent among neonates with asphyxia compared to those without. Vaginal delivery was less frequent in the asphyxia group. The high rate of CIS in the asphyxia group could be a consequence of underlying perinatal complications necessitating surgical intervention.

In comparison with their studies, they found that the mode of delivery per se was not associated with the presence of neonatal asphyxia⁽²⁸⁾.

The differences between studies reported above related to different sample size and different study design.

Conclusions

CTG monitoring in the last hour before delivery shows significant value in prediction of neonatal asphyxia. Pathological CTG patterns can guide timely obstetric interventions, which can lead in improvement of neonatal outcomes and decreases the incidence of neonatal asphyxia.

Ethical clearance: Verbal permission was obtained from each patient prior to collecting data, and information were anonymous. Names were

removed and replaced by identification codes. All informations were kept confidential in a password secured laptop and data used exclusively for the research purposes.

Ethical approval was taken from ministry of health reference no 427 and dated 23/1/2024 committed in Iraq.

Conflict of Interest: The author declares that she has no conflict of interest.

Funding: Self-funding.

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Prevalence of Comorbidities among Pulmonary Tuberculosis Cases Reporting to a Respiratory Clinic in Western Maharashtra

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How to cite this article: Tanya Murarka, Col. P.S.Chawla, Shilpa Jain. Prevalence of Comorbidities among Pulmonary Tuberculosis Cases Reporting to a Respiratory Clinic in Western Maharashtra. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Tuberculosis is a highly infectious disease responsible for millions of deaths each year, with a disproportionately high incidence in developing countries like India. Comorbidities associated with tuberculosis can complicate treatment and increase mortality risk. This study aims to assess the prevalence of comorbidities among pulmonary tuberculosis patients, which could provide insights for improving patient management and reducing mortality.

Materials and Methods: A cross-sectional study was conducted among 400 diagnosed pulmonary tuberculosis patients at a respiratory clinic in Western Maharashtra, following approval from the Institutional Ethics Committee (IEC) of SKNMCGH (Approval No.2024/274). Demographic information and comorbidity status were collected for each participant and entered into Excel spreadsheets. The Chi-square test was applied to the recorded data using OpenEpi software to study associations between comorbidities and sociodemographic factors. Sample size was determined using a comorbidity prevalence of 39% as reported by Sathish Rajaa, Yuvaraj Krishnamoorthy, et al. in a cross-sectional study of tuberculosis patients in South India, with an allowable error of 5%. This resulted in a minimum required sample size of 367, and our study includes 400 pulmonary tuberculosis patients.^[1]

Results: Out of the 400 pulmonary tuberculosis patients studied, 158 (39.5%) were found to have one or more comorbidities. The incidence of comorbidities increased with age. The most common comorbidity was found to be diabetes affecting 84 (21%) of patients, followed by hypertension, asthma and malnutrition, affecting 17.25%, 14.50% and 11% of patients respectively. There were also various other comorbidities, but none of them affected more than 2% of the patients.

Conclusion: A large proportion of tuberculosis patients have comorbidities, which can lead to unsuccessful

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Submission date: October 2, 2025

Revision date: November 10, 2025

Published date: April 14, 2026

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treatment and an increase in their mortality. Therefore, it is very important to detect and diagnose these comorbidities and control their progression.

Key Words: Pulmonary Tuberculosis, comorbidities, risk factors, prevalence, cross sectional analysis

Introduction

Tuberculosis affects 10 million people annually, with 1.5 million deaths, making it the deadliest infectious disease worldwide. Almost half of the tuberculosis cases are found in developing countries. [2] India accounts for 28% of the world's tuberculosis load, resulting in approximately 3 million new patients each year.[3]

Tuberculosis is associated with a wide range of comorbidities which act as risk factors and also lead to poor treatment results in the patients. According to WHO, the most common comorbidities are HIV (human immunodeficiency virus), diabetes and malnutrition.[4] Other comorbidities include hypertension, asthma, chronic obstructive pulmonary disease, lung carcinoma, chronic kidney disease, rheumatoid arthritis, systemic lupus erythematosus, and many more.[5,6,7]

In general, people living with HIV are 18 times more likely to develop tuberculosis, with a range of 15 to 21 times higher risk compared to those without HIV.[8] Individuals with diabetes mellitus have a threefold higher risk of developing tuberculosis. Diabetes in tuberculosis patients makes the duration of treatment required longer, causes poor prognosis and even increases mortality.[9]

Comorbidities can lead to a poor prognosis and may even prevent the use of some efficacious anti-tubercular drugs.[10] Therefore, it is very important to diagnose these conditions early and to treat them alongside tuberculosis to improve the patient's prognosis.

Aims and Objectives

1. To estimate the prevalence of various types of co-morbidities among patients of pulmonary tuberculosis
2. To study the association between

co - morbidities and various sociodemographic factors, if any

Materials and Methods Study design: Cross-sectional study

Study setting: an outpatient department at a respiratory clinic in Western Maharashtra

Sample size: By taking prevalence of comorbidities obtained from other research papers as 39.28% with 5% allowable error, estimated sample size was to 367 (minimum sample size). The study has taken a sample size of 400 pulmonary tuberculosis patients.

Sampling method: All patients who fit the inclusion criteria were included till the sample size is attained

Inclusion criteria: Those already suffering from pulmonary tuberculosis and consented

Exclusion criteria: Patients who do not give consent

Data analysis: The data collected was analyzed using open-Epi software

Results

400 pulmonary tuberculosis patients were studied and they were divided according to their sociodemographic factors as depicted in table 1.

Note: The Modified BG Prasad scale includes five socio-economic classes ranging from upper to lower class based on per capita monthly income. However, in this study, the five classes were combined into two broader categories, "Lower class" and "Upper class," due to small sample sizes within some individual classes. This approach was necessary to ensure sufficient statistical power for meaningful analysis while maintaining clarity in reporting socio-economic associations with pulmonary tuberculosis and comorbidities.

Table 1: Demographic and Socio-Economic Characteristics of P.TB Patients

| GENDER | FREQUENCY (n) | PERCENTAGE (%) |
|-----------------------|---------------|----------------|
| MALE | 176 | 44 |
| FEMALE | 224 | 56 |
| AGE GROUP (in years) | FREQUENCY (n) | PERCENTAGE (%) |
| 9-19 | 52 | 13 |
| 20-29 | 87 | 21.75 |
| 30-39 | 67 | 16.75 |
| 40-49 | 58 | 14.5 |
| 50-59 | 56 | 14 |
| 60 and above | 80 | 20 |
| SOCIO-ECONOMIC STATUS | FREQUENCY (n) | PERCENTAGE (%) |
| Lower class | 49 | 12.25 |
| Upper class | 351 | 87.75 |

400 pulmonary tuberculosis patients were studied, and the prevalence of various comorbidities found are listed in Table 2.

