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Fexuprazan and Esomeprazole in Gastroesophageal Reflux Disease: A Comprehensive Review of Therapeutic Efficacy, Safety and Patient Reported Outcome

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Abstract:

- ***Background:***

Gastroesophageal Reflux Disease (GERD) is a prevalent gastrointestinal disorder that considerably affect patient's quality of life, sleep disturbance and increased healthcare burden. Proton pump inhibitor (PPI), particularly Esomeprazole is used as a first line treatment in GERD, however, due to its limitation such as delayed onset of action, inadequate nocturnal symptom relief a newer development of acid- suppressive agent has been encouraged. Fexuprazan, a potassium competitive acid blocker (P-CAB) has emerged as a promising alternative for the treatment of GERD. This review compares the effectiveness and therapeutic outcome of Esomeprazole and Fexuprazan in the management of GERD.

- ***Objective:***

To review and compare the available reports on the therapeutic effectiveness, safety, nocturnal symptom relief and improvement in quality of life of Esomeprazole and Fexuprazan in the management of Gastroesophageal reflux disease (GERD).

- ***Main Finding:***

Literature from PubMed, Scopus, Google Scholar and Embase publishes between 2010 and 2026 was reviewed. The reviewed evidence indicated that Fexuprazan demonstrate comparable efficacy to Esomeprazole in the management of Erosive esophagitis (EE) and relieving GERD. Several clinical trials and recent meta-analysis have also that Fexuprazan shows comparable safety profile to that of Esomeprazole. Furthermore, Fexuprazan has demonstrated more rapid acid suppression than conventional PPIs in randomized clinical trials, superior control over nocturnal symptoms and significant improvement in Quality of life in patients reported outcome like GERD-Q, GERD-HRQoL, QOLRAD. Both medications were well tolerated with similar incident of treatment-emergent adverse events.

- ***Conclusion:***

Current evidence shows that Fexuprazan is a promising alternative to Esomeprazole in the treatment of GERD, especially in patients requiring rapid acid control or those experiencing severe nocturnal symptoms. Though existing studies support Fexuprazan comparable efficacy and safety profile, long-term studies are required to assess the maintenance therapy, recurrence of symptom after discontinuation of therapy and effectiveness of the treatment in patients diagnosed with Non-erosive reflux disease (NERD).

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Keyword: *Gastroesophageal Reflux Disease (GERD), Fexuprazan, Esomeprazole, Potassium- Competitive Acid Blocker (P-CAB), Proton Pump Inhibitor (PPI), Nocturnal Symptoms, Quality of Life, Non-Erosive Reflux Disease (NERD).*

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I. INTRODUCTION

Gastroesophageal reflux disease (GERD) occurs when the gastric contents repeatedly moves into the esophagus and beyond causing troublesome symptoms and associated complication.[1] GERD is usually associated to having decreased quality-of-life and significant morbidity and often present itself in form of physical distress, sleep disturbance and limitation in daily activity.[2,3]

The worldwide occurrence of GERD has shown an increasing trend, with recent evidence indicating a particularly noticeable rise in developing countries. This increase has been associated with changes toward western dietary habits and lifestyle patterns.[3] Almost one-third of adult report having typical GERD symptoms (i.e Heartburn, regurgitation, Esophageal chest pain) in weekly basis. [4]

The Diagnostic guideline for GERD varies according to the presence or absence of complication or alarming features. GERD diagnosis uses combination of clinical assessment, symptoms evaluation questionnaires, respond to acid suppression therapy, upper endoscopy and objective reflux testing.[5,6] Diagnosis generally incorporates clinical history and symptom assessment together with validated questionnaire, response to acid-suppressive therapy, upper gastrointestinal endoscopy, and objective reflux investigations when indicated. These self-assessment questionaries can mimic the diagnostic accuracy of gastroenterology practice.[6] NERD is referred to as functional heartburn, because 50% of NERD diagnosis respond to PPI therapy.[6]

