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Original Research Article

Real-world evidence study evaluating the effectiveness, tolerability and utilization patterns of Vonoprazan in routine clinical practice across out-patient clinical setting in India

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ABSTRACT

Background: Gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD) are two of the most common acid-related gastrointestinal conditions in India. They are associated with significant morbidity and impaired quality of life. Vonoprazan has demonstrated clinical efficacy in clinical trials and offers rapid and sustained acid suppression. However, there is still a dearth of empirical data on its therapeutic application and efficacy in Indian patients.
Methods: This multicentre, retrospective, observational real-world evidence study examined medical records from 8,325 patients prescribed Vonoprazan in outpatient settings across India during a 6-month period. Demographic details, indications, dose patterns, symptom improvement, treatment satisfaction, and safety outcomes were assessed using descriptive and comparative statistical methods.
Results: GERD (55.98%) and acid peptic disorders (APD; 33.07%) as diagnosed by the treating physicians were the most common indicators for Vonoprazan treatment. The majority of patients (93.14%) received 20 mg of Vonoprazan once daily. Symptoms improved significantly, with heartburn relief reported in 97.53% of patients and acid regurgitation improvement in 91.80%. Severe heartburn dropped from 44.06% at baseline to 1.93% after treatment ($p<0.05$), while acid regurgitation decreased from 31.95% to 6.56% ($p<0.05$). Overall treatment satisfaction was high, with 73.44% of patients reporting being extremely satisfied.
Conclusions: Vonoprazan demonstrated clinically meaningful real-world effectiveness, improvement in symptom control, favourable tolerability, and high patient satisfaction in Indian patients with GERD and other acid-related disorders, supporting its role as an effective therapeutic option in routine clinical practice.

Keywords: Vonoprazan, Gastroesophageal reflux disease, Acid peptic disorders, Real-world evidence, Treatment effectiveness

INTRODUCTION

Gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD) are two of the most common acid-related gastrointestinal diseases worldwide and are associated with significant morbidity, impaired quality of life, and increased health care utilization.[1,2] The global prevalence of GERD is approximately 13.9%, affecting nearly 1.03 billion individuals worldwide as of 2024. However, prevalence rates vary widely between regions, ranging from 8.7% to 33.1% in the Middle East, 8.8% to 25.9% in Europe, and 2.5% to 7.8% in East Asia.[3] The prevalence of GERD in Indian epidemiological studies is reported as 10–22% and is higher in urban populations, possibly due to sedentary lifestyle, obesity, dietary habits, alcohol consumption, smoking, stress, and metabolic disorders.[4,5] Acid peptic disorders (APD) are highly prevalent in India and represent a major clinical burden in outpatient practice

due to chronic symptom recurrence and long-term dependence on acid-suppressive therapy.[6] The 2021 GERD guidelines suggest individualized treatment based on disease severity.[7] Proton pump inhibitors (PPIs) remain commonly used as first-line therapy, while potassium-competitive acid blockers (P-CABs) are increasingly considered where available, particularly in patients requiring rapid or sustained acid suppression and in more severe or resistant cases.[8]

PPIs have several pharmacologic limitations, including the requirement for acid activation, delayed onset to maximal acid suppression, and significant interindividual variability, much of which is attributed to CYP2C19 polymorphisms and potential drug-drug interactions.[9,10] In contrast, P-CABs, such as Vonoprazan, inhibit gastric H^+/K^+-ATPase rapidly, potently, and in a sustained manner by reversibly blocking the K^+ binding site.[11,12] This mechanism offers faster and more consistent acid suppression compared with PPIs and is largely independent of acid activation or CYP2C19 genotype.[13-15] The acid stability of Vonoprazan and the limited effect of food intake may support more consistent intragastric pH control. Vonoprazan has demonstrated superior or equivalent effects to PPIs in various acid-related conditions, including erosive esophagitis and prevention of rebleeding in high-risk peptic ulcer disease and upper gastrointestinal bleeding.[14,16-20]

