# Therapeutic Efficacy of Vonoprazan versus Dexlansoprazole in the Treatment of Gastroesophageal Reflux Disease: A Randomized Controlled Trial

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**Background and study aim:** Gastroesophageal reflux disease (GERD) is a prevalent condition marked by acid regurgitation and/or heartburn due to the reflux of gastric contents. This study aimed to evaluate the efficacy of Vonoprazan (P-CABs) versus Dexlansoprazole (PPIs) in cases diagnosed with gastroesophageal reflux disease.

**Patients and Methods:** This study was a randomized controlled open-label trial, this study represents the first of its kind in internal medicine at Zagazig University Hospitals, spanning the period from October 2024 to February 2025.

It included eighty cases diagnosed with gastroesophageal reflux disease following upper GI endoscopy. Cases have been categorized into two groups, forty patients in each. Group A received Vonoprazan twenty milligrams once daily, whereas Group B received Dexlansoprazole sixty milligrams once daily for a duration of eight weeks. Primary Outcome Measure (Symptom relief assessed by the GERD-Q score), Secondary Outcome Measure (Frequency scale of the symptoms of gastroesophageal reflux disease questionnaire (FSSG), and mucosal healing by upper GI endoscopic evaluation.

**Results:** Analysis revealed no statistically significant difference in GERD Q scores between groups A and B before treatment (mean ± SD: 15.92 ± 1.36 vs. 15.84 ± 1.61, p = 0.81). Following treatment, both groups exhibited significant improvement (99.42% in group A and 99.39% in group B), although this difference was not statistically significant (0.09 ± 0.23 vs. 0.10 ± 0.27, p = 0.65). Similarly, no statistically significant differences in dysmotility scores were observed between groups before and after treatment. Group A demonstrated pretreatment and post-treatment mean scores of 6.71 ± 2.48 and 2.26 ± 0.75, respectively, while group B showed corresponding means of 7.24 ± 1.86 and 2.20 ± 0.5 (p=0.27 pretreatment, p=0.68 post-treatment). Furthermore, no statistically significant difference in LA classification was observed between groups A and B at baseline or after eight weeks of treatment (p=0.56, 0.71, respectively). However, statistically significant differences in LA classifications were observed within both groups when comparing baseline and post-treatment (eight-week) assessments.

**Conclusion:** The study concluded that Vonoprazan demonstrated no superiority to Dexlansoprazole in alleviating GERD symptoms or promoting mucosal healing, with the exception of a statistically significant reduction in reflux scores.

## INTRODUCTION

Gastroesophageal reflux disease (GERD) is a prevalent condition marked by acid regurgitation and/or heartburn due to the reflux of gastric contents [1]. The clinical characteristics of the condition and its significant prevalence adversely affect the case's well-being and quality of life, while also placing a significant burden on healthcare systems regarding time and expenses [2].

Gastroesophageal reflux disease (GERD) is a prevalent gastrointestinal disorder, exhibiting a pooled prevalence of 21% in the United States (US) [3], resulting in over 4.6 million annual ambulatory care visits [4]. East Asian prevalence rates range from 2.5% to 7.8% [5]. A significant presentation of GERD is erosive esophagitis, affecting an estimated 25% to 50% of symptomatic patients [6].

Cases with gastroesophageal reflux disease are classified into two primary categories: most of them have non-erosive reflux disease (NERD) without esophageal lesions, whereas erosive esophagitis (EE), marked by mucosal injury and reflux symptoms [7].

Esophageal dysmotility may be a contributing factor in GERD. Prior research indicates a higher prevalence of esophageal dysmotility in GERD patients experiencing globus sensation compared to those with typical GERD symptoms [8].

The primary objective of therapy for cases with gastroesophageal reflux disease is stomach acid suppression, with proton pump inhibitors (PPIs) that represent the current gold standard for diminishing gastric acidity, alleviating symptoms, and facilitating mucosal repair in cases with reflux esophagitis [9]. In patients receiving proton pump inhibitor therapy, esophageal mucosal healing demonstrates significantly greater predictability than symptomatic improvement [10].