Under treatment for GERD, a collection of review literature present studies on lifestyle factor, including weight loss, timing of meal, elevation of head during sleep. Many studies believes that targeting the individual element of GERD pathophysiology is the most practical therapeutic approach. Pharmacologically, Over-the-counter antacids provide rapid, short term relief from GERD symptoms. There are many randomized-clinical-trials, systematic review and meta-analysis that shows that PPI are able to achieve a very high healing rate, proximal to 80-90% of the patients within 8-12 weeks of treatment.[7,8]

Therefore, this review critically evaluates current evidence comparing the efficacy, safety, nocturnal symptom control, and patient reported outcomes of Fexuprazan and Esomeprazole in patients with GERD.

II. LITERATURE SEARCH STRATEGY

A structured literature search was performed using PubMed, Scopus, Web of Science, Embase and Google scholar. Publication appearing between January 2010 and February 2026 were considered. Randomized controlled trials, meta-analysis, systematic reviews and international clinical guidelines published in English were included.

➢ *Epidemiology*

Recent epidemiological evidence indicates that GERD affects substantial proportion of the global population, with a prevalence of 13.98% representing approximately 1.03 billion individual worldwide. Prevalence varies according to the region, ranging from 12.88% Latin American to 19.555 North American and from 4.16% Chinese to 22.4% Turkish. These regional difference likely reflect the variations in lifestyle, dietary habits, obesity, genetic susceptibility, and diagnostic criteria.[9] The American college of Gastroenterology (ACG) guideline indicates that GERD affects approximately one in seven individuals worldwide, emphasizing the importance of preventive measures and appropriate lifestyle modification to reduce overall burden.[6]

The prevalence of GERD in India varies considerable across geographical region and study population, with reported estimate ranging from 5% to 28.5%, depending on the diagnostic criteria and methodology employed. A systematic review of 20,614 participants reported a pooled prevalence of 15.6% indicating that nearly one in six Indian experience GERD symptoms. This condition is more prevalent in Urban population and in individual over 30 years of age.

Major risk factor includes obesity, smoking, alcohol use, psychological Stress, and sedentary lifestyle and unhealthy dietary habit such as frequent consumption of spicy and fatty food, excessive tea or coffee intake, or late night eating. These factor influence increase reflux by delaying gastric emptying and lower esophageal sphincter function.

GERD has significant clinical and subeconomic consequences, including impaired quality of life, increase healthcare utilization, reduced productivity, and the risk of complication such as erosive esophagitis, esophageal adenocarcinoma. The rising prevalence of obesity and life-style related risk factor suggests that the burden of GERD in India will continue to grow, highlighting the importance of early diagnosis, prevention and effective long-term management.

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➢ *Pathophysiology*

Gastroesophageal Reflux may occur as a part of normal physiological process, however, it becomes clinically significant when the frequency of reflux increases leading to injury to esophageal, oropharyngeal and laryngeal tissue. Several factor contributing to this process, including abnormalities in LES pressure, mucosal integrity, esophageal clearance, and gastric emptying.[10] The pathophysiology of GERD is illustrated in Figure 1.

