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**Original Research Article**

# Demographic and clinical profile of functional dyspepsia patients in a Northern Indian tertiary care setting

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## ABSTRACT

**Background:** Functional gastrointestinal disorders (FGIDs) are prevalent and diagnostically challenging conditions that lack structural abnormalities, but significantly contribute to patient morbidity. This study aimed to analyze the demographic and baseline clinical parameters of patients presenting with functional dyspepsia symptoms in a tertiary care hospital in Northern India.
**Methods:** This analysis was based on baseline data from a randomized controlled trial involving 71 patients (aged 18–75 years) with non-structural gastrointestinal complaints. Prior to randomization and treatment initiation, all patients underwent complete blood count, liver and renal function tests, fasting blood sugar measurement, electrocardiography (ECG), upper GI endoscopy (UGIE) and Helicobacter pylori biopsy. Demographic and baseline clinical data were analyzed using descriptive statistics and comparative tests.
**Results:** The mean age of patients was 46.37±15.2 years, with the highest representation in the 51–60 years age group. Females predominated slightly (56.34%). All patients had normal UGIE and ECG findings and tested negative for Helicobacter pylori. Laboratory parameters were within normal limits for both sexes. Most patients had moderate gastrointestinal symptom scores before treatment, as assessed by GDSS, SF-LDQ and VAS scores.
**Conclusions:** Functional Dyspepsia is more common in middle-aged individuals and slightly more prevalent in females. Despite the absence of structural findings, symptom severity is considerable, necessitating a comprehensive assessment and individualized management strategies. This study provides valuable insights into the demographic and clinical characteristics of patients with FGID in a tertiary care setting in Northern India.

**Keywords:** Clinical profile, Functional gastrointestinal disorders, FGID, Functional dyspepsia demographics, H. pylori, Tertiary care, UGIE

## INTRODUCTION

Functional gastrointestinal disorders (FGIDs) encompass a group of conditions characterized by persistent and recurring gastrointestinal symptoms without any identifiable structural or biochemical abnormalities. Common FGIDs include irritable bowel syndrome (IBS), functional dyspepsia and functional abdominal pain disorders. These conditions are diagnosed based on symptom-based criteria, such as the Rome IV criteria and require exclusion of organic diseases through appropriate investigations.[1] Functional dyspepsia is increasingly recognized as a significant burden on healthcare systems, owing to its high prevalence, chronicity and impact on patients' quality of life. It is estimated that up to 40% of individuals globally are affected by one or more FGIDs during their lifetime.[2] Patients often report substantial physical discomfort, social disruption and emotional distress, leading to increased healthcare-seeking behaviour and diagnostic investigations despite the absence of structural pathology.[3] Psychological comorbidities such as anxiety, depression and somatization are frequently

associated with functional dyspepsia, underscoring the complex biopsychosocial model of their pathogenesis.[4]

Recent research has highlighted the role of neurogastroenterological dysfunction, gut-brain axis dysregulation, low-grade inflammation, altered motility and visceral hypersensitivity in the manifestation of these disorders.[5] Sociodemographic factors, such as age, gender, educational status and urban-rural background, may also influence symptom patterns and care-seeking behavior.[6] In most populations, Functional Dyspepsia has a higher prevalence among females and middle-aged individuals.[7]

There is a dearth of region-specific data on the clinical presentation and demographic distribution of functional dyspepsia in India. Hence, this study aimed to evaluate the baseline demographic and clinical characteristics of patients presenting with symptoms suggestive of functional dyspepsia in a tertiary care hospital in Northern India.

While this study was originally designed as a randomized controlled trial comparing the safety of two pharmacological interventions in functional dyspepsia, the current paper presents a focused analysis of the baseline demographic and clinical characteristics of the enrolled patients prior to randomization. Understanding these baseline features is essential to contextualize symptom patterns and guide personalized treatment approaches in the Indian population. To explore these aspects, we designed this study using the methodology outlined below.