Vonoprazan is known as a new family in the suppression of gastric acid, which is potassium competitive acid blockers [P-CABs]. Proton pump inhibitors (PPIs) exhibit several limitations affecting their therapeutic efficacy: ineffectiveness during periods of proton pump inactivity, such as nocturnal periods; variable efficacy influenced by genetic polymorphism, particularly within Asian populations; slow onset of action; short plasma half-life; and irreversible binding to the proton pump [11], but potassium competitive acid blockers (P-CABs) reversibly inhibit H+ and K+ ATPase, resulting in a great and long-term inhibition of acid secretion [12]. As reported in some studies, the healing rate of reflux esophagitis was superior to that of a PPI [dexlansoprazole], with a greater effect seen in cases with greater severity [13]. This research aims to conduct a head-to-head randomized controlled trial evaluating the comparative efficacy of Vonoprazan (P-CABs) and Dexlansoprazole (PPIs) in Egyptian patients diagnosed with gastroesophageal reflux disease.

## PATIENTS AND METHODS

### Study design:

This study was a randomized controlled, open-label trial conducted in the outpatient clinics of the Internal Medicine Department at Zagazig University Hospitals, extending from October 2024 to February 2025. The study included two groups, Group A received Vonoprazan twenty milligrams once daily, whereas Group B received Dexlansoprazole sixty milligrams once daily for a duration of eight weeks. The Zagazig Institutional Review Board approved this study (IRB#: 745/5). It also was registered on https://clinicaltrials.gov/. Trial registration number: NCT06778395, Release Date: February 24, 2025.

### Patient Selection and Data Collection :

Participants were selected from the ZUH internal medicine department using systematic random sampling. Inclusion criteria were: patients diagnosed with GERD (based on GERD scores and confirmed via upper GI endoscopy), aged 18 years or older, and of either sex.

### Exclusion criteria included :

- Other GIT problems (Other esophageal disorders such as eosinophilic esophagitis and infectious esophagitis, scleroderma and esophageal stenosis, acute upper gastrointestinal hemorrhage, and gastric or duodenal ulcers, hypersecretion syndromes such as Zollinger Ellison syndrome).
- Other comorbidities (severe pulmonary, hepatic, renal, cardiovascular, neurological conditions, viral hepatitis or HIV, a history of cancer).
- Laboratory abnormalities (elevated serum glutamic oxaloacetic trans-aminase [SGOT] and glutamic pyruvic trans-aminase [SGPT] > 2.5 × the upper range in the limit of normal, elevated serum creatinine of more than 2 mg/dL.
- History of alcohol addiction, pregnancy and breastfeeding.
- Medications were received within 4 weeks before the start of the study (PPIs, H2RAs, improvers of gastrointestinal motility, anticholinergics, prostaglandins, antacids, mucosal protectives, and H. pylori eradicators medications).

### Sample Size :

A sample size calculation, performed using OpenEpi Info with a 95% confidence interval, 80% power, and a 1:1 allocation ratio, yielded a minimum sample size of 48 patients (24 per group). This calculation was based on a projected


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68.8% symptom relief rate for vonaprazan versus 25% for lansoprazole [14].

Eighty patients diagnosed with gastroesophageal reflux disease (GERD), based on GERD scores and upper GI endoscopy, were included in this study. These patients were categorized into two groups of 40, using computer-generated block randomization. Treatment group assignment (group A and group B) was performed in a 1:1 ratio via sealed envelope randomization using a dedicated website [15].

**Clinical and laboratory examination:**

A comprehensive assessment of all cases included sociodemographic data, detailed history, physical examination, and laboratory investigations (CBC, ESR, serum creatinine, serum urea, ALT, AST, serum albumin, serum bilirubin, PT, PTT, INR). GERD scores were obtained before treatment and at 1, 2, 4, and 8 weeks post-treatment initiation. Upper GI endoscopy was performed by experienced endoscopists at the ZUH endoscopic unit.

