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World Environment Day 2026: 5th June 2026 (Friday)

Ranjan Bhattacharyya

Journal of the Indian Medical Association (2026): 10.5005/jima-11070-0023

Theme for World Environment Day 2026

Inspired by Nature. For Climate. For Our Future

Nature has sustained life for millions of years. By embracing nature-based solutions, protecting ecosystems, and adopting sustainable practices, we can address climate change and secure a healthier, greener future for generations to come.

Source: https://www.banyannation.com/blog/world-environment-day-2026/

World Environment Day 2026: Theme

The theme for World Environment Day 2026 has just been declared as "Inspired by Nature. For Climate. For Our Future."

The World Environment Day 2026 theme, "living with nature," is clearly directed toward nature-based solutions to resolve carbon build-up in the atmosphere. This year's theme of the World Environment Day is calling to mind the need to change the way industries conduct their business by adopting closed-loop systems, where the idea of waste or trash is eliminated, and where each product becomes a clean raw material for a second life.[1]

World Environment Day 2026: Significance and Importance

What makes the global World Environment Day 2026 significant is its ability to motivate direct legislative measures and to publicly rebuke industrial polluters.[2]

Some of the World Environment Day 2026 significance from the day include:

- *Enforcing policy mandates*: On this day, governments are implementing more stringent Extended Producer Responsibility (EPR) rules and plastic neutrality targets.
- *Global leadership*: To establish a unified platform for transnational pollution and a shared degradation of the marine environment to be discussed by environmental ministries around the world.
- *Driving capital investment*: Initiative for such investment in advanced waste processing infrastructure and circular tech platforms, including by VC, and green bond funding.

The significance of World Environment Day 2026 lies in its ability to bring abstract scientific information to the concrete level of citizens' everyday demands.

World Environment Day 2026: Host Country

World Environment Day 2026 will be hosted by the Republic of Azerbaijan, and the main global events will be held in the historic capital city of Baku. 2026 is the international climate diplomacy's official host country, and Azerbaijan, in close partnership with the United Nations Environment Program (UNEP), is playing the key role in the very center of international climate diplomacy.

Azerbaijan is the host country for World Environment Day 2026 this year, and is promoting its national ambitions to inject 20% renewable energy into the country by 2030, to establish more forest conservation zones and to invest significantly in high-tech and waste-free processing plants.[3]

World Environment Day 2026: Activities

World Environment Day 2026 activities have been organized across the globe to mobilize communities and promote involvement of all people across all walks of life, from being just observers to active participants. World Environment Day 2026 activities that can be implemented at the local level to make the measure of sustainability more tangible and measurable, to be able to scale up the local sustainability measure and contribute to the global one for World Environment Day 2026.[4,5]

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Some activities of interest on a global and regional scale are:

- Industrial compliance audits: Companies will be conducting full plastic footprint audits to identify and eliminate multilayered plastic from their product lines that are not easily recyclable.
- Massive tree planting drives: Urban reforestation drives focusing on urban heat islands; restoration of natural biodiversity and decrease of localized temperatures through reforestation drives.
- Community clean-up mobilizations: Community clean-up mobilizations: coastal and riverbed clean-up volunteer community mobilizations to help prevent plastic leakage into coastal pathways.
- Educational codeathons: Schools and Universities with engineering codeathons to improve mechanical waste sorting algorithms.

World Environment Day 2026: Slogan and Awareness Messages

The world's climate change 2026 slogan is a powerful and simple message that is effective across all cultures and linguistic groups. The World Environment Day 2026 slogan, "Inspired by Nature. For Climate. For Our Future," is a powerful statement that conveys the message of environmental chemistry and the urgency of taking action.

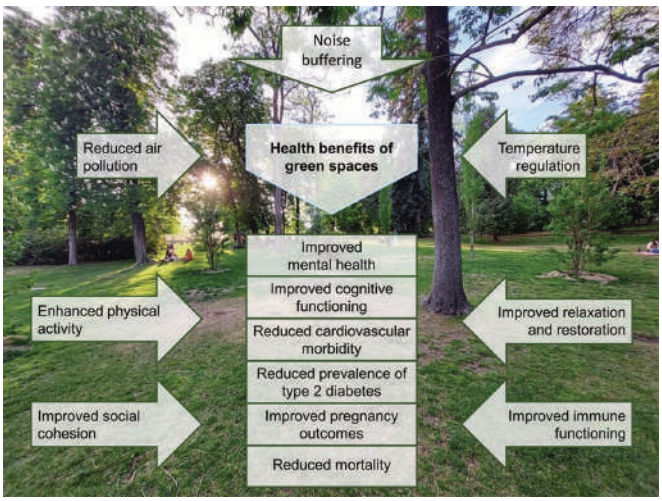
This year, some popular slogans/messages to raise awareness are:

- "Inspired by Nature. For Climate. For Our Future" #ForClimateNow
- ACT # ForClimateNow" Nature is not an option; it is our future."
- Each piece of plastic that is tossed costs the Earth peace; take the step to close the loop today.
- Do not have to give up something that cannot be replaced: Save the planet, not just for convenience.
- Plastic is not biodegradable, but if we work together, we can end the linear extraction system.

Environment and Health

The environment is one of the most important determinants of human health. Clean air, safe water, nutritious food, stable climate, and healthy ecosystems are essential for physical and mental well-being.

How the Environment Affects Health



Source: World Environment Day 2026

Air Quality

- Air pollution contributes to asthma, chronic obstructive pulmonary disease (COPD), lung cancer, heart disease, and stroke.
- Exposure to pollutants can affect children, older adults, and people with chronic illnesses more severely.

Water and Sanitation

- Access to safe drinking water and proper sanitation prevents diarrheal diseases, cholera, typhoid, and other infections.
- Contaminated water remains a major public health challenge in many regions.

Climate Change

- Rising temperatures increase heat-related illnesses and deaths.
- Extreme weather events such as floods, droughts, and cyclones can cause injuries, displacement, food insecurity, and mental health problems.
- Climate change can alter the distribution of vector-borne diseases such as malaria and dengue.

Biodiversity and Ecosystems

- Healthy ecosystems provide clean air, water filtration, pollination, and food security.
- Biodiversity loss can disrupt ecosystem services that support human health.

Built Environment

- Safe housing, green spaces, walkable communities, and sustainable transportation promote physical activity, mental well-being, and social connectedness.

How the Environment Affects Mental Health

Source: World Environment Day 2026

Access to Nature

- Exposure to green spaces, parks, forests, and natural landscapes is associated with reduced stress, anxiety, and depression.
- Time spent in nature can improve mood, attention, and psychological resilience.

Climate Change and Ecoanxiety

- Climate change can contribute to feelings of worry, grief, helplessness, and uncertainty about the future.
- Extreme weather events may lead to trauma, anxiety, depression, and post-traumatic stress symptoms.

Air and Noise Pollution

- Chronic exposure to air pollution has been linked to increased risks of depression and cognitive decline.
- Excessive noise from traffic, industry, or crowded urban settings can increase stress, sleep disturbances, and psychological distress.

Housing and Urban Environment

- Overcrowding, poor housing conditions, lack of green spaces, and unsafe neighborhoods can negatively affect mental well-being.
- Well-designed communities that encourage social interaction and physical activity support better mental health.

Social Environment

- Strong community networks and social support promote resilience and emotional well-being.
- Social isolation and environmental adversity can increase vulnerability to mental health problems.

Why It Matters

Source: World Environment Day 2026

Mental health and environmental health are closely connected. Actions that create cleaner, greener, safer, and more sustainable environments can improve both individual and community well-being.

What Does "Inspired by Nature" Mean?

Source: World Environment Day 2026

- Learning from natural systems to create sustainable solutions.
- Protecting biodiversity and ecosystems that support life.

- Using nature-based approaches such as afforestation, wetland restoration, and sustainable agriculture.
- Promoting health and well-being through cleaner environments and access to green spaces.

Why Nature Inspires Climate Action

- Forests absorb carbon dioxide and help regulate climate.
- Wetlands reduce flooding and improve water quality.
- Mangroves protect coastal communities from storms.
- Biodiversity strengthens ecosystem resilience.

Why Climate Matters for the Future

Health

- Rising temperatures increase heat-related illnesses.
- Air pollution and changing disease patterns affect public health.
- Extreme weather events can impact physical and mental well-being.

Food and Water Security

- Climate change can affect crop yields and food availability.
- Droughts and floods threaten access to safe water.

Economy and Livelihoods

- Agriculture, fisheries, and many industries are vulnerable to climate impacts.
- Investing in sustainable development creates opportunities for green jobs and innovation.

Future Generations

- Children and young people will experience the long-term consequences of today's environmental decisions.
- Climate action today helps ensure a safer, healthier, and more sustainable future.

Climate and Our Future

Climate change is not only an environmental issue—it is a health, economic, and social challenge that will shape the future of communities worldwide. The actions taken today will determine the quality of life for future generations.

Inspired by Nature

Nature is our greatest teacher. For millions of years, ecosystems have adapted, balanced resources, and sustained life. By learning from nature and working with it rather than against it, we can develop solutions to environmental, health, and climate challenges.

World Environment Day Themes (Last 10 Years)

Year	*Theme*
2026	Climate Action
2025	Beat Plastic Pollution
2024	Land Restoration, Desertification and Drought Resilience–"Our Land. Our Future. We are #GenerationRestoration"
2023	Solutions to Plastic Pollution–"#BeatPlasticPollution"
2022	Only One Earth
2021	Ecosystem Restoration–"#GenerationRestoration"
2020	Biodiversity
2019	Air Pollution–"Beat Air Pollution"
2018	Beat Plastic Pollution
2017	Connecting People to Nature
2016	Go Wild for Life (Zero Tolerance for the Illegal Wildlife Trade)

Major Trends over the Decade

Plastic Pollution

- Featured prominently in 2018, 2023, and 2025.
- Focus on reducing single-use plastics and improving waste management.

Nature and Biodiversity

- Themes in 2017, 2020, and 2021 emphasized protecting ecosystems and restoring degraded environments.

Climate and Sustainability

- Increasing focus on climate resilience, land restoration, and sustainable development, culminating in the 2026 theme Climate Action.

Human Health and Environment

- Air pollution (2019), biodiversity (2020), and climate action (2026) highlight the close connection between environmental protection and human health.

Take-home Message

1. "Be the change the climate needs—protect nature, reduce emissions, and build a sustainable future for all."
2. "Every action for nature is an action for the climate—and for our future."
3. "World Environment Day 2026 emphasizes the urgent need for climate action, highlighting both the signals the Earth is sending—rising temperatures, extreme weather, melting glaciers—and the positive actions people, communities, businesses, and governments can take to accelerate the transition to a sustainable future."
4. "Protect the environment, protect health—our future depends on both."
5. "Healthy Environment, Healthy People: Climate Action for a Sustainable Future."
6. "Caring for the environment is also caring for mental health—healthy planet, healthy minds."
7. "Climate action today is the foundation of a healthier, safer, and more sustainable tomorrow."
8. "Inspired by nature, we find the wisdom to protect our climate and secure our future."
9. "When we work with nature, we protect the climate, improve health, and create a better future for all."
10. Over the past decade, World Environment Day has evolved from raising awareness about specific environmental threats to promoting integrated solutions that link nature, climate, biodiversity, pollution control, and human well-being. The overarching message remains: Protect nature, reduce pollution, and act on climate change to secure a healthy future for people and the planet.

Source: World Environment Day 2026

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ORIGINAL ARTICLE

Assessment of Quality of Life in Chronic Spontaneous Urticaria: An Institution-based Cross-sectional Study

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Abstract

Background: Chronic spontaneous urticaria (CSU) is a distressing skin disorder affecting approximately 0.5–1% of the population. It significantly impairs patients' quality of life (QoL), making it a public health concern, especially among working professionals. Various socioeconomic and personal factors—such as employment, health status, and financial security—affect QoL. Early diagnosis and intervention may improve outcomes and reduce both psychological and economic burden.

Materials and methods: This cross-sectional observational study was conducted over a 3-month period at the Dermatology Outpatient Department of the College of Medicine and Sagore Dutta Hospital, Kolkata. 64 CSU patients were selected by census sampling from outpatient records. After informed consent, sociodemographic data were collected. Disease severity was assessed using the Urticaria Activity Score-7 (UAS-7) and Urticaria Control Test (UCT). Quality of life was evaluated using the Dermatology Life Quality Index (DLQI). Data were analyzed using appropriate statistical methods.

Results: The mean age of participants was 37 ± 11 years (M:F = 16:48), with disease duration ranging from 6 weeks to 5.5 years (mean 53 weeks). Angioedema was reported in 39%, and 45% had symptomatic dermatographism. Mean UAS-7 was 17.5 ± 9.5, UCT 9.5 ± 2.5, and DLQI 9.06 ± 8.8. QoL was impaired in 59% (38/64), with 43.8% (28/64) experiencing a large to extremely large effect. DLQI positively correlated with UAS-7 ($r = 0.8$, $p < 0.0001$).

Conclusion: QoL is markedly impaired in CSU, especially in severe cases and those with angioedema. Disease severity is the key determinant. A multidisciplinary approach, including psychological support, is essential to optimize care and outcomes.

Take-home message: CSU significantly impairs patients' QoL, especially in those with severe symptoms, lower socioeconomic status, and elevated IgE. Assessment of QoL alongside clinical severity is essential for comprehensive care. A multidisciplinary approach addressing both physical and psychological aspects can lead to improved patient outcomes.

Keywords: Chronic spontaneous urticaria, Dermatology life quality index, Quality of life, Urticaria activity score-7, Urticaria control test.

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Introduction

Chronic spontaneous urticaria (CSU) is a persistent dermatological disorder characterized by the spontaneous occurrence of wheals, angioedema, or both, lasting longer than six weeks without an identifiable external trigger. It affects approximately 0.5–1% of the general population and is associated with considerable disease burden.[1]

Lesions are typically erythematous, pruritic, and transient, but their recurrent and unpredictable nature leads to significant discomfort and psychological distress. Although non–life-threatening, CSU can severely impair patients' quality of life (QoL). Sleep disruption, chronic itch, and the aesthetic impact of skin lesions contribute to anxiety, depression, and reduced work productivity. QoL is a multidimensional construct encompassing physical, psychological, and social well-being, and it is increasingly recognized as a key outcome measure in chronic dermatologic conditions.[2]

Several studies have highlighted the psychosocial impact of CSU. Dias et al. reported depressive disorders in 40% of patients and found that 81% attributed their illness to life stress, with a significant negative impact on QoL ($p \leq 0.005$), underscoring the psychosomatic interplay in CSU pathophysiology.[3] Importantly, the impact of CSU on QoL may not always parallel clinical severity; stigmatization, unpredictability of flare-ups, and inadequate symptom control often exacerbate the emotional burden.[4,5]

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Conflict of interest: None

Recent studies reinforce this global concern. Moreira et al. in Brazil found a high prevalence of emotional distress, sleep disturbance, and social withdrawal among CSU patients, even in those with mild symptoms.[6] Similarly, Das et al. in Nepal reported that over 70% of patients experienced moderate to severe QoL impairment, with a positive correlation between symptom severity and DLQI scores.[7]

These findings highlight the universal relevance of QoL assessment in CSU and the need for holistic management approaches.

Given this background, the present study was undertaken to evaluate the impact of CSU on patients' QoL in an Indian population. The primary objectives were:

- To determine the proportion of patients with CSU who experience impaired QoL
- To assess the relationship between clinical severity and the degree of QoL impairment.

By addressing these issues, the study aims to emphasize the burden of CSU beyond physical symptoms and to support the case for integrated, multidisciplinary management.

Materials and Methods

This observational, institution-based cross-sectional study was conducted in the Department of Dermatology in collaboration with the Department of Psychiatry at the College of Medicine and Sagore Dutta Hospital, Kolkata. The study was carried out over a period of three months, from August 1, 2023 to October 31, 2023. The study population consisted of patients attending the Dermatology Outpatient Department who were newly diagnosed with CSU. A total of 64 patients were enrolled using the census method, wherein all eligible patients presenting during the study period were included.

Inclusion criteria were patients of either gender, aged between 18 and 70 years, who were newly diagnosed with CSU. Patients were excluded if they had other dermatological conditions that could confound the diagnosis (e.g., scabies, xerosis, or Hodgkin's lymphoma), other chronic illnesses, allergic disorders (such as atopic dermatitis, allergic rhinitis, or asthma), or immunosuppressive conditions like HIV.

Prior to participation, all patients were informed in detail about the nature, purpose, and procedures of the study in a language they could understand. Written informed consent was obtained from each participant, and confidentiality was maintained throughout the study.

The study was conducted after getting due permissions from the Institutional Ethical Committee of the College of Medicine and Sagore Dutta Hospital.

Each participant underwent comprehensive sociodemographic and clinical history documentation. A 5 mL blood sample was collected after overnight fasting. After centrifugation, serum was analyzed for IgE.

To assess disease severity and QoL, three validated instruments were used: Urticaria Activity Score over 7 days (UAS-7) to evaluate symptom severity,[8] Urticaria Control Test (UCT) to assess disease control,[8] and Dermatology Life Quality Index (DLQI) to measure the impact of CSU on QoL.[9,10] Data were analyzed using Microsoft Excel software. Descriptive and inferential statistical analyses were applied as appropriate.

Results

The study population consisted of 64 patients with CSU, comprising 48 females and 16 males. The male-to-female (M: F) distribution was 9:17 in the first group (no to small QoL effect), 3:7 in the second group (mild to moderate effect), and 4:24 in the third group (large to extremely large effect). Mean age was 37 ± 11 years, with subgroup means of 36 ± 11 years (first group), 37 ± 12 years (second group), and 38 ± 2 years (third group).

Regarding education, 50% of patients had formal education up to class VIII. In subgroup analysis, this was observed in 54% of patients in the first group, 30% in the second, and 54% in the third group. Socioeconomic status distribution showed 64% of patients belonged to lower SES, 28% to middle, and 8% to upper SES category. Group-wise, lower SES patients constituted 65%, 60%, and 64% in the first, second, and third groups, respectively.

Mean disease duration was 13.4 ± 17.5 months, with 69% of patients presenting within 1 year of onset. Subgroup-wise, 65% (first group), 60% (second group), and 75% (third group) reported within 1 year of symptom onset. Angioedema was present in 39% of the total population. In subgroup distribution, it was observed in 35% (first group), 20% (second group), and 50% (third group). Symptomatic dermatographism was reported by 45% of all patients, distributed as 46% in the first group, 30% in the second, and 50% in the third.

Mean serum IgE was 209.9 ± 235.8 IU/mL, with subgroup means of 198.7 ± 177.3 (first group), 240.4 ± 264.9 (second group), and 209.5 ± 277.0 (third group).

The overall mean DLQI score was 9.06 ± 8.8. A total of 59% of patients demonstrated impaired QoL, with 41% reporting no impact, 16% experiencing mild to moderate impact, and 43% reporting a large to extremely large impact.

Disease severity was assessed using UAS-7 and UCT. The mean UAS-7 score was 17.5 ± 9.5, with group-wise means of 10.5 ± 6.0 (first group), 15.3 ± 6.1 (second group), and 24.8 ± 7.9 (third group). Mean UCT score was 9.7 ± 2.5 overall, with group scores of 9.9 ± 1.9, 8.7 ± 3.2, and 9.9 ± 2.7 in first, second, and third groups, respectively.

Disease severity distribution indicated that 58% of patients in the first group had mild severity, while 40% in the second group and 54% in the third group had moderate severity. A significant positive correlation was observed between UAS-7 scores and DLQI scores ($r = 0.8$, $p < 0.0001$), indicating greater QoL impairment with increasing disease severity.

Overall, 73% of patients were found to have uncontrolled disease. This included 85% in the first group, 80% in second, and 61% in third group.

Discussion

CSU is a long-standing dermatological condition that significantly affects patients' QoL. Beyond classic symptoms of pruritus and transient wheals, patients often experience anxiety, social embarrassment, disturbed sleep, and reduced productivity. Unpredictability of flare-ups, combined with their persistence, contributes substantially to psychological stress. As such, a holistic approach to assessing CSU is essential—one that considers not only clinical severity but also patient-reported outcomes.

In our study, the impact of CSU on QoL was evaluated using DLQI, a validated instrument widely used in dermatological research. A significant proportion of patients (59%) exhibited impaired QoL, with 43% experiencing a large to extremely large effect. This reinforces existing evidence that CSU is more than a cutaneous disorder; it is a chronic disease that disrupts daily functioning and mental well-being.

A notable gender disparity was observed, with 75% of participants being female. This finding aligns with previous epidemiological data suggesting that CSU is more prevalent among women, potentially due to hormonal or immunological factors. Additionally, patients from lower socioeconomic strata (64%) and those with limited education (up to class VIII) reported greater QoL impairment, highlighting the influence of social determinants on disease burden.

Disease severity as measured UAS-7 demonstrated a strong positive correlation with DLQI scores ($r = 0.8$, $p < 0.0001$),

indicating that higher symptom burden is associated with greater QoL disruption. This supports clinical utility of combining symptom scoring with QoL assessment in routine practice. Jáuregui et al. also reported that CSU is a chronic, insidious condition with symptoms that vary significantly over time, often leading to considerable QoL impairment, especially in poorly controlled cases.[1] Their findings support strong correlation we observed between UAS-7 and DLQI, reinforcing the importance of comprehensive patient monitoring.

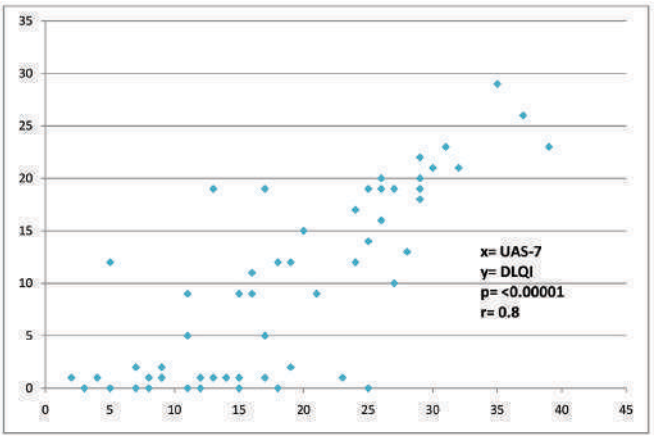

Fig. 1: Scatter diagram showing linear correlation between UAS-7 and DLQI Score

Majority of patients (69%) presented within one year of symptom onset, suggesting early disease impact is significant enough to prompt medical consultation. Despite this, 73% of the cohort had uncontrolled disease activity, and among them, over half (53%) had impaired QoL, with nearly 68% reporting large to very large effect. These findings suggest a gap between clinical management and patient-perceived disease control.

Elevated serum IgE were seen in 44% of cases, of which 54% reported impaired QoL. Among these, 67% experienced large to extremely large QoL impact, pointing toward a possible association between atopic profile and disease burden—although this requires further investigation.

Our findings emphasize the multifactorial nature of QoL impairment in CSU, influenced by disease severity, socioeconomic factors, and possible immunological markers. Comprehensive and multidisciplinary management, including dermatological care, psychological support, and patient education—is essential for improving both clinical outcomes and overall QoL in patients with CSU (Fig. 1 and Table 1 and 2).

Conclusion

Chronic spontaneous urticaria is a distressing condition that significantly impairs patients' quality of life, particularly among

Table 1: Sociodemographic data and disease characteristics

Sociodemographic and disease characteristics		*n = 64*
Age (mean ± SD)		37 ± 11
Gender (M:F)		16:48
Education, *n* (%)	<Class VIII	32 (50)
	≥Class VIII	32 (50)
SES, *n* (%)	Lower	41 (64)
	Middle	18 (28)
	Upper	5 (8)
Duration, mean ± SD		13.4 ± 17.5
Duration, *n* (%)	≤12 months	44 (69)
	>12 months	20 (31)
Angioedema, *n* (%)	Present	25 (39)
	Absent	39 (61)
Symp dermatographism, *n* (%)	Present	29 (45)
	Absent	35 (55)
Quality of life	Not impaired	26 (41)
	Impaired	38 (59)
UAS-7 score, mean ± SD		17.5 ± 9.5
UAS-7 grading, *n* (%)	Well controlled	10 (15)
	Mild	20 (30)
	Moderate	22 (35)
	Severe	12 (20)
UCT score, mean ± SD		9.7 ± 2.5
UCT grading, *n* (%)	Controlled	17 (27)
	Uncontrolled	47 (73)
IgE, mean ± SD		209.9 ± 235.8
IgE grading, *n* (%)	Normal	36 (56)
	High	28 (44)

Table 2: Impact of CSU on quality of life

Sociodemographic and disease characteristics	*No to small effect on QoL (n = 26)*	*Mild to moderate effect on QoL (n = 10)*	*Large to extreme effect on QoL (n = 28)*	*p-value*
Age, mean ± SD	36 ± 11	37 ± 12	38 ± 2	0.59
Gender (M:F)	9:17	3:7	4:24	0.21
Education, *n* (%)				0.39
<Class VIII	14 (54)	3 (30)	15 (54)	
≥Class VIII	12 (46)	7 (70)	13 (46)	
SES, *n* (%)				0.59
Lower	17 (65)	6 (60)	18 (64)	
Middle	8 (31)	2 (20)	8 (29)	
Upper	1 (4)	2 (20)	2 (7)	
Duration, mean ± SD	12.62 ± 14.10	19.10 ± 24.35	12.10 ± 17.90	0.61
Duration, *n* (%)				0.61
≤12 months	17 (65)	6 (60)	21 (75)	
>12 months	9 (35)	4 (40)	7 (25)	
Angioedema, *n* (%)				0.21
Present	9 (35)	2 (20)	14 (50)	
Absent	17 (65)	8 (80)	14 (50)	
Symptomatic dermatographism, *n* (%)				0.55
Present	12 (46)	3 (30)	14 (50)	
Absent	14 (54)	7 (70)	14 (50)	
UAS-7 score, mean ± SD	10.5 ± 6.0	15.3 ± 6.1	24.8 ± 7.9	< 0.0001
UAS-7 grading, *n* (%)				< 0.0001
Well controlled	7 (27)	2 (20)	1 (4)	
Mild	15 (58)	3 (30)	2 (7)	
Moderate	3 (12)	4 (40)	15 (54)	
Severe	1 (4)	1 (10)	10 (36)	
UCT score, mean ± SD	9.9 ± 1.9	8.7 ± 3.2	9.9 ± 2.7	0.39
UCT grading, *n* (%)				0.12
Controlled	4 (15)	2 (20)	11 (39)	
Uncontrolled	22 (85)	8 (80)	17 (61)	
IgE, mean ± SD	198.7 ± 177.3	240.4 ± 264.9	209.5 ± 277.0	0.55
IgE grading, *n* (%)				0.52
Normal	13 (50)	5 (50)	18 (64)	
High	13 (50)	5 (50)	10 (36)	

those with severe disease, lower socioeconomic status, and elevated immunological markers such as serum IgE. Our study demonstrates a strong correlation between disease severity and quality-of-life impairment, as measured by UAS-7 and DLQI scores. Despite early presentation in the majority of cases, a large proportion of patients remain with uncontrolled disease, underscoring the need for improved therapeutic strategies and comprehensive care.

