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Prescription trends in the management of gastro-esophageal reflux disease (GERD) in India

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Abstract
Background: Gastroesophageal reflux disease (GERD) is one of the most common diseases seen in many countries for which majority of the population prefer proton pump inhibitors (PPI) and histamine-2 (H2) blockers along with medications like non-steroidal anti-inflammatory drugs (NSAIDs) and other drugs. Concerns have been raised about the prescription of these drugs as they are often prescribed without clear indications. Prescribing pattern should be evaluated periodically to promote rational use of medicine. Moreover, an understanding of the appropriate treatment plan for GERD based on the patient's condition is essential for practitioners across medical specialties.
Methodology: A cross-sectional questionnaire-based survey conducted among 249 clinicians focusing on the prevalence, symptoms, causes, clinical characteristics, management of GERD and the usage of its medications in clinical practice was conducted.
Results: Obesity (39%) is the most common risk factor for GERD. About 42% respondents said the most commonly age group diagnosed with GERD was 40-55 years. Heart burn (56%) is the most common symptoms present in patients with GERD. Obesity (43%), diabetes mellitus (27%), dyslipidemia (11%), hypertension (16%) and asthma (3%) are the most common co-morbid conditions observed with GERD. Only 39% respondents said their patients complained of reflux symptoms being at both day and night, 29% said night time, 9% said both the above options and 3% said daytime. 41% respondents suggested PPI+ pro-kinetic agents as preferred therapy for GERD treatment. Pantoprazole (79%) is the most preferred PPIs in practice for GERD treatment. About 31% of respondents said that pantoprazole and domperidone cure rate for treatment of GERD is 70-80%. Pantoprazole 40mg twice daily (41%) is chosen by respondents as most effective therapy for refractory GERD when high dose of pantoprazole is required. PPI low dose (63%) is the most preferred therapy by respondents in GERD cases.
Conclusion: Despite the challenges in managing GERD, clinicians generally felt confident in their ability to address this condition effectively. This survey highlights the importance of tailored management and the significance of evidence-based approaches to reduce GERD complications.

Keywords: Gastroesophageal reflux disease (GERD), Proton pump inhibitors, pantoprazole, obesity, antacids, domperidone

Introduction

Gastroesophageal reflux disease (GERD) is a medical condition that occurs when stomach acid frequently flows back into the tube connecting your mouth and stomach (esophagus). This backwash of acid can irritate the lining of your esophagus, leading to symptoms such as heartburn, regurgitation, chest pain, and difficulty swallowing [1]. GERD is more commonly observed in urban areas of India compared to rural areas. This difference is often attributed to lifestyle factors such as changes in diet, increased stress, and reduced physical activity in urban settings. The prevalence of GERD in India has been estimated to range from 10% to 20% in urban populations [2]. However, it is important to note that prevalence rates can vary among studies, and there may be underreporting due to differences in awareness and healthcare-seeking behaviour.

Dietary habits play a significant role in the occurrence of GERD. Spicy and acidic foods, which are commonly consumed in Indian cuisine, can exacerbate GERD symptoms. High-fat diets and large, heavy meals can also contribute to the condition. Smoking and excessive alcohol consumption are additional risk factors for GERD, and these behaviours are observed in some segments of the Indian population [3]. The management of GERD in India typically involves lifestyle modifications, dietary changes, and medications, including proton

pump inhibitors (PPIs) and H2 blockers. Awareness campaigns and educational initiatives have been conducted to increase knowledge about GERD among healthcare providers and the general population.

Encourage patients to make necessary lifestyle changes, including weight management, elevating the head of the bed, avoiding tight-fitting clothing, and adopting dietary modifications to reduce triggers such as spicy foods, caffeine, and alcohol [4]. Prescribe medications such as proton pump inhibitors (PPIs), H2 receptor antagonists (H2 blockers), or antacids to reduce gastric acid production and provide symptomatic relief. Recommend dietary adjustments, such as smaller and more frequent meals, avoiding large, heavy meals before bedtime, and consuming foods that are less likely to trigger reflux, like lean proteins and non-acidic fruits and vegetables [5]. Consider surgical options, such as fundoplication, in cases where lifestyle modifications and medications are ineffective or when patients prefer a more permanent solution. Surgery aims to reinforce the lower esophageal sphincter and prevent acid reflux [6].