**Assessment tools:**

1. The gastroesophageal reflux disease questionnaire (GERD Q) is designed by Dent et al. [16]. In 2007, it was a self-administered diagnostic questionnaire consisting of six items. A score of 8 or more was highly suggested to be GERD. The 4-GERD Q score assesses the frequency of reflux and reflux-associated symptoms (RRAS) or treatment response via changes in the RRAS score; a score of 0 indicates no RRAS, while 12 represents the highest RRAS frequency. For the 4-GERD Q, a new cutoff score defines sufficient relief as ≤1 and complete resolution as 0 [17].
2. The FSSG score is a widely accepted metric for evaluating GERD symptoms [17,18]. The FSSG questionnaire, a 12-item instrument, assesses both acid reflux (7 items) and dysmotility-related symptoms (5 items). An FSSG score of 8 or greater suggests probable GERD, with higher scores correlating to more severe disease [19].
3. The Los Angeles classification system is subdivided into four classes [A-D] depending on the extent mucosal breaks through in cases of esophagitis. The Los Angeles Classification system uses esophagogastroduodenoscopy to categorize the severity of reflux esophagitis into four grades: Grade A, characterized by one or more esophageal mucosal breaks less than 5 mm in length; Grade B, exhibiting one or more mucosal breaks exceeding 5 mm but maintaining continuity across mucosal folds; Grade C, defined by continuous mucosal breaks spanning at least two mucosal folds, affecting less than 75% of the esophageal circumference; and Grade D, where mucosal breaks involve more than 75% of the esophageal circumference [20].

**Intervention :**

Groups A and B received once-daily doses of 20 mg Vonoprazan and 60 mg Dexlansoprazole, respectively, for eight weeks. To optimize therapeutic outcomes according to clinical guidelines, we utilized elevated dosages of Vonoprazan (20 mg OD) and Dexlansoprazole (60 mg OD); however, neither group reported adverse events during the study period. Throughout the study, patient medication adherence and the incidence of adverse effects were monitored via scheduled phone calls and outpatient clinic visits.

**Outcomes Measures:**

Primary Outcome Measure: Symptom relief assessed by the GERD-Q score.

Secondary Outcome Measure: Focusing on symptom relief through using a frequency scale of the symptoms of gastroesophageal reflux disease questionnaire (FSSG) and mucosal healing by upper GI endoscopic evaluation.

**Statistical analysis**

Data was computerized and statistically analyzed using SPSS 27.0 for Windows [SPSS Inc., Chicago, IL, United States of America]. Qualitative data was expressed as frequency and percent Chi-square test [$\chi 2$] and Fisher exact have been utilized for independent data and McNemar Bowker test was used for paired data. The Shapiro-Wilk test was used for testing the normal distribution of quantitative data, mean and SD [standard deviation] were used in parametric data, and median in non-parametric data independent T-test and a Mann-Whitney test was utilized for independent data and Paired t and Wilcoxon test for paired data. If P-value ≤ 0.05 means a significant level, if p <0.001

demonstrates highly significant variance, on the other hand, P > 0.05 indicates insignificant variance.

## RESULTS

The study included eighty patients with GERD, who had attended the ZUH Internal Medicine Department, **Table (1)** reveals no statistically significant differences ($p \geq 0.05$) among the two groups regarding age, BMI, sex, residence, clinical presentation, and red flag symptoms. Furthermore, no statistically significant differences were observed in laboratory data, with p-values for Hb, TLC, PLT, albumin, ALT, AST, serum creatinine, and BUN being 0.14, 0.09, 0.41, 0.19, 0.38, 0.44, 0.24, and 0.43, respectively.