These findings highlight the importance of integrating QoL assessments into routine clinical practice for CSU. Addressing the physical, emotional, and social dimensions of the disease through a multidisciplinary approach—encompassing dermatological, immunological, and psychological support—can lead to better disease control and improved patient outcomes. Future research should further explore the role of biomarkers such as IgE and develop tailored interventions aimed at minimizing the burden of CSU on patients' lives.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of the College of Medicine and Sagore Dutta Hospital (Approval No. CMSDH/IEC/96/08-2023, dated 31 August 2023).

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analysed during this study are included in this published article.

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AI Use Declaration

AI tools were used only for language editing; all intellectual content was developed by the authors.

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ORIGINAL ARTICLE

TROP-2 Immunohistochemistry: The Evaluation of TROP-2 in the Diagnosis of Thyroid Neoplasms

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Abstract

Background: Thyroid neoplasms encompass a diverse spectrum of benign and malignant tumors, posing diagnostic challenges due to overlapping histomorphological features. Among thyroid malignancies, papillary thyroid carcinoma (PTC) is the most common, accounting for approximately 80% of all thyroid cancers. Among various immunohistochemical markers, TROP-2 (trophoblast cell-surface antigen-2) has emerged as a potential diagnostic and prognostic biomarker in epithelial malignancies. TROP-2, a transmembrane glycoprotein encoded by the *TACSTD2* gene, plays a key role in cell proliferation, adhesion, migration, invasion, and metastasis.

Objective: This study aims to evaluate and validate the diagnostic utility of TROP-2 in thyroid neoplasms using whole-slide immunohistochemistry.

Methods: Out of 60 cases of thyroid neoplasms, 39 cases were TROP-2 positive.

Results: Papillary carcinoma, particularly, showed 81.25% positivity, with the majority showing grade 3+ and grade 2+ positivity. Papillary carcinoma, classic type, showed 90% positivity, and among these, 50% of cases showed grade 3+ strong diffuse positivity. The findings of this study indicate that TROP-2 is frequently overexpressed in PTC, often with significant intensity. Special emphasis is placed on its expression in PTC and its variants, particularly FVPTC, given its diagnostic challenges. The study analyzes the correlation of TROP-2 expression with various clinicopathological parameters, including tumor type and its histological variant.

Conclusion: Its membranous and cytoplasmic staining patterns, along with its distinct expression in PTC subtypes, make it a promising candidate for enhancing diagnostic precision in thyroid histopathology.

Keywords: Papillary thyroid carcinoma, Thyroid neoplasms, Trophoblast cell-surface antigen 2.

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Introduction

Thyroid tumors are a wide spectrum of lesions, ranging from benign nodules to highly aggressive carcinomas. According to the latest GLOBOCAN 2022 data from the International Agency for Research on Cancer (IARC), thyroid cancer ranked 7th globally in incidence, with 821,214 new cases reported and an age-standardized incidence rate (ASR) of 9.1 per 100,000 people.[1] Among various immunohistochemical markers, trophoblast cell-surface antigen-2 (TROP-2) has emerged as a potential diagnostic and prognostic biomarker in epithelial malignancies. TROP-2, a transmembrane glycoprotein encoded by the *TACSTD2* gene, plays a key role in cell proliferation, adhesion, migration, invasion, and metastasis.[2] Initially identified in trophoblastic tissues, TROP-2 has been found to be overexpressed in various human carcinomas, including colorectal, gastric, pancreatic adenocarcinoma, oral squamous cell carcinoma, nonsmall cell lung carcinoma, endometrial, and ovarian carcinoma, with limited expression in normal tissues. Its overexpression has been associated with poor prognosis and aggressive tumor behavior. While TROP-2 has been extensively studied in several malignancies, its role in thyroid neoplasms remains relatively unexplored. Recent studies suggest that TROP-2 expression is significantly higher in papillary thyroid carcinoma (PTC) than in benign thyroid lesions, indicating its potential as a diagnostic marker. The pattern and intensity of TROP-2 staining may vary among different histological variants of PTC, with diffuse positivity in FVPTC and focal membranous staining in other variants.[3] Given these findings, TROP-2 could serve as a valuable immunohistochemical marker in differentiating follicular-patterned thyroid neoplasms and distinguishing malignant from benign lesions. The diagnosis of thyroid tumors primarily relies on hematoxylin and eosin (H&E) stained sections, but in challenging cases, IHC markers such as HBME-1, Galectin-3, CK19, CD56, and TROP-2 help refine the diagnosis. While HBME-1 and Galectin-3 are well-established markers for PTC, their specificity and sensitivity vary, necessitating the exploration of additional markers such as TROP-2.[4,5] Its membranous and cytoplasmic staining patterns, along with its distinct expression in PTC subtypes, make it a promising candidate for enhancing diagnostic precision in thyroid histopathology.

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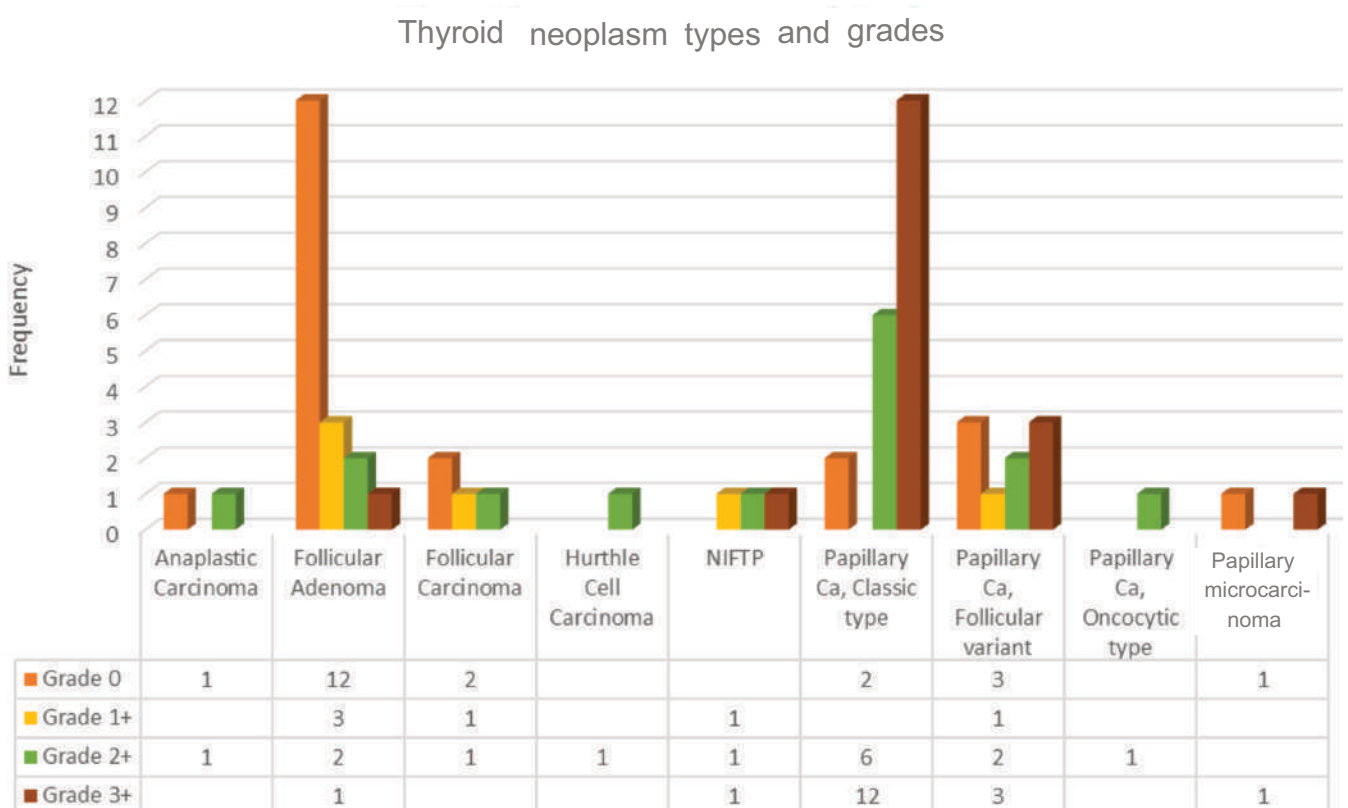
This study aims to evaluate and validate the diagnostic utility of TROP-2 in thyroid neoplasms using whole-slide immunohistochemistry. And its correlation between TROP-2 expression and various clinicopathological parameters, including tumor type, histological variant, tumor size, lymph node status, and extrathyroidal extension.[6]

Materials and Methods

The research includes 60 confirmed cases confirmed by histopathological examination of thyroid gland specimens. This was a cross-sectional analytical study done on 60 thyroidectomy specimens with neoplasm received over the span of 24 months at the Department of Pathology, Dr. D. Y. Patil Medical College, Hospital and Research Center, Pimpri, Pune. The Clinical history and other information were noted from the requisition forms. Ethical approval was received to conduct this study [IESC/PGS/2023/192].

The inclusion criteria included patients of all age and sex groups. All specimens of thyroid neoplasms and the exclusion criteria included poorly fixed or unfixed specimens. Relevant clinical history, presentation, and other details were noted from the requisition form. Sampled tissue was fixed in 10% formalin. The tissue underwent paraffin processing to make blocks. Tissue sections of approximately 3–4 µm thick were cut with a microtome and stained with routine Hematoxylin and Eosin (H&E) stain. Immunohistochemical procedure and staining were performed. 4–5 µm-thick sections from premalignant and malignant cases were taken and subjected to a primary monoclonal antimouse anti-TROP-2 antibody for 1 hour, followed by a secondary antibody. The stained sections were observed under an Olympus research microscope and reported under standard CAP guidelines.

Each type of thyroid tumor exhibited characteristic microscopic features that helped in differentiating between benign and malignant lesions, as well as among the various subtypes of thyroid carcinoma. Among the benign thyroid neoplasms, follicular adenoma microscopy showed well-encapsulated lesions with a uniform population of follicular cells forming colloid-filled follicles with an intact and noninvasive capsule. It lacks the nuclear atypia as seen in papillary carcinoma, with absent or minimal mitotic activity. The malignant neoplasms–PTC showed papillary, follicular, solid, or cystic growth patterns, with the hallmark of PTC being nuclear features of enlarged, overlapping nuclei with Orphan Annie eye nuclei (cleared-out chromatin), nuclear grooves, and pseudo-inclusions. Psammoma bodies were frequently present.[7] Different variants, classic, follicular, and oncocytic variants, were included in the study. Follicular thyroid carcinoma (FTC) microscopy showed a follicular pattern similar to adenoma. Capsular and vascular invasion was seen. Tumor cells invaded blood vessels within or beyond the capsule, and it lacked the nuclear features of PTC. Anaplastic carcinoma was highly undifferentiated and an aggressive type with pleomorphic, giant, spindle-shaped, or squamoid cells. High mitotic activity with atypical mitoses was seen, associated with necrosis and vascular invasion. Hürthle cell carcinoma is a distinct and rare thyroid carcinoma characterized by the presence of Hürthle cells. On microscopy, large, polygonal Hürthle cells with abundant eosinophilic, granular cytoplasm and prominent nucleoli with a trabecular and solid type of growth pattern were seen. The distribution of patients based on the different histopathological variants and their subtypes is elaborated in Figure 1.



	Anaplastic Carcinoma	Follicular Adenoma	Follicular Carcinoma	Hurthle Cell Carcinoma	NIFTP	Papillary Ca, Classic type	Papillary Ca, Follicular variant	Papillary Ca, Oncocytic type	Papillary microcarci-noma
Grade 0	1	12	2			2	3		1
Grade 1+		3	1		1		1		
Grade 2+	1	2	1	1	1	6	2	1	
Grade 3+		1			1	12	3		1

Fig. 1 Bar graph and table showing the distribution of patients according to different histopathologic variants and subtypes, with corresponding TROP-2 expression and grades

Based on the histopathological diagnosis, the tumor sections were selected for IHC. Defining positivity of immunohistochemical stain by the presence of a brown-colored end product (DAB positivity) was indicative of positive immunoreactivity. The intensity of IHC expression of positive controls was utilized as a reference to grade the intensity of IHC expression. Interpretation of immunohistochemistry expression was based on the intensity of IHC expression, which was determined using intensity score criteria, and the scores were interpreted as staining being membranous, with staining intensity grading into three grades:[8–10] grade 0 (negative), grade 1+ (weak positivity): faint, incomplete, or patchy membranous staining in <10% of tumor cells. Grade 2+ (moderate positivity): distinct membranous staining in 10–70% of tumor cells, but not uniform across the tumor. Grade 3+ (strong positivity): intense, well-defined membranous staining in >70% of tumor cells, often associated with aggressive behavior. In addition, a semiquantitative quartile assessment was performed to determine the degree of confluence of TROP-2 staining: scattered expression (<30%): low-level positivity, mostly focal staining. Intermediate expression (30–70%): moderate positivity, often in tumor clusters. Diffuse expression (>70%): strong positivity, covering most tumor cells. For analysis, however, cases were divided binarily into positive (1 to 3+) and negative (0) groups. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 17.0.

Results

This research evaluated TROP-2 expression in 60 thyroid neoplasm specimens to assess its diagnostic potential. All of these 60 cases were subjected to TROP-2 immunohistochemistry. Other parameters included were age, sex, tumor focality, tumor site, tumor size, tumor proliferative activity, TNM staging, tumor necrosis, capsular invasion, angioinvasion, lymphatic invasion, perineural invasion, and extrathyroidal extension. Out of 60 cases, 39 cases were TROP-2 positive and 21 cases were negative. The maximum number of patients fell into the age-group 40–50 years and were females (90%). Among 60 cases, 32 cases were papillary carcinoma, including its subtypes, and 18 cases of follicular adenoma (Table 1).

TROP-2 expression varied across all histological types, with 65% of tumors showing positivity. Papillary carcinoma showed higher positivity (81.25%), especially the classic subtype (90%). Figure 2 shows a pie chart demonstrating the distribution of patients according to histopathological diagnosis. A significant association ($p < 0.001$) was found between TROP-2 grade and both TROP-2 expression and confluence. Higher grades correlated with increased confluence. The key findings of the study were TROP-2 Expression in PTC, where TROP-2 is predominantly expressed in PTC, especially in the classic type.

The results demonstrated TROP-2 positivity in a majority of PTC (classic, follicular, and oncocytic variants), often with moderate to strong intensity (grade 2+ to 3+). Follicular adenomas exhibited variable TROP-2 expression, with some cases showing weak to moderate positivity while others were negative. Noninvasive follicular thyroid neoplasm (NIFTP) cases were positive, showing a range of staining intensities. Follicular carcinomas and anaplastic carcinomas also displayed heterogeneous TROP-2 expression patterns. Overall, TROP-2 expression was more consistently observed and generally more intense in malignant subtypes, especially PTC, compared to benign follicular adenomas, though exceptions were noted in both categories. No significant associations were found between TROP-2 grade and other clinicopathological features like tumor focality, tumor site, or invasive characteristics. TROP-2 expression was more frequently observed in higher tumor stages, particularly in pT1a and pT2, but the association with TNM staging was not statistically significant (Table 2).

Immunohistochemical analysis revealed TROP-2 positivity in a significant proportion of the malignant cases examined, particularly PTC. 26 (81.25%) cases out of 32 cases of papillary carcinoma showed TROP-2 positivity. Among these 26 cases, 16 cases were grade 3 positive, showing diffuse membrane positivity, whereas 9 cases

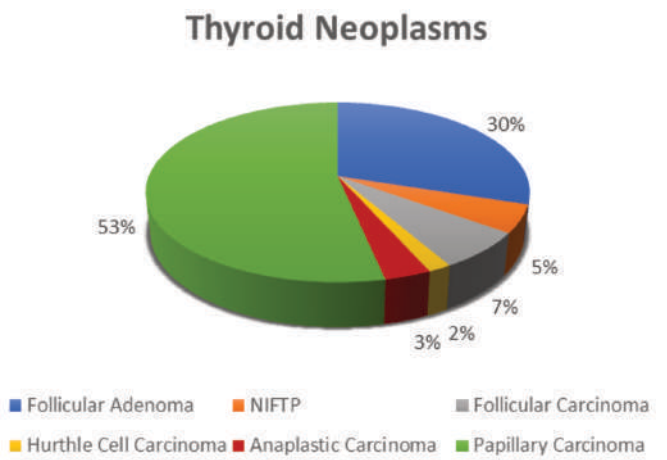


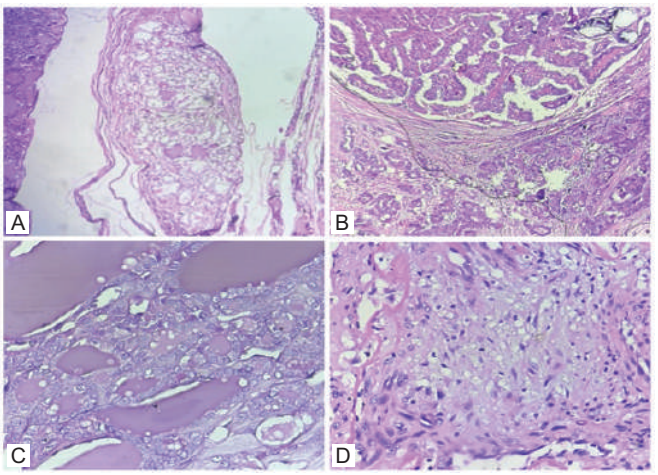
Fig. 2: Distribution of patients according to histopathologic diagnosis

Table 1: Distribution of TROP-2 expression with grades in different histopathological subtypes

Histologic tumor type/subtype	*Grade 0*	*Grade 1+*	*Grade 2+*	*Grade 3+*	*Grand total*
Anaplastic carcinoma	1	–	1	–	2
Follicular adenoma	12	3	2	1	18
Follicular carcinoma	2	1	1	–	4
Hurthle cell carcinoma	–	–	1	–	1
NIFTP	–	1	1	1	3
Papillary carcinoma, classic type	2	–	6	12	20
Papillary carcinoma, follicular variant	3	1	2	3	9
Papillary carcinoma, oncocytic type	–	–	1	–	1
Papillary microcarcinoma	1	–	–	1	2
Grand total	21	6	15	18	60

Table 2: Distribution patients in different subtypes of papillary carcinoma

Papillary carcinoma subtypes	*Frequency*	*Percentage (%)*
Papillary microcarcinoma	2	6.25
Papillary carcinoma, classic type	20	62.5
Papillary carcinoma, follicular type	9	28
Papillary carcinoma, oncocytic type	1	3.1
Total	32	100



Figs 3A to D: Photomicrographs showing: (A) Papillary microcarcinoma; (B) Classic papillary carcinoma; (C) Follicular variant of papillary thyroid carcinoma; and (D) Anaplastic carcinoma of the thyroid with papillary features [Hematoxylin and eosin (H&E), A and B: 100×; C and D: 400×]

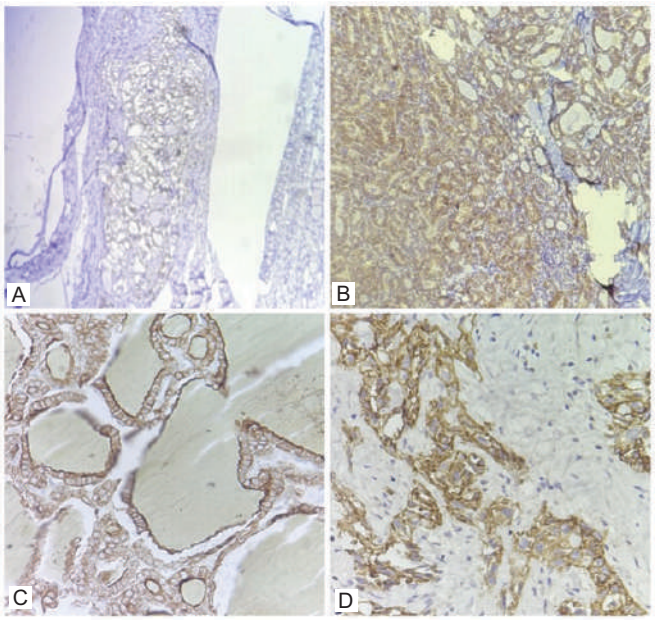
showed moderate grade 2 membrane positivity, and the remaining 1 case showed grade 1 positivity.

Within the PTC Group, Papillary carcinoma classic type was 20 cases, of which 18 cases were positive, and 2 were negative. In contrast, benign lesions such as follicular adenoma showed variable results. Out of the total 18 cases of follicular adenoma, 6 turned out to be TROP-2 positive, where 3 cases were weakly positive (grade 1+), and 2 cases of FA showed grade 2+ positivity, and one showed grade 3+ diffuse positivity. While some cases exhibited positive TROP-2 staining, often weak (grade 1+) or moderate (grade 2+), a notable number, 12 cases of follicular adenomas, were negative for TROP-2.

However, no significant correlation was observed between TROP-2 grade and tumor focality (p = 0.664), tumor site (p = 0.413), tumor necrosis (p = 0.73), capsular invasion (p = 0.728), angioinvasion (p = 0.18), lymphatic invasion (p = 0.68), perineural invasion (NA), or extrathyroidal extension (p = 0.106). For instance, only 5 out of 60 tumors showed tumor necrosis, and TROP-2 grade distribution was not significantly different between necrotic and nonnecrotic tumors (Figs 3 and 4).

Discussion

Thyroid carcinoma has shown varying prevalence across different regions globally. In India, the burden of thyroid cancer has been significant. This study investigated the prevalence of trophoblast cell-surface antigen 2 (TROP-2) expression in a cohort of 60 thyroid neoplasm cases. The findings indicate variable TROP-2 expression across different histological subtypes of thyroid neoplasms. Immunohistochemical analysis revealed TROP-2 positivity in a



Figs 4A to D: Immunohistochemical staining of TROP-2 showing: (A) Membranous positivity in papillary microcarcinoma; (B) Strong, diffuse membranous positivity in classic papillary carcinoma; (C) Grade 2+ membranous positivity in the follicular variant of papillary carcinoma; and (D) Membranous positivity in anaplastic carcinoma [TROP-2, 100×]

significant proportion of the malignant cases examined, particularly PTC. 26 (81.25%) cases out of 32 cases of papillary carcinoma showed TROP-2 positivity. Among these 26 cases, 16 cases were grade 3 positive, showing diffuse membrane positivity, whereas 9 cases showed moderate grade 2 membrane positivity, and the remaining 1 case showed grade 1 positivity.

The data suggest a trend towards higher frequency and intensity of TROP-2 expression in malignant thyroid neoplasms, particularly PTC, compared to benign lesions such as follicular adenoma, although expression was not universally absent in benign cases or universally present in malignant ones. The observation of strong TROP-2 positivity in several PTC cases aligns with findings in other studies suggesting TROP-2's role in epithelial cancers, although direct comparison requires caution. The variable expression patterns underscore the heterogeneity within thyroid neoplasms. Further investigation into the correlation between TROP-2 expression levels and specific clinicopathological parameters, such as TNM stage, invasion patterns, and patient outcomes, would be beneficial, though preliminary observations from this dataset show positive cases across various stages and features.

The study findings indicate that TROP-2 expression is significantly higher in malignant thyroid neoplasms[11,12] than in benign lesions. The intensity and confluence of TROP-2 staining correlate with tumor grade and aggressiveness, suggesting its potential utility as a biomarker for prognosis and targeted therapy. Future research with larger sample sizes and molecular studies may further validate TROP-2 as a promising therapeutic target in thyroid cancers.

The present study observed a high prevalence of TROP-2 expression in thyroid neoplasms, with 65% of cases demonstrating positive TROP-2 staining. These findings are in line with previous studies that reported elevated TROP-2 expression in thyroid malignancies, particularly PTC. Abu-Seadah et al. found that TROP-2 expression was significantly upregulated in malignant thyroid lesions compared to benign follicular-derived thyroid lesions.[13] Similarly, Turan and Erkılıç

identified TROP-2 as a highly sensitive marker for differentiating PTC from benign follicular adenomas, supporting the notion that TROP-2 plays a role in thyroid tumorigenesis.[14] The consistency between these findings suggests that TROP-2 could serve as a reliable marker in distinguishing benign from malignant thyroid neoplasms.

In the current study, a significant proportion of papillary thyroid carcinoma cases exhibited strong TROP-2 expression, corroborating findings from Attia et al., who demonstrated that TROP-2 is specifically overexpressed in PTC compared to other thyroid neoplasms.[15,16] Eid and Abo Safia also highlighted the diagnostic utility of TROP-2 in PTC, emphasizing its potential in distinguishing PTC from follicular neoplasms. These findings align with the present study's results, which suggest that TROP-2 expression could serve as a useful adjunct marker in PTC diagnosis.

The distribution of tumor focality in this study showed that the majority of cases were unifocal (60.0%), while 40.0% were multifocal. This finding is in agreement with Seok et al., who reported a similar distribution of tumor focality in their cohort of thyroid carcinoma cases.[17] Additionally, Saffar et al. (2021) found that multifocality in PTC correlated with higher TROP-2 expression, which is consistent with the current study's findings.[18] The clinical significance of these findings suggests that TROP-2 expression may be associated with more aggressive disease phenotypes in multifocal PTC.

Limitations

The relatively small number of cases (n = 60) may limit the generalizability of the findings to a broader population. This study did not incorporate molecular profiling (e.g., BRAF, RAS, RET/PTC mutations) to further delineate the role of TROP-2 in different genetic subtypes. Also, this study was conducted at a single institution, which may introduce selection bias and limit external validity. Since patient follow-up data were not included, the prognostic significance of TROP-2 expression remains to be fully elucidated.

Future Aspects

The future of TROP-2 research in thyroid neoplasms holds several promising directions. Ongoing advancements in antibody-drug conjugates targeting TROP-2 could provide novel therapeutic options for aggressive thyroid cancers. Integration of TROP-2 expression analysis in personalized treatment strategies could help tailor therapy based on individual tumor biology.

Conclusion

This study highlights the significant role of TROP-2 as a diagnostic marker in thyroid neoplasms, particularly in distinguishing papillary thyroid carcinoma from other follicular-patterned lesions. The findings of this study indicate that TROP-2 is frequently overexpressed in PTC, often with significant intensity. However, its use as a broad marker for all thyroid neoplasms is limited. With further validation, TROP-2 could become an integral part of the clinical workflow for diagnosing and managing thyroid cancer, ultimately improving patient outcomes. The correlation between TROP-2 expression and tumor aggressiveness further suggests that it may serve as a useful prognostic indicator, aiding in risk stratification and treatment planning.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of Dr. D. Y. Patil Medical College Hospital and Research Center, Pune, Maharashtra (Approval No. IESC/383/2023, dated 25 September 2023).