TABLE 2: The prevalence of various comorbidities among pulmonary tuberculosis patients.

| COMORBIDITIES | FREQUENCY (n) | PERCENTAGE (%) |
|---------------------------|---------------|----------------|
| 1. Diabetes | 84 | 21 |
| 2. HIV | 4 | 1 |
| 3. Malnutrition | 44 | 11 |
| 4. Hypertension | 69 | 17.25 |
| 5. Asthma | 58 | 14.50 |
| 6. COPD | 44 | 11 |
| 7. Lung cancer | 1 | 0.25 |
| 8. Pneumothorax | 1 | 0.25 |
| 9. RHD | 0 | 0 |
| 10. Chronic bronchitis | 1 | 0.25 |
| 11. Bronchiectasis | 0 | 0 |
| 12. RA | 3 | 0.75 |
| 13. SLE | 0 | 0 |
| 14. CRF | 3 | 0.75 |
| 15. Hypothyroidism | 7 | 1.75 |
| 16. Psychiatric disorders | 5 | 1.25 |

Note: Frequencies are for individual comorbidities. Patients may have more than one comorbidity; therefore, sums of frequencies do not equate to total number of patients.

After estimating the prevalence of the comorbidities, we divided the patients having comorbidities according to their age, gender and socioeconomic status. We then applied the chi-square

test to determine if there was any correlation (association) between the prevalence of a specific comorbidity and the age, gender or socioeconomic class of the study participant.

Among the 176 males, 43.18% had comorbidities compared to 36.6% in 224 females (Table 3). This difference was not statistically significant. ($\chi^2 = 1.695$, p-value =0.193)

TABLE 3: Gender Distribution of Pulmonary Tuberculosis Patients with Comorbidities.

| GENDER | NO. OF PATIENTS WITH COMORBIDITIES | NUMBER OF P.TB PATIENTS | PERCENTAGE (%) | CHI-SQUARE STATISTIC | P-VALUE |
|--------|------------------------------------|-------------------------|----------------|----------------------|---------|
| Male | 76 | 176 | 43.18 | 1.695 | 0.193 |
| Female | 82 | 224 | 36.6 | | |

The study group was also divided according to their age group as depicted in table 4. On applying the chi-square test, the calculated chi-square statistic (47.831) was much greater than the critical value (11.070). Thus, it proves that age is an important factor

influencing the presence of co-morbidities in P.TB patients. Comorbidities varied significantly across age groups (Table 4), with the highest prevalence in the 50-59 group (69.64%) and the lowest in the 20-29 group (11.49%).

TABLE 4: Age Group Distribution of Pulmonary Tuberculosis Patients with Comorbidities

| AGE GROUP (in years) | NO. OF P.TB PATIENTS WITH COMORBIDITIES | NUMBER OF P.TB PATIENTS | PERCENTAGE (%) | CHI-SQUARE STATISTIC | P-VALUE |
|----------------------|---|-------------------------|----------------|----------------------|----------|
| 9-19 | 10 | 52 | 19.23 | 47.831 | <0.00001 |
| 20-29 | 10 | 87 | 11.49 | | |
| 30-39 | 19 | 67 | 28.36 | | |
| 40-49 | 28 | 58 | 48.28 | | |
| 50-59 | 39 | 56 | 69.64 | | |
| 60 and above | 52 | 80 | 65 | | |

The socioeconomic status of the study group was determined using the modified BG Prasad scale. Upon applying the chi-square test to Table 5, we found that the p-value (2.34×10^{-9}) was significantly lower than the standard significance level (0.05), indicating a

significant association between socioeconomic status and the presence of comorbidities in P.TB patients. As shown in Table 5, comorbidities were more prevalent in the lower socioeconomic class compared to the upper class.

TABLE 5: Socio-Economic Status of Pulmonary Tuberculosis Patients with Comorbidities

| SOCIO-ECONOMIC STATUS | NO. OF P.TB PATIENTS WITH COMORBIDITIES | NUMBER OF P.TB PATIENTS | PERCENTAGE (%) | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|---|-------------------------|----------------|----------------------|-----------------------|
| Lower class | 39 (79.59%) | 49 | 79.59 | 82.63 | 2.34×10^{-9} |
| Upper Class | 119 (33.9%) | 351 | 33.9 | | |

Table 2 shows that the most common comorbidities among pulmonary tuberculosis patients were diabetes, hypertension, asthma, malnutrition, and COPD. Other comorbidities affected less than 2% of patients.

Table 6 presents the distribution of diabetes among pulmonary tuberculosis patients, revealing significant associations with age group and gender but no significant association with socioeconomic status.

TABLE 6: Distribution of Pulmonary Tuberculosis Patients with and without Diabetes by Gender, Age Group, and Socio-Economic Status

| GENDER | P.TB AND DIABETES | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|-------------------|-------------|----------------------|-----------|
| Male | 48 (27.3%) | 128 (72.7%) | 7.43 | 0.0064 |
| Female | 36 (16.1%) | 188 (83.9%) | | |
| AGE GROUP | P.TB AND DIABETES | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Less than 50 years | 14 (4.7%) | 250 (95.3%) | 20.75 | < 0.00001 |
| Above 50 years | 70 (51.1%) | 66 (48.9%) | | |
| SOCIO-ECONOMIC STATUS | P.TB AND DIABETES | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Lower class | 15 (30.6%) | 34 (69.4%) | 2.48 | 0.115 |
| Upper class | 69 (19.7%) | 282 (80.3%) | | |

The second most common comorbidity among the P.TB cases found was hypertension. In table 7 given below, we applied the chi-square test and we studied the relationship of hypertension as a comorbidity of P.TB with various socio-demographic variables.

Since the p-value is less than 0.05, we can confidently reject the null hypothesis and conclude that gender, age and socio-economic status are significantly associated with the presence of P.TB and Hypertension vs. Only P.TB.

TABLE 7: Distribution of Pulmonary Tuberculosis Patients with and without Hypertension by Gender, Age Group, and Socio-Economic Status

| GENDER | P.TB AND HYPERTENSION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|-----------------------|--------------|----------------------|-----------|
| Male | 39 (22.16%) | 137 (77.84%) | 5.13 | 0.023 |
| Female | 30 (13.39%) | 194 (86.61%) | | |
| AGE GROUP | P.TB AND HYPERTENSION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Less than 50 years | 27 (10.91%) | 237 (89.09%) | 21.49 | < 0.00001 |
| above 50 years | 42 (31.82%) | 94 (68.18%) | | |
| SOCIO-ECONOMIC STATUS | P.TB AND HYPERTENSION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Lower class | 14 (28.57%) | 35 (71.43%) | 4.15 | 0.0416 |
| Upper class | 55 (15.67%) | 296 (84.33%) | | |

Table 8 compares pulmonary tuberculosis patients with asthma to those without. There was no significant association with gender or socio-economic

status, but age showed a significant association with the presence of asthma.

TABLE 8: Distribution of Pulmonary Tuberculosis Patients with and without Asthma by Gender, Age Group, and Socio-Economic Status.

| GENDER | P.TB AND ASTHMA | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|--------|-----------------|--------------|----------------------|---------|
| Male | 25 (14.2%) | 151 (85.8%) | 0.02 | 0.89 |
| Female | 33 (14.73%) | 191 (85.27%) | | |

| AGE GROUP | P.TB AND ASTHMA | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|-----------------|--------------|----------------------|---------|
| Less than 50 years | 30 (10.71%) | 234 (89.29%) | 5.40 | 0.02 |
| Above 50 years | 28 (16.67%) | 108 (83.33%) | | |
| SOCIO-ECONOMIC STATUS | P.TB AND ASTHMA | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Lower class | 6 (12.24%) | 43 (87.76%) | 0.07 | 0.79 |
| Upper class | 52 (14.81%) | 299 (85.19%) | | |

Table 9 shows no significant association between gender and COPD among pulmonary tuberculosis patients. However, significant associations were observed with age group and socio-economic status, indicating these are important factors related to COPD in this population.