The increasing prevalence of obesity in India has been linked to a higher risk of developing GERD. Excess body weight can put pressure on the abdomen and promote the reflux of stomach acid into the esophagus. So, the present study was undertaken to analyse recent prescribing trends in the management of GERD.

Methodology

A cross sectional, multiple-response questionnaire based survey conducted among physicians specialized in managing GERD in the major Indian cities from June 2022 to December 2022.

Questionnaire

The questionnaire booklet titled RAPID (Management of GERD with Pantoprazole-Domperidone Therapy) study was sent to the doctors who were interested to participate. The RAPID study questionnaire consisted of 17 questions that focussed on the prevalence, symptoms, causes, clinical characteristics, management of GERD and the usage of its medications in clinical practice. The study was performed after obtaining approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

An invitation was sent to professionals across India based on their expertise and experience in treating GERD in the month of March 2022 for participation in this Indian survey. About 249 clinicians from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. They were explicitly instructed to provide individual responses without consulting their colleagues. Before commencing the study, written informed consent was obtained from all survey participants.

Statistical analysis

The data were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear insight into their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, graphs were created using Microsoft Excel 2013 (version 16.0.13901.20400).

Results

This study involving 249 clinicians, in that 31% respondents treat 30-60 patients with GERD per month, 25% treat 70-100 patients, 17% treat more than 100 patients and 8% treat 0-30 patients. The most common group of patients were observed to be male by 45% of respondents whereas 25% observed it to be female and 10% said both.

In this survey, obesity (39%), drug induced (29%), beverages like tea, coffee (28%), alcohol/tobacco (2%) and spicy/junk/oily food (2%) are the most common risk factors of GERD (Figure 1). About 42% of respondents participated in this survey said the most commonly age group diagnosed with GERD was 40-55 years, 27% said 25-40 years, 6% said more than 55 years whereas 5% said 25-55 years. Also, Heart burn (56%), Regurgitation (16%), Sleep disturbance (10%), Early seriety (9%), hyper salivation (8%) and bloating (1%) are the most common symptoms present in patients with GERD (Table 1).