**Primary Outcomes:**

**Table (2)** demonstrates that no statistically significant difference exists between the study groups regarding GERD Q scores before treatment. Group A (Vonoprazan) exhibited a mean ± SD of 15.92 ± 1.36, compared to 15.84 ± 1.61 in Group B (Dexlansoprazole), yielding a p-value of 0.81. Post-treatment, both groups showed significant improvement (99.42% in group A and 99.39% in group B), although the difference between the groups remained statistically insignificant (0.09 ± 0.23 in group A versus 0.10 ± 0.27 in group B, p-value = 0.65). At one week, Vonoprazan (Group A) demonstrated 37.5% complete resolution and 62.5% sufficient relief, compared to Dexlansoprazole (Group B) at 50% and 50%, respectively (p=0.26). At two weeks, Vonoprazan showed 50% complete resolution and 50% sufficient relief versus Dexlansoprazole at 52.5% and 47.5% (p=0.82). Four-week results indicated 62.5% complete resolution and 37.5% sufficient relief for Vonoprazan compared to 67.5% and 32.5% for Dexlansoprazole (p=0.64). Finally, at eight weeks, Vonoprazan exhibited 82.5% complete resolution and 17.5% sufficient relief, while Dexlansoprazole showed 87.5% and 12.5% (p=0.53.(

**Secondary Outcomes:**

**Table (3)** and **Figure (1)** demonstrate a statistically insignificant difference in mean reflux scores among the study groups (11.44 ± 2.10 in the Vonoprazan group [Group A] versus 10.93 ± 2.25 in Dexlansoprazole group [Group B], p = 0.30) before treatment. Following eight weeks of treatment, a statistically significant reduction in mean reflux scores (FSSG) was observed, with lower scores in group B (2.5 ± 0.78) compared to group A (3.33 ± 0.91, p < 0.001). This represents a 70.77% reduction in group A and a 77.87% reduction in group B. Furthermore, no statistically significant difference in dysmotility scores was observed between the study groups before or after eight weeks of treatment. Group A (Vonoprazan) exhibited a mean score of 6.71 ± 2.48 pretreatment and 2.26 ± 0.75 post-treatment, while group B (Dexlansoprazole) showed mean scores of 7.24 ± 1.86 and 2.20 ± 0.5, respectively (p=0.27 pretreatment, p=0.68 post-treatment). The percentage reduction in dysmotility scores was 63.56% in group A and 62.79% in group B.

**Tables (4)** and **Figure (2)** reveal no statistically significant difference in LA classification between groups A and B at baseline or following eight weeks of treatment (p=0.56, 0.71, respectively). However, statistically significant differences were observed in LA classifications within both groups when comparing baseline and post-treatment (eight-week) assessments. In group A (Vonoprazan), this involved changes from 30.0% to 52.5% in grade A, 37.5% to 27.5% in grade B, 22.5% to 12.5% in grade C, and 10.0% to 7.5% in grade D (p=0.002*). Similarly, in group B (Dexlansoprazole), changes were observed from 32.5% to 50.0% in grade A, 37.5% to 30.0% in grade B, 27.5% to 17.5% in grade C, and 2.5% to 2.5% in grade D (p=0.004).