## METHODS

Study Design and Setting: This randomized, comparative trial was conducted in the Department of Pharmacology and Gastroenterology, Dr. R.P.G.M.C. Tanda is a multispecialty tertiary healthcare center situated in the foothills of the Dhauladhar mountain range, at a latitude of 32.0986360 N and longitude of 76.3003390 E, amidst the Kangra valley of Himachal Pradesh in India. This study was conducted from April 2023 to March 2024.

### *Study population*

The study population included the consenting adult patients of dyspepsia who according to Rome IV criteria fall under the category of Functional dyspepsia (in particular epigastric pain syndrome) coming to gastroenterology OPD over the period of 1 year.

### *Ethical approval*

The study was conducted after due permissions from the protocol review committee, institutional ethics committee and registration with the clinical trial registry, India (CTRI).

PRC approval vides letter no. HFW-H(DRPGMC)PRC/2022-10, Dated: 07/12/2022 IEC approval vide letter no. HFW-H-DRPGMC/Ethics/2023/024, Dated: 06.04.2023. CTRI Registration number CTRI/2023/07/055175

### *Inclusion criteria*

Age 18-75 years, of either sex. No evidence of structural disease (including upper endoscopy findings) was likely to explain the symptoms.

### *Exclusion criteria*

The patients were not willing to provide written informed consent. Pregnant and lactating females. Active alcohol users. Allergic or with known contraindications to any of the study drugs. Known patient with cirrhosis, chronic kidney disease, chronic heart failure and coronary artery disease.

### *Sampling technique*

The sample size for this study was calculated using G Power version 3.1.9.7. The effect size (Cohen's d)=0.7 was determined by the mean and standard deviation from the index study. A total of 71 adult patients (aged 18–75 years) presenting with symptoms of Functional Dyspepsia were recruited and randomized into two treatment arms. However, for the purposes of this study, only baseline (pre-treatment) clinical and demographic data were analyzed to describe the patient profile. This subset analysis aimed to explore population-specific patterns in demographics, symptom burden and investigation findings, independent of treatment allocation or outcomes.

### *Data collection*

Data were collected on age, sex and baseline laboratory and diagnostic parameters, including CBC, LFT, RFT, FBS, ECG, UGIE and *H. pylori* biopsy.

To measure symptom severity, a series of validated questionnaires, including the short-form Glasgow dyspepsia severity score (GDSS) 8, short-form leeds dyspepsia questionnaire (SFLDQ) 9 and visual analog scale (VAS) 10, were used.

### *Statistical analysis*

The data collected were tabulated in Microsoft Excel and analyzed for various parameters. Data entry was performed using Microsoft EXCEL spreadsheet and the final analysis was performed using the Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 25.0. The presentation of the Categorical variables was done in the form of number and percentage (%). Quantitative data are presented as mean±SD and as median with 25th and 75th percentiles (interquartile range). The Student's t-test was used to compare continuous variables between the two groups. Chi-square or Fisher's exact probability tests were used to

compare the qualitative data between the two groups. Statistical significance was set at P<0.05.

## RESULTS

### *Demographic data*

*Age distribution*

The mean age of the study population was 46.37±15.2 years. The most represented age group was 51–60 years (25.35%), followed by 61–70 years (22.54%) and 19–30 years (23.94%) (Figure 1).

*Gender distribution*

Among the 71 participants, 40 (56.34%) were female and 31 (43.66%) were male, indicating a slight female predominance (Figure 2).

The demographic data underscore the prevalence of FD across various age groups, with a notable female predominance. Understanding these patterns is crucial for developing targeted interventions. We next examined the laboratory parameters to further characterize the clinical profiles of these patients.

### *Laboratory parameters*

Laboratory investigations, including hematologic and biochemical markers, were within normal limits for all participants.

Key findings are summarized in Table 1, which lists the mean and standard deviation of core parameters: Mean haemoglobin was 12.38±1.42 g/dl, mean total leukocyte count was 6687±811 cells/mm³ and mean fasting blood sugar was 83.45±8.62 mg/dl. Liver and renal function markers were within the normal ranges for all patients.