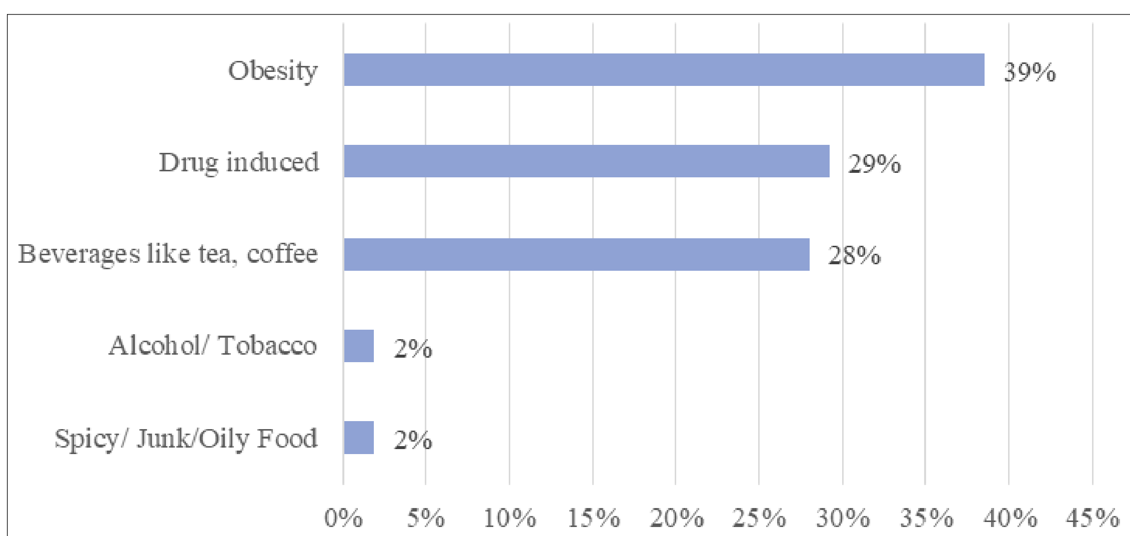

Fig 1: Most common GERD risk factor in clinical practice

Table 1: Distribution of most common symptom among patients presented with GERD

Symptoms	Response rate (n= 249)
Heart burn	56%
Regurgitation	16%
Sleep disturbance	10%
Early seriety	9%
Hyper salivation	8%
Bloating	1%

Obesity (43%), diabetes mellitus (27%), dyslipidemia (11%), hypertension (16%) and asthma (3%) are the most common co-morbid conditions observed with GERD. In addition, 39% respondents said their patients complained of reflux symptoms being at both day and night, 29% said night time, 9% said both the above options and 3% said daytime. No one complained of reflux symptoms after early morning after walking. Overall, 41% respondents suggested PPIs+ Pro-kinetics as preferred therapy for treatment followed by PPIs (17%), PPIs+ Pro-kinetics (Domperidone/ Levosulpiride) (11%), PPIs, PPIs+ Pro-kinetics (4%) and H2 blockers+ Pro-kinetics combination (4%) (Table 2). It was noted that the most preferred PPIs in practice for GERD treatment were pantoprazole (79%), esomeprazole (10%), rabeprazole (8%), lansoprazole (2%) and omeprazole (1%) (Figure 2). Furthermore, 31% of respondents said that pantoprazole and domperidone cure rate for treatment of GERD is 70-80%, 30% respondents said cure is more than 80%, 18% said its cure rate were about 60-70% and 2% with less than 60%.

Table 2: Preferred therapy for GERD in clinical practice

Preferred therapy	Response rate (n= 249)
PPIs + Pro-kinetics combination	41%
PPIs	17%
PPIs + Pro-kinetics (Domperidone/ Levosulpiride) combination	11%
PPIs, PPIs + Pro-kinetics combination	4%
H2 blockers + Pro-kinetics combination	4%
H2 blockers + Pro-kinetics combination, PPIs, PPIs + Pro-kinetics combination	1%
H2 blockers + Pro-kinetics combination, PPIs + Pro-kinetics combination	1%
H2 blockers + Pro-kinetics combination, PPIs	1%