Vonoprazan 20 mg has been shown in clinical trials to be effective in patients with PPI-refractory reflux esophagitis, with higher mucosal healing rates and earlier symptom relief than lansoprazole, particularly in patients with severe erosive esophagitis.[21,22] Vonoprazan has also been associated with improved mucosal repair in PPI-refractory populations compared with previous PPI studies.[21,23] However, evidence regarding long-term outcomes, relapse after discontinuation, retreatment patterns, and dose modification in routine clinical practice remains limited.[24,25]

The safety and effectiveness of Vonoprazan have been demonstrated in randomized clinical studies; however, data from routine clinical practice remain limited, especially in India, where patient responses and real-world prescribing patterns may differ from controlled clinical settings. Real-world evidence studies are needed to assess treatment utilization patterns, effectiveness, patient-reported outcomes, tolerability, and safety in larger and more diverse patient groups encountered in routine clinical practice.[26] Given the high prevalence of GERD, the extensive use of PPIs, and the need for effective long-term acid suppression strategies; such evidence is particularly relevant in India.

Therefore, the present multicentre real-world evidence study was conducted to characterize the clinical use, effectiveness, and safety of Vonoprazan in patients with acid-related disorders treated in routine outpatient settings across India. The primary objective was to evaluate improvement in symptoms associated with these disorders under real-world clinical practice conditions.

METHODS

Study design

The present clinical study was an observational, multicentre, retrospective, medical record-based real-world evidence study conducted during the period from November 2024 to November 2025, aimed to analyse the prescribing patterns of Vonoprazan by healthcare professionals and to assess the overall utilization of Vonoprazan among patients in India. Since anonymized data from the medical records of patients already treated with the prescribed treatment were used in this retrospective study, informed consent of the patients was not required. Patient identities were anonymized and were not disclosed during the study at any point during the study. The study investigator and site personnel identified patients who matched the study selection criteria from the available patient medical records at the study site. Prescriptions of individual patients were screened, and data from the electronic health records, pharmacy records and clinical notes were captured in the predesigned structured case record forms. Patient records at each site were given a unique ID number, starting with 001 for each investigator. The data were extracted from prescriptions and medical records of patients prescribed Vonoprazan. Moreover, the Ethics Committee's permission was taken before study initiation.

Patient population

The study included medical records of patients who had been prescribed Vonoprazan by their treating physician as part of routine clinical care at outpatient clinics and hospitals across India. Eligible records were identified and reviewed during the 6-month data-collection period. Records with sufficient clinical and follow-up information were included. Records with incomplete or insufficient information, as well as those of patients with severe comorbid conditions that could interfere with the assessment of study outcomes, were excluded from the analysis.

Study assessments

The study evaluated real-world prescribing patterns and clinical usage of Vonoprazan in patients with GERD, peptic ulcer, and other acid related disorders in outpatient departments (OPD) of various clinics across India. The study also analyzed demographic characteristics of patients on Vonoprazan, safety and tolerability of Vonoprazan including the frequency, and usage patterns with dosing regimens. Additionally, prescriptions and medical records were reviewed to assess demographic characteristics, comorbidities, symptom severity, dosing patterns, and patient-reported symptom outcomes.

Study flow and conduct

Clinical data were extracted from the medical records of patients prescribed Vonoprazan during routine clinical practice. The recorded information included demographic characteristics, medical history, clinical diagnosis, Vonoprazan dosage, treatment outcomes.

Statistical analysis

The data collected from the database were analyzed for demographics, treatment regimens, and outcomes. Data were presented as number (percentage). Baseline and post-treatment symptom severity were compared and post-treatment symptom severity using paired statistical tests. The p value of <0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the institutional ethics committee (IEC). The study adhered to the principles outlined in the declaration of Helsinki and good clinical practice (GCP) guidelines.

RESULTS

Over the study period of 6 months, a total of 8,325 patients who were prescribed Vonoprazan and whose medical records were available were included in the study for prescribing patterns and utilization.

