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Research Article

CLINICAL PREVALENCE AND CURRENT TREATMENT STANDARDS FOR GERD AND DYSPEPSIA, AND PERCEPTION OF EFFECTIVENESS AND SAFETY OF ITOPRIDE IN INDIAN PATIENTS - A PHYSICIANS' SURVEY

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ABSTRACT

In India, little information is available regarding physicians' use of various treatment options in the management of Gastroesophageal Reflux Disease (GERD) and Functional Dyspepsia (FD). This survey aimed to understand the prevalence of GERD and FD across age and gender, and the treatment options used in the management of FD and GERD in the Indian clinical setting. A physician-based research survey was conducted between August 2020 and January 2021using a 22-item questionnaire. A total of 379 physicians spread over 159 cities in India participated in the survey. Nearly 70% of physicians encountered 20%-40% of patients with symptoms of GERD and dyspepsia every month, with 10-20% being newly diagnosed. Moreover, FD was reported in 10%-30% of patients by 70% of physicians; further, 20%-40% of them had 30% patients with overlapping GERD+FD. For patients with FD, 56% of respondents reported an overlap between epigastric pain syndrome (EPS) and post-prandial syndrome (PDS). Most patients were aged 30-55 years. The most preferred choice for treatment of EPS was proton pump inhibitors (PPIs) followed by prokinetics other than itopride, and itopride. The use of prokinetics for EPS was quite low and for PDS, PPIs were prescribed by almost 50% of the physicians. Pantoprazole was the most preferred PPI. Itopride was considered for all patient profiles, with most respondents using the sustained-release preparation. Findings from this research survey will help guide physicians on the actual prevalence of and optimal management strategies for GERD and FD in India.

Keywords: Gastroesophageal reflux disease, Functional dyspepsia, Proton pump inhibitors, Epigastric pain syndrome, Post-prandial syndrome, Itopride.

1. INTRODUCTION

Intestinal dysmotility leads to disorders, such as functional dyspepsia (FD) and gastroesophageal reflux disease (GERD) [1]. Gastroesophageal reflux is the regurgitation of gastric contents and acid into the esophagus. Typical symptoms include heartburn and reflux; there might be atypical symptoms such as dyspepsia, cough, asthma, pharyngitis, laryngitis, pneumonia, or sometimes gum and dental erosions with mucosal injury seen on endoscopy [2]. Globally, the prevalence of GERD is approximately 15% [3].

In India, the prevalence of GERD is reported to be 8%-12%, and it is increasing due to lifestyle changes [3-5]. The prevalence in urban versus rural areas varies in different studies [3, 6, 7]. GERD might require life-long medication, invasive surgery, and lifestyle changes. Investigations to rule out carcinoma should be performed if there are symptoms like dysphagia, odynophagia, gastrointestinal bleeding, iron deficiency anemia, progressive weight loss, and new onset of atypical symptoms at age 45-55 years [8].

No evidence of structural disease on endoscopyis observed in 72%-82% of patients with symptoms of dyspepsia; hence, this condition is classified as functional gastrointestinal disorders (FD) [9]. FD is defined as the presence of at least one of the following symptoms: postprandial fullness, early satiation, epigastric pain, or burning, without evidence of structural disease. The criteria for diagnosis include symptom onset at least six months before diagnosis, with regular symptoms since the last three months for at least three days a week [10]. Based on the most recent Rome IV criteria, FD includes the presence of troublesome dyspeptic symptoms (early satiation, postprandial fullness, epigastric pain, or

burning) in the absence of any organic disease. The Rome consensus has also proposed a distinction between meal-induced symptoms and meal-unrelated symptoms. Thus, FD now consists of two main diagnostic categories: i) meal-induced dyspeptic symptoms [postprandial distress syndrome (PDS)], characterized by postprandial fullness and early satiation, and ii) epigastric pain syndrome (EPS), characterized by epigastric pain and burning [11].

Though Rome IV criteria have been helpful in better standardization of patients included in studies of dyspepsia, they are less relevant to clinical practice due to considerable overlap in symptoms. The American College of Gastroenterology (ACG) and Canadian Association of Gastroenterology (CAG) clinical guidelines for the management of dyspepsia define a clinically relevant definition of dyspepsia as predominant epigastric pain lasting at least for one month [12]. Gastrointestinal dysmotility is involved in the pathophysiology of FD [11, 13], and almost 80% of patients with FD report symptoms after ingesting a meal [14]. The global prevalence of FD varies from 11%-30% [15]. The overlap between FD and GERD is common, and early identification is mandatory for treatment.

Considering the different lifestyles across India, differences in the prevalence of GERD across India are expected. Little information is available regarding physicians' use of various available treatment options in the management of these disorders.

This survey aimed to understand physicians' perspectives on the prevalence of GERD and FD across age and gender, and the treatment options used in the management of FD and GERD, namely, prokinetics, prokinetics with proton pump inhibitor (PPI) therapy, or fixed-dose combination (FDC) of prokinetics and PPI.