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Clinical Trial Registration / Research Approval

The Research and Recognition Committee under the Faculty of Medicine approved the thesis topic and study on 26 December 2023.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

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AI Use Declaration

AI tools were used only for language editing; all intellectual content was developed by the authors.

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ORIGINAL ARTICLE

Role of Chest CT Radiomics in Distinguishing Infective and Neoplastic Pulmonary Lesions

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Abstract

Background: Differentiating infective from malignant pulmonary lesions on routine chest CT often requires invasive procedures and may suffer from interobserver variability. This study compares expert radiological assessment with a quantitative radiomic pipeline to determine their relative diagnostic performance.

Materials and methods: 30 patients (15 infective, 15 malignant) with histopathological or microbiological confirmation underwent chest CT. Two trained thoracic radiologists independently reviewed all scans, classifying each lesion as benign or malignant. Separately, semiautomatic 3D Slicer segmentation was performed, and 85 IBSI-compliant radiomic features (shape, first-order, GLCM, GLDM, GLRLM, GLSZM) were extracted via PyRadiomics. Performance metrics sensitivity, specificity, accuracy, and area under the ROC curve (AUC) were calculated for both approaches, with significance assessed by Fisher's exact test ($p < 0.001$).

Results: Radiologists correctly identified all 15 benign lesions (specificity = 100%) and 14 of 15 malignant lesions (sensitivity = 93.3%), yielding 96.7% accuracy and AUC = 0.967. The radiomic model achieved perfect sensitivity (100%), correctly detecting all malignancies, and 93.3% specificity (14/15 benign), with 96.7% accuracy and an AUC of 0.967. Both methods' associations with true lesion status were highly significant ($p \approx 2 \times 10^{-7}$).

Conclusion: Expert radiology and radiomic analysis demonstrate equivalent overall accuracy and discrimination (AUC ≈ 0.97) but exhibit complementary strengths. Radiologists maximize specificity, whereas radiomics ensures no malignancies are missed. A hybrid workflow leveraging radiomic screening followed by radiologist review may optimize diagnostic safety and efficiency.

Keywords: Area under the curve, Chest computed tomography, Diagnostic accuracy, Machine learning, Pulmonary lesions, Radiomics, Sensitivity, Specificity.

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Introduction

Radiomics has emerged as a transformative tool in medical imaging, enabling the conversion of standard radiological images into high-dimensional, mineable data. Through advanced computational techniques, a vast array of quantitative features capturing shape, texture, intensity, and spatial relationships can be extracted and analyzed. This process augments clinical decision-making by offering enhanced diagnostic, prognostic, and predictive accuracy. While radiomics has broad applications, its most extensive use has been in thoracic oncology, particularly lung cancer imaging.[1]

Lung cancer remains the most prevalent and fatal cancer globally. As of 2022, it accounted for 2.5 million new cases and 1.8 million deaths, representing 12.4% of all new cancer diagnoses and 18.7% of cancer-related deaths. The disease burden is significant, especially in developed countries, and is projected to rise sharply by 2050. Effective screening and early diagnosis remain pivotal strategies in curbing this trend.[2]

Traditional imaging interpretation relies on radiologists' visual assessment, which, although effective, is subject to variability and limited in detecting subtle tumor characteristics. Studies have shown that a substantial portion of clinically relevant information remains hidden in standard images.[3] Introduced by Lambin et al.[1] in 2012, radiomics offers a solution by quantitatively analyzing image features beyond visual recognition.[4] This methodology provides insights into tumor heterogeneity, biological behavior, and microenvironmental attributes.

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Radiomic analysis typically follows a standardized workflow: image acquisition and preprocessing, segmentation of the region of interest, feature extraction, dimensionality reduction, model construction, and clinical application. This structured approach enables the extraction of hundreds of features from a single image set, allowing for deeper phenotypic characterization of lesions.[5]

A key advantage of radiomics is its ability to serve as a noninvasive, reproducible biomarker that reflects both macroscopic and microscopic tumor properties. These features can be used to assess tumor type, predict clinical outcomes, and guide personalized therapy. However, inconsistencies across software tools and computational algorithms have posed challenges to reproducibility

and standardization. To address this, the image biomarker standardization initiative (IBSI) was developed, offering unified definitions, workflows, and nomenclatures for radiomic features.[6]

A major step forward was the development of PyRadiomics, an open-source platform compliant with IBSI standards. As detailed by van Griethuysen et al.,[7] PyRadiomics facilitates 2D and 3D segmentation and extracts a broad range of handcrafted features from CT, PET, and MRI data. It improves accessibility, reproducibility, and transparency in radiomics research. The platform has gained widespread adoption, serving as a benchmark tool in imaging analysis and artificial intelligence-based diagnosis.

In pulmonary imaging, both infectious and malignant lesions often share similar radiological features such as cavitation, spiculated margins, and consolidation, making them difficult to distinguish based on CT alone. Conventional diagnosis often depends on invasive methods or clinical correlation, which are not always feasible. Moreover, interobserver variability remains a major limitation in radiologic interpretation.[8]

Radiomics, particularly when integrated with machine learning, offers an objective framework for classifying lesions. Quantitative features can be grouped and analyzed using algorithms to distinguish between disease categories. Studies by Beig et al. have demonstrated that radiomics can effectively differentiate benign from malignant lung nodules, improving diagnostic accuracy and reducing variability.[3,9,10]

Despite increasing interest, few studies have specifically explored radiomic differentiation between infectious and neoplastic lung lesions. This study addresses that gap by comparing radiomic feature-based classification with expert radiologist interpretation, aiming to improve diagnostic precision and support clinical decision-making in ambiguous pulmonary lesions.[11,12]

Materials and Methods

Study Design and Setting

A retrospective cohort study was conducted at the Department of Radiodiagnosis, Mahatma Gandhi Medical College and Research Institute, Puducherry. Data were collected over a 10-year period (2013–2023). Ethical clearance and a waiver of consent were obtained from the Institutional Human Ethics Committee.

Inclusion Criteria

Adult patients (>18 years) of either sex with confirmed infectious or neoplastic pulmonary pathology and complete inspiratory chest CT scans were included.

Exclusion Criteria

Patients without parenchymal lesions, with motion artifacts, prior pulmonary resections, or lacking confirmatory histopathology/microbiology were excluded.

Sample Size and Sampling

Based on prior studies, a sample size of 30 patients (15 infective, 15 neoplastic) was determined. Purposive sampling was used.

Data Collection

DICOM chest CT data and corresponding microbiological/histopathological reports were retrieved from PACS and anonymized by MRD staff. Only patients who met eligibility criteria were included.

Image Analysis

Chest CT scans were reviewed and volumetric segmentation was performed using 3D Slicer software. Manual segmentation of regions of interest (ROIs) was performed on mediastinal window settings to encompass consolidation while excluding vessels and cavities.

Radiomic Feature Extraction

Using PyRadiomics within 3D Slicer, 85 radiomic features were extracted: 13 shape features, 16 GLSZM, 14 GLDM, 24 GLCM, 16 GLRLM, and 5 NGTDM features. These were based on IBSI-compliant protocols.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics. Continuous variables were expressed as mean ± SD. Normality was assessed using the Shapiro–Wilk test. Group comparisons were made using Student's *t*-test (parametric) and Mann–Whitney *U* test (nonparametric). ROC curves and AUC values were used to evaluate diagnostic performance. Holm–Bonferroni correction addressed multiple comparisons. Statistical significance was set at $p < 0.05$.

Outcome Measures

Key outcome measures included sensitivity, specificity, accuracy, and AUC for differentiating malignant from infective lesions using radiomics.

Software Tools Used

3D Slicer (segmentation), PyRadiomics (feature extraction), and IBM SPSS (statistical analysis).

Data Safety and Ethical Considerations

All data were anonymized before investigator access. The study involved no patient contact and posed minimal risk. Informed consent was waived due to the retrospective and anonymized nature of data analysis.

Observations

Out of 30 patients included in the study (15 with infective lesions and 15 with malignant lesions), the mean age-group was most concentrated in the 61–70-year range. However, there was no statistically significant difference in age distribution between the groups ($p = 0.08$). Gender, smoking status, comorbidities, WBC count, and predominant presenting symptoms also showed no significant variation between the two groups ($p > 0.05$ for all).

Radiomic features were significantly different between the two groups:

- *Shape descriptor*: The surface area-to-volume ratio was significantly higher in infective lesions (0.32 ± 0.06) than in malignant ones (0.22 ± 0.07; $p < 0.001$), with a diagnostic accuracy of 94%, sensitivity of 92%, and specificity of 96%.
- *Gray-level co-occurrence matrix (GLCM) features*: Average difference was higher in infective lesions (1.36 ± 0.57 vs 0.37 ± 0.26; $p < 0.001$), while IDM was higher in malignant lesions (0.90 ± 0.04 vs 0.76 ± 0.08; $p < 0.001$). AUCs for both features exceeded 95%.
- *Gray-level dependence matrix (GLDM) features*: Large dependence emphasis was higher in malignant lesions (413.20 ± 60.04 vs 242.50 ± 68.84; $p < 0.001$). Small dependence emphasis was higher in infective lesions (0.13 ± 0.04 vs 0.05 ± 0.02; $p < 0.001$).

- *Gray-level run length matrix and gray level size zone matrix (GLRLM and GLSZM) features*: Showed statistically significant differences between malignant and infective lesions. Malignancies had higher long-run emphasis (26.21 ± 11.96 vs 8.93 ± 8.27, $p < 0.001$), large area emphasis (84,230.63 ± 71,870.45 vs 20,368.42 ± 35,921.54, $p < 0.001$), and large area low gray level emphasis (10,180.98 ± 6,748.04 vs 545.96 ± 1,610.38, $p < 0.001$). Infective lesions had higher short-run emphasis (0.72 ± 0.07 vs 0.56 ± 0.10, $p < 0.001$) and run percentage (0.55 ± 0.10 vs 0.32 ± 0.07, $p < 0.001$).
- NGTDM was excluded due to instability and lower reproducibility in small-volume pulmonary lesions.

Diagnostic performance of radiomic and radiological classification:
- Radiomics classification: Sensitivity = 100%, specificity = 93.3%, accuracy = 96.7%, AUC = 0.967.
- Radiologist classification: Sensitivity = 93.3%, specificity = 100%, accuracy = 96.7%, AUC = 0.967.

Both radiologist assessment and radiomics achieved high diagnostic accuracy. However, radiomics had higher sensitivity, whereas radiologists demonstrated superior specificity.

Discussion

Findings of the current study reinforce that radiomics can complement traditional radiologist assessment in distinguishing between infective and malignant pulmonary lesions. While conventional clinical parameters such as age, gender, comorbidities, and WBC count did not significantly differ between groups, radiomic features provided clear discriminatory power.

Shape and texture metrics, especially surface area-to-volume ratio, GLCM-derived average difference and IDM, and GLDM-based dependence emphasis, were particularly effective in highlighting imaging heterogeneity between lesion types. The robustness of these features was further validated by strong AUCs (≥ 95%) and high diagnostic accuracy.

Although radiologists achieved excellent specificity, radiomics ensured no malignancies were missed, achieving perfect sensitivity. This reflects radiomics' strength in capturing quantitative intralesional heterogeneity, even when not visually appreciable.

Radiomics is emerging as a powerful adjunct to conventional imaging in differentiating pulmonary infections from malignancies. The current study confirms that radiomics offers diagnostic performance comparable to that of expert radiologists, with a sensitivity of 100% and specificity of 93.3%. This high sensitivity implies that radiomics is effective in minimizing false negatives and identifying malignancies that may otherwise be overlooked.

Shape and texture-based features such as surface area-to-volume ratio, GLCM Inverse Difference Moment, and GLDM Large Dependence Emphasis significantly differed between groups and contributed to the model's high accuracy. These findings align with prior studies by Padmakumari et al. and Cui et al., where features such as long run emphasis and large area low gray level emphasis were also prominent indicators.[13,14]

Compared to earlier studies reporting AUCs around 0.90–0.92,[13,14] the current study achieved a higher AUC of 0.96 for differentiating lung cancer from infection. Importantly, this study validated the potential of radiomics in minimizing interobserver variability, a well-recognized limitation in CT interpretation.

Recent models have integrated clinical and imaging features to improve lesion classification. We found that demographic variables such as age and WBC count were not significantly associated with lesion type, reinforcing the added value of radiomic features for classification. Other studies, including those using deep learning and CNNs on histopathology images, similarly show that integrating imaging with AI enhances diagnostic precision.[3,14]

Radiomics presents a noninvasive, objective, and reproducible approach that quantifies lesion heterogeneity, often invisible to the human eye.[1,15] Current study results suggest that a hybrid model combining radiomic triage with radiologist confirmation may optimize clinical workflows, reduce unnecessary biopsies, and improve outcomes in TB-endemic regions.[13,16]

Limitations

- Small sample size ($n = 30$), affected by motion artifacts and incomplete imaging, limits statistical power and may overestimate model performance.
- Retrospective design introduces potential selection bias and inconsistent imaging parameters over time, reducing generalizability.
- Radiomics faces methodological challenges such as operator-dependent segmentation, variable preprocessing pipelines, and the absence of external validation.

Recommendations

- Validate performance in larger, prospective multicenter cohorts using standardized CT acquisition.
- Apply harmonization methods (e.g., ComBat) and IBSI-compliant preprocessing to mitigate scanner variability.
- Integrate radiomic tools into clinical PACS with visual overlays and risk scores.
- Employ explainability techniques like SHAP and saliency maps to enhance clinical interpretability.
- Combine radiomics with clinical markers (e.g., inflammatory indices) for a more comprehensive diagnostic model.
- With standardization and validation, radiomics has the potential to reduce unnecessary interventions and support more accurate, early diagnosis of pulmonary lesions.

Conclusion

In this study, both radiological and radiomic evaluations of chest CT demonstrated high diagnostic accuracy (AUC ≈ 0.97, overall accuracy = 96.7%) in differentiating between infective and malignant pulmonary lesions. Radiologists achieved perfect specificity (100%) but missed one malignancy (sensitivity 93.3%), whereas radiomics demonstrated perfect sensitivity (100%) with slightly reduced specificity (93.3%). Radiomics effectively quantifies lesion characteristics such as shape irregularity and textural heterogeneity that may be imperceptible on visual inspection. These findings highlight the complementary strengths of both approaches. A hybrid workflow involving radiomic screening followed by radiologist confirmation could enhance diagnostic safety and reduce false negatives.

Declarations

Ethics Approval

Ethics approval was obtained from the Institutional Human Ethics Committee of Mahatma Gandhi Medical College and Research Institute (Approval No. MGMCRI/Res/01/2022/46/IHEC/82; dated August 10, 2023).

Informed Consent

As this was a retrospective study with a waiver of consent, informed consent was not applicable.

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

Acknowledgment

Nil.

Author Contributions

Vaishnavi Vaiyapuri Mathi: Conceptualization, methodology, data collection, writing – original draft preparation.
Vigneshwaran S, Krishna Kumar R, Pajanivel R, and Lokesh Kumar T: Writing – review and editing.

AI Use Declaration

AI tools were used only for language editing. All intellectual content, scientific interpretation, and conclusions were developed by the authors.

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ORIGINAL ARTICLE

Comparison of Complementary Feeding Practices by Mothers of Children between 6 and 12 Months of Age Attending Outpatient Departments of Government and Private Hospitals in Central Gujarat

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Abstract

Introduction: Appropriate feeding practices should be followed up in patients attending government as well as private facilities to achieve the desired results.

Objectives: To compare complementary feeding practices by mothers of 6- to 12-month-old infants attending government and private hospitals and to identify factors associated with complementary feeding practices.

Materials and methods: An analytical cross-sectional study was carried out to compare complementary feeding practices employed by mothers attending government and private pediatrics outpatient departments. Mothers of infants aged 6–12 months were purposively selected. The total sample size was 362, with 181 mothers selected from each study setting. For data collection, the EpiCollect5 mobile-based data collection tool was used. Data were analyzed using Chi-square test, and multivariate analysis was done using logistic regression.

Results: Complementary feeding was started at 6 months in 56.35% of infants in government and 65.74% of infants in private setup (*p*-value: 0.0078). Mothers attending private hospitals (49.17%) were more likely to provide a minimum acceptable diet than mothers attending government hospitals (34.81%) (*p*-value: 0.006). Mothers attending government settings that provided food that met minimum acceptable standards were associated with maternal age of 30 years and above (*p*-value: 0.006) and maternal education up to graduate level (*p*-value: 0.023). Among mothers attending private hospitals, it was associated with maternal education up to graduate level (*p*-value: 0.008).

Conclusion: Mothers attending private hospitals were more likely to provide a minimum acceptable diet than mothers from government hospitals. In both study settings, high maternal education was associated with providing a diet that met minimum acceptable standards.

Keywords: Children aged 6–12 months, Complementary feeding, Infant and young child feeding indicators.

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Introduction

The nutritional well-being of a population is an outcome and an indicator of national development. 12 of the 17 Sustainable Development Goals of 2030 include indicators relevant for nutrition.[1] India contributes one-third of the global burden of undernutrition. Undernutrition is well known to reduce population productivity and play a significant role in the burden of disease worldwide, including maternal and infant mortality. It is associated with 45% of child deaths. Undernutrition puts children at greater risk of dying from common infections, increases the frequency and severity of such infections, and delays recovery.[2] Infant and young child feeding (IYCF) is a set of well-known, common, and scientific recommendations for appropriate feeding of newborns and children under 2 years of age. The link between malnutrition and infant feeding is well established.[2] IYCF practices directly affect the health, development, and nutritional status of children less than 2 years of age and ultimately impact child survival. Complementary feeding is necessary to meet increased need for energy and nutrition requirements after 6 months of age.[3–6] Appropriately thick homogeneous complementary foods made from locally available foods should be introduced at 6 completed months to all babies while continuing breastfeeding.[7,8] Complementary feeding should be considered as the bridge between the liquid-to-solid transition and to prepare the baby to "family pot feeding".[8] The goal of complementary feeding is to supplement breast milk and ensure

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that the young child gets enough energy, protein, and other nutrients to grow normally. Breastfeeding should be continued until the child is 2 years old or beyond because it provides a significant amount of energy, high-quality protein, and other nutrients. Many studies were done in the past to evaluate the IYCF practices employed by mothers in a study population at the community level and who attended government hospitals. There is little knowledge about IYCF practices done by mothers who attend private clinics. The purpose of this study was to compare complementary feeding practices employed by mothers of 6 to 12-month-old infants attending government and private hospitals and to identify factors associated with complementary feeding practices.

Materials and Methods

A analytical cross-sectional study was carried out in hospitals in the urban area of the Vadodara district for assessment of IYCF practices of mothers. The present study was conducted in the outpatient departments (OPD) of both government and private pediatric hospitals in the urban area. Two hospitals were selected for the government setup. For the private setup, four hospitals from each north and west zones and five hospitals from each south and east zone were selected randomly. Mothers of infants aged 6–12 months who visited these hospitals were recruited for this study. The total study period was 15 months. Data were collected from June 2020 to November 2021. For calculating the sample size, a pilot study was conducted to obtain the proportion of minimum acceptable diet as a reference in both study settings. A total of 15 mothers were asked about their complementary feeding practices in both study settings. The proportion of minimum acceptable diet from government settings obtained from the pilot study was 33.7%, while from private settings it was 50.3%. These proportions of minimum acceptable diet were used to calculate the sample size using a 5% significance level and 90% power of the study. The sample size was calculated using MedCalc software by using a comparison of proportions. After using both proportions, the calculated sample size was 362. To compare the two study settings, 181 participants were chosen from both study settings.[9] Mothers who only attended either government or private health facilities, but not both, were included in the respective study settings. Mothers of infants aged 6–12 months who attended these hospitals and gave consent for this study were included. Mothers who refused to give consent for this study were excluded. In government hospitals, mothers who visited the pediatrics OPD were assigned to this study by purposive sampling. Each mother was interviewed about their feeding practices. Simple random sampling was used to allocate private hospitals, providing routine OPD services. Mothers attending the OPD were selected by purposive sampling for collecting data regarding their IYCF practices. To obtain a sample size of 181, interviews were conducted with approximately 10 mothers from each hospital with a private setup. The study was conducted after approval from the institutional ethical committee. The data were collected from two setups, namely, government hospitals and private pediatric clinics. Mothers of infants aged 6–12 months were interviewed for IYCF practices. Before collecting data from the OPD, authorization from the Head of the Department of Pediatrics was obtained for government hospitals, while permission from the pediatrician was obtained for private hospitals. Mothers/caregivers of infants aged 6–12 months were given an information sheet with brief information on the study in Gujarati or English, whichever language they preferred. Then, informed written consent was taken from the participants. Pretested and semistructured questionnaires were used to collect data. The data were entered in the EpiCollect 5 mobile data collection tool. The questionnaire contains information regarding sociodemographic details and complementary feeding practices. Questions about feeding practice include frequency of complementary feeding and quality and quantity of complementary feeding.

Operational Definitions

Operational definitions for introduction of complementary foods, minimum dietary diversity, minimum meal frequency, and minimum acceptable diet were taken from WHO guidelines.[10]

Results

A total of 362 infants were included in the study; of them, half (181) were from government and half (181) were from private hospitals.

In this study, which included 362 infants aged 6–12 months, the majority of the participants, 210 (58%), belonged to the age-group of 9–12 months. Among the mothers attending government hospitals, 70 (38.67%) belonged to the age-group of 6–8 months, and 111 (61.33%) were from the age-group of 9 to 12 months, with a mean age of 9.09 ± 2.07 (mean ± SD) months. Among mothers attending private hospitals, 82 (45.30%) belonged to the age-group of 6–8 months, and 99 (54.70%) belonged to the age-group of 9–12 months, with a mean age of 8.81 ± 1.86 months. Among government setups, 53.04% were male and 46.96% were female. While in private hospitals, 59.67% were male and 40.33% were female. There was no significant difference in age or gender between the two groups (p-value > 0.05). Ages of mothers attending government hospitals ranged from 19 to 40 years, with a mean of 26.31 ± 4.53 years, while those who attended private hospitals ranged from 20 to 42 years, with a mean of 28.37 ± 3.81 years. The majority of mothers, both from government (170, 93.92%) and private (168, 92.82%) hospitals, were housewives. Age of fathers who attended government hospitals ranged from 22 to 45 years, with a mean of 29.35 ± 4.79 years, while among fathers who attended private hospitals ranged from 22 to 42 years, with mean of 31.05 ± 3.84 years. On comparison of various characteristics, a statistically significant difference was noted in the age and education status of parents between both the study settings (p-value < 0.01). There was no significant difference in the employment status of mothers attending these hospitals (p-value = 0.673). According to the religion distribution, the majority of children came from Hindu families, with a significant number of Hindus being covered in private settings (p-value = 0.019). In the government setting, 120 (66.30%) were from a joint family, whereas in the private setting, 127 (70.17%) were from a joint family; the difference between the two groups was not statistically significant (p-value: 0.430). The participants' socioeconomic status was classified using the modified BG Prasad classification for the year 2022. Participants in the government setup were mainly from the middle class (35.91%), whereas those in the private setup were mainly from the upper class (56.35%). There was a statistically significant difference between the socioeconomic status of both groups (p-value < 0.01).

As per Table 1, in this study, complementary feeding was introduced at 6 months of age by 56.35% of mothers in government hospitals and 65.74% of mothers in private hospitals, while 24.86% of mothers in government hospitals and 12.15% of mothers in private

Table 1: Distribution of indicators of Infant and young child feeding (IYCF) practices related to complementary feeding ($N = 362$)

Variable	*Government (n = 181)*	*Private (n = 181)*	*Total (n = 362)*	χ^2	*p-value*
Introduction of complementary food					
< 6 months	4 (2.21)	14 (7.74)	18 (4.97)	7.081 (trend)	0.0078
At 6 months	102 (56.35)	119 (65.74)	221 (61.05)	–	–
> 6 months	45 (24.86)	22 (12.15)	67 (18.51)	–	–
Not started yet	30 (16.57)	26 (14.36)	56 (15.47)	–	–
Minimum dietary diversity					
Adequate	78 (43.09)	102 (56.35)	180 (49.72)	6.347	0.012
Inadequate	103 (56.91)	79 (43.65)	182 (50.28)	–	–
Minimum meal frequency					
Adequate	117 (64.64)	130 (71.82)	247 (68.23)	2.148	0.143
Inadequate	64 (35.36)	51 (28.18)	115 (31.77)	–	–
Minimum acceptable diet					
Adequate	63 (34.81)	89 (49.17)	152 (41.99)	7.645	0.006
Inadequate	118 (65.19)	92 (50.83)	210 (58.01)	–	–

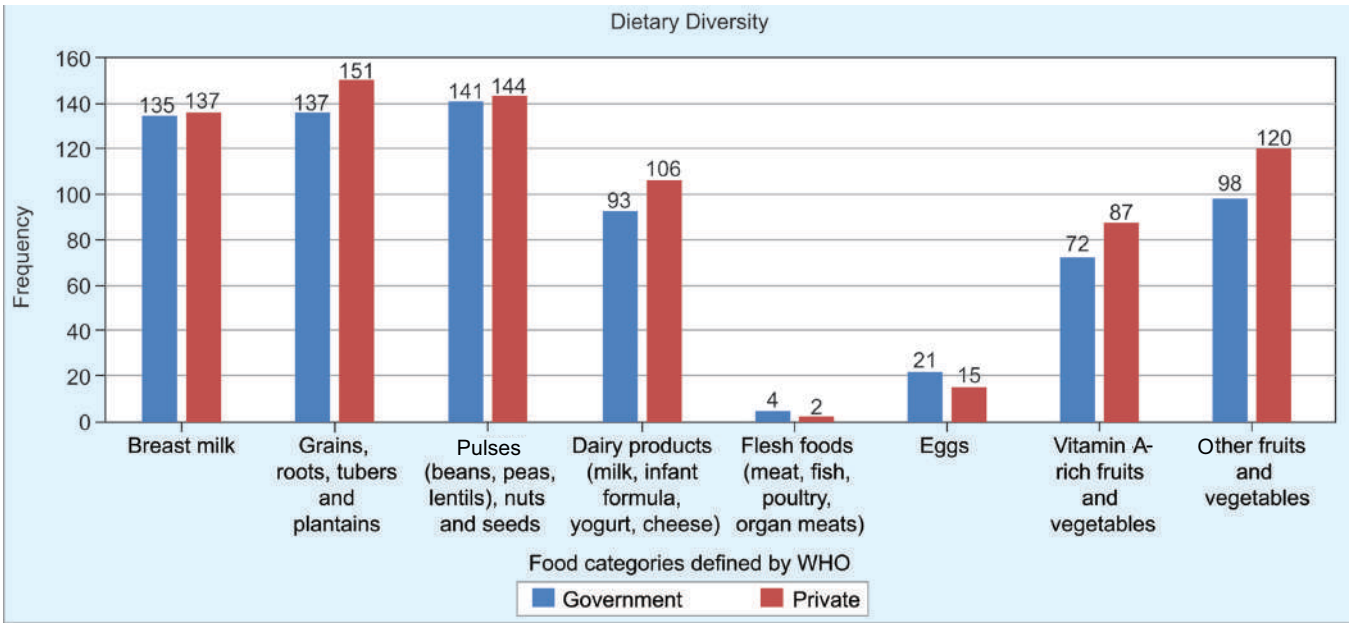

Fig. 1: Distribution of infants 6 to 12 months of age who consumed complementary feeding from defined food groups

hospitals were introduced to complementary food after 6 months (Chi-square with trend =7.081, *p*-value: 0.0078). Complementary food with minimum dietary diversity (MDD) was given to 180 (49.72%) infants from a total of 362 infants aged 6–12 months. Mothers attending private hospitals (56.35%) were more likely to provide food with dietary diversity than mothers attending government hospitals (43.09%) (Chi-square value: 6.347, *p*-value: 0.012). In this study, minimum meal frequency (MMF) according to the feeding frequency and age-group (6–12 months) was followed by 247 (68.23%) overall, of which 64.64% were from government setup and the remaining 71.82% were from private setup. There was no significant difference between MMF practices followed by mothers attending government or private setups (*p*-value: 0.143). This demonstrates that despite higher percentages of children receiving the minimum number of times, they are not fed the food with the right diversity of food. Minimum acceptable diet (MAD) was followed by 152 (41.99%) mothers included in this study. Mothers attending private hospitals (49.17%) were more likely to provide minimum acceptable diet than mothers attending government hospitals (34.81%) (Chi-square value: 7.645, *p*-value: 0.006) (Table 1).