TABLE 9: Distribution of Pulmonary Tuberculosis Patients with and without COPD by Gender, Age Group, and Socio-Economic Status

| GENDER | P.TB AND COPD | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|---------------|--------------|----------------------|-----------|
| Male | 20 (11.36%) | 156 (88.64%) | 0.04 | 0.8374 |
| Female | 24 (10.71%) | 200 (89.29%) | | |
| AGE GROUP | P.TB AND COPD | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Less than 50 years | 22 (7.85%) | 242 (92.15%) | 4.88 | 0.027 |
| Above 50 years | 22 (13.64%) | 114 (86.36%) | | |
| SOCIO-ECONOMIC STATUS | P.TB AND COPD | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Lower class | 16 (32.65%) | 33 (67.35%) | 22.23 | < 0.00001 |
| Upper class | 28 (7.98%) | 323 (92.02%) | | |

As shown in Table 10, socio-economic status was significantly associated with malnutrition among pulmonary tuberculosis patients, while gender and age group were not.

TABLE 10: Distribution of Pulmonary Tuberculosis Patients with and without Malnutrition by Gender, Age Group, and Socio-Economic Status.

| GENDER | P.TB AND MALNUTRITION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
|-----------------------|-----------------------|--------------|----------------------|----------|
| Male | 23 (13.07%) | 153 (86.93%) | 1.38 | 0.241 |
| Female | 21 (9.38%) | 203 (90.62%) | | |
| AGE GROUP | P.TB AND MALNUTRITION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Less than 50 years | 27 (9.64%) | 237 (90.36%) | 0.27 | 0.603 |
| Above 50 years | 17 (10.53%) | 119 (89.47%) | | |
| SOCIO-ECONOMIC STATUS | P.TB AND MALNUTRITION | ONLY P.TB | CHI-SQUARE STATISTIC | P-VALUE |
| Lower class | 16 (32.65%) | 33 (67.35%) | 18.12 | <0.00001 |
| Upper class | 28 (7.98%) | 323 (92.02%) | | |

Discussion

The study revealed that 39.5% (158) of the 400 pulmonary tuberculosis (P.TB) cases examined had comorbidities, representing a significant proportion. These comorbidities were associated to both age group and socio-economic status, with no significant association observed with gender. The most common comorbidities identified were diabetes, hypertension, asthma, malnutrition, and COPD.

Upon examining the relationship between specific comorbidities and factors such as age, gender, and socio-economic status, we found that both diabetes and hypertension were significantly associated with all three factors. In contrast, asthma and COPD showed associations only with age and socio-economic status, but not with gender. Malnutrition, on the other hand, was significantly linked only to socio-economic status, with no association found with gender or age.

Another paper based in Maharashtra found a higher incidence of P.TB to be significantly higher in males.^[11] The same results of males having a higher prevalence of P.TB was also found in a study in Dehradun, India.^[12] A meta-analysis of 28 countries on sex differences in tuberculosis also states the same, that TB rates are higher in men.^[13] Even though our paper has a higher percentage of men (43.18%) diagnosed with TB as compared to women (36.6%), the chi-square test states that there is no association of gender with the prevalence of TB. This could be due to the reason that men face more difficulties than women in accessing and seeking healthcare and are less likely to participate in prevalence surveys, which leads to less men getting diagnosed.^[13] Even in our study, more women compared to men have participated.

A number of studies, both in India and internationally, have shown that tuberculosis is more common in older age groups, which is consistent with the findings of this paper.^[14,15] Older adults are at an increased risk of tuberculosis due to age-related decline in immune function, co-existing health conditions, malnutrition, chronic alcohol use and greater likelihood of living in institutional settings.^[14,15] The findings of our study align with several research papers, which show that tuberculosis was

notably more prevalent among the impoverished in India.^[16,17] This can be attributed to overcrowding, poor ventilation in homes, lack of sanitation, poor nutrition and limited access to healthcare services in lower-income households.^[17] Regular screening for active TB detection, enhanced awareness of the importance of early diagnosis, and the use of mobile clinics could aid in the timely identification of cases.^[15] Since it has been identified that older individuals and those from lower socio-economic backgrounds have a higher prevalence of pulmonary TB, screening strategies should be enhanced for these groups.

The most common comorbidity associated with pulmonary TB in the study population was diabetes, affecting 21%. A study conducted in South India, along with a global meta-analysis of 2.3 million patients, reported a diabetes incidence in TB patients ranging from 15% to 30%, which is consistent with our findings.^[18,19] Similar to our study, the meta-analysis also indicates that diabetes as a comorbidity of TB is more prevalent in men and increases with age.^[19] A study also found a significant association between lower-income countries and the dual burden of TB and diabetes, suggesting that those in poverty are more vulnerable to developing both conditions as comorbidities.^[20] However, our study does not find a statistically significant association between the prevalence of diabetes and the socioeconomic status of an individual. Diabetes with TB results in atypical symptoms, complicating detection, and increases treatment failures, relapses, and mortality.^[21]

Our study found that 17.25% of pulmonary TB patients also had hypertension, highlighting it as an important comorbidity. While some studies fail to establish a significant link between hypertension and TB, many others suggest a relationship between the two conditions.^[22,23,24] This study found a higher incidence of TB and hypertension as comorbid conditions in males, older age groups, and individuals with lower socio-economic status. According to the findings of a study in Taiwan, hypertension is linked to higher mortality within the first 9 months after starting tuberculosis treatment.^[23] Therefore, it is crucial to screen TB patients for hypertension and initiate appropriate treatment for both conditions simultaneously.

A study conducted in Patiala, Punjab, examining patients with both tuberculosis and asthma, revealed

that 69.6% of the patients developed tuberculosis after being diagnosed with asthma. This suggests that tuberculosis may elevate the risk of developing bronchial asthma.^[25] Individuals with tuberculosis may experience bronchial asthma as a result of allergic reactions to medications or damage to the lungs and airways. This damage can facilitate the entry of allergens, triggering inflammation and allergic symptoms.^[26] Tuberculosis also plays a significant role in causing airflow obstruction (COPD), linking two of the most prevalent diseases globally. For most TB patients, achieving microbiological cure is just the first step in their treatment, not the end. Effective prevention and treatment of tuberculosis would help alleviate the burden of airflow obstruction, particularly in developing countries.^[27] According to this study, 14.50% of tuberculosis patients have asthma, while 11% suffer from COPD. The chi-square test results indicate that both asthma and COPD are associated with age. Socio-economic status was linked to COPD but not to asthma, and no association was found with gender.

Malnutrition significantly contributes to the burden of tuberculosis and can be both a result of and a factor that worsens the condition. It may negatively impact treatment outcomes in cases of TB and play a role in the growing issue of drug resistance in tuberculosis.^[28] This study reports that the prevalence of malnutrition among tuberculosis patients is 11%. It was found that malnutrition in TB patients is associated solely with their socio-economic status, with no association observed with age or gender. It was found to be significantly higher in the lower socio-economic groups.