2. METHODS

2.1. Survey Design and Participants

This was a prospective, multicentered, physician-based research survey conducted between August 2020 and January 2021, to understand the prevalence of GERD and FD, current treatment strategies, clinical efficacy, and safety perception of the prokinetic itopridein Indian patients. As per local legislation and national guidelines, this survey did not involve any intervention or direct participation of a patient, hence ethical approval by an independent ethics review board was not required. However, informed consent was obtained from all participating physicians, and physician confidentiality and anonymity were maintained throughout the study conduct.

2.2. Survey instrument and data collection

A 22-question survey data report form (survey DRFs) was used to assess the physicians' perception, practice, and attitudes in GERD and FD management (Table 1). Practitioners were asked about the percentage of patients with GERD, FD, or overlapping of symptoms of GERD+FD that they attended per month in their clinical practice, including percentage of new patients with age and gender-wise distribution. Questions regarding FD included subtypes of FD, the preferred first-line drug for the treatment of FD subtypes, and criteria for selection of a prokinetic in FD treatment were also included in the survey DRF. Practitioners were asked about patients' profiles that they considered when prescribing topride (Ganaton) and their opinion about its efficacy and safety amongst these patients. They were also asked about their preferred PPI, prokinetic, and FDC of prokinetic+PPI in the in the management of GERD patients intheirclinical practice.

The survey questions were evaluated for design, comprehensiveness, and content validity by an expert review group. Response to survey questions were categorized by multiple-choice response format with a single best answer obtained for the majority of questions and the option of choosing more than one response for some questions.

Only DRFs containing 'pooled' (aggregate) patient data i.e. DRFs that could not be attributed to a specific physician were collected.

Table 1: Survey questionnaire

No.	Question				
1	In your clinical practice, what percentage of patients comes to you with symptoms of GERD per month?				
	a)10%-20%	b) 20%-30%	c) 30%-40%	d) 40%-50%	e) >50%
2	What percentage of these patients are new patients?				
	a)5%-10%	b) 10%-20%	c) 20%-30%	d) 30%-40%	e) >40%
3	In your clinical practice, what percentage of patients comes to you with symptoms of FD per month?				
	a)10%-20%	b) 20%-30%	c) 30%-40%	d) 40%-50%	e) >50%

4	What percentage of these patients are new patients?				
	a)5%-10%	b) 10%-20%	c) 20%-30%	d) 30%-40%	e) >40%
5	In your clinical practice, what percentage of patients come to you with overlapping of symptoms of GERD and FD?				
	a)10%-20%	b) 20%-30%	c) 30%-40%	d) 40%-50%	e) >50%
6	What percentage of these patients are new patients?				
	a)5%-10%	b) 10%-20%	c) 20%-30%	d) 30%-40%	e) >40%
7	In your clinical practice, what is the most common age group that presents toyou with GERD and FD?				
	a)<18 years	b) 18-30 years	c) 30-40 years	d) 40-55 years	e) >55 years
8	In your clinical practice, what is gender wise % break up of GERD and FD patientsthat come to you?				
	For GERD		a) _____% males	b) _____% females	
	For FD		a) _____% males	b) _____% females	
9	In your clinical practice, if the percentage of patients with FD is 100%, please assign a percentage to the below subtypes?				
	a) EPS _____		b) PDS _____	c) Overlap of both EPS and PDS _____	
10	In your clinical practice, what is your 1st line drug for treatment inpatients of EPS, PDS, Overlap of both EPS and PDS?				
	a) EPS _____		b) PDS _____	c) Overlap of both EPS and PDS _____	
11	What are your criteria for the selection of a prokinetic in FD treatment? Rate the important criteria and assign 1, 2, 3, 4 (1 being most important and 4 being least important)?				
	a) Efficacy _____	b) Safety _____	c) Cost _____	d) Prior experience _____	
12	In what patient profiles would you consider using itopride? (Can select multiple answers)? (, All the above)				
	a) Elderly patients	b) Young ladies	c) Patients with cardiac comorbidities	d) Patient without any comorbidities	e) All of the above	f) Any other _____
13	In your clinical practice, how do you rate the efficacy and safety of itopride in your patients with FD?				
	Efficacy	a) Poor	b) Fair	c) Good	d) Very good	e) Excellent
	Safety	a) Poor	b) Fair	c) Good	d) Very good	e) Excellent
14	In your clinical practice, do you use Ganaton OD (sustained-release preparation)?				
	a) Yes		b) No	Reasons for using/not using _____--	
15	In what patient profiles would you consider using Ganaton OD?				
16	In your clinical practice, what is your preferred PPI in patients of GERD? Rate the molecule and assign 1, 2, 3, 4 (1 being most preferred and 4 being least preferred)?				
	a) Pantoprazole	b) Rabeprazole	c) Esomeprazole	d) Lansoprazole	
17	In your clinical practice, do you prefer a prokinetic +PPI or prokinetic and PPI individual therapy in managing GERD?				
	a) Prokinetic + PPI FDC therapy		b) Prokinetic	c) PPI	
18	Which is the preferred prokinetic + PPI combination in your practice? As per your preference, assign 1, 2, 3, 4, 5 (1 being most preferred and 5 being least preferred)?				
	a) Itopride + pantoprazole		b) Itopride + rabeprazole	c) Domperidone + pantoprazole	
	d) Levosulpiride + rabeprazole		e) Levosulpiride + pantoprazole	f) Any other	
19	Provide reason for selection of the particular prokinetic + PPI combination in yourpractice versus other options in question 18				
20	In your clinical practice, how do you rate efficacy and safety of itopride + pantoprazole in your patients with GERD?				
	Efficacy	a) Poor	b) Fair	c) Good	d) Very good	e) Excellent
	Safety	a) Poor	b) Fair	c) Good	d) Very good	e) Excellent
21	In your clinical practice, on a scale of 1 to 10 (1 being lowest, 10 being highest) how do you rate the symptomatic relief in GERD patients with Ganaton Total?				
22	In your clinical practice, are you concerned about the potential CNS side effects of levosulpiride				
	a) Yes		b) No		