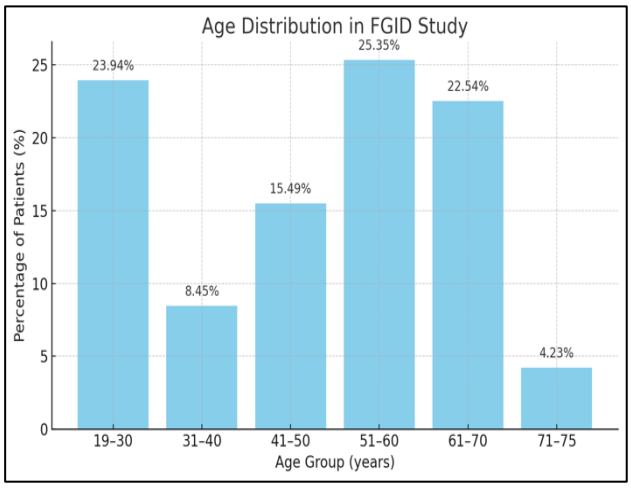


**Figure 1: Age distribution in FGID study.**

Visual illustration of the distribution of patients across different age groups, highlighting the predominance of middle-aged individuals.

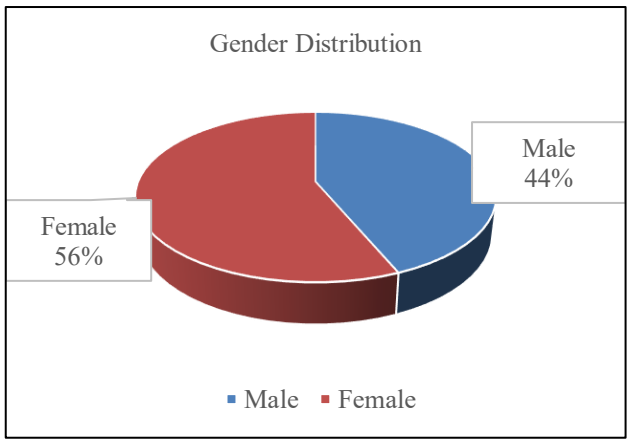


**Figure 2: Gender distribution.**

This gender distribution, underlining the female predominance in functional dyspepsia presentation in this cohort.

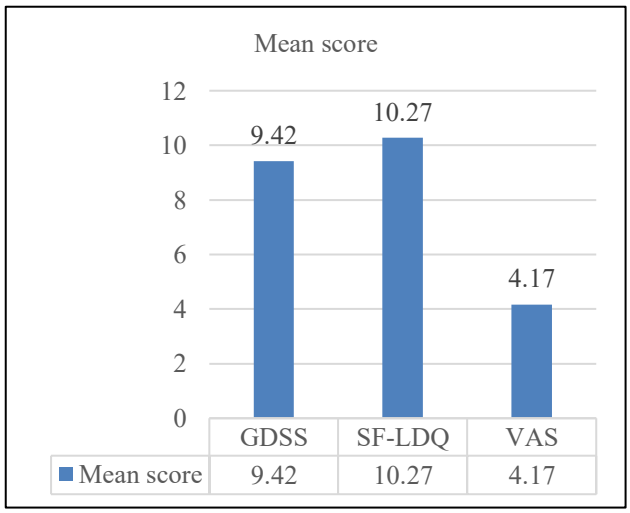


**Figure 3: The mean values for each scale.**

Figure 3 depicts the mean values for each scale, visually emphasizing the considerable symptom burden experienced by patients despite the normal investigative findings.

### *Endoscopic and ECG findings*

Upper GI endoscopy (UGIE) revealed no structural abnormalities in any of the 71 patients. Similarly, all patients tested negative for Helicobacter pylori based on mucosal biopsy. Electrocardiograms (ECG) were also within normal limits for all participants. These findings further reinforce the diagnosis of functional dyspepsia in the absence of organic pathology.