As shown in this paper, P.TB is associated with a wide range of comorbidities that affect almost 40% of the patients. Comorbid conditions along with TB may limit the use of some anti-tubercular drugs, may cause treatment failures, and also increase mortality. Thus, it is essential to develop and implement comprehensive screening strategies promptly to mitigate the impact of comorbid conditions on tuberculosis patients and support their treatment.^[29]

Conflicts of Interest: The authors declare that they have no conflict of interest regarding the publication of this paper.

Funding: No funding or financial support was received for conducting this research.

Strengths and Limitations: This study's strengths include a sizable sample of pulmonary tuberculosis patients and detailed assessment of various comorbidities and their associations with socio-demographic factors. The use of the Modified BG Prasad scale provides a standardized measure of socio-economic status.

However, limitations should also be noted. The combination of socio-economic classes due to small sample sizes may have masked some associations. Additionally, reliance on self-reported data for some comorbidities and socio-demographic factors could introduce reporting bias. Lastly, certain rarer comorbidities with very low prevalence could not be robustly analyzed.

These limitations warrant consideration when interpreting the findings and suggest directions for future prospective and larger-scale studies.

Acknowledgments I would like to express my heartfelt gratitude to Dr. Maya Nannaware, Professor, Dept. of Community Medicine for her insightful feedback throughout this research. Her guidance was invaluable to the completion of this paper. Special thanks to SKNMCGH for providing the resources and facilities necessary to carry out this research.

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Carriage of Pathogenic Organisms in Gastrointestinal Tract Among Chandigarh Population

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How to cite this article: Varsha Gupta Anku Goel, Meenakshi Singh et. al. Carriage of Pathogenic Organisms in Gastrointestinal Tract Among Chandigarh Population. Indian Journal of Public Health Research and Development / Vol. 17 No. 2, April-June 2026.

Abstract

Objectives: To understand the epidemiology of various pathogens, it is imperative to understand the carriage of these pathogens in asymptomatic individuals. This helps in understanding the transmission of disease and thus the control measures. This study was carried out to detect the carriage of various pathogenic bacteria, parasites, and Rotaviruses in stool samples of the healthy population of Chandigarh.

Materials and Methods: 500 non-duplicate fecal samples from healthy subjects were collected and processed for isolation of pathogenic bacteria by microbiological culture. An enzyme-linked immunosorbent Assay was performed for *Clostridium difficile* toxins and Rotavirus antigen detection. Intestinal parasites were detected by wet mount and iodine mount directly, and after the formol-ether concentration technique for parasites. The data were analyzed descriptively using Microsoft Excel, and the results were summarized as percentages to provide a clear understanding of the distribution and trends in the dataset.

Results: Carriage of intestinal pathogens was found to be 44.4% and 55.6% in children and adults, respectively. Carriage of *Shigella* species, *Salmonella* species, and *Vibrio cholerae* was nil in our study, with 2.6% carriage of *Clostridium difficile*. Rotavirus carriage was 3.6% in children. The carriage of parasites was more in adults than in children.

Conclusions: The two main concerns in our study were *C. difficile* carriage and intestinal parasite carriage in adults. Educating the masses regarding hand hygiene is the most important step in this regard. Regarding parasitic infections, a single dose albendazole in school-going children has resulted in lower carriage in children than adults. The same approach, along with education regarding hygienic practices, can be started in the adult population also.

Keywords: Carriage, Stool, Community, Pathogenic, Gastrointestinal tract

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Submission date: September 27, 2025

Revision date: Nov 12, 2025

Published date: April 14, 2026

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Introduction

The human gastrointestinal tract is home to a variety of bacteria, parasites, fungi, and viruses. Infectious causes of acute diarrhea in symptomatic patients, including viruses, bacteria, and parasites, can lead to high morbidity and mortality, particularly in children¹. However, the carriage of pathogens among asymptomatic patients in a community is not known in our region. Asymptomatic patients are those who do not possess signs and symptoms of gastrointestinal illness, but their gut harbors pathogens². This type of surveillance is of utmost importance due to shedding of pathogens in the environment by healthy asymptomatic populations that may potentially lead to dissemination of infection in the community and transmission to the susceptible host. Food handlers working in the food service establishments can also act as carriers of different enteropathogens, possibly causing fecal contamination of foods by their hands, which may be the cause for the transmission of infections to the local community³. A carriage rate of as high as 41% has also been reported⁴. There is currently limited epidemiological data to provide an accurate assessment of the burden of enteropathogens in the asymptomatic population of developing countries. This study was carried out with the aim of knowing the prevalence of various pathogenic bacteria, parasites, and Rotavirus in stool samples of the healthy population of Chandigarh. To our knowledge, this is the first study to look for all the major pathogens in a healthy population in our region.

Materials and Methods

This prospective, observational study was carried out at the Department of Microbiology, Government Medical College and Hospital, Chandigarh, and involved 500 healthy individuals from Chandigarh who gave informed consent. This study protocol was approved by Institute of Ethics Committee of Government Medical College and Hospital, Chandigarh on 26th November 2020 (GMCH/IEC/2020/356/120). These participants were divided into two groups: pediatric and adult. The pediatric group included individuals under 14 years old, while those over 14 years of age formed the adult group. Demographic details such as age,

sex, and address were recorded on a proforma. A comprehensive laboratory analysis was performed on non-duplicate fecal samples, including bacterial culture, Enzyme-Linked Immunosorbent Assay for *Clostridioides difficile* toxins and Rotavirus antigen, and microscopic examination for intestinal parasites using wet mount, iodine mount, and the formol-ether concentration technique. Stool samples were cultured on MacConkey agar, Xylose Lysine Deoxycholate agar, and Thioglycollate Citrate Bile Salt Sucrose agar, with enrichment in Selenite F broth and Alkaline Peptone Water to isolate pathogenic bacteria.

Results

A total of 500 participants were observed, comprising 222 [44.4%] children and 278 [55.6%] adults. Among them, females accounted for 60% (n = 300) and males represented 40% (n = 200). This distribution indicates a higher representation of females in the cohort, with a female-to-male ratio of 1.5:1. Distribution of age and sex is shown in **Table 1**.

