Research Article

A PROSPECTIVE STUDY ON THE UTILIZATION PATTERN OF VONOPROZAN ON GASTROESOPHAGEAL REFLUX DISEASE (GERD)

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Abstract

Gastroesophageal reflux disease (GERD) is a chronic gastrointestinal condition, which is marked by retrograde gastric flow to the esophagus resulting in symptoms heartburn and regurgitation. The increasing prevalence of GERD especially among youngsters has been attributed to beneficial lifestyles, life characteristics as well as malfunction of lower esophageal sphincter. Although proton pump inhibitors (PPIs) are also a frequently used method of therapy, not all patients respond. This was a prospective observational study and lasted six months at PIMS where the efficacy and tolerability of vonoprazan as a novel potassium-competitive acid blocker (P-CAB) were determined in the treatment of erosive and non-erosive GERD.

Two hundred patients took part in this study and the males were the majority (68) and the age group 31-40 years was the most affected. The use of spicy foods (97.5%), caffeine (78%), and smoking (26.5%) were major contributing lifestyle factors. Vonoprazan 20mg showed high efficacy with regard to relief of symptoms particularly heartburn, regurgitation, epigastric and nausea with total elimination of severe heartburn in all 112 cases. There was no significant difference between genders and the recovery rates and erosive and non-erosive groups were equal (P=0.31). Some patients had mild residual symptoms reported such as dyspepsia and bloating.

The research finds that vonoprazan is a safe and very effective therapy in GERD with a significant symptomatic control and quality of life. Changing lifestyle and drug therapy complement each other in terms of improving treatment results. There is a recommendation of early diagnosis and personalized therapy on the basis of demographic and clinical profiles, which is most effective in treating GERD.

Keywords: Gastroesophageal Reflux Disease (GERD), Vonoprazan, Potassium-Competitive Acid Blocker (P-CAB), Erosive Esophagitis, Non-Erosive Esophagitis.

1. Introduction

Chronic reflux of gastric acid into the esophagus, produced as a result heart burn; signs of regurgitation and discomfort in the chest area, is termed Gastro-Esophageal Reflux Disease (GERD). If GERD continues to progress it can lead to Barrett's esophagus, strictures and esophagitis which will elevate the risk of esophageal cancer[1,2]. The primary underlying processes include slow gastric emptying, lower esophageal sphincter (LES) dysfunction and lack of esophageal motility, allowing acid to reflux into esophagus[3,4]. Millions of individuals worldwide, irrespective of age, gender, or stage of life, suffer from GERD. GERD is now regarded as a medical condition if its symptoms grow more frequent and persistent[5,6]. Smoking, healthy lifestyle choices, obesity and hereditary tendencies are important risk factors[7]. In addition to digestive symptoms, GERD has been associated with asthma, cardiovascular risks, and a chronic cough the usual course of treatment includes lifestyle modifications, drugs similar to PPIs and H2RAs, and in more severe cases, surgical procedures such fundoplication[6,8,9]. New treatments that inhibit potassium-competitive acids provide promising long-term relief.

1.1 Vonoprazan

Vonoprazan is a potassium- competitive acid blocker (P-CAB) that is a potent and long-acting replacement of the already existing proton pump inhibitor (PPI) in the treatment of GERD and other acid-related conditions[10]. Vonoprazan is a P-CAB that reversibly blocks H + and K + -ATPase on the parietal cells of the stomach mucosa. Vonoprazan binds directly and competitively with the binding of potassium in contrast to PPIs that require activation in acidic environment to irreversibly bind the proton pump. This causes faster, stronger and sustained inhibition of acid secretion of the stomach[10]. This process can hence be applied to acid related diseases as it allows the continuous inhibition of acid despite the presence of food in the stomach.

1.2 Clinical Applications

Scientific publications concerning vonoprazan have reported its efficacies in GERD, erosive esophagitis, NERD, and elimination of H. pylori[11,12]. In particular, vonoprazan has been beneficial in patients with PPI resistance GERD, where many studies have demonstrated superior symptom control compared to PPI therapy[13,14]. Furthermore, vonoprazan is used for long-term maintenance therapy for healed erosive esophagitis and the prevention of peptic ulcers in patients on long-term NSAID therapy[15].