CNS, central nervous system; EPS, epigastric pain syndrome; GERD, gastroesophageal reflux disease; FDC, fixed-dose combination; OD, once daily; PDS, postprandial syndrome; PPI, proton pump inhibitor

2.3. Data Analysis

Response to each question is presented in terms of number and percentage (n [%]) for each variable. Qualitative variables were presented using descriptive statistics. Data were analyzed using SPSS® statistics software, version 23.0 (IBM Corp., Armonk, NY, USA).

3. RESULTS AND DISCUSSION

3.1. Participant characteristics

A total of 379 physicians spread over 159 cities in India participated in the survey, with each physician providing data for 15 patients with underlying FD and/or GERD and receiving some current treatment options for management of the disease.

3.2. Distribution patients with GERD and FD in Indian clinical practice

Out of 379 respondents, 36.7% of physicians reported that they attended 30%-40% patients with GERD in their clinical practice, followed by 32.5% physicians stating that this proportion was 20%-30% of patients (Table 2). Thus, nearly 70% of physicians saw 20%-40% patients monthly with symptoms of GERD. In a community-based, prospective, cross-sectional observational study among 2600 subjects in North India, in which data was collected using a questionnaire, the overall prevalence of GERD was 20.3% [2]. In the largest community-based study among 6174 subjects in Vellore, Tamil Nadu, the prevalence was 8.2% [3]. Another community-based study from Trivandrum, Kerala (n=1072) found a prevalence of 22.2% [5]. A task force from the Indian Society of Gastroenterology (ISG) conducted a prospective multicenter study on the prevalence of GERD, which included 11 urban areas, 2 rural areas, and 2 slums. The overall prevalence was 7.6% among 3224 participants (southern India 8.35% vs northern India 6.74% [p>.05]) [5]. A recently published meta-analysis and meta-regression analysis of studies on the prevalence of GERD in India comprising 20,614 subjects reported a pooled prevalence of 15.6%. However, several studies included had a small sample size and there was significant heterogeneity between the studies [16].

In our study, patients with FD were seen at proportions of 20%-30% and 10%-20% by 33.2% and 30.06% of physicians, respectively, whereas patients with overlapping GERD+FD were seen by 31.7% and 28.2% of physicians at proportions of 20%-30% and 30%-40%, respectively. Amongst the diagnosed patients, a 10%-20% proportion of patients with newly diagnosed GERD and FD was reported by 36.1% and 38.8% of physicians, while a 5%-10% proportion of patients with newly diagnosed overlapping GERD+FD was reported by 39.6% of physicians (Table 2).

Thus, in our survey, nearly 65% of physicians reported that they attended 20%-40% of patients with FD per month. Of these, 10%-30% were newly diagnosed patients. Moreover, almost 60% of physicians reported that 20%-40% of their patients present with overlapping FD, of which 5%-20% are newly diagnosed patients. A systematic review by Drossman et al. showed that dyspeptic symptoms were present in more than one-third of subjects with GERD [17]. Thus, data about the prevalence of FD in India is scant, and the prevalence reported by different studies has a wide variation from 7.6% to 49.0%. This can be attributed to the varied criteria used to diagnose FD or due to geographic differences [1].

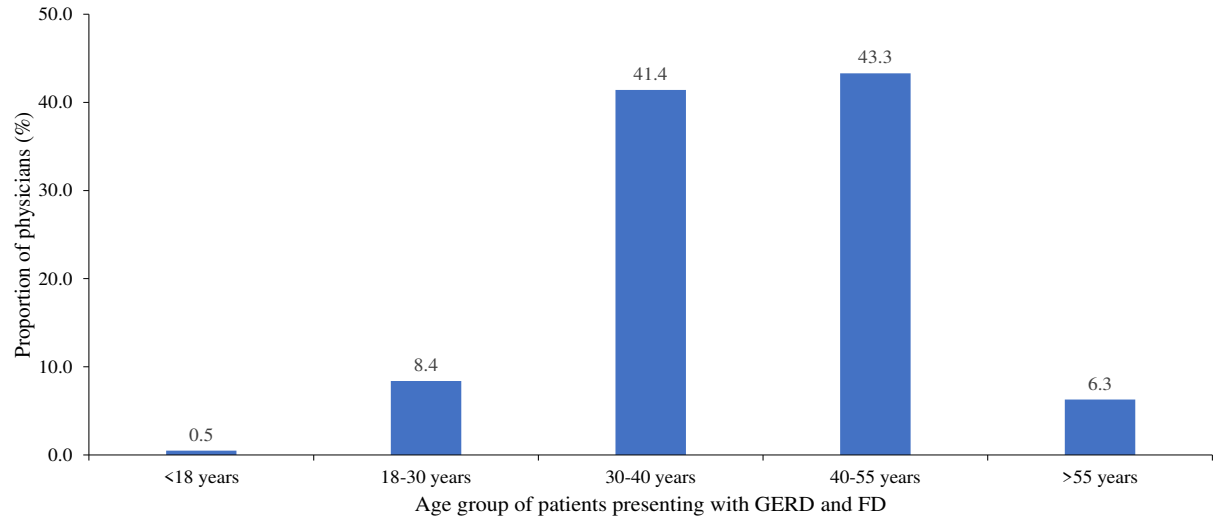
Table 2: Frequency of symptoms by type of condition