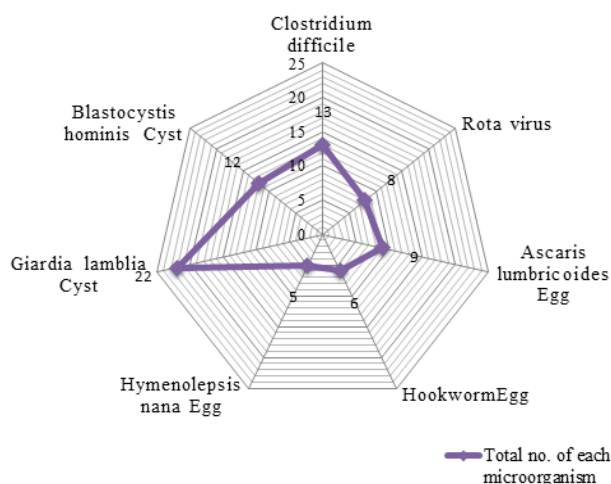
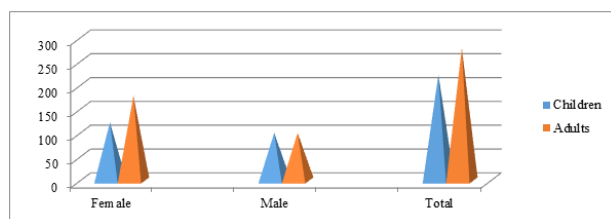
Table 1: Age and sex distribution of the stool samples collected from community

| | Female | | Male | | Total |
|----------|--------|--------|------|--------|-------|
| | N | % | N | % | |
| Children | 122 | 54.9 % | 100 | 45 % | 222 |
| Adults | 178 | 64 % | 100 | 35.9 % | 278 |

The study found no carriage of *Shigella* species, *Salmonella* species, or *Vibrio cholerae* among the participants. However, *C. difficile* carriage was detected in 2.6% (n = 13) of the study population, with a higher prevalence in adults (3.9%, n = 11) compared to children (0.9%, n = 2). Five carriers among these gave the history of animal handling, with two members from the same family. Rotavirus carriage was 1.6% (n=8) and was seen only in children, making it 3.6% in the children population (**Figure 1, Table 2**). The carriage of parasites was more in adults than children, as shown in **Figure 2**. A notable proportion (48%, n = 240) of the study participants reported a lack of adherence to handwashing practices before meals.

Table 2: Carriage of various microorganisms in the stool samples collected from community

| | Method used | Total | | Adult | | Children | |
|----------------------------------|------------------------|---------|------|---------|------------|----------|---------------|
| | | N [500] | % | N [278] | % in Adult | N [222] | % in Children |
| Bacteria | | | | | | | |
| <i>Clostridium difficile</i> | ELISA for toxins A & B | 13 | 2.6% | 11 | 3.9% | 2/222 | 0.9% |
| <i>Shigella spp.</i> | Culture | Nil | | | | | |
| <i>Salmonella spp.</i> | Culture | Nil | | | | | |
| <i>Vibrio cholera</i> | Culture | Nil | | | | | |
| Virus | | | | | | | |
| Rota virus | ELISA for Antigen | 8 | 1.6% | Nil | | 8/222 | 3.6% |
| Parasites | | | | | | | |
| <i>Ascaris lumbricoides</i> Egg | Saline & Iodine Mount | 9 | 1.8% | 7 | 2.5% | 2/222 | 0.9% |
| HookwormEgg | Saline & Iodine Mount | 6 | 1.2% | 4 | 1.4% | 2 | 0.9% |
| <i>Hymenolepis nana</i> Egg | Saline & Iodine Mount | 5 | 1.0% | 5 | 1.7% | Nil | |
| <i>Giardia lamblia</i> Cyst | Saline & Iodine Mount | 22 | 4.4% | 14 | 5.0% | 8 | 3.6% |
| <i>Blastocystis hominis</i> Cyst | Saline & Iodine Mount | 12 | 2.4% | 8 | 2.8% | 4 | 1.8% |

**Figure 1: Carriage of various microorganisms in the stool samples collected from the community****Figure 2: Age and sex distribution of the stool samples collected from the community**

Discussion

Clostridium difficile infection (CDI) is an important healthcare-associated infection (HAI) seen mostly

in Intensive Care Unit (ICU) settings⁵. *Clostridium difficile* carriage in our community came out to be 2.6% (13), with 3.9% (11) in adults and 0.9% (2) in children. It is important to know the carriage of *C. difficile* in the community as these carriers act as reservoirs for transmission of the microorganism and are also at risk of developing CDI⁶. Baron *et al* have reported that 38.1% of the asymptomatic carriers progressed to symptomatic CDI versus 2% in non-carriers, and this association was found to be statistically significant⁶. Children colonized with *C. difficile* were significantly more likely to develop CDI within 90 days compared to non-colonized children (25% vs 0%, $p = 0.002$)⁷. *C. difficile* carriage thus poses the carriers at risk of developing symptomatic CDI. Recent hospitalization and livestock proximity have been observed as important risk factors for asymptomatic carriage⁸.

Poor hand hygiene after animal contact is a contributing factor, as shown in published literature⁹. In our community, 5 out of 13 people had a history of animal contact, including two members from same family. Hands and the environment easily get contaminated with *C. difficile* from cases and carriers and act as the source of transmission of this microorganism. Gilboa *et al* found that the rooms of *C. difficile* carrier patients were as contaminated as rooms of symptomatic CDI patients, emphasizing the role of carriers also in spreading the infection¹⁰. In a

study on environmental sampling of microbiology laboratory dealing with *C.difficile* samples, 11.8 of % hands of laboratory workers were contaminated with *C.difficile*¹¹. Hand hygiene becomes a very important factor in limiting the spread of this microorganism. We also educated the carriers in our study regarding the importance of hand hygiene, especially after animal handling.

Other studies on carriage of *C.difficile* have reported 10% carriage in Iranian children less than 5 years age at day zero of hospitalization¹², 10.4% in US hospitalized patients⁸, 7.4% asymptomatic carriers in ICU settings⁵ and 2.3% in veterinary healthcare workers in Netherlands⁹. A Chinese study followed 29 children from birth till one year of age for *C.difficile* carriage and found that 20 out of 29 (68.9%) carried *C.difficile* by one year of age¹³. Antibiotic exposure has been known to be the biggest risk factor for CDI. Over the counter antibiotic intake could be a factor in the carriage of *C.difficile* in our community.

Shigella, Salmonella, and *V.cholerae* were not isolated in our study. Subclinical carriage of *Shigella* is known, which can persist for months and also account for the spread of the disease, especially because a low infective dose is required for infection but it is a hardier organism to isolate^{14, 15}. Carriage rate for Nontyphoidal Salmonella and *Vibrio cholerae* has been reported as quite low^{16, 17}.

Rotavirus is known to shed in feces of children without diarrhoea¹⁸. For the same reason recovery of rotavirus is of little diagnostic value in a diarrhoea patient because it cannot be attributed as the cause in all the cases. A study showed that among 83 children shedding Rotavirus in stool, 40 [48%] did not have diarrhea¹⁸. In our study, Rotavirus was detected in 1.6% (8/500) of the overall study population and in 3.6% (8/222) of the pediatric subgroup.

Soil-transmitted helminths (STH) is a common public health problem of all age groups. India has achieved one of the largest deworming programs in children by giving single dose albendazole twice yearly to school-going children¹⁹. Even though single dose albendazole is very effective, children tend to get re-infected from their community. Also, these programs do not target the adult population who could be acting as a source of infection. The

prevalence of parasitic carriage in our study was less in children than in adults, which is mostly due to the albendazole given to children at their school under the national programme. The parasites found in our study are *Ascarislumbricoides* 2.5% in adults vs 0.9% in children; hookworm (1.2% vs 0.9%); *H.nana* (1% vs nil); *Giardia lamblia* (5% vs 3.6%), and *Blastocystishominis* (2.4% vs 1.8%). A study from South India has shown a prevalence of 21% for hookworm and <1% for Ascaris in adults¹⁹. They showed that increasing age and higher vegetation was associated with higher prevalence while high socioeconomic status, higher education and improved sanitation with low prevalence. A few of our individuals gave a history of no hand washing before meals and were advised for do so. An Ethiopian study has shown prevalence of 12.5% for Ascaris and 7.5% for hookworm in a community-based study on adults and adolescents²⁰. For adults, education on hygiene and sanitation and albendazole treatment can help to tackle the problem.