1.3 Comparison with PPIs

PPIs like omeprazole, lansoprazole, and esomeprazole are sequentially activated and have variable efficacy because of CYP2C19 metabolism, but vonoprazan acts independently of genetic variation and has a higher potency and longer acid suppression with a faster onset of action[16]. The evidence thus indicates that in the treatment of PPI-refractory GERD and erosive esophagitis long-term remission, vonoprazan seems to be more effective than the PP[11,17]. In addition, vonoprazan-based treatments were found to have higher rates of H. pylori eradication compared with classical PPI-based triple therapy[18].

2. Literature Review

Uemura, N., Kinoshita, Y., ... & Ishiguro, K. (2024) conducted a study on "Vonoprazan as a long-term maintenance treatment for erosive esophagitis: VISION, a 5-year, randomized, open-label study." For a period of five years, researchers looked at the safety profile of vonoprazan as a continuous treatment for erosive esophagitis (EE). Prior to beginning long-term maintenance therapy, participants in the phase IV randomized trial received either vonoprazan or lansoprazole as an initial treatment for erosive esophagitis. Although vonoprazan was better at acid suppression, hypergastrinemia and changes to the gastric mucosa were raised as concerns. No evidence of malignancy in epithelial changes or gastric neuroendocrine tumors appeared during the treatment course. Fewer recurrences of EE were

said to be experienced in the vonoprazan group as opposed to the lansoprazole group. This study confirms the continued efficacy of vonoprazan but suggests that further evaluation of safety is necessary[12].

Iwakiri, K., Fujiwara, Y., … & Koike, K. (2022) conducted a study on "Evidence-based clinical practice guidelines for gastroesophageal reflux disease 2021". The 2021 GERD guidelines classify this condition as NERD, erosive esophagitis, Barrett's esophagus and extra-esophageal forms. Doctors diagnose based on observed symptoms together with endoscopy results and Ph monitoring data. PPIs remain the primary treatment option yet refractory cases respond well to P-CAB treatment using drugs such as vonoprazan. Patients with severe conditions require both lifestyle changes alongside surgical options such as fundoplication. Long-term safety cannot be determined for vonoprazan. These guidelines follow a structured methodology yet derive principally from Asian population studies which limits their universal application[6].

3. Methodology

A. Study Design: This research project was carried out in the Gastroenterology Department and were both prospective and observational.

B. Place of Study: The Prathima Institute of medical sciences, Karimnagar, Telangana, India, was the site of the study.

C. Study Period: The study was carried out over a period of six months.

D. Study Participants: This research included 200 GERD diagnosed patients.

Study prerequisites

Inclusion criteria

Patients of age <80 years, either male or female, outpatients and in patients, presence of erosive esophagitis or non-erosive reflux disease (NERD), moderate to severe GERD symptoms.

Exclusion Criteria

Pregnant or breastfeeding women, unstable cardio-vascular disease, severe liver or kidney disease, or other conditions that may impact study outcomes, known hypersensitivity to vonoprazan or other study medications, medications other than vonoprazan.

Data Sources

Data collection form includes demographic details, gender, GI symptoms, past history, diet, lifestyle, patient case sheet, laboratory report like endoscopy impressions, GERD questionnaire.

Statistical Analysis: Data were being analyzed using descriptive statistics in which the demographic data by GERD questionnaire. Difference between the healing rate and life style habits are included in this study where the statistical analysis is made by using the student's t-test. Statistical significance was defined as a p value of 0.31.

Ethical Approval

The study was conducted within ethical boundaries, and an informed consent form was provided and all the research participants signed the document.

4. Results and Discussion

The study was conducted over the duration of July 2024 to December 2024. This includes demography, life style, symptomatology, and treatment outcome in 200 patients suffering from gastro-esophageal reflux disease. The study elucidates the prevalence, symptomology, and management pertaining to GERD while underscoring the relevance of demography, lifestyle, and prior medical history as determinants of disease and treatment outcome.