Response (N = 379)	GERD, n (%)	FD, n (%)	Overlapping GERD+FD n (%)
% of patients with symptoms per month			
10-20	28 (7.4)	116 (30.6)	91 (24.0)
20-30	123 (32.5)	126 (33.2	120 (31.7)
30-40	139 (36.7)	95 (25.1)	107 (28.2)
40-50	64 (16.9)	26 (6.9)	40 (10.6)
>50	25 (6.6)	16 (4.2)	21 (5.5)
% of new patients			
5-10	99 (26.1)	129 (34.0)	150 (39.6)
10-20	137 (36.1)	147 (38.8)	123 (32.5)
20-30	96 (25.3)	70 (18.5)	63 (16.6)
30-40	35 (9.2)	25 (6.6)	29 (7.7)
>40	12 (3.2)	8 (2.1)	14 (3.7)

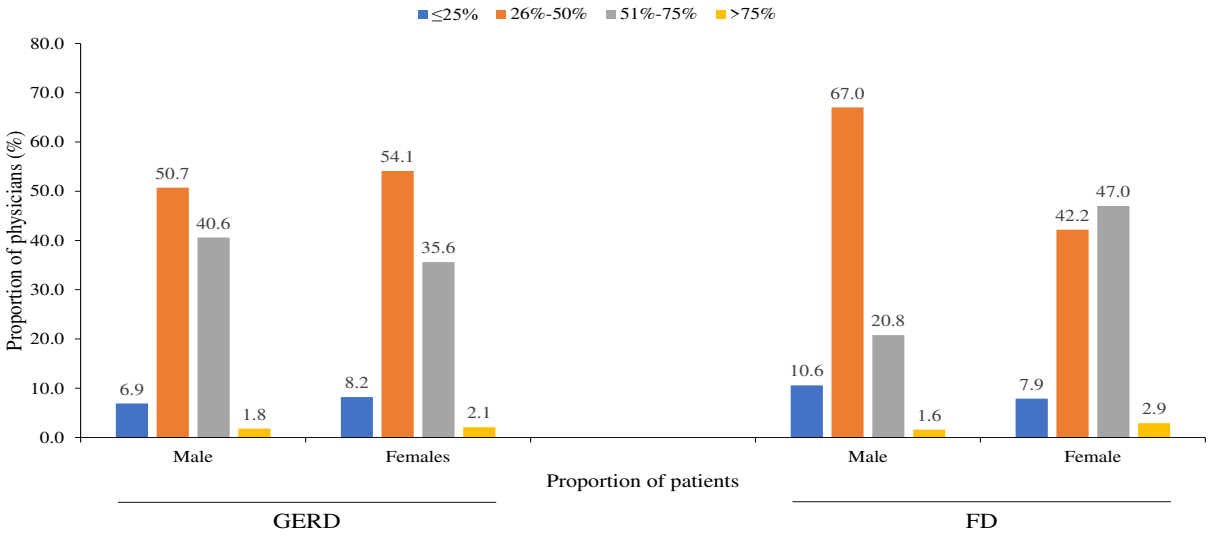
FD, functional dyspepsia; GERD, gastroesophageal reflux disease

3.3. Profile of patients with GERD and FD in Indian clinical practice

When asked to describe the profile of patients with GERD and FD in their clinical practice, 43.3% of physicians responded that most of the patients were in the 40-55 years age group, followed by 41.4% of physicians stating that patients were in the 30-40 years age group (Fig. 1A). Thus, 84.7% of physicians reported that 30-55 years was the most common age group in which patients present with GERD and FD. GERD was reported to be present in 26%-50% of male and female patients by 50.7% and 54.1% of physicians, respectively, followed by in 51%-75% of male and female patients by 40.6% and 35.6% of physicians, respectively (Fig. 1B). Presence of FD was reported in 26%-50% of male patients by 67.0% of physicians, and in 51%-75% of male patients by 20.8% of physicians; moreover, the presence of FD was reported in 51%-75% female patients by 47.0% of physicians and in 26%-50% of female patients by 42.2% of physicians (Fig. 1B). Thus, male and female patients presenting with GERD or FD symptoms were comparable, with 91.3% and 89.7% of physicians reporting proportions of 26%-75% male and female patients with GERD symptoms, respectively. Likewise, the occurrence of FD in male and female patients was reported to be between 26% and 75%, by 87.8% and 89.2% of physicians, respectively.