Protozoa are also an important cause of diarrhea, but detection of *Giardia* cannot be associated with diarrhoea in all times²¹. *Giardia* carriage in children has been reported by various studies, ranging from 1.3% to 37%^{22, 23, 24} with 3.6% in our study. Adult population showed carriage of 5% for *Giardia*, while a study from Tanzania reported 53%²⁵. An interesting observation was made in a study on Israeli children that faltering growth was observed after *Giardia lamblia* infection, rather than predisposing it, but this observation needs further studies²¹. *Blastocystishominis* carriage was also reported in the same study to be 61% which was 2.4% in our study, which is much higher than ours. These variations could be geographically determined. A study from Zambia done on the pediatric population with children 5-18 years, showed a carriage rate of 37.9% for *Blastocystis* sp., 30.9% for *Giardiaintestinalis*, 13.3% for *Entamoebadispar*, and 4.3% for *Cryptosporidium* spp. No *E.histolytica* was detected in their study. Molecular methods were used for detection in this study, which are more sensitive, and hence the higher detection rates²⁶.

Conclusion

In conclusion, pathogenic bacterial carriage for most bacteria was nil in our study, which, in all

probability, is due to the safe water supply in our city, but *C.difficile* carriage is a concern for which educating the masses is important regarding hand hygiene, especially in animal handlers. Regarding parasitic infections, a single dose of albendazole in school-going children has resulted in lower carriage in children than adults. The same approach, along with education regarding hygienic practices, can be started in the adult population also.

Funding: Department of Science and Technology, Chandigarh, India

Conflicts of interest: The authors have declared no conflicts of interest.

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Implementation of Pharmacy Services for Cases of Acute Non-Dehydrated Diarrhea in Children in South Tangerang City, Banten, Indonesia

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How to cite this article: Yardi Saibi, Alysa Prameswary, Vidia Arlaini Anwar. Implementation of Pharmacy Services for Cases of Acute Non-Dehydrated Diarrhea in Children in South Tangerang City, Banten, Indonesia. *Indian Journal of Public Health Research and Development* / Vol. 17 No. 2, April-June 2026.

Abstract

Background: Self-medication for minor ailment is a common practice worldwide, including in Indonesia such as when patient seek medication with acute non-dehydration diarrhea but many studies reported that there was still problems in patient knowledge when conducting their self medication. This study aimed to examine the implementation of services provided by Pharmacy staff in South Tangerang City, Banten Province, Indonesia, for pediatric patients with acute non-dehydration diarrhea.

Methods: This study had a cross-sectional design and the data obtained were described descriptively. Data were collected by interviewing selected pharmacy staff to explore how they responded or provided services to patients who asked for their advice on managing diarrhea. The interview rubric was created by referring to minor ailments service flow, which includes three parameters: the patient assessment, the drug recommendations given, and the information conveyed to patients. The sample were staff from 43 pharmacies in the South Tangerang city area who were randomly selected based on pharmacy data obtained from the local city health office.

Conclusion: As many as 48.84% of pharmacy staff provided treatment consistent with WHO recommendations. Pharmacy staff need to improve their role in managing acute non-dehydration diarrhea patient.

Keywords: self medication, minor ailment, pharmacy staff, acute diarrhea

Introduction or back ground

Self-medication is a form of self-care, defined as the selection and use of medications by individuals to independently treat recognized illnesses or symptoms.

⁽¹⁾Self-medication is a common practice worldwide, including in Indonesia. As many as 72.19% of

Indonesians practice self-medication (Badan Pusat Statistik, 2021). This practice is used to treat minor ailments such as pain, fever, dizziness, stomach ulcers, influenza, worms, diarrhea, and skin conditions.⁽²⁾

Appropriate knowledge about medication is essential in self-medication practices to achieve

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Submission date: November 6, 2025

Revision date: December 24, 2025

Published date: April 14, 2026

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therapeutic goals. However, several studies conducted in several regions in Indonesia found that the level of public knowledge regarding self-medication was predominantly moderate and low.⁽³⁾⁽⁴⁾⁽⁵⁾ Inadequate knowledge and irrational medication practices can pose risks to patients, including errors in self-diagnosis, inability to seek appropriate medical advice, failure to recognize contraindications, incorrect medication choices, drug-food interactions, the risk of duplicate medication, inappropriate dosages, incorrect routes of administration, inappropriate long-term use, and improper storage. Several studies in several parts of the world have found incorrect practices in self-medication. Research in Taiwan found that the prevalence of inappropriate self-medication behavior was 10%, using excessive doses (21.6%), and using prescription and non-prescription drugs simultaneously (30%).⁽⁶⁾ Another study conducted in Eritrea on over-the-counter self-medication in pharmacies reported that of 609 pharmacy customers, 93.7% self-medicated, 14% of respondents reported consuming more than the recommended dose, and 6.9% experienced problems after consuming over-the-counter medications.⁽⁷⁾

Community pharmacy staff, especially pharmacist, play an important role in educating their community about medicine. They are the healthcare professionals most readily accessible to public when seeking help with health problems. However, several studies have reported that their role in providing drug information to patients remains low, as found in pharmacies in Garut Regency, where the quality of drug information and counseling services provided by pharmacists averaged 59.82%.⁽⁸⁾ The Indonesian Ministry of Health has issued pharmaceutical service standards in pharmacies, most recently in 2016. These standards serve as guidelines for pharmaceutical staff, in providing services to patients, including for them who conduct self-medication for minor illnesses.⁽⁹⁾ This study aimed to examine the implementation of services provided by Pharmacy staff in South Tangerang City, Banten Province, Indonesia, for pediatric patients with acute non-dehydration diarrhea. Acute non-dehydration diarrhea was chosen because it is a public health problem in developing countries like Indonesia with high prevalence.

Material and Methods

This study had a cross-sectional design and the data obtained were described descriptively. Data were collected by interviewing selected pharmacy staff to explore how they responded or provided services to patients who asked for their advice on managing diarrhea. The interview rubric was created by referring to minor ailments service flow, which includes three parameters: the patient assessment, the drug recommendations given, and the information conveyed to patients. Patient assessment refers to the ASMETHOD mnemonics (Age/appearance, Self/someone else, Medication, Extra medication, Time persisting, History, Other accompanying symptoms, Danger symptoms) to obtain patient-related information. Treatment recommendations refer to the WHO diarrhea management guidelines. Drug information parameters refer to the Ministry of Health's guidelines for the use of over-the-counter and restricted-prescription drugs. The sample were staff from 43 pharmacies in the South Tangerang city area who were randomly selected based on pharmacy data obtained from the local city health office with in March 2023 with the following inclusion criteria: the pharmacy was officially registered with the city health office; the pharmacy was still operating at the time of the researcher's visit and the pharmacy staff were willing to participate where Lwanga dan Lemeshow formula was used to measure the size with margin of error 10%. Stratified random sampling was used to determine the number of samples as representatives of the 7 existing sub-districts and simple random sampling was used to determine which pharmacies would be selected as samples in each sub-districts. The interviewer was trained before collecting the data to eliminate the mistakes. Ethical clearance was obtained from the Research Ethics Committee of the Faculty of Medicine, University of Indonesia with number Un.01/F.10/KP.01.1/KE.SP/02.08.019/2023. Data were analyzed descriptively.