Demographic and baseline characteristics

Among the 8,325 included patients, 6,154 (73.92%) were male and 2,171 (26.08%) were female. The mean age of the study population was 51.31±11.73 years. The mean (±SD) height, body weight, and body mass index (BMI) were 164.01 (±9.95) cm, 72.53 (±13.29) kg, and 27.12 (±5.32) kg/m², respectively (Table 1). Hypertension was the most commonly reported comorbidity, observed in 3,211 (38.57%) patients, followed by obesity in 1,612 (19.36%), diabetes mellitus in 1,554 (18.67%), and cardiovascular diseases, including heart failure, in 1,188 (14.27%) patients. Chronic kidney disease was reported in 242 (2.91%) patients, while 518 (6.22%) patients had other comorbid conditions.

Assessment of symptom severity revealed that severe heartburn was present in 3,668 (44.06%) patients, whereas 2,678 (32.17%) and 1,979 (23.77%) patients experienced moderate and mild heartburn, respectively. Additionally, acid regurgitation was reported in 2,660 (31.95%) patients (Table 1).

Indication of Vonoprazan

Among the 8,325 patients included in the study, the indications for Vonoprazan therapy were recorded as diagnosed by the treating physicians. GERD was the most commonly reported indication, observed in 4,660 (55.98%) patients, followed by APD in 2,753 (33.07%) patients. Other reported indications included gastric ulcer in 257 (3.09%) patients, erosive esophagitis in 222 (2.67%) patients, duodenal ulcer in 126 (1.51%) patients, gastroduodenal ulcer in 113 (1.36%) patients, and reflux esophagitis in 98 (1.18%) patients. Less frequently reported indications included NSAID-induced gastritis in 45 (0.54%) patients, stress ulcer in 25 (0.30%) patients, *H. pylori* infection in 16 (0.19%) patients, and dyspepsia in 10 (0.12%) patients (Table 2).

Table 1: Demographic and baseline characteristics.

Parameters	Overall (n=8325)
Gender, N (%)	
Female	2171 (26.08)
Male	6154 (73.92)
Age (years), mean±SD	51.31±11.73
Height (cm), mean±SD	164.01±9.95
Weight (kg), mean±SD	72.53±13.29
BMI (kg/m^2), mean±SD	27.12±5.32
Comorbidities, N (%)	
Hypertension	3211 (38.57)
Obesity	1612 (19.36)
Diabetes	1554 (18.67)
Cardiovascular disease including heart failure	1188 (14.27)
Others	518 (6.22)
Chronic kidney disease	242 (2.91)

Table 2: Indication of Vonoprazan.

Parameters	Overall (n=8325), N (%)
GERD	4,660 (55.98)
Acid peptic disorder	2,753 (33.07)
Gastric ulcer	257 (3.09)
Erosive esophagitis	222 (2.67)
Duodenal ulcer	126 (1.51)
Gastroduodenal ulcer	113 (1.36)
Reflux esophagitis	98 (1.18)
NSAID-induced gastritis	45 (0.54)
Stress ulcer	25 (0.30)
***H. pylori* infection**	16 (0.19)
Dyspepsia	10 (0.12)

Usage pattern of dosing regimens

Table 3 presents the dosing patterns of Vonoprazan among the study population. Of the 8,325 patients, the majority received Vonoprazan 20 mg once daily (OD) (93.14%), followed by 20 mg twice daily (BD) in 401 (4.82%) patients.

Vonoprazan 10 mg OD and 10 mg BD were prescribed in 124 (1.49%) and 46 (0.55%) patients, respectively.

Table 3: Usage pattern of dosing regimens.