Figure 1 shows, as complementary food, the most common combination was rice and dal, and was consumed by 285 (93.14%). Continued breastfeeding practice after introduction to complementary food was done by 88.89% of the mothers. The practice of giving fruits and vegetables was observed more in mothers attending private hospitals. Only a small proportion of children received eggs (11.76%) and flesh foods (1.96%) as complementary food. Foods given outside the defined food category were biscuits (43.14%) and processed foods such as Cerelac (14.70%).

As per Table 2, the practice of providing complementary food with minimum acceptable standards by mothers attending government hospitals was associated with age of mother (*p*-value: 0.006) and education status of mother (*p*-value: 0.023). After applying multiple logistic regression, the chance of receiving

Table 2: Distribution of minimum acceptable diet in government and private facilities

	Government facility (n = 181)				*Private facility (n = 181)*			
Variable	*Yes (n = 63)*	*No (n = 118)*	χ^2	*p-value*	*Yes (n = 89)*	*No (n = 92)*	χ^2	*p-value*
Gender of infant								
Male	36 (57.14)	60 (50.84)	0.654	0.419	55 (61.70)	53 (57.61)	0.330	0.566
Female	27 (42.86)	58 (49.15)	–	–	34 (38.20)	39 (42.39)	–	–
Age of mother (years)								
18–29	43 (68.25) [95% CI: 60.93–74.96]	101 (85.59)	7.590	0.006	62 (69.66)	65 (70.65)	0.021	0.884
≥ 30	20 (31.75) [95% CI: 25.04–39.07]	17 (14.40)	–	–	27 (30.34)	27 (29.35)	–	–
Education of mother								
Illiterate/primary	15 (23.81) [95% CI: 17.81–30.69]	43 (36.44)	7.577	0.023	2 (2.24) [95% CI: 0.62–5.60]	12 (13.04)	9.560	0.008
Secondary/higher secondary	31 (49.21) [95% CI: 41.71–56.73]	61 (51.69)	–	–	39 (43.82) [95% CI: 36.47–51.37]	45 (48.92)	–	–
Graduate/postgraduate	17 (26.98) [95% CI: 20.67–34.07]	14 (11.86)	–	–	48 (53.93) [95% CI: 46.38–61.35]	35 (38.04)	–	–
Occupation of mother								
Homemaker	60 (95.24)	110 (93.22)	0.293	0.588	78 (87.64) [95% CI: 81.94–92.06]	90 (97.83)	7.040	0.008
Employed	3 (4.76)	8 (6.78)	–	–	11 (12.36) [95% CI: 7.94–18.08]	2 (2.17)	–	–
Religion								
Hindu	41 (65.08)	87 (73.73)	1.480	0.223	74 (83.15)	73 (79.35)	0.428	0.513
Muslim	22 (34.92)	31 (26.27)	–	–	15 (16.85)	19 (20.65)	–	–
Type of family								
Joint	43 (68.25)	77 (65.25)	0.165	0.684	66 (74.16)	61 (66.30)	1.330	0.248
Nuclear	20 (31.75)	41 (34.75)	–	–	23 (25.84)	31 (33.70)	–	–
Socioeconomic status								
I	2 (3.17)	7 (5.93)	3.840	0.428	52 (58.43)	50 (54.35)	3.094	0.377
II	12 (19.05)	16 (13.56)	–	–	25 (28.08)	23 (25.00)	–	–
III	22 (34.92)	43 (36.44)	–	–	7 (7.87)	15 (16.30)	–	–
IV	23 (36.51)	36 (30.50)	–	–	5 (5.62)	4 (4.35)	–	–
V*	4 (6.35)	16 (13.56)	–	–	0 (0.00)	0 (0.00)	–	–
Gestational age at birth								
Term	56 (88.89)	102 (86.44)	0.222	0.638	80 (89.89)	80 (86.96)	0.379	0.538
Preterm/postterm	7 (11.11)	16 (13.56)	–	–	9 (10.11)	12 (13.04)	–	–
Birth weight								
≥2.5 kg	49 (77.78)	87 (73.73)	0.360	0.548	66 (74.16)	61 (66.30)	1.330	0.248
<2.5 kg	14 (22.22)	31 (26.27)	–	–	23 (25.84)	31 (33.70)	–	–

*In a private setting, 0 frequency was noted in class V.

a minimum acceptable diet was high among mothers aged 30 years and more than those with age less than 30 years (aOR: 2.47, with 95% CI: 1.15–5.30, Chi-square value: 7.59, *p*-value: 0.006). Mothers with education up to the graduate or postgraduate level were more likely to provide their kid with a minimum acceptable diet than those who were illiterate or had only completed primary school (aOR: 3.03, with 95% CI: 1.18–7.77, Chi-square value: 7.557, *p*-value: 0.023). While mothers who attended private hospitals provided a minimum acceptable diet to their children was associated with education of mother (*p*-value: 0.008) and occupation of mother (*p*-value: 0.008). After applying multiple logistic regression, higher chance of providing minimum acceptable diet was with mothers educated up to graduate or postgraduate (aOR: 7.04, with 95% CI: 1.47–33.69) and up to secondary or higher secondary school (aOR: 4.94, 95% CI: 1.04–23.47) in comparison to mothers who were illiterate or educated up to primary class (Chi-square-9.56, *p*-value: 0.008) (Table 2).

Discussion

For infants, solid, semisolid, and soft foods should be introduced after 6 months (180 days), while breastfeeding should be continued. In this study, complementary feeding starts at 6 months (65.74%), i.e., at the correct time, was more in private setups, while late introduction of complementary feeding, i.e., after 6 months of age (24.86%), was more in government setups. Similar findings were observed in a study conducted by Rao et al. in two private hospitals,

where 77.5% of mothers began complementary feeding at 6 months of age.[11] While Gupta et al. found the prevalence of complementary feeding introduction at 6 months to be 54% in community-based studies.[12] 60.5% of mothers started giving complementary feeding after 6 months, as found in a study conducted by Katara et al.[13]

WHO principles for feeding the breastfed and nonbreastfed child recommend that children aged 6–23 months be fed a variety of foods to ensure that nutrient needs are met. A lack of diversity in diet can increase the risk of micronutrient deficiencies, which may be damaging to children's physical and cognitive development. For children aged 6–23 months who consumed foods and beverages from 5 out of 8 defined food groups. In this study, 43.09% of infants were fed a diet with MDD, compared to 56.35% in private hospitals. MDD was significantly higher among mothers attending private hospitals (*p*-value: 0.012). These percentages were higher than the NFHS-5 figures of 35.1% for India and 23.3% for Gujarat.[14] Similar findings were observed in a study done by Karmee et al. (66.97%), Davalgi et al. (59%), and Jain et al. (57%).[15–17]

WHO recommends that breastfed infants aged 6–8 months should be given complementary foods 2–3 times per day, while those aged 9–23 months should be given complementary foods 3–4 times per day, with additional nutritious snacks offered 1–2 times per day. For a nonbreastfed child, increase that recommendation to 4–5 meals per day. MMF in this study was 64.64% in government facilities, while it was 71.82% in private facilities (*p*-value: 0.143). In contrast to our study, MMF was low in a study conducted by Karmee et al. (52.03%), Davalgi et al. (48%), and Marroda et al. (31%).[15,16,18] Similar findings were observed in the study by Anin et. al. (69.4%).[19] MMF in India was 23%, while it was 16.4% in Gujarat, according to NFHS-5.[14]

WHO recommends that children aged 6–23 months should be provided meals at an appropriate frequency and variety to ensure that their energy and nutrient needs are met. Nonbreastfed children should receive at least 2 milk feeds per day. In this study, MAD was given to 34.81% of children in government hospitals and 49.17% of children in private hospitals. The difference between complementary feeding practices was notably high in private hospitals (*p*-value: 0.006). This may be due to high levels of education and knowledge regarding complementary feeding practices among mothers attending private hospitals. A similar finding was found in a study conducted by Farah et al. (47.2%).[20] A similar finding was observed in a hospital-based study by Rao et al. in Mangaluru, observed that prevalence of MAD was 32%, which was associated with children born in a private institution (*p*-value: 0.045).[11] In the NFHS- 5 survey, MAD was 11% for India and 5.9% for Gujarat.[14,21] In government hospitals, the odds of receiving minimum acceptable diet were 2.76 times high with mothers aged more than or equal to 30 years (aOR:2.47, with CI: 1.15-5.30, *p*-value: 0.006). There was no such correlation discovered in private hospitals.

Strength of this study and power of this study were achieved. Lots of study done at government setups, while very few studies were done at private setups. In this study, comparison was done between government and private setups.

Conclusion

Participants from private hospitals were more likely to give a diet with dietary diversity and provide a minimum acceptable diet than participants from government hospitals. Children attending government hospitals were provided better with minimum acceptable diet when their mothers were aged more than 30 years and had graduate-level education. Whereas infants attending private hospitals, mothers who were housewives but had with higher education were providing better minimum acceptable diet to their children.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of Medical College Baroda, Vadodara, Gujarat (Approval No. IECBHR/054-2022, dated 15 March 2022).

Informed Consent

Written informed consent was obtained from all participants prior to enrolment.

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

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Author Contributions

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Writing – original draft: Dr Gopi Kalariya, Dr Sangita Patel.
Writing – review & editing: Dr Sangita Patel, Dr Gopi Kalariya, Dr Rinkal Sanandiya, Dr Chandresh Pandya.

AI Use Statement

No AI tool was used in the conception or during data analysis. No AI tools were used. All intellectual content was developed by the authors.

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ORIGINAL ARTICLE

Assessment of Laparoscopic Nissen Fundoplication Procedure on Patients' Quality of Life: A Hospital-based Interventional Study

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Abstract

Background: Gastroesophageal reflux disease (GERD) is a gastrointestinal disorder leading to reflux of gastric contents into the esophagus, which may lead to typical and atypical symptoms, thereby reducing the quality of life of patients. GERD management includes a holistic approach, and one of the gold standard surgical approaches is laparoscopic Nissen fundoplication (LNF). The present study was conducted to estimate the GERD symptoms and health-related quality of life in patients before and after undergoing LNF.

Materials and methods: A hospital-based interventional study was conducted among 50 patients who presented with GERD symptoms and underwent LNF at a tertiary teaching institute and referral center in Mumbai, India, from January 2019 to December 2020, using the 36-item Short Form Health Survey questionnaire (SF-36) to assess the quality of life, GERD symptom scores, and visual analog pain scale (VAS).

Results: The mean age of the patients was 37.4 years, with almost equal numbers of males and females. Almost all GERD symptom scores after LNF significantly improved except for dysphagia and nonspecific GI symptoms. The lower esophageal sphincter (LES) pressure increased from 6.5 mm Hg (preoperative) to 12.26 mm Hg (postoperative). SF-36 scores in all domains, including physical health and mental health, showed significant improvement in quality of life postoperatively.

Conclusion: The study provided valuable insights into how LNF, a standard minimally invasive surgical treatment method, can help improve the quality of life and symptoms in GERD patients.

Keywords: 36-item short form health survey, Gastroesophageal reflux disease, Laparoscopic Nissen fundoplication, Lower esophageal sphincter.

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Introduction

Gastroesophageal reflux disease (GERD) is one of the most common chronic diseases of the gastrointestinal tract, characterized by the reflux of gastric contents to the esophagus, associated with typical and atypical esophageal symptoms including heartburn, regurgitation, epigastric abdominal pain, dysphagia, belching, abdominal bloating, coughing, wheezing, chronic sore throat, laryngitis, and asthma. If left untreated, it may lead to severe complications such as Barrett's esophagus, erosive esophagitis, and esophageal adenocarcinoma.[1,2]

The global age-standardized incidence of GERD was 3,793 per 100,000 population in 2019. The number of GERD cases increased by 77.53% from 1990 to 2019 (441.57 million to 783.95 million). Globally, GERD caused around 6.03 million people to live with disability, which corresponds to 73.63 age-standardized years lived with disability (ASYLDs) per 100,000 population in 2019. The highest prevalent cases were found in India (181.6 million), China (81.6 million), and the USA (39.7 million).[3,4] The prevalence of GERD in India ranges from 5 to 28.5% (with one or more symptoms).[5]

There are many factors associated with GERD, which include hiatal hernia, transient lower esophageal sphincter relaxation, poor motor function, reduced clearance, increased intragastric pressure, delayed gastric emptying, age, obesity, diet, smoking, caffeine, alcohol, genetics, pregnancy, and nonsteroidal anti-inflammatory drugs.[6,7]

The overall quality of life in GERD patients is reduced as it creates multiple symptoms mentioned above, including sleep disturbance, ultimately impacting the physical, mental, and social well-being. This in turn reduces productivity and affects the socioeconomic status of patients and their families.[8]

The management of GERD follows a holistic, stepwise approach. The goal is to control symptoms, prevent and treat esophagitis and further complications. It includes lifestyle modifications, pharmacological therapy, endoluminal therapy, and surgical treatment with corrective surgery for preventing reflux. Laparoscopic Nissen fundoplication (LNF) is considered a gold standard surgical approach in the management of GERD.[1]

There is a paucity of literature in India regarding comparison of health-related quality of life in LNF patients before and after the

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procedure. Therefore, the present study aimed to assess the quality of life postoperatively with the help of the 36-item Short Form Health Survey questionnaire (SF-36) and GERD symptom scores and to correlate these findings with the help of upper gastrointestinal endoscopy and esophageal manometry.

Materials and Methods

This was a hospital-based interventional study conducted among the patients diagnosed with GERD who underwent laparoscopic Nissen fundoplication at a tertiary teaching institute and referral center in Mumbai, India. The study was conducted from January 2019 to December 2020. A total of 58 patients were approached for the study, and 50 patients were selected for the study using convenience sampling. All consecutive patients who fulfilled the inclusion and exclusion criteria were enrolled in the study.

Ethical approval from the Institutional Ethical Committee was obtained before the commencement of the study. The study ensured compliance with ethical standards by obtaining written informed consent from all the participants. Additionally, to ensure anonymity, the study did not collect any identifiable information from the participants.

Inclusion criteria:

- Patients of age more than 18 years with complaints of symptoms of reflux that are responsive to but not completely eliminated by proton pump inhibitors (PPIs).
- Diagnosed cases of GERD and hiatal hernia with low compliance with PPI therapy.
- Patients with well-documented GERD who desire to stop chronic PPI therapy despite excellent symptom control for any reason (e.g., side effects, expense, lifestyle)
- Diagnosed cases of GERD with Barrett's esophagus.

Exclusion criteria:

- Patients aged below 18 years.
- Pregnant patients
- Patients who are diagnosed with cases of stomach carcinoma.
- Patients unfit for general anesthesia due to medical comorbidities.
- Morbidly obese (BMI >35 kg/m^2).
- Severe esophageal strictures not responsive to dilatation therapy.
- Patients with gastric bypass or vertical banded gastroplasty.

Patients coming to OPD with complaints of typical or atypical symptoms of GERD, satisfying the inclusion criteria, and having normal esophageal motility and a DeMeester score > 14 were chosen for our study. Symptom score (GERD score) evaluation was carried out in a standardized way using a written questionnaire, which was administered to all patients. It was ensured that no patient was taking antireflux medication at the time of administering the questionnaire. Six specific symptoms of GERD, namely heartburn, regurgitation, epigastric or chest pain, epigastric fullness, dysphagia, and cough, were scored as a product of severity (0 ± 3) and frequency (0 ± 4).[9]

The scores for severity and frequency (scores from 0 to 12 for each symptom) were multiplied together to obtain a total maximum score of 72 and a minimum score of 0. Higher scores indicate more severe symptoms. Every patient whose scores were calculated also underwent an upper gastrointestinal endoscopy. Esophagitis was classified according to the Los Angeles Classification (LA),[1] and esophageal manometry was carried out. Patients who had low LES pressure with normal peristalsis and normal relaxation were taken into the study. Endoscopically nonesophagitic GERD patients underwent a 24-hour pH study to confirm the diagnosis of GERD. A pH of <4 in the lower esophagus was considered positive.

The SF-36 questionnaire is a very popular instrument for evaluating health-related quality of life. It is well-validated and measures eight domains of quality of life: physical functioning; role physical; bodily pain; general health; vitality; social functioning; role emotional and mental health.[10]

Gastroesophageal reflux disease symptom scores and SF-36 scores were calculated preoperatively and 6 months postoperatively.

Postoperatively, the pain was assessed at 6 hours, 24 hours, and 10 days by using a visual analog pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain).

Survey responses were exported to Excel and precoded by a researcher. After cleaning and final checks, data were analyzed by using SPSS software version 21.0. $p < 0.05$ was considered statistically significant. Descriptive statistics were used to calculate frequencies of categorical variables, while measures of central tendency and dispersion were used to describe continuous variables. A paired *t*-test was performed to compare the means before and after LNF.

Results

A total of 50 adult patients aged 18 and above having symptoms of reflux that are responsive but not completely eliminated by PPIs, diagnosed cases of GERD and hiatal hernia with low compliance to PPI therapy, and desire to stop chronic PPI therapy participated in the study.

The mean age of the patients was 37.4 ± 11.34 years. The youngest patient was 19 years, while the oldest was 58 years old. There were 24 (48%) females and 26 (52%) males.

33 of the 50 patients who underwent a 24-hour pH study to confirm esophagitis had a mean DeMeester score of 36.98 ± 5.5. The mean operation time of surgery was 153.5 ± 35.69 minutes.

Among the 50 patients, the most common symptoms at the beginning of the study were heartburn, i.e., 49 (98%), followed by regurgitation in 48 (96%), while dysphagia was the least reported symptom in 21 (58%) patients. After 6 months of LNF, the most common symptom was nonspecific GI symptoms, i.e., 38 (76%), while heartburn and dysphagia were reported in 14 (28%) and regurgitation in 15 (30%) patients. Since multiple symptoms were reported in individual patients, the total exceeds 100%.

Table 1 depicts statistically significant improvements in LES pressure, SF-36 scores, and all symptom scores (except dysphagia and nonspecific GI symptoms) following LNF compared to preoperative values.

Table 2 revealed that overall physical health, mental health, and total SF-36 score were statistically significantly higher after the postoperative LNF compared to preoperative LNF.

Three patients developed postoperative complications during the follow-up period of 6 months; among them, two patients developed wound infection while one patient developed esophageal perforation.

The mean postoperative VAS scores at 6 hours, 24 hours, and the 10th day were 3.02 ± 1.1, 2.42 ± 0.64, and 0.94 ± 0.94, respectively, and the change in VAS score was statistically significant.

Table 1: Comparison of LES, symptoms, and SF-36 domain scores before and after laparoscopic Nissen fundoplication procedure (*N* = 50)

	Preoperative			*Postoperative*			
	Mean	*SD*	*SE*	*Mean*	*SD*	*SE*	*p-value*
Lower esophageal sphincter (LES)	6.50	1.48	0.2088	12.26	1.75	0.2475	0.001
Symptoms							
Heartburn	6.14	2.67	0.378	1.12	2.17	0.3072	0.001
Regurgitation	6.26	2.61	0.369	1.42	2.45	0.3465	0.001
Dysphagia	1.02	1.29	0.1818	0.84	2.00	0.2834	0.594
Atypical symptoms score	7.34	4.69	0.6637	3.10	3.91	0.5527	0.020
GERD score	20.68	5.90	0.8342	6.48	6.86	0.9707	0.001
Nonspecific GI symptoms	0.70	0.65	0.0915	0.90	0.61	0.0869	0.103
SF-36							
Physical health component							
Physical function	82.60	6.79	0.96	87.80	11.26	1.59	0.001
Role-physical	60.50	24.27	3.43	82.50	26.37	3.73	0.001
Body pain	53.94	18.30	2.59	83.54	22.36	3.16	0.001
General health	33.74	8.24	1.17	75.18	18.92	2.68	0.001
Mental health component							
Vitality	42.20	4.18	0.59	68.90	14.30	2.02	0.001
Social functioning	71.18	9.18	1.30	89.60	16.36	2.31	0.001
Role-emotional	60.84	21.11	2.99	88.00	28.38	4.01	0.001
Mental health	72.80	5.36	0.76	86.40	12.15	1.72	0.001

Table 2: Comparison of SF-36 component scores before and after laparoscopic Nissen fundoplication procedure (*N* = 50)

	Preoperative			*Postoperative*			
	Mean	*SD*	*SE*	*Mean*	*SD*	*SE*	*p-value*
Physical health	54.34	9.31	1.32	79.58	12.46	1.76	0.001
Mental health	56.20	5.17	0.73	81.62	15.37	2.17	0.001
Total SF-36 score	59.68	7.43	1.05	82.74	14.16	2.00	0.001

Paired *t*-test

Discussion

There were 50 patients enrolled in the study with a mean age of 37.4 years, with almost equal numbers of males and females. The most common symptoms reported by patients at the beginning of the study were heartburn, regurgitation, and atypical symptoms, which improved after LNF. The LES pressure, physical health, mental health, and all symptom scores except dysphagia and nonspecific GI symptoms significantly improved after LNF compared to before LNF.

In our study, the mean age of the patients was 37.4 years, with ages ranging from 19 to 58 years. Similar findings were reported by a study conducted by Balci and Turkcapar[11] where the mean age of the patients who underwent LNF was 39 years, with the youngest being 17 years and the oldest being 60 years. In contrast to this analysis, the mean age of patients was 51.6 years, with ages ranging from 15 to 85 years, as reported in the study by Castelijns et al.[12]

We noted the most common symptom as heartburn and regurgitation, while dysphagia was the least reported symptom. Similarly, as per Moore et al., Franzen et al. and Nikolic et al., heartburn is commonly observed in GERD patients, followed by regurgitation.[13–15]

The GERD symptoms, except nonspecific GI symptoms, were reduced after 6 months of the LNF. In concordance with the above findings, similar observations were reported in the studies by Franzen et al.[14] and Nikolic et al.[15]

During the process of normal swallowing, the lower esophageal sphincter and crura relax, which helps in the movement of food into the stomach, thus preventing it from refluxing. Sometimes, the relaxation of the LES occurs at different times rather than at the time of swallowing; such a type of relaxation is termed transient lower esophageal relaxations (TLESRs). These abnormal TLESRs may result in widening of the area of the gastroesophageal junction, allowing acid and gastric secretions to flow back into the esophagus, resulting in 90% of GERD reflux symptoms. In some circumstances, lower LES pressure below 10 mm Hg can cause frequent reflux symptoms.[13]

In our study, mean preoperative LES pressure was found to be 6.5 mm Hg, which is lower than 10 mm Hg, resulting in GERD symptoms. The mean post-operative LES pressure was 12.26 mm Hg. The present study showed a significant increase in LES pressure after the LNF. These findings were in concordance with a meta-analysis by Tian et al., where the mean LES pressures before LNF ranged from 4.28 to 12 mm Hg while post-operative values were 10.3 to 23 mm Hg. This meta-analysis showed that there was a significant increase in LES pressure after the LNF with a return to almost normal LES pressure.[16]

In our analysis, all mean GERD symptom scores were found to be statistically significantly high before the LNF as compared to after LNF, except dysphagia score, which was insignificantly low

after the LNF. Similar observations were noted in other studies by Papasavas et al., Allen et al., and Balci and Turkcapar.[11,17,18]

The present study revealed that SF-36 scores in all domains, including physical health, mental health, and total SF-36 score, were significantly higher postoperatively. These findings were also observed in other studies showing an improved quality of life, which increased significantly for all patients after operation.[11,18,19]

This study concluded that there was a significant improvement in health-related quality of life and substantial reduction in the symptoms of heartburn, regurgitation, and atypical symptoms in GERD patients before and after the laparoscopic Nissen fundoplication. The study has certain limitations regarding its generalizability, with respect to a limited convenient sample and no comparison group. However, the insights gathered from the study may be used to plan further research in the treatment of GERD symptoms by using LNF, a standard surgical procedure.

Declarations

Ethics Approval and Consent to Participate

This study was reviewed and approved by the BORS Committee of Grant Medical College, Mumbai, and the Maharashtra University of Health Sciences (MUHS), vide approval letter no. MUHS/Medical/MUHS-017222/2019.

Informed Consent

Written informed consent was obtained from all participants prior to their enrolment in the study.

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

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Author Contributions

Conceptualization: Shirish Bhagvat.
Methodology: Shalmali Dharmadhikari.
Data collection: Shalmali Dharmadhikari.
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Writing – review & editing: Shirish Bhagvat.

AI Use Statement

The authors declare that no artificial intelligence (AI) tools were used in the preparation of this manuscript.

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ORIGINAL ARTICLE

Triglyceride–Glucose Index: A Cost-effective Alternative to HbA1c for Glycemic Monitoring in Type 2 Diabetes: A Cross-sectional Study at a Tertiary Care Center in Uttar Pradesh

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Abstract

Background: HbA1c, while the gold standard for glycemic control monitoring in type 2 diabetes mellitus (T2DM), has limitations in resource-constrained settings. The triglyceride–glucose (TyG) index has emerged as a potential alternative marker.

Objective: To evaluate the relationship between TyG index and HbA1c in T2DM patients and assess its utility as a glycemic control marker.

Materials and methods: This cross-sectional study included 384 T2DM patients aged 18–75 years. Participants were categorized into good (HbA1c <7%, $n = 162$) and poor (HbA1c >7%, $n = 222$) glycemic control groups. TyG index was calculated using fasting triglycerides and glucose levels. Correlation analysis and ROC curve analysis were performed.