4.1 Demographic Insights

Total, 136 (68%) of the cohort were male and 64 (32%) were female; gender-age association was statistically significant (p: 0.025); this points out that within age group 31-40, males harbor a greater tendency to suffer from GERD.

Table 1: Distribution of patients based on the gender suffering with GERD

Gender	No. of Patients	Percentage
Male	136	68%
Female	64	32%

Among 100% population 68% Male and 32% Female and were suffering with GERD

The age distribution of the study participants ranged between 11 to 100 years, with maximum in groupings of the age ranges being 31-40 (26.5%) and 21-30 (26%), aggregating to 52.5% of the total sample size. This follows the trend as reported in most previous studies where the peak incidence is observed to occur among the young middle-aged adults. Interestingly, this also shows that 12% come in the age group of pediatricians wherein an age lies in the group from 11-20 years. Therefore, it does not state that GERD is the adult disease only. However, a lower proportion of the respondents (22%) was aged 60 years and above, indicating possibly a decreased number of symptoms with age from the disease or that older persons are less likely to visit medicine for problems associated with GERD.

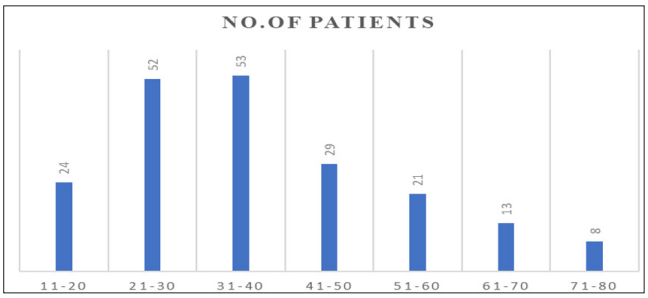

Figure 1: Distribution of patients based on age suffering with GERD

The highest percentage of subjects were from the age group 31-40 accounting 26.5% of the whole, followed by 21-30 age group with 26% of population.

4.2 Lifestyle Factors

Lifestyle habits played a crucial role in the occurrence and severity of symptoms in GERD. Indeed, an overwhelming majority (97.5% of participants) consumed spicy food, which is known to aggravate the symptoms of GERD. About 78% of participants took caffeinated beverages; hence, caffeine consumption serves as an important indication of exacerbating symptoms due to relaxing effects on the lower esophageal sphincter (LES). Most inadequacies related to lifestyle factors among them, hence indicating a relatively minor contribution to the development of GERD in this study population.

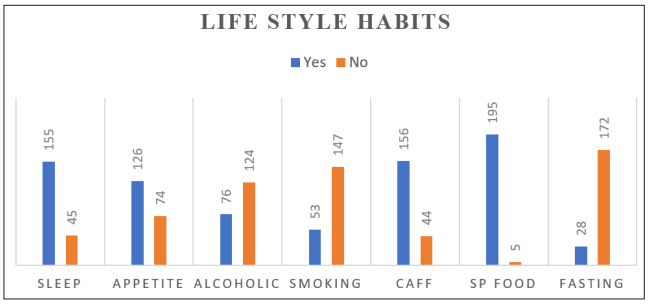

Figure 2: Distribution of patients based on the life style habits suffering with GERD

Out of 200 patients in our study, the risk factors mostly influencing the symptoms are spicy food (97.5%) and caffeine (78%).

4.3 Medical History and Comorbidities

A very large portion (34.5%) of patients had a previous history of GERD; this observation emphasizes the chronicity and recurrency associated with such a disease. In addition to that, other comorbidities as DM (6.5%), HTN (5%), and both (0.5%) mentioned appeared in association with GERD itself. Over half of study participants (53.5%) had a history without any significant past medical history; hence, it is indicated that even patients without prior chronic diseases might show susceptibility to GERD.

4.4 Endoscopic Findings and Symptom Distribution

Of the 200 patients who took part in the trial, 46.5 percent had erosive reflux esophagitis, whereas the remaining 53.5 percent had non-erosive esophagitis. More men suffer from both disorders, and the erosive group clearly has a male predominance (76.3% males vs 23.6% females), which varies more than the non-erosive group (61.3% males and 38.6%

females). Since Lax LES with antral gastritis was shown in 20% of patients and erosive gastritis in 27% of patients evaluated by endoscopy, GERD patients now require LES dysfunction in addition to stomach mucosal injury.