Parameters	Overall (n=8325), N (%)
20 mg OD	7754 (93.14)
20 mg BD	401 (4.82)
10 mg OD	124 (1.49)
10 mg BD	46 (0.55)

Change in symptom severity

Among the overall 8,325 patients assessed at baseline, heartburn severity was reported as mild in 1,979 (23.77%) patients, moderate in 2,678 (32.17%) patients, and severe in 3,668 (44.06%) patients. At follow-up assessment after treatment, among the overall 8,325 patients, mild heartburn was reported in 7,213 (86.64%) patients, moderate heartburn in 951 (11.42%) patients, and severe heartburn in 161 (1.93%) patients. The reduction in heartburn severity was statistically significant (Wilcoxon signed-rank test, $p<0.05$).

At baseline, among the overall 8,325 patients assessed, acid regurgitation was present in 2,660 (31.95%) patients and absent in 5,665 (68.05%) patients. At post-baseline evaluation after treatment, among the overall 8,325 patients, acid regurgitation was present in 546 (6.56%) patients and absent in 7,779 (93.44%) patients. This improvement was found to be statistically significant based on the McNemar test ($p<0.05$) (Figure 1).

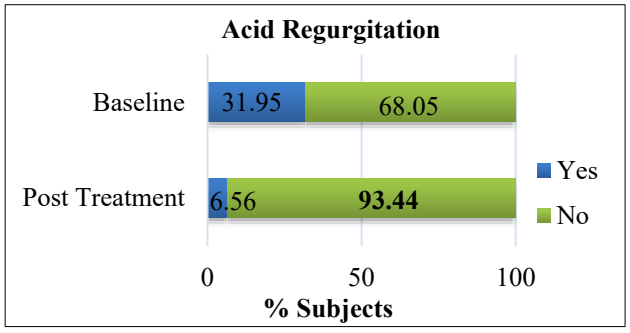

Figure 1: Acid regurgitation.

Patients related outcomes

Table 4 demonstrates that Vonoprazan provided substantial symptom relief among the 8,325 patients. Heartburn improved in 8,119 (97.53%) patients, while acid regurgitation improved in 7,642 (91.8%) patients. No change in symptoms was observed in 197 (2.37%) patients for heartburn and 661 (7.94%) patients for acid regurgitation, whereas worsening of symptoms was reported in 9 (0.11%) and 22 (0.26%) patients, respectively.

Overall satisfaction with treatment

Overall, 6,114 (73.44%) patients were very satisfied, 2,157 (25.91%) were satisfied, and only 54 (0.65%) patients reported a neutral response. The present study shows a high patient-reported treatment satisfaction with Vonoprazan treatment among the 8,325 patients.

Table 4: Patient-reported symptom outcomes.

Parameters	Overall (n=8325), N (%)
Heartburn	
Improved	8119 (97.53)
No change	197 (2.37)
Worsened	9 (0.11)
Acid regurgitation	
Improved	7642 (91.8)
No change	661 (7.94)
Worsened	22 (0.26)

DISCUSSION

The current multicentre, retrospective, real-world evidence study assessed Vonoprazan prescription practices, efficacy, safety, and usage among 8,325 patients throughout India. The study findings showed that Vonoprazan 20 mg daily was frequently used in clinical practice to treat acid-related gastrointestinal illnesses such as erosive esophagitis, gastric ulcer, dyspepsia and GERD. Following Vonoprazan therapy, the study also showed a significant reduction in heartburn severity, acid regurgitation, and overall patient satisfaction, which supports the growing evidence about the clinical value of potassium-competitive acid blockers (P-CABs) in acid-related disorders.

The study showed that middle-aged and older adults comprised a substantial proportion of patients prescribed Vonoprazan, with prescribing being more frequent among males. Previous epidemiological research from Asia and India has shown similar demographic results. They have shown that, middle-aged people and men in India had a greater prevalence of GERD because of dietary factors, obesity, smoking, alcohol intake, and sedentary lifestyles.[3,8]