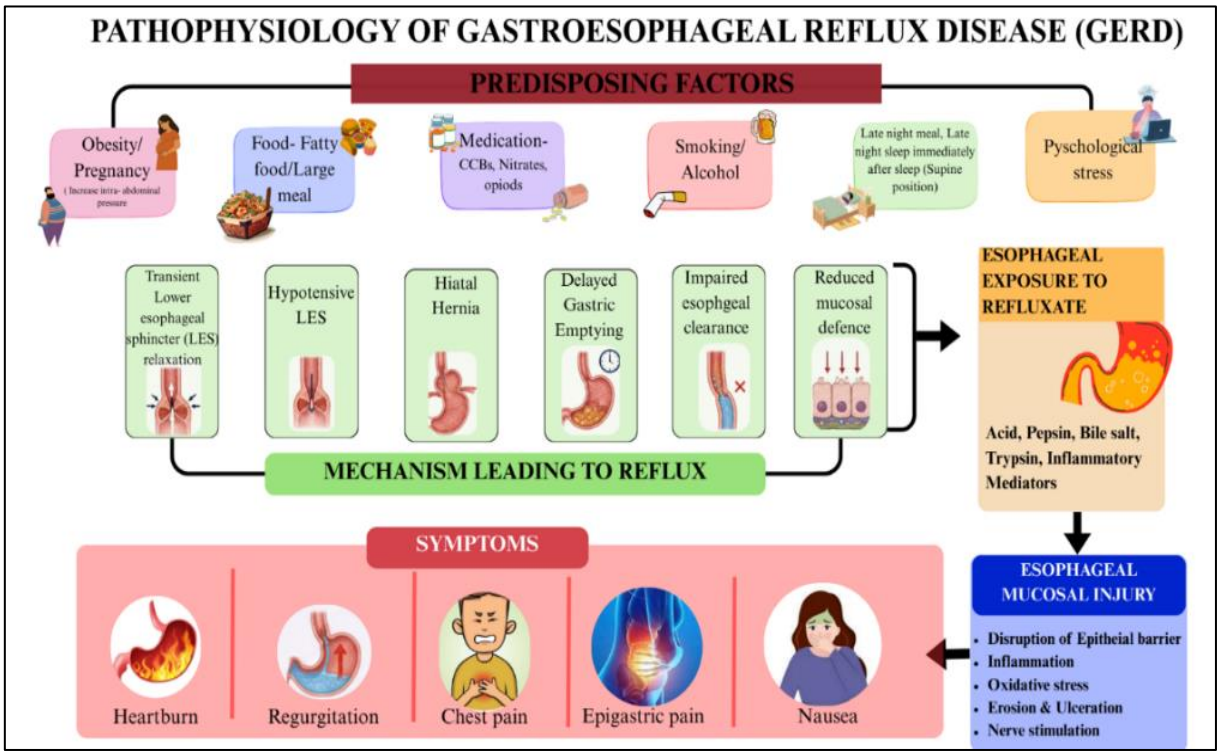


Fig 1 GERD Pathophysiology

➢ *LES Pressure*

The Lower Esophageal Sphincter (LES) serves as an important barrier that stops gastric content from refluxing into the esophagus.[10] Impairment of LES dysfunction is considered as an underlying cause of GERD. The LES acts as a protective barrier by functioning as a high-pressure barrier at the esophagogastric junction, preventing the retrograde movement of the gastric content and relaxes only when food is being swallowed. In patients with GERD, this protective barrier becomes compromised due to frequent transient lower esophageal sphincter relaxation (TLESR), reduced resting LES pressure, or structural abnormality.

➢ *Esophageal Clearance*

Damage produced by GERD depends on the contact time of gastric content and esophageal mucosa which in turn depends on the rate at which the esophagus clears the noxious material as well as frequency of reflux.

➢ *Mucosal Resistance*

Esophageal mucosal defence consists of pre-epithelial, epithelial, and post-epithelial components. The pre-epithelial protective layer is relatively limited in the esophagus, whereas epithelial defence depends on cellular and physiological mechanism that helps remove acid from the tissue. Post-epithelial protection is largely supported by mucosal blood flow, which supplies oxygen, nutrients, and bicarbonate while facilitating removal of potentially harmful substances such as hydrogen ions and carbon dioxide.[10]

➢ *Gastric Emptying*

An increase in the gastric content volume may increase the frequency of reflux and the amount of gastric content available to be refluxed. The delay in emptying may promote regurgitation of feeding, which in turn may contribute to main two common complication of gastroesophageal reflux disease i.e. failure to thrive and Pulmonary aspiration.[10]

➢ *Acid Secretion Mechanism*

Gastric acid (HCl) secretion is controlled by the coordinated interaction between Neural, endocrine and paracrine mechanism which involve 3 type of cells: G cell, Enterochromaffin (ECL) cell, and parietal cells. The acid secretion pathway is illustrated in Figure 2.