Results and Discussion

Respondents consisted of 41.86% pharmacists, while others were non-pharmacist. The study's results indicate that pharmacists' roles and responsibilities are largely delegated to non-pharmacists. This finding significantly exceeds the

findings of several previous studies conducted in several cities in Indonesia. A study conducted at several pharmacies in East Jakarta found that only 6% of pharmacists provided self-medication services.⁽¹⁰⁾ In another study in pharmacies in Jombang Regency, only 11% of pharmacists provided information on self-medication services.⁽¹¹⁾ Research in pharmacies in the Pekan Baru City area proved that not a single pharmacist collected patient information during self-medication.⁽¹²⁾ Meanwhile, studies in other countries, Germany, reported that only 24% of pharmacists provided services to patients.⁽¹³⁾ There are 3 types of pharmaceutical personnel in Indonesia, namely pharmacists, specialist pharmacists and pharmacy technician.⁽¹⁴⁾ A community pharmacy is a facility where pharmacists practice their profession. In carrying out their practice in a pharmacy, pharmacists may be assisted by other pharmacists and/or pharmacy technician. Treatment for minor ailments is one form of pharmacy service in a pharmacy. Pharmacists, as the most important health professionals in a pharmacy, should be the leading professionals in providing services to community who seek help for their health problems.⁽⁹⁾ The suboptimal role of community pharmacists in providing direct patient care remains a problem in Indonesia, as identified in several previous studies. Existing regulations requiring pharmacies to have only one pharmacist as responsible one, who can be assisted by other pharmacist or pharmacy technician, create the potential for patients to be served exclusively by non-pharmacist (pharmacy technician) during a given service period, as it is impossible for pharmacists to work throughout pharmacy hours.

Table 1. Patient Assessment Process Conducted By Pharmacy Staff

| Poin of assesment | Frequency (N= 43) | Persentage (%) |
|-------------------|-------------------|----------------|
| Age / appearance | 43 | 100 |
| Self/someone else | 37 | 83,72 |
| Medication | 40 | 93,02 |
| Extra medicines | 40 | 93,02 |
| Time persisting | 41 | 95.34 |
| History | 40 | 93,02 |
| Other symptoms | 38 | 88,37 |
| Danger symptoms | 29 | 67,44 |

Patient assessment is an important stage for minor illnesses service that must be carried out by pharmacists.

⁽¹⁵⁾ The purpose of this stage is to gain a more detailed understanding of the patient's presenting condition, ultimately avoiding the risk of errors. To conduct this, pharmacists must be able to gather as much information as possible about the patient's condition. They must listen and ask questions to obtain the necessary information. The information obtained from the patient is used to make decisions about recommending and prescribing medications. ⁽¹⁶⁾ Table 1 describe the patient assessment stage conducted by pharmacists. All respondents obtained information related to the patient's age. The least frequently obtained information was related to potentially dangerous symptoms the patient might be experiencing, at 67.44%. Information regarding patient identification, such as age/appearance and self or someone else, is the initial information pharmacists should inquire about to determine whether the patient is the individual visiting the pharmacy or someone else, possibly a family member. Information regarding age is crucial because it will determine the accuracy of medication and dosage recommendations.⁽¹⁵⁾ This finding is much higher compared to other research in the East Jakarta area, where 56.87% of pharmacy staff conducted information gathering regarding age/appearance.⁽¹⁰⁾

Pharmacy staff should inquire about medication history (the patient's medication history). This was obtained by 93.02% of respondents. This information (whether any medications are being taken regularly) is used to ensure that the patient's diarrhea is not caused by a side effect of medication. Information about extra medication (whether any other medications have been used to treat symptoms) should be inquired. This was obtained by 93.02% of respondents much higher compared to study conducted in East Jakarta where pharmacy staff who inquired about the medications patients currently taking for diarrhea were 5.56%.⁽¹⁰⁾

Information gathering regarding symptoms such as time persisting (how long has the disease been present), history (what is the patient's medical history), other symptoms (are there any other accompanying

symptoms), and danger symptoms (are there any dangerous symptoms shown) is no less important to know because this information can describe the severity of diarrhea so that it can be a consideration for pharmaceutical personnel in pharmacies in providing recommendations, whether in the form of drug product recommendations only or should be referred to a doctor. Pharmacy staff who asked about time persisting were 95.34%, History (93.02%), Other symptoms (88.37%). Information regarding Time persisting is very important to know because if a patient experiences diarrhea for more than 7 days, they must be referred to a doctor.⁽¹⁵⁾ Information regarding history can include frequency of bowel movements and stool consistency.⁽¹⁷⁾ A patient is defined to have diarrhea if they experience a frequency of loose, watery stools > 3 times in a 24-hour period and if they have experienced a frequency of loose stools 6 times or more in a 24-hour period, they must be referred to a doctor.⁽¹⁸⁾ In research in other regions, in the information gathering process, only 16.66% of pharmacy staff asked about the frequency of bowel movements in patients.⁽¹⁹⁾ Other symptoms (are there any other accompanying symptoms) that are asked during the patient assessment include other, less dangerous symptoms such as abdominal cramps, dyspepsia, and nausea. Meanwhile, danger symptoms (are there any dangerous symptoms shown) are important to ask for consideration by pharmacy staff when recommending a referral to a doctor if the patient has other dangerous symptoms or signs. Dangerous diarrhea symptoms that require referral to a doctor include: fever (≥ 38.5 °C), severe abdominal cramps, ≥ 6 loose stools in a 24-hour period, bloody stools, symptoms lasting 7 days, symptoms of dehydration (dark urine, decreased urine output, marked thirst, dizziness, dry mouth, decreased skin turgor, weight loss).⁽¹⁵⁾

Table 2 showed the medications recommended by pharmacy staff to patients. In the study scenario, the patient experienced diarrhea without any signs of dehydration or other serious symptoms. It can be seen that 48.84% of respondents recommended zinc and oral rehydration salts in accordance with the World Health Organization's recommendations for treating mild diarrhea without dehydration, as can be seen in Table 3.