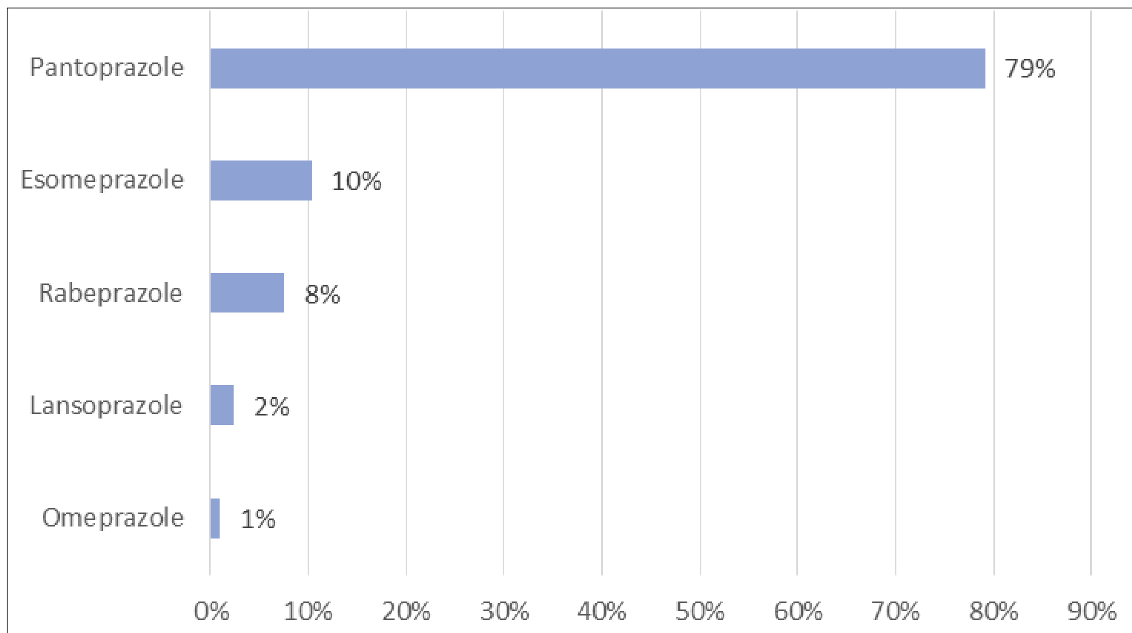

Fig 2: PPIs preferred for GERD treatment

Over 40% of doctors participated in this survey prescribed pantoprazole and domperidone combination for 4 weeks to most GERD patients, 19% respondents prescribe for 8 weeks, 15% for 2 weeks and 7% prescribe for more than 8 weeks. Along with that, 32% respondents said 10-20% of the patient suffer from refractory GERD out of total GERD patients, 25% said 20-30%, 18% said less than 10% and 7% reported 30-50%. In addition, 60% of the respondents preferred PPIs + Pro-kinetics combination, 18% preferred PPIs, 11% each opted the combination of two PPIs and H2 blockers + Pro-kinetics combination for the treatment of refractory GERD. Pantoprazole+ domperidone once daily (47%), pantoprazole+ domperidone twice daily (29%), pantoprazole 80mg SR once daily (8%) and pantoprazole 40mg twice daily (6%) are most preferred therapy dosing in refractory GERD (Figure 3). Pantoprazole 40mg twice daily (41%), pantoprazole 80mg SR once daily (26%), pantoprazole 40mg twice daily (8%) and pantoprazole 80mg sustained release once daily (6%) were chosen by respondents as most effective therapy for refractory GERD when high dose of pantoprazole was required.