The most prevalent comorbidities found in the current study were hypertension (38.57%), obesity (19.36%), diabetes mellitus (18.67%), and cardiovascular disease including heart failure (14.27%). Because metabolic syndrome, obesity, and diabetes are known risk factors for GERD and reflux-related symptoms, these findings are clinically significant. Due to elevated intra-abdominal pressure and compromised lower oesophageal sphincter function. Many studies showed that obesity, hypertension and diabetes with a higher prevalence of GERD in populations.[27,28] In this context, the use of Vonoprazan in the present study is consistent with recent Indian consensus recommendations supporting Vonoprazan as an effective acid-suppressive option for acid-related gastrointestinal illnesses such as erosive esophagitis, gastric ulcer, dyspepsia and GERD, owing to its rapid, potent, and sustained acid suppression.[29]

In the current study, GERD and APD as diagnosed by the treating physicians were the most frequent indications for Vonoprazan therapy. These findings align with previous research in which the most common indications for Vonoprazan therapy were erosive esophagitis and GERD. When compared to lansoprazole, Vonoprazan was shown by Ashida et al in a Japanese phase III trial to be very efficacious in curing erosive esophagitis and sustaining remission (healing by Week 8: 99.0% with Vonoprazan 20 mg versus 95.5% with lansoprazole 30 mg).[21] Laine et al further reported higher healing rates with Vonoprazan than with lansoprazole in patients with erosive esophagitis (healing by Week 8: 92.9% versus 84.6%; treatment difference: 8.3%, 95% CI: 4.5%-12.2%). The benefit was more pronounced in patients with Los Angeles grade C/D erosive esophagitis (week 2 healing: approximately 70% versus 52%; difference: 17.6%, 95% CI: 7.4%-27.4%).[30] The high prevalence of GERD in the current study further indicates the substantial clinical burden of reflux disease in India and the corresponding need for effective acid-suppressive treatment.

Vonoprazan was approved in the United States in 2023 for the treatment of erosive esophagitis, with the approved prescribing information recommending 20 mg once daily for 8 weeks for healing erosive esophagitis and relieving associated heartburn. In the current study, Vonoprazan 20 mg once daily (OD) was the most often given regimen, accounting for the majority of prescriptions. This prescribing pattern is consistent with published clinical trials and current clinical guidelines that prescribe Vonoprazan 20 mg OD as the standard induction therapy for severe GERD and erosive esophagitis. According to Oshima et al, Vonoprazan 20 mg quick onset of action and extended intragastric pH regulation allowed for more immediate and long-lasting gastric acid suppression than PPIs.[33] Similar to this, Vonoprazan exhibits strong acid inhibition regardless of CYP2C19 polymorphism, as shown by Hori et al, which helps explain its consistent therapeutic response.[15] Mizuno et al found that Vonoprazan 10 mg once daily maintenance medication effectively avoided recurrence of reflux symptoms in most patients over 48 weeks in another multicentre trial.[31] The widespread utilization of the 20 mg OD regimen in the current study therefore reflects alignment with commonly used clinical dosing practices in its efficacy and convenience in real-world practice.

The statistically significant improvement in patient-reported symptoms was one of the key findings. Following Vonoprazan therapy, 91.80% of patients reported improvement in acid regurgitation and 97.53% of patients reported improvement in heartburn. Additionally, the prevalence of severe heartburn dropped significantly from 44.06% at baseline to just 1.93% during treatment. These results are consistent with earlier clinical trials assessing Vonoprazan in patients with erosive esophagitis and associated heartburn. Ashida et al demonstrated that Vonoprazan was more effective than lansoprazole in maintaining healed erosive esophagitis over 24 weeks (recurrence rates: 5.1% with Vonoprazan 10 mg and 2.0% with Vonoprazan 20 mg versus 16.8% with lansoprazole 15 mg; $p=0.0002$ and $p<0.0001$, respectively). Similarly, Oshima et al reported faster heartburn relief with Vonoprazan than with lansoprazole, with complete heartburn relief on day 1 observed in 31.3% and 12.5% of patients, respectively.[32,33]

Oshima et al showed that Vonoprazan greater acid suppression during the day and at night allowed for earlier and longer-lasting heartburn relief than PPIs. Similarly, patients with PPI-refractory GERD showed quick symptom alleviation and improved nocturnal acid control when using Vonoprazan.[33]

The current study's notable decrease in acid regurgitation further supports Vonoprazan effectiveness in this real-world cohort in reducing reflux symptoms. Similar findings were reported by Xiao et al, who exhibited non-inferiority and long-term efficacy of Vonoprazan compared with lansoprazole among Asian patients with erosive esophagitis.[34] All of these trials point to Vonoprazan long-term therapeutic advantages in the regular treatment of reflux illness.