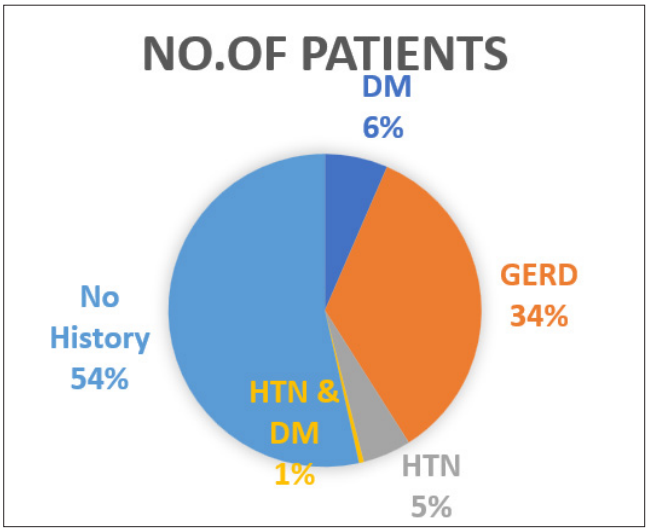

Figure 3: Distribution of patients based on the past medical history suffering with GERD: Out of 200 patients in our study, patients with past medical history of K/C/O GERD are 67 patients with 34.5%

Out of 200 patients in our study, 93 are erosive patients with 46.5% and 106 are non-erosive patients with 53% where male was more predominant.

Out of 200 patients in our study, patients with Erosive Gastritis are 54 patients with 27% and Lax less Hills Grade 2, Antral gastritis is 40 patients with 20%.

4.5 Therapeutic Response to Vonoprazan

Heartburn (85%), regurgitation (82.5%), postprandial distress (62%), dyspepsia (51%), and epigastric pain (43%) are some of the typical symptoms known among the GERD patients. These findings also coincide with the previous studies that diagnose heartburn and regurgitation as the hallmark symptoms among GERD patients. Therefore, this study used a symptom scoring system to assess the severity of GERD symptoms both before and after therapy with vonoprazan. The results revealed a considerable reduction in the severity of the symptoms, hence demonstrating the effectiveness of vonoprazan in GERD management. Severe symptoms, i.e., scores 4 and 5, were very prevalent before treatment for heartburn at 85%, regurgitation at 82.5%, nausea at 61%, and epigastric pain at 43%. Post-treatment, however, there was marked improvement, with most symptoms lying in the lower severity point (0, 1, and 2). For example, intolerably bothersome heartburn (score 5) reported before treatment by 112 patients manifested complete resolution at this level post-treatment. Likewise, regurgitation and nausea reported by 63 and 61 patients, respectively, at score 5 showed complete absence of symptoms at that level after treatment. Similarly released was epigastric pain affecting 27 patients at score 5 initially.