Table 2. Profile of medicine recommended by pharmacists

| No | Medicine | Frequency | Percentage (%) |
|----|---|-----------|----------------|
| 1 | Diapet (Guava leaf extract and turmeric (herbal)) | 1 | 2,33 |
| 2 | Kaolin-pectin + probiotic | 1 | 2,33 |
| 3 | probiotic, kaolin-pectin, Diapet | 1 | 2,33 |
| 4 | Nifuroxazide | 1 | 2,33 |
| 5 | Probiotic, Oralit | 1 | 2,33 |
| 6 | Kaolin-pectin | 3 | 6,98 |
| 7 | One brand of probiotic | 10 | 23,26 |
| 8 | two different brand of probiotics | 3 | 6,99 |
| 9 | three different brand of probiotics | 1 | 2,33 |
| 10 | Zinc dan Oralit | 21 | 48,84 |

Table 3. Management of diarrhea without dehydration based on WHO guidelines⁽²⁰⁾

| Diarrhea without dehydration therapy | |
|---|--|
| 1. | administer more fluids than usual. Administer ORS until the diarrhea stops. If vomiting occurs, wait 10 minutes and then gradually increase the dose. Children over 1 year old should be given 100-200 ml each time they have diarrhea. |
| 2. | administer zinc medication administer zinc for 10 consecutive days, even if the diarrhea has stopped. It can be given by chewing or dissolving it in 1 tablespoon of boiled water. Children over 6 months old are given 20 mg (1 tablet) per day. |
| 3. | Provide Food to Prevent Malnutrition <ul style="list-style-type: none"> • Provide age-appropriate food with the same menu as when the child was healthy. • Add 1-2 teaspoons of vegetable oil to each meal. • Provide potassium-rich foods such as fresh fruit juice, bananas, and green coconut water. • Provide smaller portions more frequently than usual (every 3-4 hours). • After the diarrhea stops, provide the same food and additional food for 2 weeks. |

Diarrhea without dehydration therapy

4. Advise the mother/caregiver to bring the child back to staff if:
- Watery stools more frequently
 - Recurrent vomiting
 - Very thirsty
 - Eat and drink very little
 - Fever develops
 - Bloody stools
 - Does not improve within 3 days

The study results showed that 48.84% of pharmacy staff provided recommendations consistent with WHO recommendations for diarrhea management, namely administering oral rehydration salts (ORS) and zinc supplements. This finding is higher than a similar study conducted in Surabaya, where only 13.09% of pharmacists provided appropriate recommendations for zinc and ORS.⁽²¹⁾^{81%} The results of a similar study conducted in Ethiopia reported higher results that more than 90% of pharmacists recommended oralit and zinc.⁽²²⁾ Oral rehydration salts (ORS) are essential because toddlers with diarrhea lose a lot of fluid, so the focus of treatment is to prevent dehydration. Even if there are no symptoms of dehydration, patients still need to be given ORS to replace water and electrolytes lost due to diarrhea. If ORS is not given, signs of dehydration can develop and worsen the patient's condition. Meanwhile, zinc is needed immediately after diarrhea begins to reduce the duration and severity of diarrhea and the risk of dehydration. Zinc should be given for 10 days, even if the diarrhea has stopped, the goal is to prevent diarrhea from recurring within the next 3 months.⁽²⁰⁾ According to the medical guidelines for acute diarrhea issued by the Indonesian Pediatrician Association, antidiarrheal medications are unnecessary for toddlers. When toddlers have diarrhea, there is increased motility and peristaltic movement in the intestines, which usually causes nausea, vomiting, and diarrhea to expel waste and toxins from the body. If given antidiarrheals, this peristaltic movement will inhibit, so that waste that should be excreted is actually hampered. Therefore, the focus of toddler diarrhea treatment is not on administering medication, but rather on preventing the patient from becoming dehydrated. Because

dehydration can worsen the patient's health.⁽²³⁾ Zinc is a micronutrient in the body that can inhibit the enzyme INOS (Inducible Nitric Oxide Synthase), which can increase during diarrhea and can cause intestinal epithelial hypersecretion. Using zinc in recommended doses can reduce the incidence of diarrhea for the next 3 months, and reduce accidental deaths by 50%. According to the WHO and the Indonesian Ministry of Health's toddler diarrhea guidebook, the appropriate recommendation for toddler diarrhea is to provide a combination of ORS and zinc. Providing zinc alone cannot be considered appropriate, because zinc only plays a role in the epithelialization of the intestinal wall that experiences morphological and functional damage during diarrhea.⁽²³⁾ Meanwhile, toddlers with diarrhea should also be given electrolyte fluids, so using zinc alone without a combination of oral rehydration salts cannot be said to be appropriate. Another interesting finding from this study was that quite a number of pharmacy staff recommended probiotics. This is in line with research in Turkey, where probiotics were more commonly used to treat infant diarrhea than other diarrhea medications, either alone or in combination with other medications.⁽²⁴⁾ Probiotics are live, non-pathogenic microorganisms. When consumed, they survive passage through the stomach and small intestine. Research has shown that probiotics are effective in reducing the duration of diarrhea by 14% and the frequency of bowel movements on the second day of treatment by 13.10% in pediatric patients with acute diarrhea.⁽²⁵⁾ The high number of pharmacy staff who do not follow WHO recommendations for giving medications for diarrhea may be due to limited knowledge and a lack of updating on current treatment trends. Professional organizations and the Ministry of Health have made efforts to maintain and improve the competence of pharmacists through seminars, workshops, and other similar activities.

Patients need to be provided with adequate information regarding the medications/pharmaceutical preparations they receive. Table 4 showed the drug information provided by pharmacists to patients. It can be seen that the most common information provided by pharmacists was information on how to use, at 97.14%, followed by information on the time of use, indications, duration

of use, and dosage, at 92.5%, 89.64%, 88.57%, and 88.21%, respectively. Information regarding drug indications needs to be provided so that patients know what medication they are taking and can feel calm and confident that the medication they are taking is appropriate for their symptoms. In this study, although not all pharmacies provided information regarding indications, the percentage was quite good compared to studies in other areas, where information on indications provided by pharmacy staff in the Mertiyudan District was only 7%.⁽²⁶⁾

Table 4. Drug information items provided by pharmacy staff

| Point of drug information | Percentage (%) |
|-----------------------------|----------------|
| indication | 89.64 |
| contraindication | 67.38 |
| Side effect | 83.09 |
| How to take | 97.14 |
| dose | 88.21 |
| Time of administration | 92.5 |
| duration | 88.57 |
| Attention/warning | 80.91 |
| storage | 83.76 |
| Treatment of residual drugs | 67.57 |
| Identify damaged drugs | 55.79 |

Information on how long the medication should be used is also important. Knowing how long patients can self-medicate without a doctor's help is crucial so they know when to seek medical help if the condition persists. Information about medication side effects is crucial so patients can be more vigilant when taking their medication and be more aware of any unusual symptoms, allowing them to stop taking the medication and see a doctor immediately. For example, information provided by pharmacists about the side effects of kaolin-pectin, which can cause itching. However, this is not a cause for concern, as the itching is usually brief and does not occur in all patients. Overall, more than half of the respondents reported receiving these information points based on this study. This result is significantly higher than that of a study conducted in East Jakarta, where pharmacy staff did not provide any information regarding side effects, drug interactions, storage instructions, precautions/warnings, contraindications, handling

of leftover medication, or identification of damaged medication.⁽¹⁰⁾

Conclusion

Pharmaceutical services by pharmacy staff for pediatric patients with acute diarrhea without dehydration in pharmacies in South Tangerang city can be said to be good in terms of patient assessment and drug information provided to patients, however, in terms of appropriate drug recommendations to patients, only 48.84% of pharmacy staff gave medication recommendation in accordance with WHO guideline. Pharmacy staff still need to improve their services to patients so that therapeutic goals can be achieved optimally. Other methods besides interviews in evaluating the implementation of pharmaceutical services are recommended, such as the simulated patient method.

Source of funding: I declare that no funding or financial aid was taken for the conducting of this study which could influence the work reported.

Conflict of Interest: NIL

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