Results: The TyG index showed significant differences between good and poor glycemic control groups (8.32 ± 0.41 vs 9.18 ± 0.53, $p < 0.001$). Strong correlations were observed between TyG index and HbA1c ($r = 0.756$, $p < 0.001$), fasting glucose ($r = 0.724$, $p < 0.001$), and triglycerides ($r = 0.892$, $p < 0.001$). ROC curve analysis demonstrated good diagnostic capability (AUC = 0.846, 95% CI: 0.807–0.885) with an optimal cutoff value of 8.75 (sensitivity 82.4%, specificity 78.9%).

Conclusion: The TyG index demonstrates strong correlation with HbA1c and could serve as a cost-effective alternative marker for glycemic control assessment in T2DM, particularly in resource-limited settings.

Keywords: Diabetic dyslipidemia, Glycated hemoglobin, Glycemic control, Triglyceride–glucose index, Type 2 diabetes mellitus.

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Introduction

Type 2 diabetes mellitus (T2DM) represents one of the most significant public health challenges of the 21st century, affecting approximately 10.5% of the global population and 8.3% of the Indian population.[1] The International Diabetes Federation estimates that by 2045, the number of people with diabetes will rise to 783 million, which would be an increase of 46% globally, placing an unprecedented burden on healthcare systems worldwide.[1] As per the Indian Council of Medical Research–India Diabetes (ICMR INDIAB) study published in 2023, the prevalence of diabetes is 10.1 crores.[2]

Glycemic control monitoring remains a cornerstone in T2DM management, with HbA1c serving as the gold-standard marker. HbA1c provides valuable information about average blood glucose levels over the preceding 2–3 months and has shown strong correlations with diabetes-related complications.[3–5] However, several limitations affect its widespread use, particularly in resource-constrained settings. These include cost considerations, limited accessibility in rural areas, and variations in results due to conditions affecting red blood cell turnover such as iron deficiency anemia, B12 deficiency anemia, folate deficiency anemia, chronic alcohol use, and asplenia, which falsely elevate HbA1c, and acute and chronic blood loss, hemolytic anemia, splenomegaly, and pregnancy, which falsely reduce HbA1c levels.[4,5]

Recent research has highlighted the intricate relationship between glucose metabolism and lipid homeostasis in T2DM. Insulin resistance, a key pathophysiological feature of T2DM, affects both glucose uptake and lipid metabolism, leading to characteristic dyslipidemia patterns.[6]

The TyG index, which combines measurements of fasting triglycerides and glucose levels, has emerged as a promising indicator of insulin resistance (IR). This index correlates well with the hyperglycemic clamp technique, which is considered the gold standard for measuring insulin resistance.[7,8] Beyond its primary application, the TyG index has proven valuable in identifying individuals who, despite having normal weight, exhibit metabolic obesity characteristics.[9] Studies have also indicated its utility in predicting various health conditions, including coronary artery calcification, subclinical atherosclerosis,[10] and nonalcoholic

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fatty liver disease.[11] Furthermore, elevated triglyceride levels are widely recognized as a risk factor for coronary heart disease[12] and constitute one of the defining features of metabolic syndrome.[13] Given these associations, measuring triglyceride levels—whether as part of the TyG index or independently—offers a cost-effective method for simultaneously assessing both cardiovascular and glycemic health status. However, its relationship with HbA1c and its potential role as an alternative marker for glycemic control monitoring needs further investigation. To calculate the TyG index, use either of these formulas: TyG index = ln [fasting triglycerides (mg/dL) × fasting glucose (mg/dL)]/2 or TyG index = ln [fasting triglycerides (mmol/L) × 88.57 × fasting glucose (mmol/L) × 18)/2].[7,14]

Our study aims to evaluate the relationship between the TyG index and HbA1c in T2DM patients, while also examining its associations with other metabolic parameters. We hypothesize that the TyG index could serve as a cost-effective alternative to HbA1c for glycemic control assessment, particularly in resource-limited settings.

Materials and Methods

Study Design and Setting

We conducted a cross-sectional analytical study at our institution's Medicine department over a 12-month period from December 2023 to November 2024. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Study Population

Using a 95% confidence level and 80% power, we calculated a minimum sample size of 384 patients. The study included T2DM patients aged 18–75 years who were on stable antidiabetic medication for at least 3 months. We excluded patients with type 1 diabetes mellitus, pregnancy, acute illness or infection, recent surgery, liver disease, kidney disease (eGFR < 30 mL/min/1.73 m^2), and those using lipid-modifying medications. Based on the criteria of the American Diabetes Association (ADA), diabetes was defined as levels of fasting glucose ≥ 126 mg/dL or HbA1c ≥ 6.5% and/or the current use of antihyperglycemic drugs.[15]

Data Collection

Clinical Parameters

We recorded comprehensive demographic data and medical history for each participant, including: (a) Age, gender, and duration of diabetes; (b) detailed medical history and current medications; (c) physical examination findings; (d) anthropometric measurements (height, weight, BMI, waist circumference, hip circumference, waist-to-hip ratio).

Laboratory Investigations

All participants underwent the following laboratory tests after an overnight fast: fasting blood glucose, HbA1c, complete lipid profile (total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol), liver function tests, and kidney function tests.

Calculations and Indices

Patients were divided into two groups based on their HbA1c levels: good glycemic control (HbA1c <7%) and poor glycemic control (HbA1c >7%). TyG index was calculated according to the following formula: TyG index = ln [fasting TG (mg/dL) × fasting glucose (mg/dL)/2].

Statistical Analysis

Data analysis was performed using SPSS version 25.0. Continuous variables were expressed as mean ± SD and compared using Student's *t*-test. Categorical variables were expressed as percentages and compared using Chi-square test. Pearson's correlation coefficient was calculated to assess relationships between variables. ROC curve analysis was performed to determine the optimal TyG index cutoff values for identifying poor glycemic control.

Results

Our study examined 384 patients with type 2 diabetes mellitus, analyzing various demographic, clinical, and biochemical parameters to evaluate the relationship between the TyG index and glycemic control. The results revealed significant patterns across multiple domains of assessment.

Demographic and Clinical Profile

The study population comprised 211 males (55%) and 173 females (45%), with a mean age of 52.6 ± 11.3 years. The average duration of diabetes among participants was 7.4 ± 4.8 years. Based on HbA1c levels, we categorized patients into two groups: good glycemic control (HbA1c <7%; n = 162, 42.2%) and poor glycemic control (HbA1c >7%; n = 222, 57.8%). The gender distribution remained relatively consistent between groups, with males constituting 54.9% of the good control group and 55% of the poor control group (Tables 1 and 2).

Anthropometric Measurements

Analysis of anthropometric parameters revealed significant differences between the glycemic control groups. Patients with poor glycemic control demonstrated higher body mass index (28.7 ± 3.8 kg/m^2 vs 26.4 ± 3.2 kg/m^2, $p < 0.05$) compared to those with good control. Waist circumference measurements showed notable gender-specific differences, with males in the poor control group having significantly higher values (94.6 ± 9.8 cm vs 88.3 ± 8.9 cm, $p < 0.01$). Similarly, females in the poor control group exhibited higher waist circumference measurements (96.4 ± 10.2 cm vs 92.4 ± 9.2 cm, $p < 0.01$) (Table 2).

Glycemic Parameters

The mean fasting blood glucose levels demonstrated marked differences between groups, with the poor control group showing significantly higher values (178.5 ± 32.7 mg/dL) compared to the good control group (126.3 ± 18.4 mg/dL, $p < 0.001$). As expected by group definition, HbA1c levels also showed significant variation, with means of 8.7 ± 1.2% and 6.4 ± 0.3% in the poor and good control groups, respectively ($p < 0.001$) (Table 2).

Lipid Profile Analysis

Comprehensive lipid profiling revealed systematic differences between the glycemic control groups. The poor control group demonstrated significantly elevated levels across multiple parameters: total cholesterol levels were higher in the poor control group (198.7 ± 38.6 mg/dL vs 176.4 ± 32.8 mg/dL, $p < 0.001$), as were triglycerides (186.4 ± 58.2 mg/dL vs 142.6 ± 45.8 mg/dL, $p < 0.001$). LDL cholesterol showed similar patterns (124.8 ± 33.2 mg/dL vs 102.3 ± 28.4 mg/dL, $p < 0.001$), while HDL cholesterol was significantly lower in the poor control group (41.2 ± 7.6 mg/dL vs 46.8 ± 8.4 mg/dL, $p < 0.01$). VLDL cholesterol also showed significant elevation in the poor control group (37.3 ± 11.6 mg/dL vs 28.5 ± 9.2 mg/dL, $p < 0.001$) (Table 2).

TyG Index and Related Parameters

The TyG index demonstrated significant differences between glycemic control groups, with higher values in the poor control group (9.18 ± 0.53 vs 8.32 ± 0.41, $p < 0.001$) (Table 2).

Correlation Analysis

The TyG index showed strong positive correlations with several metabolic parameters (Table 3). Most notably, it demonstrated a robust correlation with HbA1c ($r = 0.756$, $p < 0.001$). Significant correlations were also observed with total cholesterol ($r = 0.465$, $p < 0.001$), and particularly strong correlations with both triglycerides and VLDL cholesterol ($r = 0.892$, $p < 0.001$ for both). An inverse correlation was noted with HDL cholesterol ($r = -0.442$, $p < 0.001$), while LDL cholesterol showed a moderate positive correlation ($r = 0.432$, $p < 0.001$). Among anthropometric measurements, both waist circumference ($r = 0.512$, $p < 0.001$) and body mass index ($r = 0.486$, $p < 0.001$) demonstrated moderate positive correlations. Fasting serum glucose also showed a strong positive correlation with the TyG index ($r = 0.724$, $p < 0.001$).

Table 1: Baseline characteristics of the studied population

Parameter	*Mean ± SD*
Age (years)	52.6 ± 11.3
Male, *n* (%)	211 (55.0)
Female, *n* (%)	173 (45.0)
Duration of diabetes (years)	7.4 ± 4.8
Weight (kg)	78.4 ± 15.2
Height (m)	1.68 ± 0.09
Body mass index (kg/m^2)	27.8 ± 4.2
Waist circumference, male (cm)	88.3 ± 8.9
Waist circumference, female (cm)	94.6 ± 9.8
Fasting serum glucose (mg/dL)	156.2 ± 45.8
HbA1c (%)	7.7 ± 1.4
Total cholesterol (mg/dL)	189.2 ± 36.4
Triglycerides (mg/dL)	167.8 ± 53.6
HDL-C (mg/dL)	43.6 ± 8.1
LDL-C (mg/dL)	114.2 ± 31.6
VLDL-C (mg/dL)	33.5 ± 10.7
TyG index	8.82 ± 0.54

Diagnostic Performance

ROC curve analysis (Fig. 1) demonstrated strong diagnostic capability of the TyG index for identifying poor glycemic control, with an area under the curve (AUC) of 0.846 (95% CI: 0.807–0.885, $p < 0.001$) suggesting that the TyG index might be a reliable marker for glycemic control assessment.

Discussion

Our study provides comprehensive evidence supporting the potential utility of the TyG index as a marker for glycemic control in T2DM patients. The findings demonstrate strong correlations between the TyG index and established glycemic control parameters.

The observed strong correlation between TyG index and HbA1c ($r = 0.756$, $p < 0.001$) aligns with previous studies[16–20] and suggests

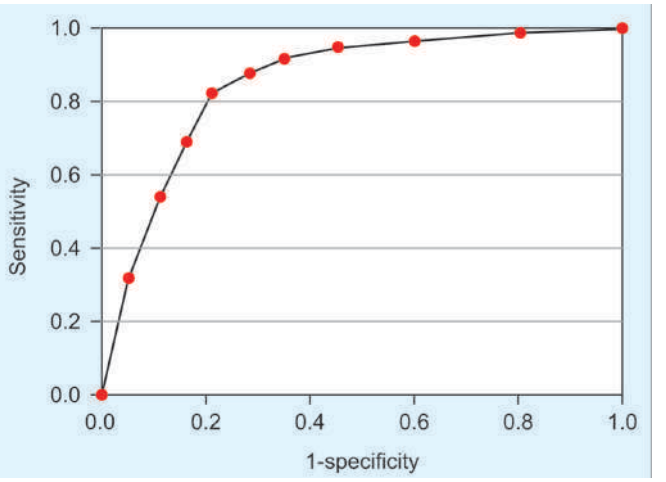

Fig. 1: Receiver operating characteristic (ROC) curve demonstrating the diagnostic performance of the triglyceride–glucose (TyG) index for identifying poor glycemic control (HbA1c >7%) in patients with type 2 diabetes mellitus

Table 2: Comparison between patients with good and poor glycemic control

Parameter	*Good glycemic control (n = 162; 42.2%)*	*Poor glycemic control (n = 222; 57.8%)*	*p-value*
Male, *n* (%)	89 (54.9)	122 (55.0)	–
Female, *n* (%)	73 (42.2)	100 (57.8)	–
Age (years)	51.8 ± 10.9	53.2 ± 11.6	0.241
Duration of diabetes (years)	7.1 ± 4.6	7.6 ± 4.9	0.315
Weight (kg)	76.8 ± 14.6	79.6 ± 15.6	0.078
Body mass index (kg/m^2)	26.4 ± 3.2	28.7 ± 3.8	<0.05
Waist circumference, male (cm)	88.3 ± 8.9	94.6 ± 9.8	<0.01
Waist circumference, female (cm)	92.4 ± 9.2	96.4 ± 10.2	<0.01
Fasting serum glucose (mg/dL)	126.3 ± 18.4	178.5 ± 32.7	<0.001
HbA1c (%)	6.4 ± 0.3	8.7 ± 1.2	<0.001
Total cholesterol (mg/dL)	176.4 ± 32.8	198.7 ± 38.6	<0.001
Triglycerides (mg/dL)	142.6 ± 45.8	186.4 ± 58.2	<0.001
HDL-C (mg/dL)	46.8 ± 8.4	41.2 ± 7.6	<0.01
LDL-C (mg/dL)	102.3 ± 28.4	124.8 ± 33.2	<0.001
VLDL-C (mg/dL)	28.5 ± 9.2	37.3 ± 11.6	<0.001
TyG index	8.32 ± 0.41	9.18 ± 0.53	<0.001

Table 3: Correlation analysis of TyG index with clinical and biochemical parameters

Parameter	*Correlation coefficient (r)*	*p-value*
Body mass index	0.486	<0.001
Waist circumference	0.512	<0.001
Fasting serum glucose	0.724	<0.001
HbA1c	0.756	<0.001
Total cholesterol	0.465	<0.001
Triglycerides	0.892	<0.001
HDL-C	–0.442	<0.001
LDL-C	0.432	<0.001
VLDL-C	0.892	<0.001

that the TyG index could serve as a reliable alternative marker for glycemic control assessment. This relationship remained robust after adjusting for potential confounders including age, gender, and BMI, supporting the independent association between these parameters. Notably, our study revealed that the TyG index also strongly correlates with fasting serum glucose ($r = 0.724$, $p < 0.001$), further validating its role in glycemic assessment.

Our findings revealed significant metabolic differences between glycemic control groups that extend beyond glucose parameters. The poor control group demonstrated significantly higher triglycerides and lower HDL cholesterol, which seems to reflect the characteristic diabetic dyslipidemia pattern, which has been attributed to insulin resistance and impaired lipid metabolism, a pattern similar to those observed in other populations.[16,17] The strong correlations between TyG index and lipid parameters—particularly with triglycerides and VLDL cholesterol ($r = 0.892$, $p < 0.001$ for both) suggest that this index captures important aspects of metabolic dysfunction in T2DM.

The anthropometric findings further support the TyG index's relationship with metabolic health. Patients with poor glycemic control had significantly higher BMI and waist circumference. The moderate positive correlations between the TyG index and both waist circumference ($r = 0.512$, $p < 0.001$) and BMI ($r = 0.486$, $p < 0.001$) suggest its potential utility in evaluating overall metabolic risk.

The ROC curve analysis demonstrated good diagnostic accuracy for the TyG index in identifying poor glycemic control, with an optimal cutoff value of 8.75 showing high sensitivity (82.4%) and specificity (78.9%). These findings suggest that the TyG index could be particularly valuable in resource-limited settings where HbA1c testing may not be readily available or affordable. The simple calculation method and reliance on commonly available laboratory parameters make it an attractive option for routine clinical use.

The biological basis for these relationships lies in the interconnected nature of glucose and lipid metabolism in insulin-resistant states. In T2DM, insulin resistance leads to increased VLDL production and chylomicron release, resulting in elevated triglycerides.[21] Simultaneously, hepatic insulin resistance disrupts glucose homeostasis through reduced glycogenesis and enhanced gluconeogenesis.[22] The TyG index, by incorporating both triglycerides and glucose, effectively captures this metabolic dysregulation.

From a practical perspective, the TyG index offers several *advantages* over HbA1c testing: (1) lower cost and wider availability of required tests; (2) no special handling or storage requirements; (3) independence from conditions affecting red blood cell turnover; (4) additional information about lipid metabolism.

Limitations of the Study

Several important limitations should be considered when interpreting our findings. The cross-sectional design of the study limits our ability to make causal inferences about the relationships observed. As this was a single-center study, the generalizability of our results to other populations and settings may be limited. Additionally, there may be potential confounding factors that were not accounted for in our analysis. The lack of long-term follow-up data also prevents us from drawing conclusions about the temporal stability of our findings. To address these limitations, future research should focus on conducting longitudinal studies to evaluate TyG index changes over time, implementing multicenter studies across diverse populations, performing cost-effectiveness analyses comparing TyG index with HbA1c, and investigating the utility of TyG index in predicting diabetes complications.

Conclusion

Our study demonstrates that the TyG index has a strong correlation with HbA1c and exhibits good diagnostic capability for identifying poor glycemic control. With an optimal cutoff value of 8.75, the index shows high sensitivity and specificity. The TyG index also correlates significantly with other metabolic parameters, including lipid profiles and anthropometric measurements. Given its cost-effectiveness, wider availability, and independence from conditions affecting red blood cell turnover, the TyG index could serve as a viable alternative to HbA1c for glycemic control assessment, particularly in resource-limited settings. However, longitudinal studies across diverse populations are needed to validate these findings.

Ethical Approval

Ethics approval was obtained from the Institutional Ethics Committee of FH Medical College (Approval No. FHMC/IEC/R. Cell/2023/71 dated 21 October 2023).

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

Acknowledgment

Nil.

Author Contributions

Rahul Garg: Conceptualization, writing – original draft.
Anmol Thakre: Data Collection, writing – review & editing.
Rahul Garg, Anmol Thakre: Methodology.

AI Use Declaration

No AI tools were used in the preparation of this manuscript.

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ORIGINAL ARTICLE

Profile of Elderly Patients Presenting to the Emergency Department: A Prospective Observational Study

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Abstract

Aim: To study the profile of clinical presentations and their outcomes among the elderly patients presenting to the emergency department (ED) of a tertiary health care center in Bengaluru.

Materials and methods: Data were collected from patients aged 60 years or more who visited the ED of Bangalore Baptist Hospital during a period of 2 years. The data collection was done using a semi-structured questionnaire after taking informed consent. Data were entered and analyzed using SPSS version 22.0.

Results: The elderly comprised 24.3% of all visits to the emergency department. The mean age of presentation was 70.9 years. They had multiple comorbidities, with the majority having two or more (n = 312) comorbidities, with diabetes mellitus being the most common. Elderly patients with nonspecific complaints (NSCs) comprised 7.1% of the total, while the remaining came with specific complaints (SCs). They presented to the emergency with higher acuity, i.e., triage 1 (40.8%, n = 207) and triage 2 (52.8%, n = 290). A large portion of them got admitted (51.8%, n = 263), while 27% (n = 137) were discharged, out of which 5.1% (n = 7) returned to the ED within 15 days. The diagnostic accuracy in the ED according to our study is 91.75%

Conclusion: In our study, we conclude that the elderly make up a large share of the total ED presentations. We had more young-old (55.4%) coming to our ED with overall male predominance. They suffer from multiple comorbidities, and the majority had two or more comorbidities. NSCs were a frequent occurrence. They presented to the ED with higher triage level requiring immediate care/treatment. They are more likely to get admitted and had longer length of stay.

Keywords: Elderly, Emergency department, Geriatrics, Nonspecific complaints.

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Introduction

"Caring for those who once took care of, us is the service of highest honor." This quote becomes more practical in our profession, which deals with the day-to-day health problems in the elderly population and tries to make the senescence part of life a more comfortable one.

Over time, the majority of them gather multiple comorbidities. With the toll of time and stress on body and mind, and the gradual wear and tear of various systems in the body, they become more dependent on caregivers for their usual needs.

According to current demographic trends over the long run, if mortality continues to decline, the share of the population of working age will decline, and that of older persons will increase, leading to rising dependency ratios, and when this happens, the phenomenon is termed as the 'demographic burden'. This is an inevitable consequence of demographic transition, and every country has to face this problem with development and a successful demographic transition.[1]

Various countries use varied definitions and terms for defining the old-age population, such as senior citizens, elderly geriatric population, etc.

United Nations has agreed on the age of ≥ 60 years to be included in the old age group.[2] WHO reduced the age limit to 50 years for study in Africa.[3] In India, we refer to senior citizens/elderly as ≥ 60 years of age, as indicated in the Maintenance and Welfare of Parents and Senior Citizens Act, 2007. Therefore, for this study the elderly will be taken as age equal to or above 60 years.[4]

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Patient informed consent: Written informed consent was obtained from all participants prior to enrolment.

According to data from World Population Prospects: the 2019 revision, by 2050, one in six people in the world will be over age 65 years (16%), up from 1 in 11 in 2019 (9%). For India, a report released by the United Nations Population Fund and HelpAge India suggests that the number of elderly persons is expected to grow to 173 million by 2026.[5]

Availability of better health care facilities and decreasing mortality rate probably contributed to this demographic change, thus acquiring India the label of "an aging nation." Therefore, older

patients in the modern emergency department (ED) are going to make up an increasing number of presentations. They are a patient population who provide unique challenges to emergency department (ED) physicians given the frequent complexity of their background medical conditions.

Along with multiple comorbidities, every system in the body undergoes natural aging, which is accompanied by progressive biological changes in the immune system also, some of which lead to its declining function as evidenced by increased susceptibility to various infections. These changes in concert with comorbidities, render older individuals vulnerable to latent or novel infections and lead to the observed increases in morbidity and mortality.[6]

The combined effect of age and failing immunity along with polypharmacy, altered mental condition and inability to convey the exact problem effectively, leads to blurring of the clinical picture, which further leads to complaints like "not feeling well," "feeling weak," "being tired," feeling "dizzy," or simply being unable to cope with usual daily activities. These complaints are what we call as nonspecific complaints (NSCs), which are one of the biggest challenges faced by EPs[7] They are often undertriaged (i.e., their initial risk assessments are too low), and the severity of the illness causing their NSC is often misjudged. These systematic misjudgments can result in delays in definitive treatment of the underlying cause of their chief NSCs.[8]

Therefore, older patients are more likely to present with a greater level of acuity, have longer ED stays, higher rates of admission to hospital and Intensive Care. ED re-attendances in older patients are also high in the elderly population, causing an increasing burden on the already busy ED.[9]

The delivery of acute care in a busy environment to this vulnerable population will be an increasingly larger challenge in the future. EDs across India need to be prepared to handle this change in the demography, and hence, it is important to know the patient profile of geriatric emergencies. However, literature from India on this subject is scant.[10] Hence, we would like to conduct this study to describe the profile of geriatric emergencies in a large tertiary care hospital, which will help us to better understand the pattern in our country and help us in coming up with solutions to the challenges posed by the elderly in the ED.

Aim and Objectives

Aim

To study the profile of the clinical presentations and their outcomes among elderly patients coming to the ED of a tertiary healthcare Centre in Bengaluru.

Primary objective

To profile the clinical presentations of the elderly coming to the ED of a tertiary health care Center, in terms of their symptoms, age, gender, and comorbidities.

Secondary Objectives

- To determine the percentage of SCs and NSCs among study population and with their outcomes.
- To study the treatment outcome of elderly patients coming to ED.
- To determine percentage of re-visits to Emergency within 15 days in patients discharged from ED.

Materials and Methods

Study Site

The study will be conducted in the Emergency Department of the Bangalore Baptist Hospital, Bengaluru. ED has a total of 24 beds with an average of 100–110 patients per day, peaking to 140 patients on weekends. Bangalore Baptist Hospital is a 340-bedded NABH-accredited, multispecialty, tertiary health care center.

Study Population

All elderly patients (aged above 60 years) coming to the ED who met the inclusion criteria.

Inclusion criteria:

- All the patients aged ≥ 60 years presenting to the ED.
- All those who give their consent will be included in the study

Exclusion criteria:

- Moribund patients on palliative care.
- Patients who are referred from other hospitals for further management.
- Patients who have taken Discharge against medical advice (DAMA) from other hospital and present to the ED for further management.

Study Design

An observational study.

Time Period of Study

From 1st September 2019 to 31st May 2021.

Sample Size

Sample size = $4PQ/d^2$

Where, P = 23.5*, Q = 100–23.5 = 76.5, d = 15% of P = 4.76

Therefore, sample size = $4 \times 23.5 \times 76.5/(3.525)^2 = 579$

*According to a study done in Karachi, Pakistan, which showed the most common was found to be nonspecific complaints grouped together (23.5%).[11]

Study Definitions

Elderly/senior Citizen

According to the Maintenance and Welfare of Parents act, 2007, a person aged 60 years and above is called as senior citizen/elderly in India.

Specific Complaints

These are defined as all complaints for which initial working diagnosis can be made with certainty and evidence-based management protocols exist for emergency physicians. The typical examples of this kind of complaints include chest pain, trauma, abdomen pain, hemodynamically unstable (shock, respiratory failure, etc.).[7]

Nonspecific Complaints

These are defined as the entity of complaints not part of the set of specific complaints (SCs) for which evidence-based management protocols for emergency physicians (EPs) exist, for example, not feeling well, feeling weak, being tired, decreased appetite, or just not being able to cope up with daily activities. These complaints are identified after excluding all SCs and ruling out hemodynamic instability.[7]

Methodology

All patients above 60 years were identified, and written informed consent for study was taken. Demographics were recorded, clinical history was elicited, and examination was done, following which they were grouped into SCs and NSCs groups. Then their disposition from the ED was noted; if discharged, their return to ED was followed till 15 days. If admitted, their length of stay (LOS) was seen. Further, in admitted patients, LOS among SCs and NSCs groups was compared, and their final diagnosis was noted. The final diagnosis was compared to the ED diagnosis to look for consistency.

Study instrument: Semistructured questionnaire.

Ethics

- Written consent prior to the inclusion will be taken in a predesigned Pro forma.
- No additional cost or tests will be levied on patients in our study.
- All patients' personal data will be used for study purposes only, and confidentiality will be maintained.

Data Management and Analysis

Data were entered into a Microsoft Excel data sheet and were analyzed using SPSS 22 version software. Categorical data were represented in the form of frequencies and proportions. Chi-square test and unpaired *t*-test were used as tests of significance for qualitative data. Continuous data were represented as mean and standard deviation.