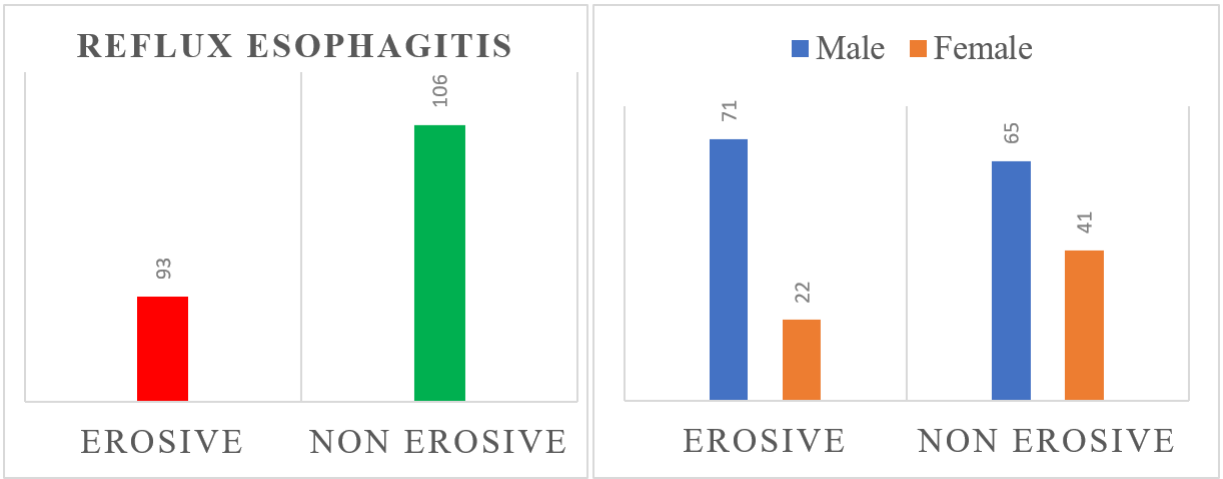

Figure 4: Distribution of patients based on the reflux esophagitis suffering with GERD

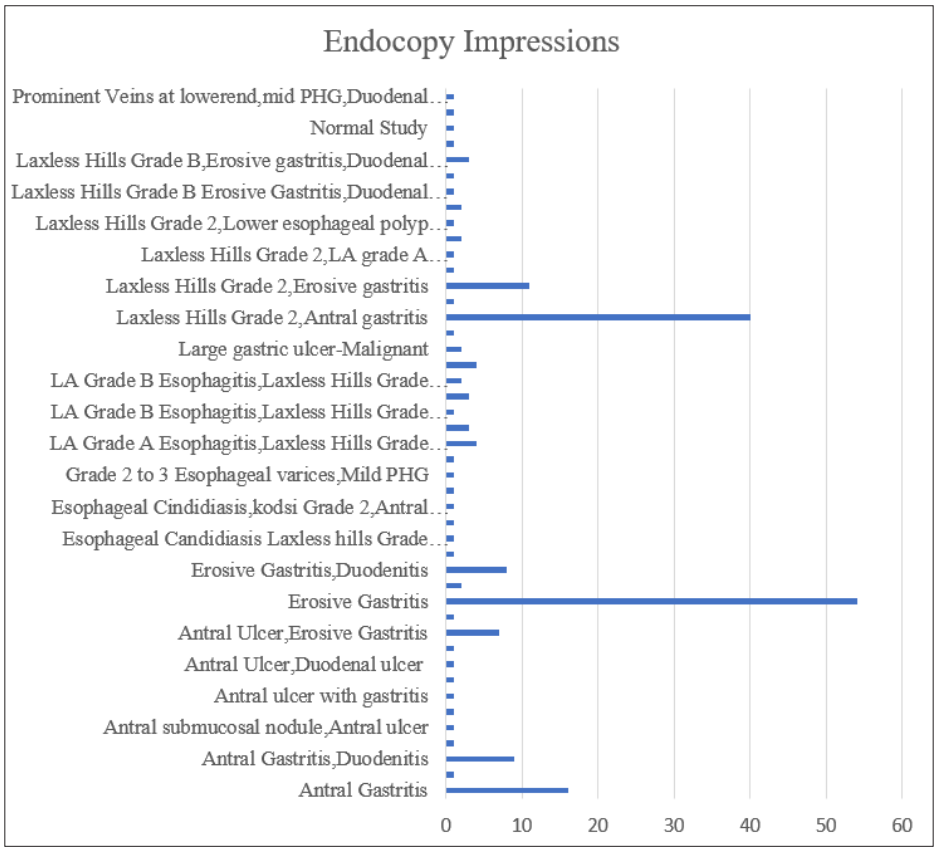

Figure 5: Distribution of patients based on endoscopic impressions

Significant improvement in terms of symptoms was recorded. However, bothersome symptoms remain, mostly with dyspepsia, bloating, and postprandial distress, regurgitation, still in the bothered level (score 3). This indicates that vonoprazan is effective, yet modifications in lifestyle and following up with patients over the long term may also be necessary for complete dissection of symptoms. Vonoprazan became self-verified once again as a proven highly efficacious treatment option for GERD where both erosive and non-erosive cases witness improvement in their condition.