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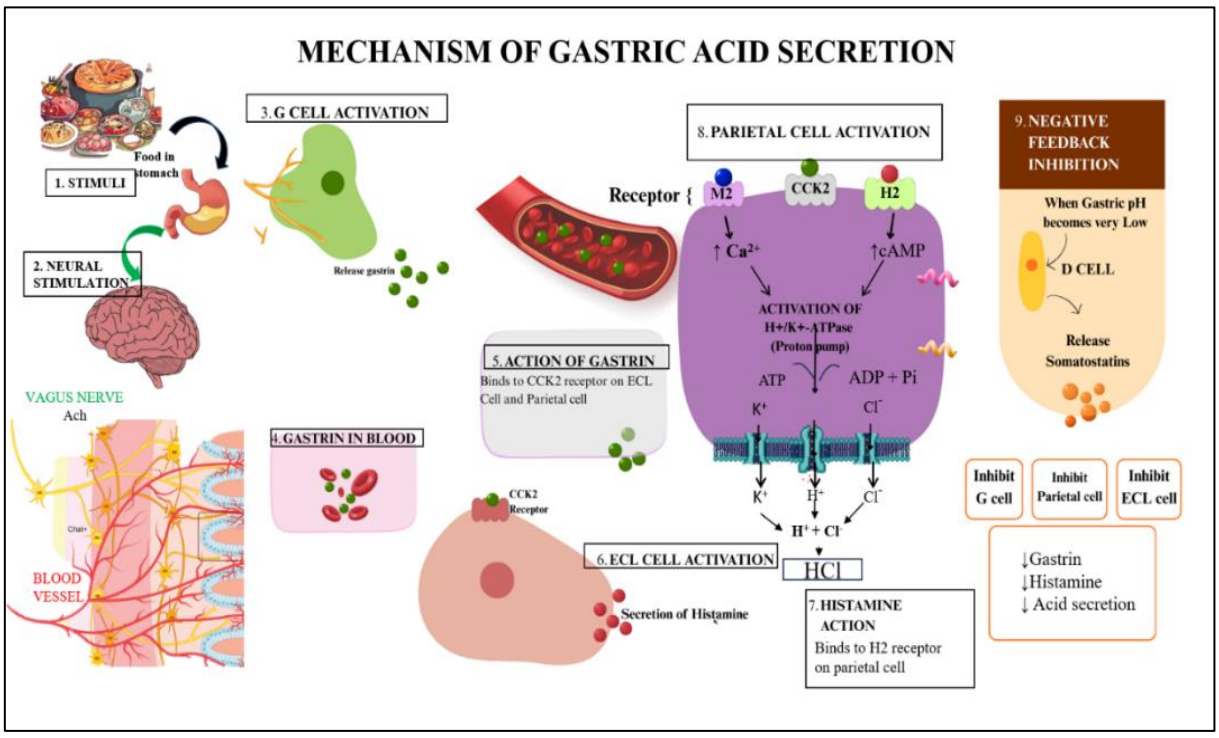


Fig 2 Gastric Acid Secretion Pathway

When food enters the stomach, the G cell releases gastrin into the bloodstream. Gastrin binds to CCK2 receptor present on ECL cell and parietal cells. Stimulation of ECL cells leads to release of Histamine which goes and binds to H2 receptor in parietal cells. Histamine is the most potent stimulant of acid secretion and activate the H+/K+- ATP (proton pump), resulting in release of hydrochloric acid (Hcl) release into the stomach lumen.