Graphical Representation of Data

- MS Excel and MS Word were used to obtain various types of graphs such as bar diagram and pie diagram.
- *p*-value (probability that the result is true) of < 0.05 was considered statistically significant after assuming all the rules of statistical tests.
- *Statistical software*: MS Excel and SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) were used to analyze the data.

Results

The study was conducted at the Emergency Department of Bangalore Baptist Hospital, during the period of September 1st, 2019 to May 31st, 2021. During this study period, the total number of patients visiting our ED was 51,057, of which 12,406 were above 60 years of age. Therefore, the total incidence of the elderly in our ED is 24.3%. Among these patients, we recruited 507 patients for our study. The data were analyzed for the same.

In our study, we found that the range of distribution of age extended from 60–96 years, and the majority of our patients in the study belonged to the 60–70-year age group. As shown in Figure 1 and Table 1.

The gender-wise distribution in our study reveals a male predominance. Out of 507 patients recruited in the study, we found that the elderly male patients made up 55.2%, while the elderly female patients made up 44.8% of total visits to our ED. As shown in Figure 2.

Going through the comorbidities, we found out that the elderly most commonly suffered from diabetes mellitus, which was followed by hypertension. The other most common comorbidities were ischemic heart disease, Neoplastic, cerebrovascular accident, bronchial asthma, hypothyroidism, chronic kidney disease, and benign prostate hypertrophy. The other category included people having chronic obstructive pulmonary disease, chronic liver disease, seizure disorders, and psychiatric disorders. As shown in Figure 3.

Based on the number of comorbidities per person, the distribution of our sample showed most people to be having two ($n = 161$) comorbidities, while 129 patients had only one comorbidity. 66 patients in our study had no comorbidities, and 151 patients had three or more comorbidities. As shown in Figure 4.

The data on substance abuse in the elderly presenting to the ED shows us that alcohol is the most commonly abused agent ($n = 5$). The overall abuse done by our patients was significantly less. As shown in Table 2.

All patients coming to our ED are triaged into four categories based on our locally modified criteria for triaging. Triage 1 is for patients with condition which warrant immediate treatment; triage 2 category is patients with conditions requiring urgent care–meaning they need monitoring or evaluation or with a potential to deteriorate; triage 3 is for patients with nonurgent conditions, and triage 4 is for brought-dead patients. The analysis showed that the majority of the study population came to ED with triage 2 ($n = 290$), followed by the triage 1 category of patients with 207 patients. In our study, we had a very less number of patients coming to the ED as nonurgent. As shown in Table 3.

Next, we analyzed the visits made by the elderly to our ED from entry to exit. On presentation, history was elicited, and

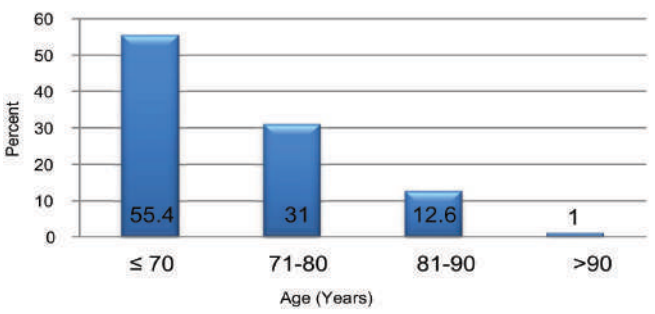

Fig. 1: Distribution of age

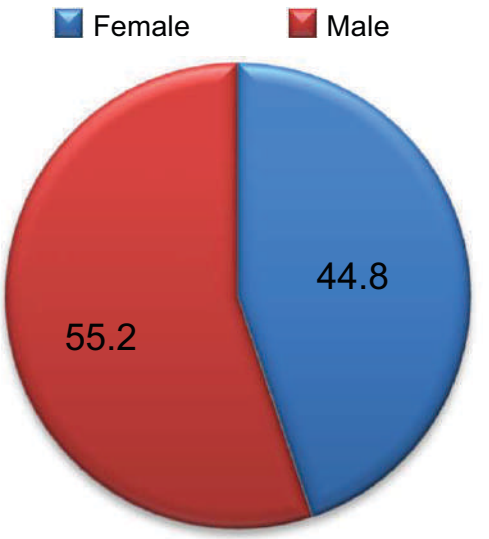

Fig. 2: Distribution of gender

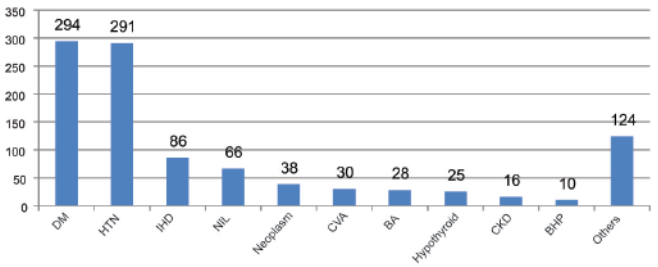

Fig. 3: Most common comorbidities (*n* = 507)

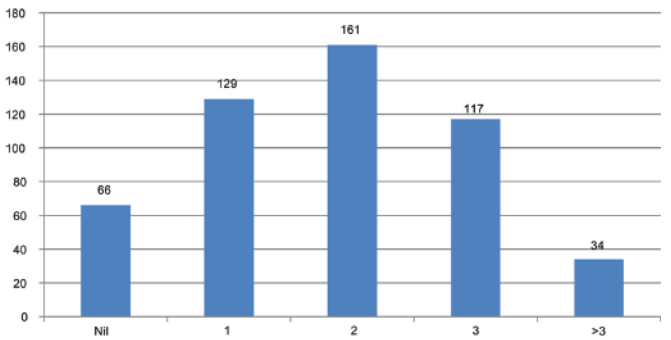

Fig. 4: No of comorbidities per person (*n* = 507)

Table 1: Distribution of study subjects according to age (in years) (n = 507)

Age (years)	*No.*	*Percent*
60–70	281	55.4
71–80	157	31.0
81–90	64	12.6
>90	5	1.0
Mean (SD)	70.96 (8.25)	
Range	60–96	

Table 2: Distribution of study subjects according to substance abuse (*n* = 507)

Substance Use	*No.*	*Percent*
Alcohol	5	1.0
Smoker	2	0.4
None	500	98.6

as majority of our patients came with multiple complaints, the most predominant symptom was considered for the analysis. They were then divided into specific and nonspecific symptoms. These varieties of symptoms presenting to the ED were grouped together under categories such as neurological, cardiac, abdomen.

Our analysis of the most predominant symptoms with which patients came to our ED showed that 201 patients coming to our ED had predominantly NSCs (39.6%), while 306 patients who came to our ED had predominantly SCs (60.4%). As shown in Table 4.

In our study, we found that the patient who had come with NSCs had predominantly generalized weakness (*n* = 121) as their most common complaint, which was followed by tiredness, decreased appetite, and decreased mobility in decreasing order. As shown in Table 5.

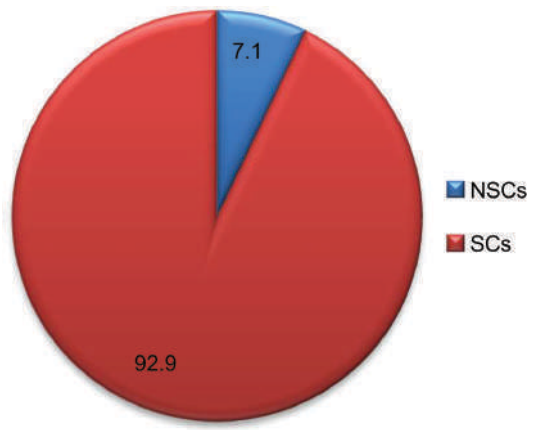

Fig. 5: Distribution of NSCs/SCs

Table 3: Distribution of study subjects according to the triage (*n* = 507)

Triage	*No.*	*Percent*
1	207	40.8
2	290	57.2
3	10	2.0

Table 4: Frequency of nonspecific and specific complaints (*n* = 507)

Group	*Frequency*	*Percentage*
Nonspecific complaints	201	39.6%
Specific complaints	306	60.4%

Table 5: Predominant nonspecific symptoms

Nonspecific complaints (NSCs) Presenting symptom	*n (201)*
Generalized weakness	121
Tiredness	46
Decreased appetite	32
Decreased mobility	2

While analyzing the SCs side, the most predominant complaint with which patients came to our ED was neurological (*n* = 55), which was closely followed by the respiratory, infectious, and traumatic injuries. Abdomen, genitourinary, gastrointestinal, musculoskeletal, cardiac, nasopharyngeal, and others were the remaining categories. The others category included postsurgery, drug overdoses, dermatologic and ophthalmic complaints. As shown in Table 6.

Among the patients visiting our ED, detailed history and clinical examination were done for all. After the evaluation, those who still had no specific symptoms were grouped under NSCs. This was done as part of the secondary objective of our study. Those with pure nonspecific complaints only were grouped into NSCs, which were around 7.1%, and the rest were grouped under SCs. The distribution of SCs and NSCs showed that 92.9% of our patients came with specific complaints, and the remaining came with pure NSCs. As shown in Figure 5 and Table 7.

The patients were worked up in the ED and their provisional diagnosis was made in ED. These diagnoses were classified based on their major system involvement and grouped accordingly. This group wise distribution was done as the total number of different diagnoses made in ED was very extensive. The analysis of this

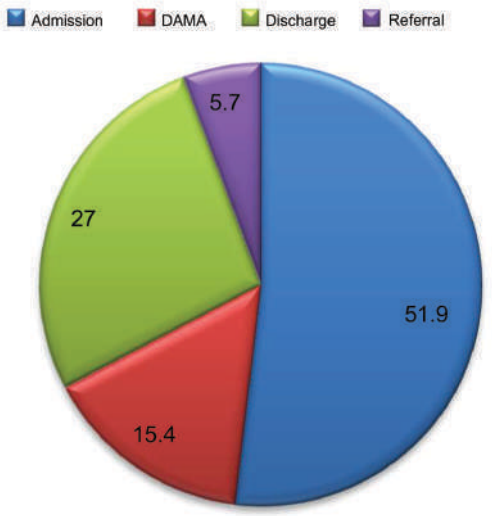

Fig. 6: Distribution of disposition from ED

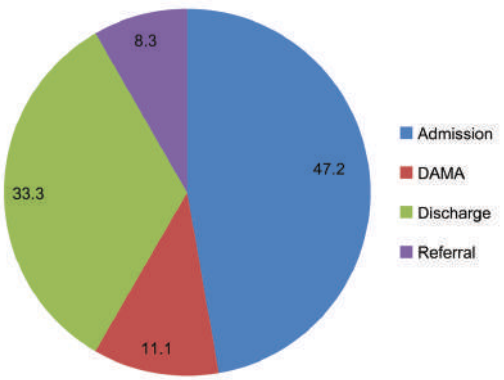

Fig. 7: Disposition of NSCs from ED

Table 6: Predominant specific complaints

Specific complaints (SCs) Presenting symptom	*n (306)*
Neurological complaints	55
Respiratory complaints	42
Infections	41
Trauma	39
Abdominal complaints	27
Genitourinary complaints	20
GI complaints	20
Musculoskeletal complaints	20
Cardiac symptoms	16
Naso-oropharyngeal complaints	10
Others	14

showed that the most common diagnoses were of respiratory tract illness (*n* = 172), followed by Abdomen (11.4%), Cardiovascular illness (9.3%) and central nervous system illness (8.8%). As shown in Table 8.

The data regarding the disposition from ED was assessed for all patients. It showed that admission to hospital (51.8%) was the most common mode of disposition from ED for the elderly patients. This makes it every 2nd elderly patient coming to ED was admitted to the hospital. This was followed by Discharge from hospital (27%).

Table 7: Distribution of study subjects according to the NSCs/SCs (*n* = 507)

NSCs/SCs	*No.*	*Percent*
NSCs	36	7.1
SCs	471	92.9

Table 8: ED diagnosis

Diagnosis	*ER diagnosis N (%)*
CVS	47 (9.3)
CNS	45 (8.8)
RS	172 (33.9)
Abdomen	58 (11.4)
Endocrine/Metabolic	30 (5.9)
Infectious	28 (5.5)
Neoplastic	11 (2.2)
Ortho	21 (4.0)
ENT	16 (3.2)
Skin and Soft Tissue	31 (6.1)
Genito-Urinary	49 (9.8)
Total	508

Table 9: Distribution of study subjects according to the disposition from ED (*n* = 507)

Disposition from ER	*No.*	*Percent*
Admission	263	51.8
DAMA	78	15.4
Discharge	137	27.0
Referral	29	5.7

Other modes of disposition in the order of decreasing frequency were DAMA which made up 15.4% and a few were sent as referral to other center which made up 5.7% of the total elderly patients coming to emergency. As shown in Figure 6 and Table 9.

Disposition of patients grouped under NSCs was also analyzed as a part of our secondary object. The analysis done showed that 47% of patients who came with pure NSCs got admitted to the hospital. The other common modes of disposition in the order of decreasing frequency were Discharge from the hospital, which was 33.3% while 11.1% of patients went to DAMA, and 8.3% of patients were sent as referral to the other center. As shown in Figure 7 and Table 10.

To look for the burden added to ED by the recurrent visits from the same patient, we analyzed return to ED within 15 days for the patients discharged from ED (*n* = 137). The analysis showed that a total of seven patients returned to ED with different complaints. These complaints were also grouped into specific and nonspecific. In the return to ED patients, five patients had specific complaints, while two patients still came with nonspecific complaints. As shown in Tables 11 and 12 respectively.

On the other hand, among the patients who got admitted to the hospital, their length of stay was observed, and the analysis of it showed that the mean duration of stay among the admitted patients was 8 days. The range for length of stay extended from 1 to 36 days. In our study, the majority of patients stayed between 4 and 7 days (*n* = 120), which was followed by 8–14 days (*n* = 74), 1–3 days (*n* = 41), and >14 days (*n* = 28) in the decreasing order of frequency.

Table 10: Disposition of NSCs from ED

Disposition of NSCs	*No.*	*Percent*
Admission	17	47.2
DAMA	4	11.1
Discharge	12	33.3
Referral	3	8.3

Table 11: Distribution of study subjects according to the return to ED within 15 days (n = 137)

Return to ED within 15 days	*No.*	*Percent*
Yes	7	5.1
No	130	94.9

Table 12: Distribution of study subjects according to the complaints if return to ED (n = 7)

SC/NSC	*Complaints*	*No.*	*Percent*
Specific 5 (71.5%)	Pain abdomen	2	28.6
	Altered sensorium	1	14.3
	Displaced catheter	1	14.3
	Metastatic pain	1	14.3
Nonspecific 2 (28.5%)	Generalized weakness	2	28.6

Table 13: Distribution of study subjects according to the duration of stay (n = 263)

Duration of Stay (Days)	*No.*	*Percent*
1–3	41	15.6
4–7	120	45.6
8–14	74	28.1
>14	28	10.6
Mean (SD)	8.00 (5.83)	
Range	1–38	

The median and mode for the length of stay in the hospital came out to be 6 and 4 days, respectively, which shows the majority of our patients stayed for 4 days in the hospital. The above data makes our distribution skewed. As shown in Table 13.

In the comparison done between the length of stay in the patients grouped under NSCs and SCs, the comparison showed that the patients under the SCs group to had longer length of stay compared to the NSCs group. The mean length of stay in NSCs and SCs was 6.65 days and 8.09 days, respectively. As shown in Table 14.

At discharge, the final diagnosis of patients admitted under NSCs was followed, which showed the majority of patients had underlying Infection (n = 8, 47%), which included lower respiratory tract infection (n = 4), sepsis (n = 3), and urinary tract infection (n = 1). Infections were followed by dyselectrolytemia (n = 3, 17%). As shown in Table 15.

At the discharge time of admitted patients, diagnoses made in the ED were compared to final diagnosis, which showed that the majority of ED diagnoses were consistent with the final diagnosis. The accuracy of final diagnosis compared to ED diagnosis was found to be 91.25% (n = 240), meaning more than 9 out of 10 times the ED was able to make the correct diagnosis. The other 8.75% (n = 23) of patients were wrongly diagnosed at the ED.

Table 14: Association between duration of stay and NSCs/SCs (n = 263)

NSCs/SCs	*Mean*	*SD*
NSCs	6.65	2.84
SCs	8.09	5.98

Unpaired t-test, p-value = 0.325, not significant

Table 15: Final outcome of NSCs

Diagnosis	*Frequency (%)*
Lower respiratory tract infection	4
Dyselectrolytemia	3
Sepsis	3
Acute coronary syndrome	2
Nutritional anemia	2
Urinary tract infection	1
Atrial fibrillation	1
Total	16

Table 16: ED diagnosis vs final diagnosis in admitted patients (n = 263)

Group	*Final diagnosis (n)*	*Consistent ED diagnosis (n)*	*Missed (n) (%)*
Nonspecific	17	13	4(23.5%)
Specific	246	227	19(7.7%)

Chi-square test, p-value = 0.025, statistically significant

Table 17: System-wise consistency of ED diagnosis with final diagnosis

Diagnosis group	*ED diagnosis (n)*	*Final diagnosis consistent with ED (n)*
CVS	28	24
CNS	30	29
RS	93	89
Abdomen	27	22
Endocrine/metabolic	19	16
Infectious	13	12
Neoplastic	7	7
Ortho	4	4
ENT	3	1
Skin and soft tissue	12	11
Genitourinary	27	25
Total	263	240

While in NSCs group, the percentage of patients with wrong diagnosis was higher compared to the total (23.5%). The other 76.5% of patients were correctly diagnosed, which makes it two wrong diagnoses out of 10 every time. This, on further analysis with Chi-square test, was found to be statistically significant. As shown in Table 16.

On analyzing system-wise accuracy of ED diagnosis, neoplastic, CNS, CVS, and respiratory diagnoses to be most accurate, while genitourinary and skin group diagnoses turned out to be relatively inconsistent. As shown in Table 17.

Discussion

Emergencies related to older age groups are quite common throughout the world. The magnitude of this problem is quite underestimated,

and there are not enough studies from the perspective of the ED physician in the Indian population regarding the same. The incidence of the elderly at our facility was 24.3%, and this is similar to the study done in Pakistan, Italy, Finland and South Africa respectively.[11–14] They had incidence of 25%, 25% and 15% for elderly. One in four patients coming to the emergency department is elderly and the data is clearly evident of the need. The above similarities in results could be due to the similar population pattern of the two countries. Hence, this study was conducted to identify the clinical profile of elderly patients presenting to the ED of a tertiary care hospital in India.

This study was conducted among 507 patients of the age group above 60 years presenting to the Emergency Department of Bangalore Baptist Hospital, which is a tertiary care center with 340 beds in Karnataka, India.

We analyzed the demographics, and hence elderly patients coming to our ED were distributed according to age, sex, and comorbidities. Age distribution showed that the range of patients coming to our ED covered a broad range (60–96 years), with the mean age of presentation being 70.96 years with an SD of 8.25. The above results corresponded well to Fayyaz et al. and Pembe et al.[11,15]

In our study, we subdivided the elderly in age groups of 60–70, 71–80, 81–90, and above 90; the maximum number of patients belonged to 60–70 years, consistent with the study done by Song et al.,[16] in South Korea, where they saw that the majority of elders belonged to the 60–70 years age group. But the percentage was slightly higher in our population, 55.4% vs 49.2%, which could be attributed to the difference in demographics of both countries. This is probably due to the fact that in India the population of young-olds (60–70 years) is higher than the older aged population group. This may be the reason for the comparison with other countries not to correlate.

The gender distribution reveals that the majority of our patients were males (55.2%), which was similar to the study done by Abhilash et al.,[17] which had 65.4% of males. Probably the percentage of males was more in that study as the demographics covered more of a rural setting as compared to the urban setting in our study, though both the studies were conducted in India.

They were further divided depending on the number of comorbidities per person, which showed the majority of people had two comorbidities (*n* = 161, 31.7%), followed by one (*n* = 129, 25.4%), while 117 patients had three and above comorbidities. These results are different from the BANC study,[7] which had the majority of patients having three comorbidities; the variation could be considered due to the mean age difference, which was higher in the BANC study, and differences in demographic location.

Among the comorbidities, the most commonly occurring comorbidity in our population was Diabetes mellitus, closely followed by hypertension, which were different from the Longitudinal Aging Study in India (LASI-1) in 2021, where 72,000 people were analyzed, but the age group included was above 45 years. The explainable reason could be the difference in age groups and population sample.[18]

The analysis of symptoms yielded that the non-specific symptoms were around 39.6% and specific symptoms made up to 60.4%. The above results show that almost 4 out of every 10 elderly patients came with predominantly nonspecific complaints.

In the NSCs, symptoms like generalized weakness turned out to be the most predominant complaint in the elderly with which they present to the ED. The above results were different from Fayyaz et al.,[11] which had around 25% of patients with nonspecific symptoms. In another study done by Sauter et al.[19] at the Bern University Hospital, which also showed results similar to Fayyaz et al., with NSCs predominance of 23.2%., while in a multinational study by Gray et al, the incidence of geriatric syndrome.[20] The difference in incidence of NSCs could be due to differences in definitions of NSCs used by both the quoted studies. Sauter et al. also had a different age group compared to our study; they included all patients above 18 years, which could have reduced the incidence of NSCs in their study.

On the specific symptom side, the most common complaints were neurologic (10.8%), followed by respiratory (8.2%), which were again different from Fayyaz et al., which had shortness of breath as the most common specific complaint, followed by fever. This could be attributed to different ways in which the symptoms were categorized in both studies. Compared to our study, Fayyaz et al. did not include shortness of breath in respiratory, while headache was also calculated separately from neurologic. Fever was calculated as an isolated complaint, while in our study it was added to all infectious symptoms.

After symptoms, they were triaged into different categories according to the need for urgency of intervention. Our analysis showed the majority of our patients were triage 2 (*n* = 290, 57.2%), but the triage 1 patients also accounted for 40.2%, which indicates that a large share of our patients came with serious illness. The above results were similar to the results of a study done by Wachelder et al. in Netherlands,[9] which had 56.6% of patients as triage 2 and 34.8% patients as triage 1. This could be due to ignorance of the initial nonspecific symptoms by the elderly, as their aging immune system abilities are on decline[6] and specific symptoms are produced relatively later in the course of disease. Overall, this leads to progression of disease to a critical point by the time they present to the ED. Lockdown affected patient visits to the hospital, and the visits were only when the condition was really an emergency for them. This may be the reason for very few non-urgent visits to the ED.

After triage analysis, patients were grouped under SCs and NSCs. The analysis of our distribution on the basis of NSCs and SCs showed that 7.1% (*n* = 36) belonged to the NSCs group, rest 92.9% (*n* = 471) were SCs. This result was also consistent with the research done by Kemp et al. and Bhalla et al. on the adults coming to ED.[21,22] The prevalence of NSCs in the elderly varied from 6.4% to 14% in their review of nine studies which met their criteria for analysis while in study by Bhalla et al generalized weakness and fatigue counted for 6.0% of total visits by older people.

The mode of disposition from ED was also assessed by us. The analysis showed that the most common method of disposition of the elderly from ED was admission to hospital (51.8%). This was followed by discharge of patients, which was around 27%; the percentage of elderly patients going DAMA was 15.4%, and referral sent to other hospitals was 5.7%. Admission rates in our study were comparable to those of Foo et al.,[23] conducted in Singapore. They had relatively higher admission rates of 59.1%, which could be due to the difference in mean age and age group (>65 years) used by Foo et al. Another difference noted here was the less number of DAMA and referrals in their study, which may be due to locally prevailing socio-economic conditions and facilities in the center.

We also observed the disposition of patients in the NSCs group (*n* = 36), which showed that 47.1% (*n* = 17) were admitted and 33.3% (*n* = 12) were discharged. On the other hand, patients going to DAMA were 11.1% (*n* = 4), and 8.3% (*n* = 3) were sent as referrals to another center. The above admission rates for the NSCs group were lower compared to the results of research done by Kemp et al.[21] where they found the admission rates in elderly patients with NSCs to be ranging from 55% to 84%. The admission rates were 58% in the study done by Misch et al.,[24] which were higher compared to our study. The above difference could be due to patients going

DAMA and referral, which, if included, will increase the admission rates and bring it in line with the above-mentioned studies.

The length of stay was analyzed for all the admitted patients, which showed that the mean length of stay among the admitted patients was 8 days, SD 5.83 (range 1–36). The majority of our patients stayed 4–7 days (*n* = 120, 45.7%). The mode of the data was 4, which indicated the majority of patients stayed for 4 days. The range for length of stay in our study varied from 1 to 36 days, which could be explained due to the ongoing COVID pandemic and the prolonged discharge criteria set by the local governing body, prolonged need for ventilation, and ICU stays.

Length of stay among NSCs and SCs was compared in our study, which showed that average length of stay in NSCs was 6.65 days with SD of 2.84, which was consistent with research done by Kemp et al.[21] The length of stay in their literature review showed the majority of studies to have LOS around 6 days in NSC group.

Mean length of stay in SC group was found to be 8.09 days with SD of 5.98. The mean length of stay is relatively higher in our study compared to results from Kemp et al.[21] which had an average of 4 days in SC group. The higher mean length of stay in our study for SC group could be explained on the basis of skewed data. The mean, mode and median of length of stay in the data showed values of 8 days, 4 days, and 6 days, respectively. In our study, length of stay data showed a range of 1–38 days and 28 patients stayed for more than 14 days. These prolonged stays can be attributed to the ongoing COVID pandemic and the discharge criteria set by the local governing body for the COVID-19-infected patients.

At discharge time, the final diagnosis made for each patient was compared with the ED diagnosis made during admission time. The analysis showed that 91.25% of the diagnoses made at admission time in the ED were consistent with the final diagnosis and 8.25% were missed. These results were better compared to the results by Schewe et al.,[25] where they missed diagnoses in around 15% of the elderly.

While comparing the diagnostic accuracy in SCs and NSCs groups, 4 out of 17 diagnoses were missed in the NSCs group, whereas 19 out of 246 were missed in SCs group, making our percentage of missed diagnosis 23.5% and 7.7%, respectively. The percentage of missed diagnosis in NSCs was lower compared to Peng et al.,[26] where they had missed up to 52% in patients with NSCs. The chi-square test was statistically significant at a *p*-value of 0.025, which proves that higher chance of missing a diagnosis in patients with NSCs.

The higher consistency between final diagnosis and ED diagnosis in comparison with earlier study could be attributed to the increasing awareness among the EPs regarding the special needs of elderly and hence leading to more careful and extensive evaluation.