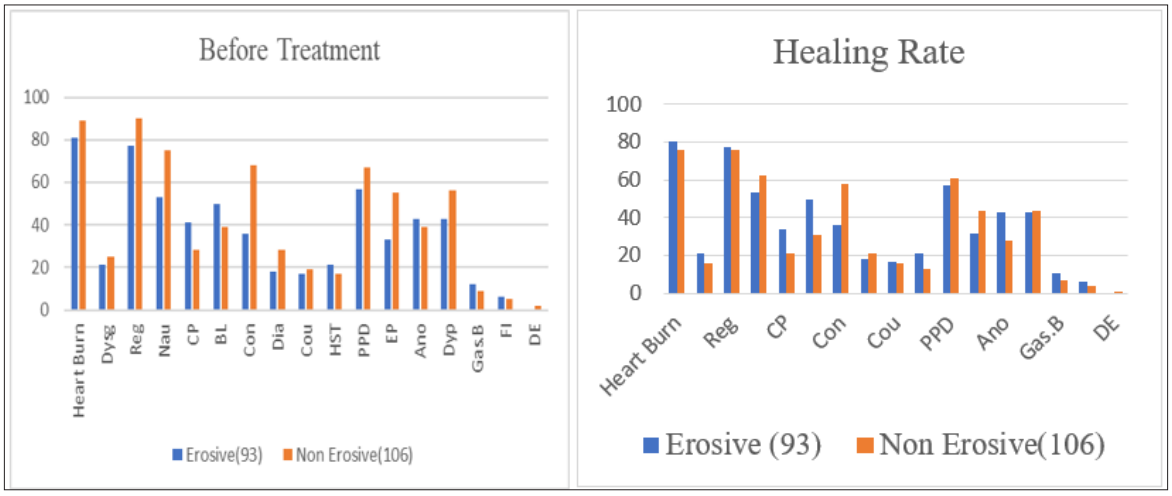

Figure-6.1: Distribution of patients based on the erosive and non-erosive symptoms before treatment suffering with GERD: Out of 200 patients, Erosive are 93 with Heart burn 87% and Regurgitation 82.7% & Non-erosive with Regurgitation 84.9% and Heart burn 83.9%

Figure-6.2: Distribution of patients based on the erosive and non-erosive symptoms after treatment based on healing rate of patients suffering with GERD: Erosive healing rate is greater than non-erosive after treatment

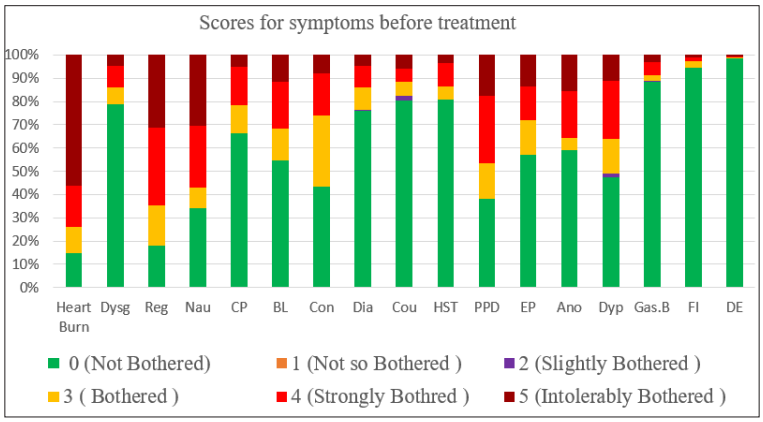

Figure-7.1: Scores given for the patient who are suffering with GERD based on severity