The Vagus nerve further enhances the acid secretion by releasing Acetylcholine, which acts on M3 receptor present on G cell, parietal cell, and ECL cell, thereby increasing gastrin, histamine and acid secretion. In contrast, Somatostatin, released from D cell, inhibit G cell, ECL cell and parietal cells, forming a negative feedback mechanism, that limit acid production when gastric pH becomes very low.[11]

➢ *Gastric Motility and Gastric Acid Secretion*

Delayed gastric emptying can increase intragastric pressure and thereby promote reflux. At the same time, impaired esophageal motility, reduced salivary secretion, and weaker peristaltic activity can interfere with acid clearance and neutralization, reducing the ability of the esophageal mucosa to protect itself from refluxed gastric contents.

Gastric acid and pepsin are important damaging components of refluxate. Pepsin becomes increasingly active under acidic conditions and can be taken up by mucosal cells through endocytosis. Its persistence within acidic intracellular compartments may contribute to prolonged injury of esophageal tissue.[12]

➢ *Clinical Presentation*

Gastroesophageal reflux disease (GERD) produces both esophageal (typical) and extraesophageal (Atypical) manifestation. Under one study, analysis was performed on 1031 GERD patients, Heartburn was among the most frequently reported chief complaint, seen in 61% patients. Heartburn and Regurgitation were reported as the predominant symptoms, occurring in a substantial proportion of patients (82.4% and 58.8% respectively).[13]

Chronic exposure of upper airway to refluxed gastric content may results in several extraesophageal manifestation. A persistent or chronic cough is frequently observed and is thought to arise from direct micro aspiration of gastric content or vagally mediated reflex mechanism triggered by acid exposure in the distal esophagus. Some patients may also experience wheezing or worsening of pre-existing asthma, highlighting the close relationship between GERD and respiratory disorder. Hoarseness of voice is another common extraesophageal symptom that results from irritation and inflammation of the laryngeal mucosa following repeated exposure to gastric acid.

Dysphagia or difficulty swallowing, may arise from of chronic esophageal inflammation, edema or the development of peptic stricture. Patients typically describe the sensation of food becoming lodged in the chest or difficulty swallowing solid food.

GERD may also manifest as non-cardiac chest discomfort, belching, water brash, globus sensation, chronic throat irritation, laryngitis, pharyngitis, dental erosion, and sleep disturbance. Collectively, these manifestations can adversely affect physical well-being,

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sleep, occupational productivity, and overall quality of life, highlighting the importance of timely recognition and appropriate treatment.

➢ *Diagnosis*

Because no single diagnostic method is applicable to every patient, GERD diagnosis relies on a combination of clinical presentation, endoscopic findings, and assessment of response to treatment, with objective reflux testing used when required.(6). GERD is subdivided into: Severe reflux esophagitis (RE) [LA grade C and D], mild RE [LA grade B] and NERD.(14)

➢ *Endoscopy*

Upper gastrointestinal endoscopy is an important objective investigation for evaluating the esophageal mucosa. The identification of Erosive Esophagitis (EE) provides evidence supporting GERD, although mild endoscopic changes may not independently establish the diagnosis. Current consensus recommendations indicate that LA Grade A esophagitis alone may be insufficient to establish GERD definitively, whereas LA Grade B and Grade C EE, however can be diagnostic for GERD.(15) Diagnosis for Non-erosive reflux disease (NERD) should be supported by appropriate reflux assessment when endoscopy does not demonstrate visible mucosal injury.(6)

➢ *Ambulatory pH monitoring*

During ambulatory reflux assessment, prolonged pH monitoring can be used to quantify esophageal acid exposure over an extended period. Longer monitoring durations may improve the ability to identify abnormal acid exposure and help determine the likelihood of continuing or discontinuing PPI therapy(15)

Impedance pH monitoring additionally detects weakly acidic or non acidic reflux episodes. Correlating reflux events with reported symptoms can assist in identifying reflux hypersensitivity and assessing the relationship between symptoms and reflux episodes.(6)