(A)



(B)

FD, functional dyspepsia; GERD, gastroesophageal reflux disease

Fig. 1: Distribution of patients presenting with GERD and FD by (A) age and (B) gender

In a study among 2600 subjects in a hilly region of north India, the prevalence of GERD was found to be higher (26%) in subjects ≥60 years of age, but a combined prevalence of GERD and FD was reported in 59% of subjects in the age group of 30-59 year s[2]. The mean (standard deviation) age of subjects with GERD was 44.9 (19.4) years, with females being reported to be more prone to the development of GERD [2]. However, most studies have not reported data on gender-based prevalence or that across various age groups.

When asked about the subtypes of patients with FD, 57.8%, 65.4%, and 55.7% of physicians reported attending 26%-50% patients with epigastric pain syndrome (EPS), post-prandial syndrome (PDS), and overlap of both EPS and PDS, respectively (Table 3). The most commonly seen subtype of FD was PDS. However, the prevalence of the other two subtypes namely, EPS, and the overlap of both EPS and PDS was also quite high.In a study among 178 patients with FD in a city in South India, reflux type comprised 60.6% with predominance seen in women, 7% had early satiety, and 13.5% had PDS [18]. In another study among 153 patients with FD, 73% had PDS, 65% had EPS, and 49% had both classes of symptoms [19]. However, no other study in India has reported the prevalence of FD subtypes.

The top three drugs of choice for treating EPS and PDS were PPIs (85.8% and 48.8%, respectively), followed by prokinetics other than itopride (11.3% and 39.3%, respectively) and itopride (9.8% and 34.0%, respectively); furthermore, in patients with overlap of both EPS and PDS, PPIs (53.8%), followed by itopride (17.7%) and prokinetics other than itopride (11.1%) were top three drugs of choice.

Thus, the use of prokinetics for EPS was quite low, and for PDS, PPIs were prescribed by almost 50% of the physicians.

Table 3: Subtypes of patients with FD

Response (N = 379) , n (%)	EPS, n (%)	PDS, n (%)	EPS + PDS, n (%)
% of patients			
≤25	117 (30.9)	112 (29.6)	128 (33.8)
26-50	219 (57.8)	248 (65.4)	211 (55.7)
51-75	42 (11.1)	19 (5.0)	37 (9.8)
>75	1 (0.3)	0 (0.0)	3 (0.8)

EPS, epigastric pain syndrome; FD, functional dyspepsia; PDS, postprandial syndrome

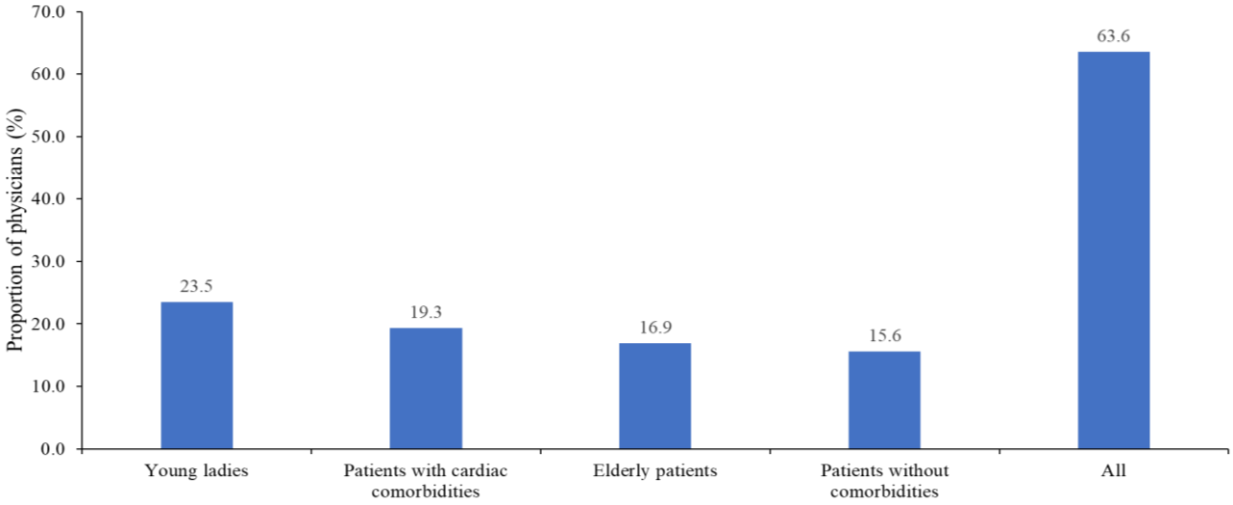
3.4. Recommendations for prescription of itopride in Indian clinical practice

When asked to describe the patient profiles they consider for prescribing itopride at a dose of 50 mg, 63.6% of physicians responded that they consider all profiles (elderly, young ladies, patients with cardiac comorbidities, and patients without comorbidities) as candidates for itopride prescription, while 23.5% physicians prescribing it to young ladies and 19.3% to patients with cardiac comorbidities (Fig. 2A). When asked to rate the efficacy and safety of itopride in FD patients, 79.1% and 81.5% of physicians, respectively, described the efficacy and safety of the drug as excellent to very good (Fig. 2B). In all, 88.4% of physicians acknowledged that they used a sustained-release preparation of itopride in their clinical practice.