At the discharge time, final diagnosis of all patients under NSCs group (*n* = 17) were assessed to look for the common outcomes. The results showed that the most common outcome of NSCs was infectious (*n* = 8, 47%), which included LRTI (*n* = 4), sepsis (*n* = 3), and UTI (*n* = 1), followed by dyselectrolytemia (*n* = 3, 17.6%). Other common diagnoses of NSCs in our study were acute coronary syndrome (*n* = 2, 11.7%), anemia (*n* = 2, 11.7%), atrial fibrillation (n = 1, 5.8%), and postviral myalgia (*n* = 1, 5.8%). Compared to the study by Nemec et al.and Karakoumis et al.[7,27] in Basel, Switzerland, where they had similar predominance of infectious disease as the final outcome in the elderly. In their study, around 60% had infectious outcome followed by metabolic dysfunction which occurred in 18% In study by Karakoumis et al. males had predominantly LRTI vs UTI in females as our study was male predominant, hence our study had LRTI as more predominance.

On the other hand, in discharged patients, the return to ED was followed till 15 days from the date of discharge. Which showed that 5.6% (*n* = 7) returned to ED within 15 days. This was less compared to results reported by Wachelder et al. and Quinn et al. They reported 23% and 16% patients returning to ED, respectively. This variation in our study can be attributed to lesser period of observation for return to ER. Both Wachelder et al. and Quinn et al. had 90- and 30-day follow-up periods, respectively.[9,28]

Conclusion

In our study, we conclude that the elderly make up a large share of the total ED presentations. We found that we had more young-old (55.4%) coming to our ED compared to very old.[29] Elderly population was predominantly male, with a mean age of 70.9 years. They suffer from various comorbidities, and the majority of them have multiple comorbidities, which was evident in our study where 312 patients had two or more comorbidities.

The majority of the elderly presented to the ED with higher triage level requiring immediate care/treatment. A large share of elderly patients came with predominant nonspecific symptoms (39.6%) as their primary presenting reason to the ED. On further elicitation of history and clinical examination, the true NSC was found to be only 7.1%.

They also have increased admission rates (51.8%) and had similarly higher admission rates in NSCs (47.2%). Return to ED in discharged patients is also on the higher side (5.1%), which ultimately adds up to the burden of ED. The diagnostic accuracy in the ED, according to our study, is 91.75% but among NSCs group, it was lower, and it needs to be improved to reduce the overall burden on ED and help the Elderly.

Limitations

- The ongoing COVID pandemic could have skewed the study.
- The presentation of elderly may have been impacted by the pandemic situation as they were suggested to stay indoors.
- Lockdown affected patient visits to the hospital and the visits were only when the condition was really an emergency for them.
- The studied sample size was 507 which is slightly lower the actual calculated sample size (579), the reason for that being the loss of charts during the follow-up period
- The true outcome of patients who left against medical advice (DAMA) and those who were referred from ED were not reflected in the final results of outcomes.
- Socioeconomic status of the patients was not considered in our study which is a known risk factor for improper care and morbidity in the elderly.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of Bangalore Baptist Hospital (Approval No. BBH/NBE/Thesis pro 2019/001, dated 20 August 2019).

Clinical Trial Registration

Not applicable.

Data Availability Statement

All data generated or analysed during this study are included in this published article.

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Author Contributions

Conceptualization: Dr Sagar and Dr Kingsly.
Methodology: Dr Sagar and Dr Kingsly;
Data collection: Dr Sagar;
Writing – qriginal draft: Dr Sagar;
Writing – review & editing: Dr Sagar, Dr Kingsly, and Dr C Sreekanth.

AI Use Declaration

The authors declare that no artificial intelligence (AI) tools were used in the preparation of this manuscript.

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ORIGINAL ARTICLE

Diagnostic Accuracy of Fetal Epicardial Fat Thickness between 16 and 24 Weeks of Gestation by Ultrasonography for the Diagnosis of Gestational Diabetes Mellitus

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Abstract

Background: Gestational diabetes mellitus (GDM) is a prevalent metabolic disorder affecting 1% to 14% of pregnancies worldwide, with significant implications for both maternal and fetal health.

Objective: This study explores the role of fetal epicardial fat thickness (fEFT) as a potential diagnostic marker for GDM, aiming to enhance early detection and management.

Methods: Conducted as a diagnostic cross-sectional study at a tertiary care hospital in central India, the research included pregnant women aged 16–24 weeks undergoing an oral glucose tolerance test (OGTT) between 24 and 28 weeks. Anthropometric parameters such as maternal subcutaneous fat thickness (mSFT), abdominal circumference (AC), and fEFT were measured using ultrasonography.

Results: The findings revealed a significant association between increased fEFT and GDM prevalence, with higher values observed in affected individuals (0.13 cm vs. 0.07 cm, $p = 0.00$). Sensitivity analysis showed that fEFT had an 83.33% sensitivity but only a 12.5% specificity in diagnosing GDM, indicating its potential utility as an early screening tool rather than a standalone diagnostic marker. Additionally, maternal BMI, HbA1c levels, and weight were strongly correlated with GDM risk, reinforcing the multifactorial nature of the condition

Conclusion: The study highlights the need for comprehensive screening strategies incorporating fEFT alongside traditional diagnostic methods to improve predictive accuracy and early intervention. Given its high sensitivity, fEFT may serve as a valuable adjunct in prenatal care, facilitating personalized management strategies to mitigate adverse maternal and fetal outcomes. Further research is warranted to refine fEFT thresholds and validate its utility in larger populations.

Keywords: Abdominal thickness, Fetal epicardial fat thickness, Gestational diabetes mellitus, Oral glucose tolerance test, Ultrasound.

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Introduction

Gestational diabetes mellitus (GDM) is a condition characterized by impaired carbohydrate tolerance that emerges during pregnancy, affecting 1–14% of pregnancies worldwide, with a reported prevalence of 11.4% in the study from India.[1–3] This variability is influenced by demographics and screening practices, and GDM poses significant risks for both mothers and infants, potentially leading to long-term complications such as type 2 diabetes.[2,4,5] Epicardial fat tissue (EFT), a unique visceral fat depot around the heart, plays several physiological roles, including energy storage and cardiac protection, and its increase is associated with decreased insulin sensitivity and heightened insulin resistance in the context of GDM.[6–12] Measuring fetal epicardial fat thickness (fEFT) has been proposed as a diagnostic marker for early identification of GDM, potentially revolutionizing screening processes. Diagnosis typically involves glucose tolerance tests conducted between 24 and 28 weeks of gestation, with early screening recommended for at-risk women. Management includes lifestyle modifications and, in some cases, insulin therapy to minimize adverse outcomes such as fetal macrosomia. Additionally, maternal subcutaneous fat thickness (mSFT) and abdominal circumference (AC) measurements help assess risk and monitor fetal growth, with elevated values indicating higher risks of GDM-related complications. This study aims to validate fEFT as a reliable diagnostic tool, facilitating earlier detection of metabolic changes associated with GDM and paving the way for personalized management strategies that improve outcomes for both mothers and their babies.

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Materials and Methods

Study Design and Setting

The present study is a prospective observational study conducted in the Departments of Radiodiagnosis and Obstetrics and Gynecology

at a tertiary care hospital in central India over 18 months, from September 2022 to March 2024.

Study Population

The study included pregnant women aged 16–24 weeks, specifically those scheduled for an oral glucose tolerance test (OGTT) between 24 and 28 weeks.

Inclusion and Exclusion Criteria

Inclusion criteria comprised women with singleton pregnancies who had undergone a dating scan in the first trimester and consented to the study, while exclusion criteria included those with type 1 or type 2 diabetes, multiple gestations, chronic systemic diseases, congenital or chromosomal abnormalities, and the presence of fetal epicardial fluid.

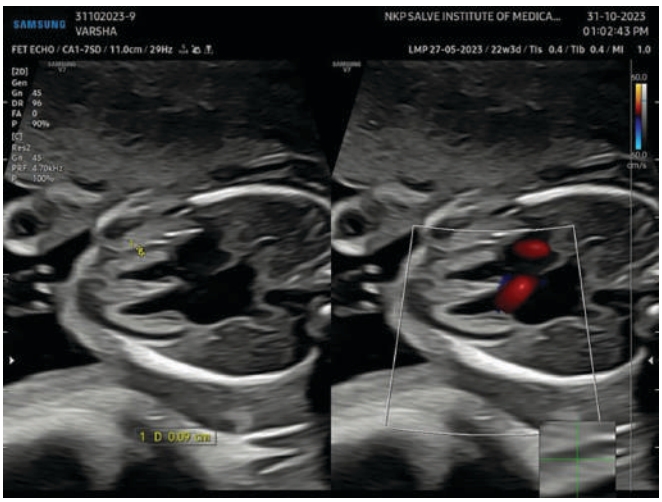

Fig. 1: Image showing fetal epicardial fat thickness (fEFT) measurement in the standard four-chamber cardiac view at the midpoint of the right ventricular wall, with color Doppler aiding differentiation from pericardial fluid

Sample Size

A sample size of 100 participants was determined based on prior research indicating that a fEFT cutoff value of 0.95 can predict GDM with 65% sensitivity, considering a 10% allowance for incomplete data.

Sampling Technique

Participants were consecutively recruited, and data were collected using a predesigned questionnaire covering sociodemographic details, family and medical history, and examination findings.

Data Collection

During gestational weeks 16–24, various anthropometric parameters were measured, and fEFT was assessed via color Doppler ultrasound at the midpoint of the right ventricle wall. Maternal subcutaneous fat thickness (mSFT) was measured using a 7 MHz linear transducer in the subxiphoid area, while abdominal circumference (AC) was recorded in a transverse section of the fetal abdomen (Figs 1 to 3).

Diagnosis of GDM

Between 24 and 28 weeks, GDM diagnosis was based on the American Diabetes Association guidelines using a 2-hour 75-gm OGTT, with diagnosis criteria including fasting plasma glucose ≥92 mg/dL, 1-hour glucose ≥180 mg/dL, or 2-hour glucose ≥153 mg/dL.[13]

Statistical Analysis

Statistical analysis will be performed using SPSS Ver 21. Continuous parameters will be reported as mean ± standard deviation or median (interquartile range) for non-normally distributed data. The independent-samples *t*-test will compare normally distributed continuous parameters, while the Mann–Whitney *U* test will be used for non-normally distributed data. Categorical parameters will be analyzed with Pearson's chi-squared test. Receiver operating characteristic (ROC) analysis will assess the predictive capacity of maternal factors for GDM, with statistical significance set at $p < 0.05$.

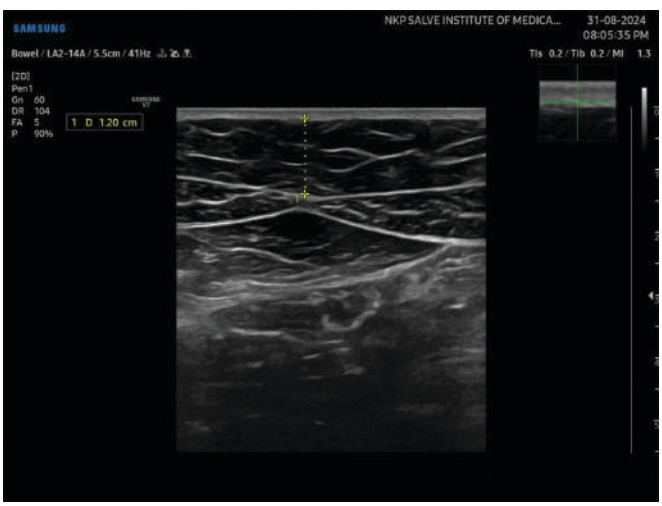

Fig. 2: Image showing measurement of maternal subcutaneous fat thickness (mSFT) in the subxiphoid region, obtained as the distance from the skin surface to the rectus muscle, with the ultrasound probe placed perpendicular to the abdominal wall

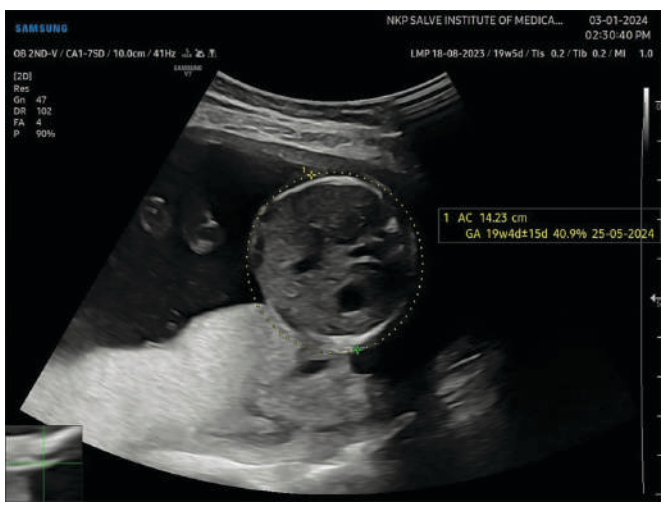

Fig. 3: Standard fetal abdominal circumference (AC) plane showing a circular transverse abdomen with the umbilical vein at the portal sinus, visible stomach, nonvisualized kidneys, and the fetal spine positioned at the 3 or 9 o'clock position

Table 1: Comparison of the means of BMI, mSFT, AC, EFW, and fEFT with respect to the GDM status of participants

Variable	*GDM status*	*Mean*	*SD*	*Mean difference*	*95% CI lower limit*	*95% CI upper limit*	*p-value**
BMI	GDM^+	23.69	1.46	3.10629	1.41022	4.80236	< 0.001
	GDM^-	20.59	2.90	–	–	–	–
mSFT	GDM^+	1.40	0.06	0.24420	0.16829	0.32012	< 0.001
	GDM^-	0.90	0.13	–	–	–	–
AC	GDM^+	15.84	1.55	0.69708	–0.16543	1.55960	0.112
	GDM^-	15.15	1.39	–	–	–	–
EFW	GDM^+	408.08	76.890	49.742	–1.554	101.038	0.057
	GDM^-	358.34	84.855	–	–	–	–
fEFT (cm)	GDM^+	0.13	0.01	0.05629	0.00632	0.04376	< 0.001
	GDM^-	0.07	0.02	–	–	–	–

The table compares the means of various measurements between participants with and without GDM. For BMI, GDM^+ individuals had a higher mean (23.69) compared to GDM^- (20.59), with a significant difference ($p = 0.00$). mSFT also differed significantly, with GDM^+ having a higher mean (1.4) than GDM^- (0.9, $p = 0.00$). AC and EFW showed no significant differences. However, fEFT was significantly higher in GDM^+ participants (0.13 cm) compared to GDM^- (0.07 cm, $p = 0.00$); **t*-test

Table 2: Correlation matrix between GDM, HbA1c, age, gravida, and other anthropometric parameters

Variable	*Statistic*	*GDM*	*HbA1c*	*Age*	*Gravida*	*Weeks of gestation*	*Weight (kg)*	*Height (cm)*	*BMI*
GDM	*r*	1	1.000**	0.264**	0.109	0.284**	0.345**	0.209*	0.345**
	p-value	–	< 0.001	0.008	0.281	0.004	< 0.001	0.037	< 0.001
HbA1c	*r*	1.000**	1	0.264**	0.109	0.284**	0.345**	0.209*	0.345**
	p-value	< 0.001	–	0.008	0.281	0.004	< 0.001	0.037	< 0.001
Age	*r*	0.264**	0.264**	1	0.134	0.032	0.065	0.241*	0.012
	p-value	0.008	0.008	–	0.184	0.756	0.518	0.016	0.908
Gravida	*r*	0.109	0.109	0.134	1	–0.028	0.342**	0.282**	0.353**
	p-value	0.281	0.281	0.184	–	0.780	< 0.001	0.004	< 0.001
Weeks of gestation	*r*	0.284**	0.284**	0.032	–0.028	1	0.109	0.075	0.075
	p-value	0.004	0.004	0.756	0.780	–	0.281	0.457	0.456
Weight (kg)	*r*	0.345**	0.345**	0.065	0.342**	0.109	1	0.270**	0.874**
	p-value	< 0.001	< 0.001	0.518	< 0.001	0.281	–	0.007	< 0.001
Height (cm)	*r*	0.209*	0.209*	0.241*	0.282**	0.075	0.270**	1	0.072
	p-value	0.037	0.037	0.016	0.004	0.457	0.007	–	0.478
BMI	*r*	0.345**	0.345**	0.012	0.353**	0.075	0.874**	0.072	1
	p-value	< 0.001	< 0.001	0.908	< 0.001	0.456	< 0.001	0.478	–

The table presents the correlation matrix between GDM, HbA1c, age, gravida, weeks of gestation, and anthropometric parameters. GDM correlates positively with HbA1c ($r = 1.000$, $p < 0.001$) and age ($r = –0.264$, $p = 0.008$), weight ($r = –0.345$, $p < 0.001$), and BMI ($r = –0.345$, $p < 0.001$). HbA1c shows similar patterns, positively correlating with GDM and with age, weight, and BMI. Gravida positively correlates with weight ($r = 0.342$, $p < 0.001$) and BMI ($r = 0.353$, $p < 0.001$). *Correlation is significant at the 0.05 level (2-tailed); **Correlation is significant at the 0.01 level (2-tailed)

Results

The study's participants predominantly fall within the age group of 20–25 years (62%), followed by 30% aged 26–30 years, and 8% aged 31–35 years, with a mean age of 25.26 years and a standard deviation of 3.24 years.

Most participants are graduates (57%), while 30% hold a higher secondary school certificate, 9% have a secondary school certificate, and only 4% possess a postgraduate degree.

In terms of employment, 70% are housewives and 30% are working. Regarding pregnancy status, 72% are first-time mothers, and the majority (61%) are between 16 and 20 weeks of gestation, with an average gestational age of 20.12 weeks.

Blood sugar levels assessed through the OGTT reveal that 87% of participants had normal fasting glucose levels, with 12% diagnosed with GDM and 9% having elevated HbA1c levels.

Notably, GDM prevalence was 6.5% among those aged 20–25 years, 16.7% in the 26–30 age group, and 37.5% for those aged 31–35 years, indicating a statistically significant association between increasing maternal age and GDM prevalence (*p*-value = 0.025).

Sensitivity analysis of fEFT for diagnosing GDM. Sensitivity is 83.33%, indicating that fEFT correctly identifies 83.33% of GDM cases. Specificity is low at 12.5%, meaning fEFT is less effective at identifying non-GDM cases. The positive predictive value is 11.49%, showing a low probability that a positive fEFT result indicates GDM. The negative predictive value is 84.62%, reflecting a high probability that a negative result indicates the absence of GDM. Overall, diagnostic accuracy is 21%, suggesting limited effectiveness in accurately diagnosing GDM (Tables 1 to 3).

Figure 4 demonstrates the receiver operating characteristic (ROC) curve for fEFT in diagnosing gestational diabetes mellitus (GDM),

Table 3: Correlation between GDM, HbA1c, and other ultrasonographic measurements of the fetus

Variable	*Statistic*	*GDM*	*HbA1c*	*mSFT (cm)*	*AC*	*EFW*	*fEFT (cm)*
GDM	*r*	1	1.000**	0.542**	0.160	0.191	0.669**
	p-value	–	< 0.001	< 0.001	0.112	0.057	< 0.001
HbA1c	*r*	1.000**	1	0.542**	0.160	0.191	0.669**
	p-value	< 0.001	–	< 0.001	0.112	0.057	< 0.001
mSFT (cm)	*r*	0.542**	0.542**	1	0.046	0.087	0.617**
	p-value	< 0.001	< 0.001	–	0.648	0.387	< 0.001
AC	*r*	0.160	0.160	0.046	1	0.913**	–0.078
	p-value	0.112	0.112	0.648	–	< 0.001	0.439
EFW	*r*	0.191	0.191	0.087	0.913**	1	–0.092
	p-value	0.057	0.057	0.387	< 0.001	–	0.363
fEFT (cm)	*r*	0.669**	0.669**	0.617**	–0.078	–0.092	1
	p-value	< 0.001	< 0.001	< 0.001	0.439	0.363	–

The table explores the correlation between GDM, HbA1c, and various fetal ultrasonographic measurements. GDM shows a strong positive correlation with mSFT ($r = 0.542$, $p < 0.001$) and fEFT ($r = 0.669$, $p < 0.001$), indicating higher GDM prevalence with raised measurements. HbA1c mirrors these patterns, correlating positively with mSFT ($r = 0.542$, $p < 0.001$) and fEFT ($r = 0.669$, $p < 0.001$). The measurements for AC and EFW show weaker correlations with GDM and HbA1c, with no significant values. **Correlation is significant at the 0.01 level (2-tailed)

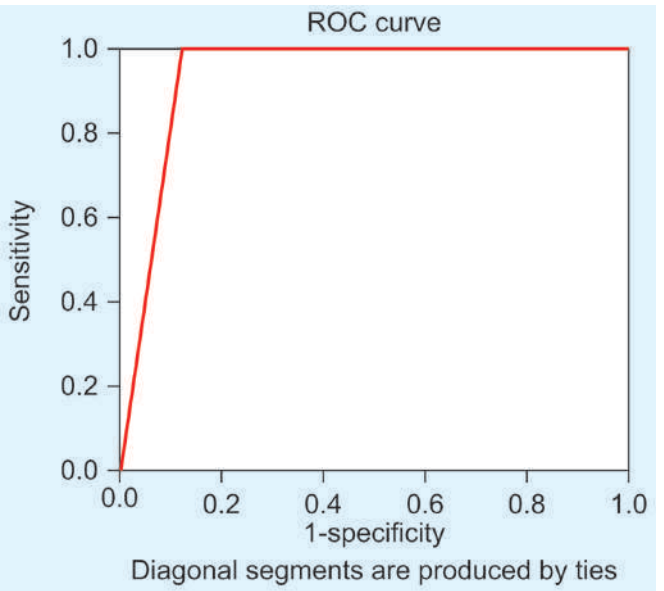

Fig. 4: Receiver operating characteristic (ROC) curve for fetal epicardial fat thickness (fEFT) in diagnosing gestational diabetes mellitus, demonstrating excellent diagnostic performance [area under the curve (AUC) = 0.938; 95% confidence interval (CI): 0.890–0.985]

showing an area under the curve (AUC) of 0.938. This high AUC value, with a 95% confidence interval between 0.890 and 0.985, indicates excellent diagnostic accuracy. The test's ability to distinguish between GDM and non-GDM cases is significantly greater than chance, as the null hypothesis that the true AUC is 0.5 (no discrimination) is rejected.

Discussion

The study's participants primarily consisted of younger individuals, with 62% aged 20–25 years and a mean age of 25.26 years. This age distribution is significant as younger maternal age is generally associated with a lower risk of GDM. Only 12% of participants were diagnosed with GDM, a rate likely influenced by their younger age.

Educationally, 57% of participants were graduates, suggesting that higher educational levels may contribute to better health literacy and management of GDM risk factors. Among the participants, 70% were housewives, and while employment can impact lifestyle factors related to GDM, no significant association between occupation and GDM prevalence was found.

Geographically, most participants (80%) were from Nagpur, where better access to healthcare could affect GDM management. The study noted that the majority of participants were first-time mothers (72%), and gravida status did not show a significant association with GDM. The gestational age ranged from 16 to 24 weeks, with 61% between 16 and 20 weeks. The timing of screening is critical, and no significant association was found between gestational age and GDM.

Results from the OGTT indicated that 87% had normal fasting glucose levels, aligning with the global GDM prevalence of 10–14%. Additionally, only 9% had elevated HbA1c levels, indicating good long-term glucose control for most participants. A statistically significant association was found between GDM prevalence and age ($p = 0.025$), with older participants more likely to have GDM. Education level also showed a significant association ($p = 0.026$), with lower educational attainment linked to higher GDM risk.

Body mass index was a notable factor, as participants with a BMI over 23 had a higher prevalence of GDM (30%) compared to those with a lower BMI (6.3%). The mean BMI of GDM^+ participants was 23.69, reinforcing the connection between higher BMI and GDM risk. Despite the expectation of higher GDM rates in multigravida, the study found no significant association with gravida status ($p = 0.324$).

Ultrasonographic measurements revealed significant differences in mSFT and fEFT between GDM^+ and GDM^- participants, indicating their potential as predictive markers for GDM. The correlation analysis showed strong positive correlations between GDM and HbA1c, BMI, and weight, emphasizing the importance of monitoring these parameters. Notably, fEFT demonstrated high sensitivity (83.33%) but low specificity (12.5%) for diagnosing GDM, suggesting it should be used alongside other diagnostic tools to improve accuracy.[14–16]

Few studies have investigated the relationship between fEFT and GDM, consistently finding that increased fEFT is

associated with maternal GDM.[16–24] Melchiorre et al. first noted this correlation, revealing greater midgestational fEFT in GDM cases, which was positively linked to maternal fasting glucose levels.[16] Subsequent research by Rosner et al. and Cosmi et al. reinforced these findings, suggesting that fetal EFT could be a predictive marker for GDM, even when maternal glucose levels are controlled.[17,18] Aydin further supported this notion by demonstrating that higher fetal EFT could predict GDM prior to 24 weeks' gestation.[19] Additional studies, including those by Yakut et al. and Singh et al., emphasized the connection between elevated fetal EFT and adverse perinatal outcomes.[20,21] Overall, these investigations highlight the potential of fetal EFT as a noninvasive early diagnostic tool for GDM, suggesting that its measurement in routine prenatal care could facilitate timely interventions to improve maternal and fetal health outcomes.

Emerging Diagnostic Markers

Notably, 83.37% of participants with GDM had elevated fEFT, indicating its potential as a GDM diagnostic marker. Although fEFT shows high sensitivity (83.33%) in identifying GDM, its low specificity (12.5%) suggests a high false-positive rate, necessitating its use alongside other diagnostic measures.

Conclusion

Overall, the study underscores the importance of monitoring various sociodemographic, anthropometric, and obstetric factors in GDM risk assessment. Elevated HbA1c and fEFT show promise as effective tools in GDM diagnosis and management, while the findings reinforce the necessity of early intervention for at-risk populations to improve maternal and fetal outcomes.

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ORIGINAL ARTICLE

Hypomagnesemia is Linked with a Higher Risk of Long Bone Fractures: A Cross-sectional Study

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Abstract

Introduction: Magnesium is an essential trace element that plays a key role in several cellular processes. It is a major component of bone, which is 67% of total body magnesium. As the hydrogen/potassium-ATPase pump in the cells of periosteum and endosteum is magnesium-dependent, the pH of the bone extracellular fluid may fall in magnesium deficiency, resulting in demineralization of bone. However, its relationship with the risk of major bone fractures is uncertain. Here, we aimed to find out the association of baseline serum magnesium level with the risk of fractures.

Material and methods: A cross-sectional study was carried out on 210 male participants having age between 40 and 60 years. 105 patients with long bone fractures were considered in the case group, while 105 age-matched healthy male controls were taken as the control group. Serum ionized calcium and serum magnesium estimation were carried out for all samples. Results were noted as median and interquartile range. Comparison of variables of serum magnesium and serum ionized calcium levels between the case and control groups was done by the Mann–Whitney U test using MedCalc software.

Results: A statistically significant difference was observed in serum magnesium levels between cases involving patients with large bone fractures, having normal serum ionized calcium levels when compared with the control group ($p < 0.001$).

Conclusion: It indicates that low serum magnesium levels are associated with an increased risk of long bone fractures in middle-aged men. Further study is required to optimize magnesium levels by diet or medication.