➢ *Gastroesophageal Reflux Disease- Questionnaire (GERD-Q)*

The GERD-Q represents a non-invasive approach for assessing adult patients with suspected GERD. Its diagnostic performance has been evaluated against objective investigations such as endoscopy and pH monitoring as a gold standard. Reproducibility for GERD was very good and its discriminating validity was 88%. Patients with abnormal pH-ambulatory scored >8, meanwhile patients with functional heartburn and hypersensitive esophagus scored <8. GERD diagnosis was considered positive if the scores were >8 with the maximum score being 18.(16)

➢ *The PPI Test*

The PPI test has demonstrated moderate diagnostic sensitivity and specificity for GERD. However, it may be more informative in Individuals with erosive reflux disease than in those with non-erosive reflux disease. Patients with NERD who demonstrate a positive symptom – reflux association may be more likely to benefit from acid – suppressive therapy.(17)

➢ *Complication*

GERD – related complications may be develop following repeated exposure of the esophageal mucosa to gastric acid and other refluxed contents. Persistent mucosal injury can contribute to conditions ranging from erosive esophagitis to Barrett's esophagus and esophageal adenocarcinoma.

Erosive esophagitis represents one of the most frequently encountered complications of GERD. Its clinical severity can be difficult to predict solely from the frequency or intensity of symptoms. Among individuals with chronic GERD, erosive esophagitis has been reported in approximately one – fifth of the patients, although estimates vary among studies.

Esophageal strictures. GERD accounts for a substantial proportion of distal esophagus are caused by GERD. Estimates of the prevalence of the stricture in the patients with untreated erosive esophagitis ranges from 75 to 23%. Patients with stricture often present with lower LES pressure, impaired esophageal motility and prolonged acid exposure. Chronic acid exposure can produce repeated mucosal injury followed by inflammation and healing, ultimately resulting in fibrosis and luminal narrowing.

Barrette's esophagus is characterized by replacement of the normal esophageal lining with metaplastic columnar epithelium, typically involving the tubular esophagus. Its estimated prevalence in general population is 0.41% to 0.89%.

Esophageal adenocarcinoma may present with symptoms such as dysphagia and weight loss, particularly in patients with advanced disease. According to GLOBOCAN 2022, Esophageal adenocarcinoma accounts for 20-30% of esophageal cancer worldwide(18). The incidence rate is approximately 0.7-1.2 cases per 100,000 population per year.(19)

➢ *Management*

Management of GERD generally combines lifestyle measures with pharmacological therapy aimed at reducing esophageal acid exposure, either through neutralization of refluxed acid or suppression of gastric acid production.

Individuals experiencing occasional heartburn, particularly when symptoms occur less than twice weekly, may obtain symptomatic relief from antacids or alginate – containing preparations.

Non-pharmacological management includes recommendation for diet modification, appropriate positioning during and after meals, weight management and measures aimed at improving sleep – related reflux. Strong evidence shows that raising head while sleeping reduces night time GERD symptoms and also sleeping

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on the left side is more advised than sleeping on the right side. Researches have also studied how different food effects the LES pressure. Laboratory studies have found that alcohol, smoking, chocolate, peppermint and high fatty food can reduce the LES pressure.

Patients experiencing more persistent or frequent symptoms may require a longer course of pharmacological treatment. Once GERD has been established, acid – suppressive therapy with PPI or H2 – receptor antagonist may be considered according to clinical circumstances.