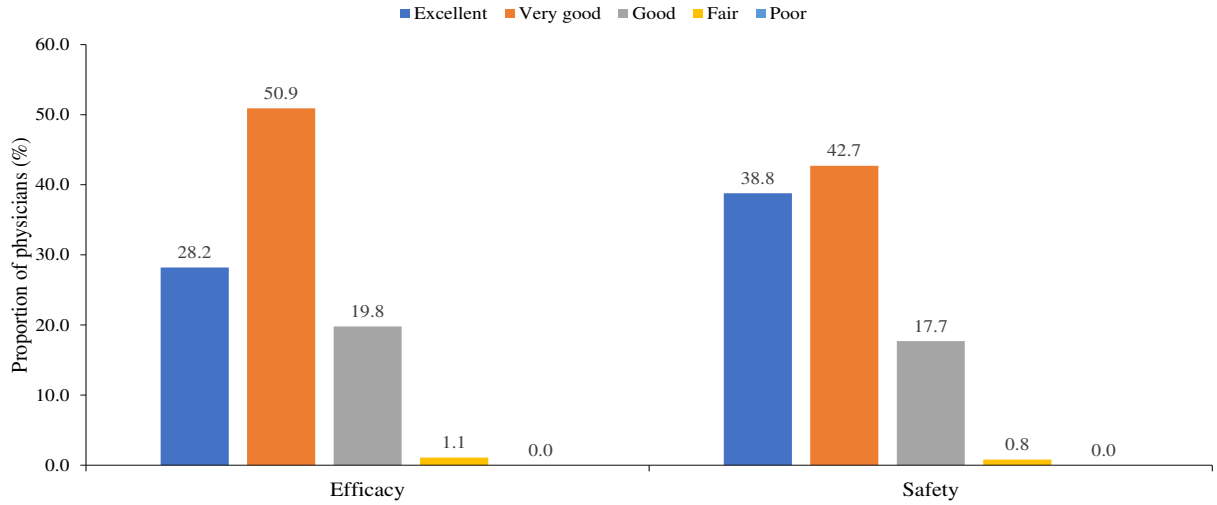
3.5. Recommendations for prescription of PPIs alone or in combination with prokinetics in Indian clinical practice

When asked to rate PPI of preference for GERD patients on a scale of 1 to 4 (1 being most preferred and 4 being least preferred), pantoprazole (67.8%), followed by rabeprazole or esomeprazole (18.7% each) were the drugs of choice, with lansoprazole (0.5%) being least preferred (Table 4). FDCs of prokinetic+PPI were the preferred therapy for the management of GERD according to 93.7% of physicians, with 6.3% of physicians preferring prokinetic and PPIsas separate therapies.

When physicians were asked to rate the preferred prokinetic+PPI combination in their clinical practice on a scale of one (1) to five (5) (1 being most and5 being least preferred), itopride+pantoprazole (87.3%)was the most preferred combination (rating 1 or 2) followed by domperidone+pantoprazole (45.9%), and itopride+ rabeprazole (36.7%), with the combinations of levosulpiride+pantoprazole (18.2%) and levosulpiride +rabeprazole (15.3%) being less preferred (Table 5). Efficacy and safety were the main criteria for choosing a drug combination for 80.2% and 74.9% of physicians, respectively.



(A) Profile of patients prescribed itopride at 50 mg dose



B) Efficacy and safety of itopride in patients with FD

FD, functional dyspepsia

Fig. 2: Physicians' experience with itopride for patients with FD

Table 4: Preferred PPI in patients of GERD

Drug (N = 379)	Pantoprazole, n (%)	Rabeprazole, n (%)	Esomeprazole, n (%)	Lansoprazole, n (%)
Ratings				
1	257 (67.8)	71 (18.7)	71 (18.7)	2 (0.5)
2	85 (22.4)	166 (43.8)	92 (24.3)	10 (2.6)
3	33 (8.7)	100 (26.4)	169 (44.6)	27 (7.1)
4	4 (1.1)	13 (3.4)	13 (3.4)	293 (77.3)