Keywords: Bone, Fracture, Magnesium, Osteoporosis, Trace elements.

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Introduction

In the human body, magnesium (Mg^{2+}) is a necessary trace element that is found in natural form. It serves as an active ingredient in over 600 enzymatic reactions, including those that generate adenosine triphosphate (ATP), synthesize nucleotides, DNA replication, RNA transcription, glucose regulation, blood pressure control, and lipid peroxidation.[1] The second-most important cation inside the cell is magnesium (Mg^{2+}), after potassium (K^{+}). It has a major effect on nerve conduction, bone strength, and muscular contraction. The average adult human body has 0.4 gm Mg^{2+}/kg, with the bones making up 50–60% of this amount and the skeletal muscle and soft tissues making up the remaining portion.[2]

The potential of the hydrogen (pH) in the extracellular fluid of the bone may decrease in a magnesium deficiency, leading to demineralization of bone. Lower Mg^{2+} is linked to elevated osteoclast and reduced osteoblast activity. This occurs as a result of the magnesium dependence of the K^{+}/H^{+}ATPase pump in the periosteum and endosteum cells.[3] Especially in the elderly population, fractures rank among the world's most common causes of illness and disability. Studies on bone health have primarily looked at particular dietary components such as calcium and vitamin D.[4]

Although Mg^{2+} appears to be a crucial cation for many cellular activities and a large component of bone, the connection between fracture risk and magnesium is yet uncertain. The current research attempts to look into the connection between blood Mg^{2+} levels and fracture risk occurrence in individuals with normal serum ionized calcium levels.

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Conflict of interest: None

Materials and Methods

The cross-sectional study involved 210 male volunteers between the ages of 40–60 years who visited the orthopedics outpatient department at SSG Hospital in Vadodara. The participants were split into two groups. 105 patients with long bone fractures, having normal serum ionized calcium levels, were considered in the case group, while 105 age-matched healthy male individuals were taken in the control group. For study participation and blood

Table 1: Levels of serum magnesium and serum ionized calcium in case and control

Parameter		*Case (n = 105)*	*Control (n = 105)*	*p-value*
Serum magnesium (mg/dL)	Median	1.55	1.82	< 0.001
	Interquartile range	1.49–1.65	1.75–1.98	
	Highest value	1.89	2.31	
	Lowest value	1.55	1.82	
Serum ionized calcium (mmol/L)	Median	1.138	1.147	0.29
	Interquartile range	1.096–1.241	1.1155–1.242	
	Highest value	1.297	1.301	
	Lowest value	0.984	1.023	

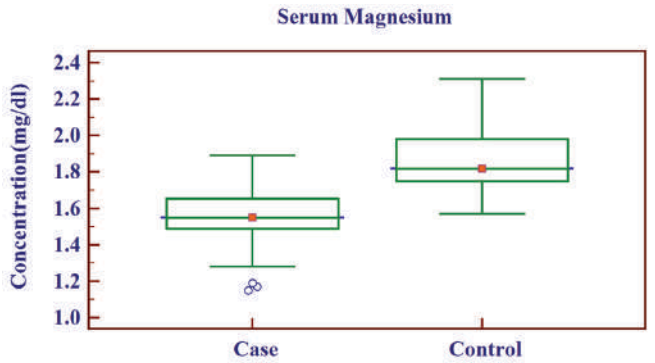

Fig. 1: Serum magnesium level comparison between case and control

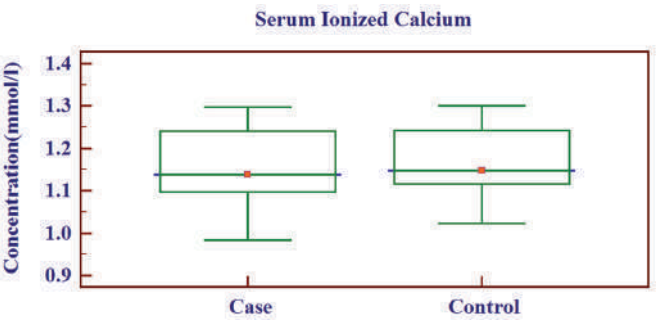

Fig. 2: Serum ionized calcium levels in the case and control groups

collection, patients' informed consent was acquired. Patients having history of bone fracture in 6 months, hypertension (BP >140/90 mm Hg), diabetes mellitus (fasting sugar > 126 mg/dL), Liver function impairment [total bilirubin > 1.2 mg/dL, SGPT (ALT) > 40 U/L, SGOT (AST) > 37 U/L], renal function impairment (creatinine >1.4 mg/dL), anemia (Hb < 10 gm/dL), any thyroid or parathyroid disorders, ongoing medication such as diuretics, proton-pump inhibitors, antibiotics, corticosteroids, and multivitamins, chronic smokers and alcoholics were not included in the study.

A thorough medical history was obtained for each subject, encompassing personal information, current complaints, past medical history, treatment history, family history, and personal history. After an overnight fasting of 10–12 hours, samples were collected by venipuncture using standard aseptic methods before taking any preoperative treatment except analgesic drugs. Serum magnesium estimation was carried out by the Calmagite method[5] on a semiautoanalyzer ERBA Chem 7. Serum ionized calcium was carried out by the Direct ISE method on a Microlyte electrolyte analyzer for all samples. Results were noted as median and interquartile range. Comparison of variables of serum magnesium and serum ionized calcium levels between the case and control groups was done by the Mann–Whitney U test with the Medcalc program. A *p*-value of less than 0.05 is deemed statistically significant.

Results

A total of 210 male participants, aged 40–60 years, who visited the orthopedics outpatient department of SSG Hospital, Vadodara, were recruited for an 8-month cross-sectional study. They were divided into two subgroups: 105 participants each for patients with long bone fractures and healthy controls, respectively. The mean age of patients in the case group was 50.34 ± 5.2 years, and 51.09 ± 4.97 years in the control group. The results of serum magnesium and serum ionized calcium estimation are given in Table 1 and Figures 1 and 2.

Discussion

There is a lot of data to support the idea that magnesium is good for bone health, but most research has looked at dietary magnesium exposure rather than magnesium content in serum. Elevated bone mineral density has been linked to a diet rich in magnesium; however, there is little and inconclusive evidence that it reduces the incidence of fractures.[6–8]

A deficit in magnesium can result in low levels of parathyroid hormone and vitamin D, resistance, and impaired bone growth, all of which increase the risk of fractures. By modifying calcium homeostasis, magnesium also has an impact on bone metabolism.[9–15]

Although hydroxyapatite promotes bone mass, hydroxyapatite activity is suppressed by magnesium, which stabilizes and reduces the rate at which hydroxyapatite is formed from amorphous calcium phosphate.[16,17] Hypomagnesemia can cause seizures and muscle weakness, which can result in falls and fractures because it is necessary for optimal neurological and muscular function.[18,19]

During an 8-year follow-up period, Veronese et al. identified a significant connection between a higher dietary Mg^{2+} consumption and a lower incidence of fracture. In fact, 53% of males who consumed the most Mg^{2+} reported a significant reduction in fracture risk.[20] Low serum magnesium concentrations have been reported by Kunutsor et al. to be independently linked to a higher incidence of femoral and total fractures in middle-aged Caucasian men.[4] Similar findings were reported by Sojka et al., who discovered that a considerable percentage of osteoporotic individuals' bone density is improved by supplementing with magnesium.[21]

Our results support these findings by showing a significant difference in serum magnesium levels between the bone fracture

patients and the healthy control group, particularly in the case of those with normal serum ionized calcium levels. This implies that magnesium may play a part in the formation of fractures by influencing bone cell activity, bone density, and the equilibrium of other vital minerals such as calcium and vitamin D.[4] Even while the data now available point to a high correlation between serum magnesium levels and fracture risk, further extensive prospective studies are required to validate this finding and clarify the underlying mechanisms.

Ethics Approval

The study was carried out at Medical College Baroda (S.S. G. Medical College, Baroda) for poster presentation at the 15th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress (APFCB) in 2019. At that time, ethical approval for small studies was not required at our institute.

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Clinical Trial Registration

This study was not a clinical trial and, therefore, was not registered with the Clinical Trials Registry of India.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Author Contributions

Conceptualization, design, data collection, data analysis: Neeti Patel.
Literature Search: Neeti Patel, Kandarp Patel, Arpita Patel, Nidhi Rohan Purandare.
Writing – Original Draft: Neeti Patel, Kandarp Patel.
Writing – Review & Editing: Kandarp Patel, Arpita Patel, Nidhi Rohan Purandare.

AI Use Declaration

AI tools were used only for language editing; all intellectual content was developed by the authors.

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REVIEW ARTICLE

Empiric Therapy in Acute Undifferentiated Fever and Pyrexia of Unknown Origin

Sirshendu Pal[1], Rupsha Dutta Pal[2]

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Abstract

Empiric therapy is given against an anticipated etiology of infection. Early administration of empiric antibiotics reduces risk, morbidity, and complications. It is essentially broad-spectrum and is started on surveillance data basis. Though broad-spectrum antibiotics may increase the risk of bacterial resistance, it is given keeping in mind the risk–benefit ratio. Pyrexia of unknown origin (PUO) and acute undifferentiated fever (fever of 2 weeks duration or less) should be treated empirically if the patient is seriously ill or diagnosis is not reached after a reasonable diagnostic workup. This leads to a significant reduction in mortality and a shorter hospital stay.

Keywords: Empirical, Fever, PUO.

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Introduction

Empirical therapy is treatment relying on experience and particularly treatment started on the basis of an "educated guess" without perfect or total information.[1] Thus, it is begun without a definitive medical diagnosis or even without knowing the etiology, pathogenesis, or mechanism of action.

Empiric antibiotic therapy is given against a likely or anticipated cause of infection. It is prescribed without knowing the bacteria or fungus causing the disease. When the cause is known, it is called specific or directed therapy. It is to be remembered that early administration of empiric antibiotics is required to reduce risk, morbidity, and complications, especially in serious infections such as bacterial meningitis or septicemia.

Empiric antibiotic therapy should cover gram-positive and/or gram-negative bacteria, multiple fungi or parasites, and these should essentially be broad-spectrum. When specific and more information is obtained (e.g., from a blood culture), the therapy may be altered to a narrow-spectrum antibiotic that specifically targets the fungus or bacterium diagnosed to be causing the disease. Formulating empirical antibiotic therapy is a complicated procedure, which takes into account a person's age, comorbidities, immunity, chances of microbial etiology, and pretest probability of antibiotic resistance prior to treatment, risk of failure or poor outcomes, etc.

Samples (blood, urine, tissue, etc.) should be collected before antibiotics are prescribed. If hospital-acquired pneumonia is detected in a patient in the intensive care unit, chances are that the bacteria or their sensitivity to antibiotics will be different from community-acquired pneumonia.[2] Empiric treatment is usually started on surveillance data basis involving the common local bacterial causes. The initial treatment on the basis of statistical information from previous patients and targeted at a large group of potentially involved organisms is called empiric treatment.[3]

The benefits of starting antibiotics empirically exist where a causative agent is likely unknown and where diagnostic investigation will not alter the course of treatment. In this scenario, there may be little or no perceived utility of going for expensive and inconclusive tests that will delay management by the same antibiotics. Broad-spectrum antibiotics, if used empirically, may, by selection, increase the prevalence of bacteria resistant to several antibiotics. But the expense and delay that would be necessary to perform species' identification in all clinical cases are not affordable, and thus some degree of trade-off is accepted on the basis of risk–benefit ratio (Fig. 1).

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History

In older days, "empiric" as a noun had been used as a synonym of quack.[4] This is now outdated. This meaning applies when the clinician guesses so much that it goes way beyond science and the standard of care goes for a toss. Prescribing a broad-spectrum antimicrobial to tame an infection as early as possible is entirely judicious and scientific, but prescribing pseudoscientific schemes or rituals is not scientific.

In the 21st century, further differentiation is on the anvil. Efforts are being made to ensure that all of science in any medical topic is routinely applied in the clinic, with the best portion of it graded and weighed. Now personal experiences (even expert opinions with scientific basis) are not even considered good enough. In evidence-based medicine, the aim is that every doctor will decide every patient with complete mastery and critical analysis of the entire available literature at his command. This is operationally difficult to implement

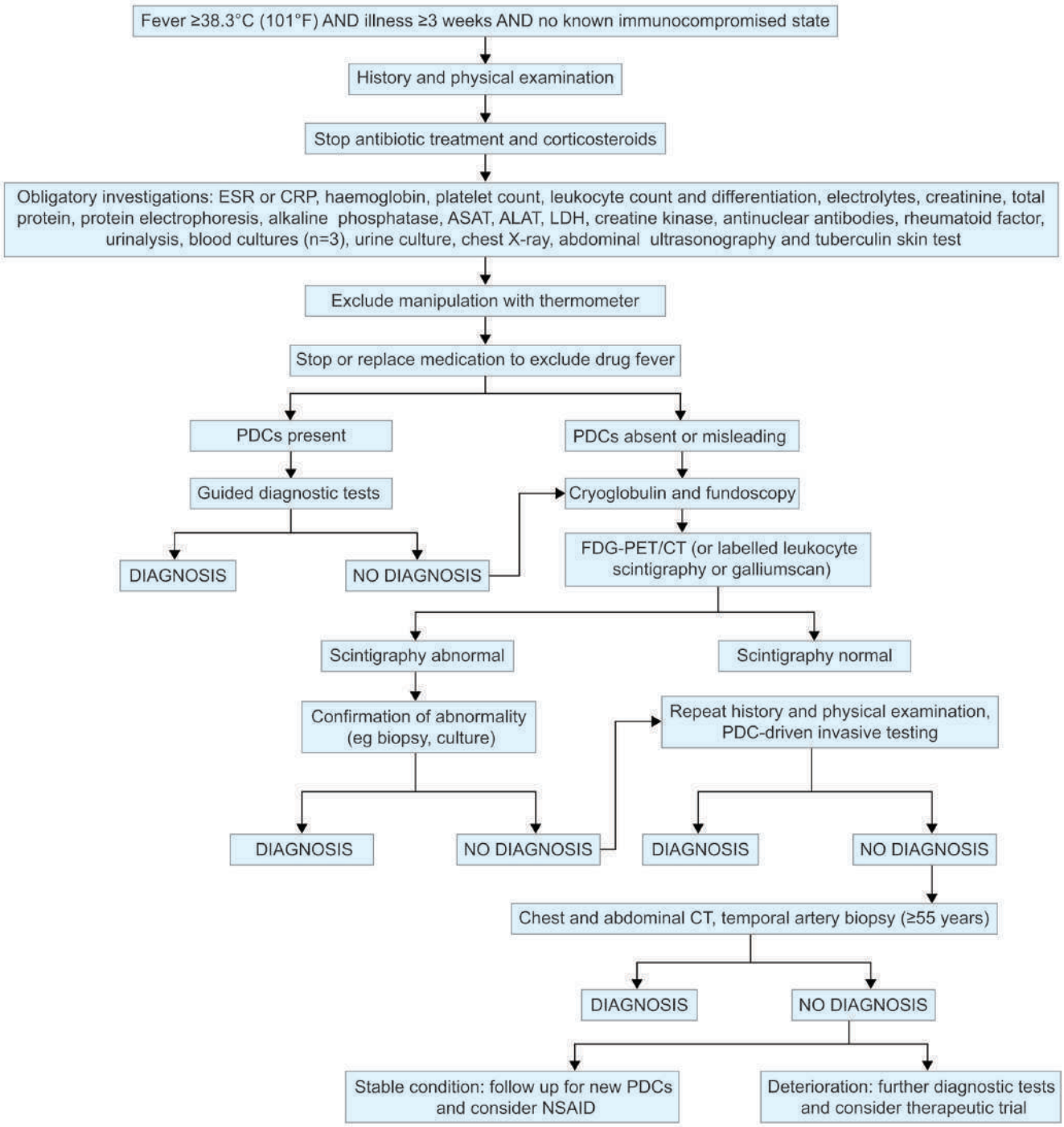

Fig. 1: Approach to a patient with PUO; PDCs, potential diagnostic clues

(because one person cannot master all extant biomedical information on the basis of individual knowledge), but development of health information technology such as artificial intelligence and expert systems in medicine is underway to make this a reality.[5]

Definition of PUO

In 1961, Petersdorf and Beeson defined pyrexia of unknown origin (PUO) as:

- Greater than 38.3 °C on a number of occasions.
- Illness lasting for more than 3 weeks.
- No diagnosis established after one week of inpatient investigation.[6]

It has now been modified to include cases diagnosed after 2 visits or 3 days in hospital. PUO and fever of unknown origin (FUO) are used interchangeably in scientific literature.

Further classes were introduced in 1991, which included:[7]

- Pyrexia of unknown origin in hospital patients (nosocomial) with fever of 38.3 °C on multiple occasions caused by a process not incubating or present on admission, cultures on admission are negative and diagnosis not known after 3 days of investigation.

- Neutropenic PUO involving fever patients with $<1 \times 10^9$ neutrophils with initial culture negative and diagnosis uncertain after 3 days.
- HIV-associated PUO, in which HIV positive with fever for 4 weeks as outpatients or 3 days as inpatients, with diagnosis not established after 3 days of investigation, where at least 2 days have been allowed for incubation of cultures.
- In general, empiric therapy has little or no role in cases of classic pyrexia of unknown origin. Treatment should be directed against the specific cause once diagnosis is established. However, there are a few exceptions which include:
  - Patients who fall under culture-negative endocarditis
  - Finding or clinical setting suggests cryptogenic disseminated Tuberculosis (ATD)
  - Patients of temporal arteritis with suspicion of vision loss (Steroids)
  - An exception may also be made for neutropenic patients or patients who are severely immunocompromised, in whom serious complications may be caused by the delay.[8]
- Prolonged undiagnosed PUO usually has a favorable prognosis, as found in several studies.[9]
- Pyrexia of unknown origin patients rarely need surgical treatment because of better understanding of etiologies and careful diagnostic approaches.

Definition of AUF

Unlike fever of unknown origin (FUO), which has a standard definition, acute undifferentiated fever (AUF) or "acute febrile illness" or "short febrile illness" or "acute fever" does not have an international consensus definition. Some authors define AUF as fever that resolves within 3 weeks.[10] But usually, AUF is defined as a fever of 2 weeks or shorter in duration.[11] So, the term AUF is for fevers that typically do not last more than a fortnight and lack localizable or organ signs and symptoms.[12]

Empiric Treatment

Supportive treatment with acetaminophen 650 mg every 6 hours is advisable, accompanied by tepid sponging for fever or chills >103 °F.

Empirical treatment with doxycycline or azithromycin in patients with negative rapid diagnostic test for malaria may be a clinically apt strategy for reducing morbidity and mortality in acute undifferentiated fevers.[13] Both drugs have a comparable efficacy against *Salmonella*, rickettsial organisms, as well as leptospirosis.[14] Oral doxycycline is not advised in pregnancy, and azithromycin is an alternative.[15]

Severely ill patients should be referred to a hospital and treated as inpatients. Empirical therapy with a combination of parenteral third-generation cephalosporin (injection ceftriaxone) together with doxycycline or azithromycin is ideal while diagnostic confirmation is sought. Dose modification for this combination is not required in renal failure and multiorgan failure.[16] We should be aware of local resistance patterns, and local disease patterns help us to choose treatment. In regions where melioidosis is present, even ceftazidime or meropenem may be the initial choice. Platelet transfusion should be considered when count is less than 10,000/cm^3 or there is clinical evidence of bleeding. Even if fever subsides with empirical therapy, a repeat specimen may be tested a few weeks later to confirm IgM seroconversion or a fourfold rise in titer to confirm probable diagnosis.[17]

Special Situations

For culture-negative endocarditis, the choice of antibiotics depends on the clinical setting. For subacute onset, penicillin and gentamicin may suffice; if there is acute onset, flucloxacillin and gentamicin may be appropriate. Vancomycin and ceftriaxone may be an option. Vancomycin is required for intravenous drug abusers, and those who have had a prosthetic valve inserted recently should receive rifampicin with vancomycin and gentamicin.[18]

For neutropenic sepsis in 2010, updated guidelines issued by the Infectious Diseases Society of America recommended the use of carbapenems, cefepime, or piperacillin/tazobactam for high-risk patients, and amoxicillin-clavulanic acid and ciprofloxacin for low-risk patients.

Empiric treatment should be started within 60 minutes of being admitted.

Conclusion

Infections, particularly tuberculosis, remain the most common cause of PUO or AUF in India, in contrast to the Western nations where infections are on the decline. Empiric treatment should be started when the patient is seriously ill, or no diagnosis is reached after a reasonable diagnostic workup.

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Author Contributions

Sirshendu Pal and Rupsha Dutta Pal: Conceptualization, literature review, writing – original draft preparation, writing – review and editing.

AI Use Declaration

No AI tools were used in the preparation of this manuscript.

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LETTER TO THE EDITOR

Libraries in Medical School: An Overlooked Section Needs Attention

Sameena Khan[1], Amitesh Datta[2], Rajashri Patil[3], Deepali Desai[4]

Journal of the Indian Medical Association (2026): 10.5005/jima-11070-0016

Dear Editor,

Albert Einstein famously wrote, "Education is not the learning of facts, but training the mind to think." Today's medical education system is evolving fast and approaching competency-based medical education (CBME) from traditional knowledge-based teaching methods.[1] So, we are experiencing a paradigm shift in medical education, demanding up-to-date knowledge for medical professionals, including students. Libraries in medical schools are mainly designed to assist faculty, doctors, health professionals, and students in searching for information to improve, update, and evaluate the healthcare system. It is an important "reservoir of knowledge" in the form of books, journals, theses, etc. Typically, two types of libraries are found in medical school: one is a central library, which supports every discipline and subject taught at the university, whereas a departmental library specializes in subject-specific stuff.[2]

Medical libraries serve as a bridge between the medical information resources and the users of the fraternity. Due to the establishment of new medical schools and expanded research activities in the medical field, the number of medical libraries in our country has also increased.

But if we look back at the history of Indian medical libraries, the initial journey started in the second century Before Christ (BC) when the Charaka Samhita and Sushruta Samhita were housed in the Nalanda and Taxila Universities.[3] Gradually, it has changed its shape from "shelf-based" to "internet-dependent." Today's modern medical libraries not only store printed versions of study materials but also embrace digitization because of recent advancements in information and communication technologies and changing trends in study habits. A digital medical library is user-friendly and digitally preserves books, journals, manuscripts, newspapers, images, audio, and videos without the fear of losing them. Digital content can be saved locally or accessed remotely through computer networks. It can also be linked with online databases such as ClinicalKey, Osmosis, Knowledge Hub, and Q-Med, which are the need of the hour for medical students preparing for postgraduation or even higher medical education degrees, while still in medical school.[4,5]

We want to conclude that medical libraries are an essential educational tool that plays a crucial role in medical practice, teaching, and research. A medical library with all state-of-the-art facilities, including digitalization and trained certified librarians, may be one of the most important key factors for the overall quality improvement of any medical school. In addition, regular supervision, periodic upgradation, maintaining recognition, and adequate budgeting are also important for the long-term vision. Without the presence of excellent libraries, how can we expect modern medical practice and improved patient care to move forward in the future?

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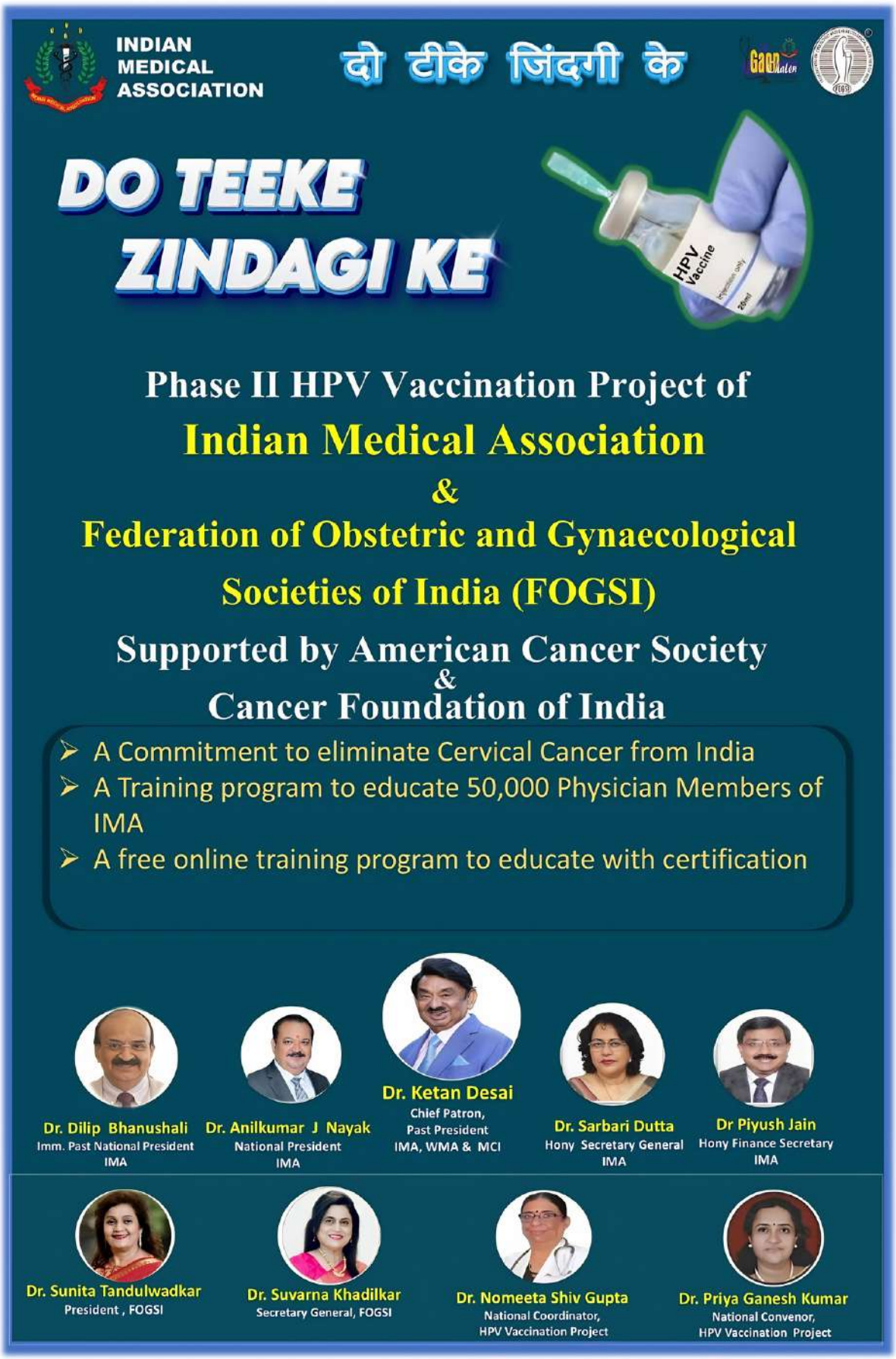
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