➢ *Proton Pump Inhibitor: Esomeprazole*

Esomeprazole is a proton pump inhibitor commonly prescribed for the treatment of Gastroesophageal reflux disease (GERD). It suppresses gastric acid secretion by irreversibly binds to the H+/K+ ATPase (Proton pump) located in gastric parietal cell, thereby blocking the final stage of acid production. Activation of the drug occurs within the acidic environment of the parietal cell. Because restoration of acid secretion requires synthesis of new proton – pump molecules, the inhibitory effects of esomeprazole can persist beyond its plasma half – life.[20]

Esomeprazole relieve GERD symptoms, promotes healing of Erosive esophagitis and reduces the risk of disease recurrence. Various clinical studies have demonstrated healing rate of Esomeprazole to be approximately 80-90% following approximately 8 weeks of therapy. This makes PPI the first-line treatment for GERD. Despite its established efficacy, treatment response may vary according to factors such as meal timing, genetic polymorphism (CYP2C19), delayed onset of action. Additionally, some patients continue to experience nocturnal reflux despite PPI therapy, highlighting the limitation of PPI.

Long term PPI therapy is generally well tolerated but its also been associated with concerns regarding nutrient deficiency, osteoporosis-related fracture, alteration in gut microbiome and chronic kidney disease. This limitation have encouraged development of alternative acid-suppression therapy.

➢ *Potassium-Competitive Acid Blocker (P-CAB): Fexuprazan*

Fexuprazan is a newer potassium-competitive acid blocker (P-CAB) developed as an alternative conventional PPI therapy. It inhibits the gastric H+/K+- ATPase through reversible competition at the potassium – binding site and does not depend on prior activation in an acidic environment.

Another advantage of Fexuprazan is that it is meal-independent. As it does not require acidic environment for its activation, this allows flexible dosing interval. Clinical studies have shown that Fexuprazan rapidly alleviates GERD symptoms, achieving healing rate comparable to Esomeprazole and also offer superior control over nocturnal symptoms, thereby improving patients quality of life.[21]

The safety profile is also comparable to the conventional PPI. Current studies suggest that Fexuprazan may provides therapeutic advantage in patients with nocturnal symptoms. In order to make dependable decision about the therapeutic efficacy of Fexuprazan, long-term studies are required.[22]

III. COMPARISON OF FEXUPRAZAN AND ESOMEPRAZOLE

➢ *Clinical Trials*

Various clinical trials evaluating Fexuprazan demonstrated that it is non-inferior to Esomeprazole in treating GERD and Erosive Esophagitis and few other aspect. Several Phase III clinical trial have shown comparable efficacy and healing rate in both Fexuprazan and Esomeprazole treatment group. In a Phase III, randomized, double blind clinical study, healing rate and safety in patients with Erosive Esophagitis was compared after 4 weeks of treatment and the results showed that Fexuprazan is non inferior to Esomeprazole. Even the Treatment-emergent adverse events (TEAEs) were similar in both the drugs.[23] More recent studies suggest that Fexuprazan provide better control over Nocturnal symptoms.

➢ *Meta Analysis*

A systematic review and meta-analysis on various randomized trial suggested that Fexuprazan has comparable efficacy and mucosal healing as Esomeprazole. The overall evidence support the favorable safety profile and confirms non-inferiority to Conventional PPI. Heterogeneity among studies reflect difference in patients population and follow up duration.[22]

➢ *Nocturnal GERD*

In a randomized cross-over study, patients with nocturnal symptoms and impaired quality of life received Fexuprazan and Esomeprazole for 4 week. After 4 weeks, symptom severity score, sleep disturbance, quality of life and patients treatment preference were assessed. Post-treatment results indicated that Fexuprazan provided better symptom control, especially in patients with severe symptoms than Esomeprazole. This study indicated that Fexuprazan has therapeutic advantage for patients with nocturnal symptoms.[24]

➢ *Quality-of-Life Outcome*

A study demonstrated that GERD symptom severity and frequency correlated directly with their poor physical health, poor sleep quality and social well being. The frequent heartburn, disturbed sleep, decreased work productivity directly effects the person psychological health.[25]

Another study establish that GERD-HRQL questionnaire is highly responsive to clinical improvement, this allows clinician to interpret patients

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treatment satisfaction and daily functioning.[26] Similarly, the GERD-Q questionaries reliably measure the symptom severity and monitor the response to therapy over time.[27] Together, this instrument provide complementary assessment to both symptom relieve and patients response to therapy.