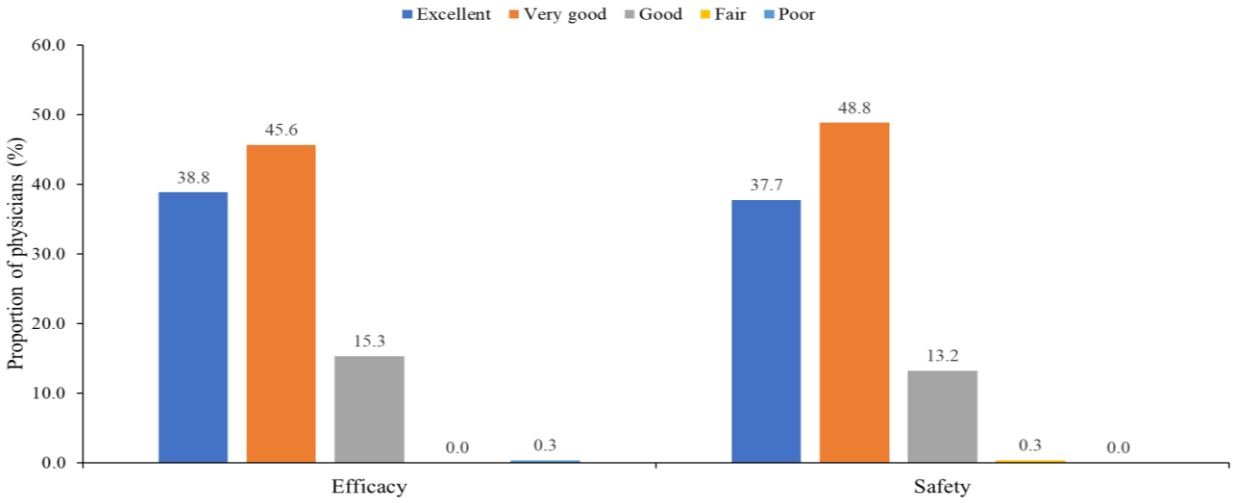
GERD, gastroesophageal reflux disease; PPI, proton pump inhibitors

When asked to rate the efficacy and safety of FDC of itopride+ pantoprazole in GERD patients, 84.4% of physicians described the efficacy of the drug as excellent to very good, with 86.5% of physicians describing the safety of the drug as excellent to very good (Fig. 3A). Furthermore, when asked to rate the extent of symptomatic relief achieved by the FDC in GERD patientson a scale of 1 to 10 (10 being the highest), 38.3%physicians gave a rating of nine (9), followed by a rating of eight (8) and 10 by 35.1% and 15.6% physicians, respectively (Fig. 3B). Additionally, 95.3% of physiciansresponded that they were concerned about the potential central nervous system side effects of levosulpiride.

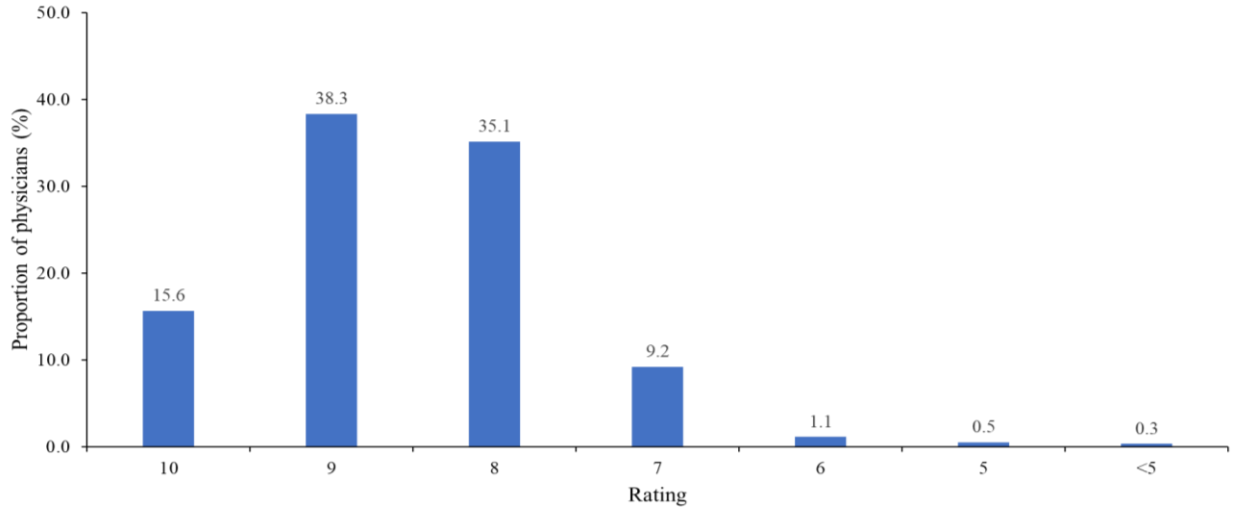
Table 5: Preferred prokinetic+PPI combination in clinical practice

Drug (N = 379)	Itopride + pantoprazole n (%)	Itopride + rabeprazole n (%)	Domperidone + pantoprazole n (%)	Levosulpiride + rabeprazole n (%)	Levosulpiride + pantoprazole n (%)
Rating					
1	259 (68.3)	26 (6.9)	70 (18.5)	19 (5.0)	26 (6.9)
2	72 (19.0)	113 (29.8)	104 (27.4)	39 (10.3)	43 (11.3)
3	27 (7.1)	79 (20.8)	105 (27.7)	48 (12.7)	73 (19.3)
4	8 (2.1)	66 (17.4)	39 (10.3)	111 (29.3)	87 (23.0)
5	5 (1.3)	48 (12.7)	33 (8.7)	98 (25.9)	104 (27.4)