With 73.44% of patients being extremely satisfied and 25.91% being satisfied with therapy, patient satisfaction in the current study was high. Rapid symptom relief, convenient once-daily dosing, and enhanced quality of life may have contributed to the high level of patient satisfaction. In a real-world observational trial, Tanabe et al found that patients taking Vonoprazan reported better symptom control and high treatment satisfaction, especially in cases of refractory GERD. When compared to traditional PPIs, faster start of action and longer-lasting acid suppression may considerably improve adherence and patient-reported outcomes.[35]

The positive results seen in this trial could be explained by Vonoprazan pharmacological benefits over PPIs. Vonoprazan exhibits acid-stable characteristics with prolonged inhibition of H+/K+-ATPase, in contrast to PPIs, and does not require acid activation. P-CABs provide quick, strong, and long-lasting acid suppression with less interindividual variability than PPIs.[9,12] Graham and Dore also noted that Vonoprazan improves therapeutic response in a variety of groups by providing more constant intragastric pH regulation regardless of CYP2C19 genetic variations.[14] In Indian clinical settings, where inconsistent PPI responses are common, these pharmacodynamic benefits are particularly pertinent.

The current study adds credence to the mounting empirical data on Vonoprazan safety and tolerability. A small proportion of patients reported symptom worsening following treatment, suggesting favourable clinical tolerability within the limitations of retrospective safety data capture. Vonoprazan has also shown favourable safety profiles in earlier randomized controlled trials and observational studies.[30] However, because Vonoprazan

causes potent acid suppression, long-term treatment has been linked to increased serum gastrin levels. While no major clinical safety concerns were identified during follow-up, Kojima et al found that Vonoprazan-treated individuals had considerably greater gastrin levels than PPI-treated patients.[36] Therefore, periodic monitoring may be considered during long-term therapy.

A major strength of the current study was its large, geographically diverse patient population, which reflected routine outpatient clinical practice across India and enhanced the generalizability of the findings. The use of real-world medical records provided clinically relevant information on Vonoprazan prescribing patterns, treatment effectiveness, patient outcomes, demographics, comorbidities and treatment duration, supporting analyses beyond the controlled setting of randomized clinical trials.

As highlighted by Makady et al, real-world evidence can improve understanding of treatment effectiveness in broader patient populations and support healthcare decision-making.[37] However, the retrospective design and variability in record completeness across centres may have resulted in under-reporting or missing information. Despite these limitations, the study provides valuable Indian real-world evidence on the utilization and clinical effectiveness of Vonoprazan.

Overall, the findings of the present study demonstrate that Vonoprazan is extensively utilized in Indian clinical practice and provides significant improvement in heartburn, acid regurgitation, and patient satisfaction among patients with GERD and acid-related disorders.

The study findings are consistent with previous randomized controlled trials and observational studies conducted globally, supporting Vonoprazan as an effective and well-tolerated therapeutic option in routine clinical practice.

CONCLUSION

The present real-world evidence study demonstrated that Vonoprazan was associated with clinically meaningful symptom improvement in heartburn and acid regurgitation, high patient satisfaction, and favourable tolerability among patients with GERD and other acid-related gastrointestinal disorders in Indian clinical practice. These findings support the use of Vonoprazan as a useful therapeutic option for the routine management of acid-related disorders, while further prospective comparative studies are required to confirm its long-term effectiveness and safety in broader patient populations.

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