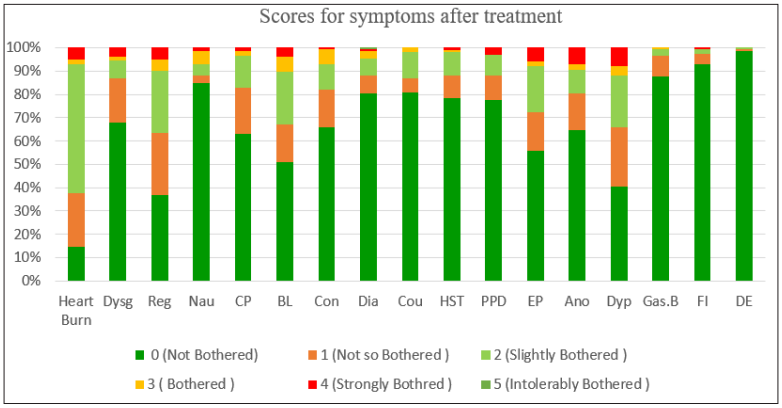

Figure-7.2: Scores given for the patient after treatment who are suffering with GERD

4.6 Gender and Symptom Correlation

The relationship of symptoms with the gender under several aspects was tested statistically by using paired t-test analysis, and the p value was 1.09 indicating that it was not statistically different. This means that though there are more males than females suffering from GERD, symptoms related to it are alike between the genders.

4.7 Erosive vs. Non-Erosive GERD: Treatment Efficacy

The study reviewed the impact of vonoprazan therapy in both erosive and non-erosive GERD patients. Prior to initiation of treatment, both symptom patterns were almost identical, heartburn and regurgitation being the most important among others.

Healed, the erosive group had a higher healing rate, with 8.7% of all patients in that group completely free from heartburn symptoms. In spite of this, statistical analysis (p-value=0.31) showed no significant difference in healing rates of the two groups, which would suggest that treatment with vonoprazan is efficacious for GERD symptom control regardless of esophagitis type.

4.8 Clinical Implications

The results of this study have substantial clinical importance for GERD diagnosis and treatment. Since this disease has found high prevalence from younger to middle adulthood, prompt diagnosis and proper lifestyle modifications are extremely important to prevent disease progression. Hence, liaison modification such as minimizing intake of spicy food and caffeine should be highlighted along with medication, as this kind of diet is responsible for the most extreme aggravation of GERD. This near-equal amount of erosive and non-erosive esophagitis also emphasizes a need for endoscopy to ensure correct diagnosis and custom tailoring treatment strategies. Also, comparable healing rates in the two groups receiving vonoprazan treatment indicate efficacy regardless of GERD type. These findings further highlight the need to adapt an all-inclusive strategy, including lifestyle changes, early

intervention, and appropriate medical therapy to enhance the outcome of patients.

5. Conclusion

It is a prospective observational study that depicts the effectiveness of vonoprazan in GERD management, according to the goals and objectives of the study. The results reflect that the administration of vonoprazan substantially enhances the symptoms of GERD, thus reducing the severity of heartburn, regurgitation, nausea, and epigastric pain. Therapy benefit has been extracted from both erosive and non-erosive GERD with healing rates within these two categories being the same. Furthermore, the study brings to notice how demographics, lifestyle habits, and past medical history influence disease expression and response to treatment.

Several patients are still having minor symptoms even after a dramatic improvement in symptom control; however, their major complaints are still dyspepsia, bloating, and discomfort post eating, showing that lifestyle modification will go along with medicine. The study also advocates the adoption of early diagnosis and individual treatment regimen in consideration of the high burden of GERD amongst young to middle-aged adults.

In summary, vonoprazan can be seen as a highly effective and well-tolerated treatment for GERD as a relief of significant symptoms and improvement of the quality of life among patients.

6. Acknowlegement

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7. Authors Contribution

Bhukya Swecha Sanjana Rathod, Ganapaka Kalpana, Nagula Sanjana, Sammeta Varsha contributed equally to the data collection for this research work. Bhukya Swecha Sanjana Rathod and Ganapaka Kalpana were primarily responsible for data analysis and manuscript writing. Bhukya Swecha Sanjana Rathod also acquired supervision of , overseeing the entire study, interpreting the research findings, and giving the finishing touches to the manuscript. In addition, the authors ensured the scientific accuracy, ethical compliance, and overall coherence of the study throughout the research process. All the authors supported the preparation of tables and figures, assisted in literature review, and contributed valuable inputs during the revision phase. All authors collaboratively reviewed, edited, and approved the final version of the manuscript for submission.

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9. Conflict of Interest

The authors have disclosed no conflicts of interest.

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