PPI, proton pump inhibitor



(A) Efficacy and safety



(B) Extent of symptomatic relief

FDC, fixed-dose combination; GERD, gastroesophageal reflux disease

Fig. 3: Effect of FDC of itopride and pantoprazole in patients with GERD

The Association of Physicians of India (API)-ISG consensus guidelines recommend that the initial standard of care of GERD is PPI and that prokinetics have no proven role in the routine management of GERD. All available PPIs in equipotent doses have similar efficacy for symptom control [3]. Although prokinetics might provide relief by increasing gastric and esophageal emptying, the evidence about their

clinical efficacy as add-on therapy to PPI is lacking. In a recent meta-analysis of 12 randomized controlled trials (2403 patients), combination therapy did not show better efficacy over PPI alone for symptom control or endoscopic response; moreover, the combination therapy was associated with worse adverse effects [20]. Since many prokinetics have adverse effects on cardiac and neurologic function, these drugs should be prescribed and used judiciously [21]. The API-ISG consensus guidelines also recommend that routine use of FDC therapy of PPI and prokinetics should be avoided [3].

According to the ACG/CAG guidelines patients with FD who are *Helciobacterpylori*-negative or remain symptomatic despite eradication of the infection should be treated with PPI therapy [9]. The response of EPS to acid inhibitory therapy is known to be better than that of PDS [23]. The role of prokinetics in the treatment of FD is unclear. Improving gastric emptying with a prokinetic might improve dyspeptic symptoms including PDS and EPS. According to a meta-analysis, studies from both western and eastern countries showed improvement in dyspeptic symptoms with prokinetic therapy. Furthermore, patients in eastern countries showed a greater response to prokinetics. This might be due to differences in the quality of the studies and patient factors (e.g., genetics, diet, culture, and physiology). However, the quality of evidence was very low, and there was insufficient evidence to conclude which prokinetic was the most effective [14].

A recent meta-analysis showed significant benefit with prokinetic agents in patients with FD [24]. The 2015 FD guideline in Japan recommends prokinetic as a first-line treatment in patients with FD [22]. Conversely, prokinetic agents are suggested as third-line treatments following no response to PPIs and tricyclic antidepressants in the recent ACG/CAG guideline for FD treatment [9]. According to the API-ISG consensus guidelines patients with GERD having FD overlap, volume reflux, and evidence of delayed gastric emptying might benefit from the addition of prokinetics [3].

In India, itopride is approved for the treatment of FD and gastroparesis [1]. A recent meta-analysis evaluated the effect of itopride compared to domperidone, mosapride, and placebo in subjects with a diagnosis of FD. It included nine randomized placebo-controlled trials involving a total of 2,620 individuals. Of these, 1,372 were treated with itopride 50mg three times a day and 1,248 subjects in the control group were treated with drugs such as domperidone, mosapride, or placebo. Individuals in the itopride group reported statistically significant improvement in PDS (RR: 1.21; 95% CI: 1.03-1.44; p=0.02), early satiation (RR: 1.24; 95% CI: 1.01-1.53; p=0.04), and global patient assessment scores (RR: 1.11; 95% CI: 1.03-1.19; p=0.006) compared to control group [25].

In this survey, 63.6% of physicians did not associate any particular profile of patients in which they would consider using itopride50 mg and considered it to be suitable for all patients. Almost 80% of physicians reported that itopride had very good to excellent efficacy and 81.5% reported the same for safety. 88.4% of physicians also use itoprideOD, which is a sustained release dosage form. Evidence however shows that sustained-release high dose prokinetic does not offer any additional advantage of PPI, in the routine management of GERD. Moreover, it increases the cost of therapy [3].

As seen from this survey, the prevalence of GERD and FD was more common than that reported in previous studies. This might be because most previous studies were community-based and did not include the physicians' perspective of the diagnosis. This survey also revealed for the first time, the treatment patterns for GERD and FD in India, which makes it an important contribution to literature.

3.6. Strengths and Limitations

There are several limitations to this study. First, the number of participating physicians was distributed across 159 cities. Hence, the reported prevalence might be significantly different based on the geography due to the different lifestyles and literacy levels of the patients they see. Second, the treatment patterns might vary widely depending on the affordability pattern of the patients across geographies. Third, the cultural differences across geographies might impact the behavior of patients with respect to seeking medical advice and treatment for seemingly non-serious disease conditions. Lastly, the availability of experts in gastrointestinal disease varies across geographies, which could affect the accuracy of diagnosis. Nevertheless, the strength of the study is that this is the first pan-India survey that captures the in-clinic prevalence of GERD.

4. CONCLUSION

In conclusion, overlap of GERD and dyspepsia is frequently encountered in Indian clinical practice, with patients usually exhibiting an overlap between EPS and

PDS. The most preferred choice for treatment of EPS is a PPI like pantoprazole followed by a prokinetic including itopride. Further similar studies including questions about the physicians' awareness of the treatment guidelines for GERD and FD and their reasons for the choices of therapy might provide better insight into the reasons for the treatment patterns seen in this survey. Moreover, the data about the epidemiology and diagnosis of FD in India is still scarce and more studies focused on investigating the same are necessary.

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Conflicts of interest

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