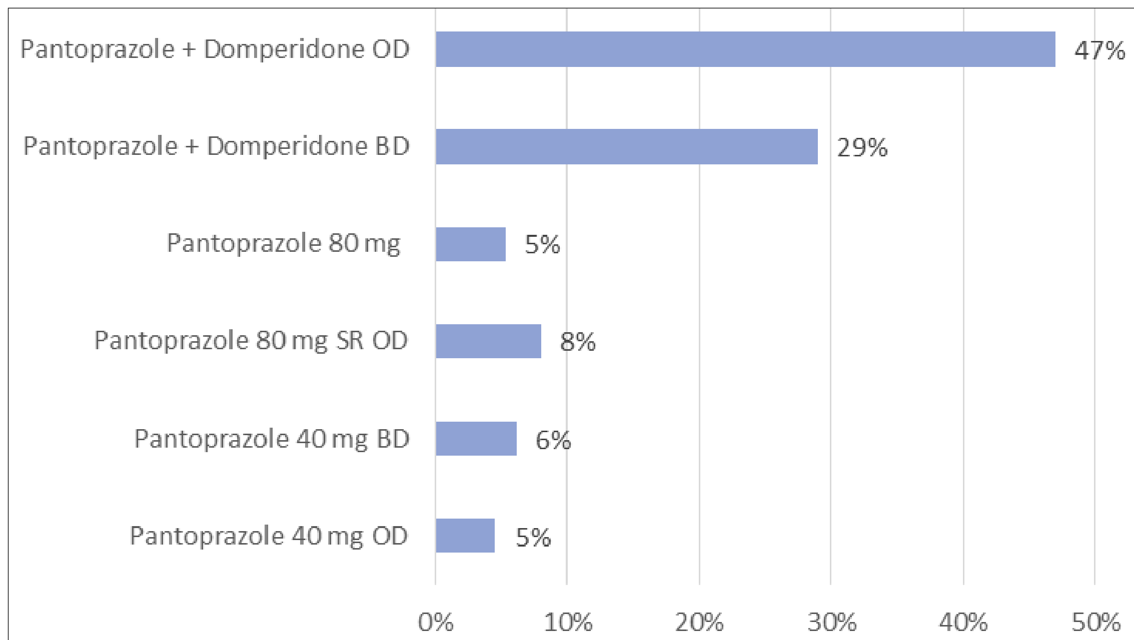

Fig 3: Preferred therapy dosing in refractory GERD

Moreover, PPIs + Pro-kinetics combination (52%), levosulpiride (8%), combination of two PPIs (7%), and PPIs (6%) were preferred pro-kinetic agents for patients with functional dyspepsia. Contrarily, 33% of respondents participated said only 10% or less patients did not get relief with pantoprazole therapy and required therapy change, 29% said 10%-20% patients did not get relief and 13% said 20-30% patients did not get relief. About 41% respondents said that no significant cases in GERD in children observed any increase in GERD symptoms in children due to obesity and 37% saw that cases of GERD increased significantly in last 2-3 years. In pediatric GERD cases, PPI low dose (63%), H2 blockers + Pro-kinetics combination (17%) and PPIs + Pro-kinetics (Domperidone/ Levosulpiride) (15%) were the most preferred therapy by respondents.

Discussion

The present study aimed to examine the prevalence, symptoms, causes, clinical characteristics, management GERD and the usage of its medications in clinical practice shows that obesity (39%), drugs (29%) and beverages like tea, coffee (28%) are the most common risk factors of GERD. GERD has multiple etiologies mainly induced by factors that increase pressure and compliance on the junction, leading to pathological regurgitation of stomach acidic content. The different lifestyle factors like consumption of soft drinks, coffee/tea, and alcohol, smoking, body mass index (BMI), usage of nonsteroidal anti-inflammatory drugs (NSAIDs), and sleeping position are also considered to be associated with GERD. The findings appearing in this survey also shows significantly associated between lifestyle factors and occurrence of GERD [7,8]. This survey shows that majority of clinicians (42%) commonly diagnose GERD in 40-55 year's age group. This finding correlates with previous study findings that show prevalence of GERD was more common among older subjects and men [9]. Heart burn (56%), regurgitation (16%), sleep disturbance (10%), early satiety (9%), hyper salivation (8%) and bloating (1%) are the most common symptoms present in patients with GERD. Common GERD symptoms observed in previous studies are heartburn and regurgitation, but overall symptom profile for patients may change depending on the type of questionnaire [10].

The most common co-morbid conditions observed with GERD in this survey are obesity (43%), diabetes mellitus (27%), dyslipidaemia (11%), hypertension (16%) and asthma (3%). Previous studies have often been identified diabetes as a risk factor for GERD occurrence. A recent meta-analysis also reported a correlation between DM and GERD. In fact, overweight or obesity was more commonly observed among type 2 diabetes patients. Some studies have indicated that overweight and obesity are also risk factors for symptoms of GERD. It is well understood that stress and dietary habits along with tobacco and alcohol misuse is associated with high blood pressure. It has been observed that high levels of stress hormones may slow down the gastric emptying [11]. This in turn may allow for an increase in gastric acid and gas production, thereby propelling the development of GERD. Sleep disturbances are frequently encountered in up to 25% of the GERD patients, likely due to nocturnal gastroesophageal reflux.

In this study, 39% respondents said their patients complained of reflux symptoms being at both day and night, 29% said night time. Most GERD patients experience both daytime and night-time symptoms, and it is relatively rare to encounter a patient who has only daytime or night-time symptoms [12]. The combination of pro-kinetics with proton pump inhibitors (PPI) treatment is more effective than PPI alone in GERD patients. Over 41% respondents participated in this study also suggested that PPI+ pro-kinetic combination as the preferred therapy for GERD. The mainstay of therapy for GERD is acid suppression. Pantoprazole being a first-generation PPI, was approved by the FDA in 2000 for the treatment of erosive esophagitis associated with GERD. It is one of the few PPIs available in multiple forms: a delayed-release oral capsule, oral suspension, and intravenous. Pantoprazole been shown to improve acid reflux-related symptoms, heal esophagitis, and improve health-related quality of life more effectively. Evaluated in over 100 clinical trials, pantoprazole has an excellent safety profile, is as efficacious as other PPIs, and has a low incidence of drug interactions [13]. Even in this