***Symptom severity scores***

Symptom burden was objectively quantified using three validated instruments.

Glasgow dyspepsia severity score (GDSS): 9.42±2.07. Short form leeds dyspepsia questionnaire (SF-LDQ): 10.27±4. Visual analog scale (VAS): 4.17±0.94.

These scores indicate moderate symptom severity in the study cohort (Figure 3).

**Table 1: Mean laboratory parameters.**

| Parameter | Mean±standard deviation |
|---|---|
| **Hb** | 12.38±1.42 g/dl |
| **TLC** | 6687.32±811.34/ul |
| **FBS** | 83.45±8.62 g/dl |
| **SGOT** | 26.92±10.26 |
| **SGPT** | 25.14±8.40 |
| **Creatinine** | 0.73±0.17 |

This table summarizes the mean laboratory parameters, all of which remained within the normal limits. These values confirm that no underlying systemic illness (e.g., liver, renal or hematologic) contributed to the dyspeptic symptoms.

## DISCUSSION

This study evaluated the demographic and clinical profiles of patients with functional dyspepsia (FD) in a tertiary care setting in Northern India. These findings reinforce known epidemiological patterns and reveal region-specific nuances that have implications for clinical management. The mean age of the patients was 46.37±15.2 years, with the majority in the 51–60 years age group, consistent with global and Indian data that identify FD as more common among middle-aged adults.[6] The slight female predominance observed (56.34%) also mirrors prior studies, potentially attributable to hormonal influences, increased visceral hypersensitivity and a higher prevalence of psychological comorbidities among women.[7]

A notable finding in this cohort was the complete absence of structural abnormalities on upper gastrointestinal endoscopy (UGIE) and uniformly negative Helicobacter pylori biopsy results. While our findings of a high symptom burden in patients with FD align with global trends, the marked absence of *H. pylori* contrasts with many studies from other regions, where its prevalence is substantially higher and often implicated in dyspeptic symptoms.[4,11] This discrepancy suggests regional variations in FD pathophysiology and supports the view that *H. pylori* infection may not be a universal driver of dyspepsia symptoms, particularly in certain Indian subpopulations. Consequently, empirical eradication strategies may require re-evaluation in such settings.

The use of validated symptom scales (GDSS, SF-LDQ and VAS) demonstrated moderate symptom severity in all participants, despite a lack of objective pathology. This underlines the importance of recognizing FD as a genuine clinical entity with a considerable impact on quality of life. The high symptom burden, despite normal investigations, also emphasizes the need for physicians to avoid excessive diagnostic testing and instead consider early adoption of symptom-based, patient-centered management models.

Moreover, the exclusion of structural and infectious causes of dyspepsia in this study reinforced the relevance of the Rome IV diagnostic framework. However, the lack of formal psychological assessment in the present study is a limitation given the well-established interplay between FD and anxiety, depression and somatization.[7,12] Future studies should incorporate psychometric tools and dietary assessments to further dissect the multifactorial origins of FD and to guide holistic care strategies.

While the single-center design and modest sample size may limit the generalizability of these findings, this study adds valuable regional insights to the global FD literature. The absence of *H. pylori*, consistent lack of structural disease and presence of substantial subjective symptoms collectively highlight the need for locally adapted diagnostic pathways and psychosocial support integration in dyspepsia management protocols.

## CONCLUSION

Functional dyspepsia commonly affects middle-aged individuals and is slightly more prevalent in females. Despite the absence of structural abnormalities, these patients present considerable symptom severity. A comprehensive baseline assessment is vital for accurate diagnosis and tailored treatment. Understanding regional patient profiles can help clinicians prioritize non-invasive diagnostic approaches and choose patient-centered therapies. These findings underscore the need for further exploration of the psychosocial and dietary factors affecting functional dyspepsia in Indian populations.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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