On evaluating therapeutic outcome from these validated questionnaire, significant reduction in GERD-Q and GERD-HRQoL score indicate successful therapy. Thus, these questionnaire are useful in comparing effectiveness of Fexuprazan and Esomeprazole in improving both symptom and quality of life in patients diagnosed with GERD.

Table 1 Fexuprazan vs Esomeprazole: GERD Comparison

FEXUPRAZAN (P-CAB)		ESOMEPRAZOLE (PPI)
Rapid Onset (Peak effect in 1-2 hrs)	**ONSET OF ACTION**	Delayed onset (Require activation; 3-6hrs)
Reversible inhibition of H+/K+ ATPase by binding to Potassium binding site	**MECHANISM**	Irreversible inhibition of H+/K+ ATPase after activation in acidic environment
Potent acid suppression maintained 24 hours	**ACID SUPPRESSION**	Effective acid suppression lasting 18-24 hours
Independent of Gastric acid(Active in neutral pH)	**DEPENDENCY ON ACID ACTIVATION**	Require acidic environment for activation (Inactive in non-acidic pH)
Faster onset, Longer duration of action	**ONSET AND DURATION OF EFFECT**	Slower onset, Shorter duration compared to Fexuprazan
Meal independent	**MEAL DEPENDENCY**	Meal dependent (Better efficacy in fasting state)
More consistent acid suppression including nocturnal control	**ACID SUPPRESSION CONSISTENCY**	Variable acid suppression (Nocturnal acid breakthrough may occur)
Superior control of nocturnal reflux and early morning symptoms	**EFFICACY IN NOCTURNAL SYMPTOMS**	Moderate control of nocturnal acid breakthrough
Well tolerated; similar safety profile to PPIs	**SAFETY AND TOLERABILITY**	Well tolerated; long-term safety established
Minimal; Fewer drug interaction	**DRUG INTERACTIONS**	Metabolized by CYP2C19 potential drug interactions
Once daily (20 mg)	**DOSING**	Once daily (20-40 mg)
Primary renal excretion	**METABOLISM / ELIMINATION**	Hepatic metabolism (CYP2C19, CYP3A4)

IV. CONCLUSION

Gastroesophageal reflux disease (GERD) remains a common gastrointestinal disorder that substantially impairs patients' quality of life. This article indicates that Fexuprazan is a safe and effective alternative to conventional Proton pump inhibitor/ Esomeprazole in the management of GERD. Clinical trials have demonstrated that Fexuprazan provides rapid suppression of acid, resulting in improvement of GERD and over all safety profile is comparable to Esomeprazole. Moreover, studies have also reported Fexuprazan showing superior control over nocturnal symptoms compared to Esomeprazole. Evidence from systematic review and meta analysis further strengthen the point that Fexuprazan safety and efficacy is comparable to Esomeprazole.

In addition, patients reported outcomes, like GERD-Q, GERD-HRQoL, QOLRAD, demonstrated that effective suppression of GERD with Fexuprazan is translated into upgrade in patients over all quality of life.

Despite these finding, the current evidence base has several important limitations. Most clinical studies have relatively short follow up and have been conducted predominantly in East Asian population, limiting the generalizability of their finding. Other limitation such as lack of information on effectiveness in Non-erosive reflux disease (NERD) patients, recurrence of symptom on discontinuation of therapy, long-term study of maintenance therapy needs to be studied.

Overall, this article suggests that Fexuprazan is a safe, effective therapeutic option for the management in GERD, especially in patients requiring rapid symptom relieve and patients with nocturnal symptoms.

➢ *Conflict of Interest*

There was no funding or conflict of interest related to this work.

➢ *Author Contribution*

All the author have played significance role in this work.

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