survey, pantoprazole (79%) was the most preferred PPIs in practice for GERD treatment. Besides proton pump inhibitors (PPIs), prokinetic agents are also commonly prescribed to treat GERD. Domperidone, a well-known antiemetic, is an example of a prokinetic agent. It is a dopaminergic blocker that increases lower oesophagus sphincter pressure and activates gastric motility [14].

Notably 31% of respondents said that pantoprazole and domperidone cure rate for the treatment of GERD is 70-80%, 30% respondents said cure is more than 80% and 18% said its cure rate were about 60-70%. Majority of doctors (40%) participated in this survey prescribed pantoprazole and domperidone combination for 4 weeks to most GERD patients. Proton pump inhibitors (PPIs) are effective in improving GERD symptoms in most cases, although up to 40% of patients do not respond adequately to PPI therapy. Refractory GERD (rGERD) is one of the most challenging problems, given its impact on the quality of life [15]. The management strategies regarding refractory GERD is the possible change in the timing of their administration and the choice of a PPI with a different metabolic pathway, include other pharmacologic treatments [16].

About 32% respondents said 10-20% of the patient suffer from refractory GERD out of total GERD patients, 25% said 20-30% and 18% said less than 10%. In addition, the commonly preferred treatment for refractory GERD are PPI+ Pro-kinetics (60%), PPI(18%), combination of two PPIs (11%) and H2 blockers + Pro-kinetics combination (11%). This survey also show that pantoprazole+ domperidone once daily (47%) is the most preferred therapy dosing in refractory GERD. This once again proves the efficacy of pro-kinetic agent, domperidone in refractory GERD. Pantoprazole 40mg twice daily was chosen by majority of respondents as most effective therapy for refractory GERD when high dose of pantoprazole is required. Previous studies have shown that rate of sufficient improvement for typical symptoms was significantly higher in the high-dose group than in the standard-dose group [17].

For atypical symptoms, the rate of sufficient improvement tended to be higher in the high-dose group. Functional dyspepsia is a common functional gastrointestinal (GI) disorder of gastroduodenal origin, diagnosed clinically in the presence of epigastric pain and meal-related symptoms. Management of dyspepsia symptoms relies upon both pharmacologic treatments and non-pharmacologic approaches [18]. In this survey, the combination of PPI and Pro-kinetic agent is the most treatment option for patients with functional dyspepsia. Here, 33% of respondent said only 10% or less patients did not get relief with pantoprazole therapy and required therapy change. This highlights the importance of combination therapy for GERD. The rations of children with GERD are characterized by higher calorie values and larger amounts of fat intake compared to the control group. Low dietary fiber consumption is additional factor associated with GERD in children with excessive weight and obesity [19,20]. In this survey, 41% respondents said that no significant cases in GERD in children observed any increase in GERD symptoms in children due to obesity and 37% saw that cases of GERD increased significantly in last 2-3 years. In such pediatric cases, this survey showed that PPI low dose (63%) is the most preferred therapy by respondents.

Conclusion

The majority of clinicians identified obesity, drugs, beverages like tea, coffee, alcohol/tobacco and spicy/junk/oily foods were the most common lifestyle risk factors of GERD. Heart burn and regurgitation were commonly present among GERD patients. Diabetes, dyslipidemia, hypertension and asthma were the common comorbidities associated with GERD. Pantoprazole emerged as the preferred proton pump inhibitors (PPI) for GERD management. Additionally, most clinicians agreed with combination therapy of pantoprazole and domperidone, especially for refractory GERD. This survey underscores the importance of tailored GERD management and highlights the significance of evidence-based approaches to reduce complications. Further research and collaboration among healthcare providers are essential to enhance GERD management and improve patient outcomes.

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