**Table (1): Distribution of patient characteristics among examined groups**

| Variable | | Group A (Vonoprazan) (N= 40) | | Group B (Dexlansoprazole) (N=40) | | P-Value |
|---|---|---|---|---|---|---|
| **Age (years)** | **Mean±SD** | 50.54±10.32 | | 51.62±9.65 | | 0.63 NS# |
| **BMI (kg/m2)** | **Mean±SD** | 26.11±2.9 | | 25.8±2.8 | | 0.62 NS# |
| **Variable** | | **N** | **%** | **N** | **%** | P |
| **Sex** | Male | 28 | 70 | 29 | 72.5 | 0.8 NS ¶ |
| | Female | 12 | 30 | 11 | 27.5 | |
| **Residence** | Rural | 19 | 47.5 | 16 | 40 | 0.49 NS ¶ |
| | Urban | 21 | 52.5 | 24 | 60 | |
| **Clinical presentation** | Heartburn | 20 | 50 | 23 | 57.5 | 0.67 NS ¶ |
| | Regurgitation | 13 | 32.5 | 15 | 37.5 | 0.64 NS¶ |
| | Chest pain | 17 | 42.5 | 16 | 40 | 0.82 NS ¶ |
| | Cough | 9 | 22.5 | 11 | 27.5 | 0.61 NS ¶ |
| | Dysphagia | 5 | 12.5 | 7 | 17.5 | 0.53 NS ¶ |
| | Vomiting | 8 | 20 | 5 | 12.5 | 0.36 NS ¶ |
| | Nausea | 15 | 37.5 | 12 | 30 | 0.48 NS ¶ |
| | Epigastric pain | 23 | 57.5 | 21 | 52.5 | 0.65 NS ¶ |
| **Red flag symptoms** | Persistent vomiting | 3 | 7.5 | 3 | 7.5 | 1.00 NS ¶ |
| | Weight loss | 5 | 12.5 | 4 | 10 | 0.72 NS ¶ |
| | Esophageal bleeding | 3 | 7.5 | 1 | 2.5 | 0.30 NS ¶ |
| | Dysphagia | 5 | 12.5 | 7 | 17.5 | 0.53 NS ¶ |
| | Odynophagia | 3 | 7.5 | 5 | 12.5 | 0.45 NS ¶ |
| **Hemoglobin (g/dl)** | **Mean±SD** | 11.86±1.35 | | 11.43±1.22 | | 0.14 NS# |
| **TLC ($10^3$/µL)** | **Mean±SD** | 11.49±2.34 | | 10.54±2.72 | | 0.09 NS# |
| **PLT ($10^3$/µL)** | **Mean±SD** | 318.64±55.72 | | 329.18±58.41 | | 0.41 NS# |
| **Albumin (g/dl)** | **Mean±SD** | 4.02±0.7 | | 3.84±0.5 | | 0.19 NS# |
| **ALT (U/L)** | **Mean±SD** | 29.86±6.38 | | 31.11±6.15 | | 0.38 NS# |
| **AST (U/L)** | **Mean±SD** | 31.11±6.31 | | 32.2±6.2 | | 0.44 NS# |
| **Creatinine (mg/dl)** | **Mean±SD** | 0.94±0.07 | | 0.96±0.08 | | 0.24 NS# |
| **BUN (mg/dl)** | **Mean±SD** | 21.55±4.21 | | 22.3±4.18 | | 0.43 NS# |

SD: standard deviation, TLC: Total Leukocyte Count, PLT: Platelets, ALT: alanine transaminase, AST: aspartate aminotransferase, BUN: blood urea nitrogen. #: Independent t-test, ¶: chi-square test, NS: Not significant (P value >0.05)


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**Table (2): Distribution of GERD Q score before and after treatment among examined groups**

| GERD Q Score | | Group A (Vonoprazan) (N=40) | | Group B (Dexlansoprazole) (N=40) | | P |
|---|---|---|---|---|---|---|
| **Baseline:** | **Mean±SD** | 15.92±1.36 | | 15.84±1.61 | | 0.81 NS# |
| **After 8 weeks:** | **Mean±SD (median)** | 0.09±0.23 (0) | | 0.1±0.27 (0) | | 0.65 NS § |
| **P †** | | **<0.001**** | | **<0.001**** | | |
| **% of reduction** | | **99.42%** | | **99.39%** | | |
| **GERD Q Score classification:** | | **N** | **%** | **N** | **%** | P¶ |
| **After 1 week** | Complete resolution | 15 | 37.5 | 20 | 50 | 0.26 |
| | Sufficient relief | 25 | 62.5 | 20 | 50 | NS |
| **After 2 weeks** | Complete resolution | 20 | 50 | 21 | 52.5 | 0.82 |
| | Sufficient relief | 20 | 50 | 19 | 47.5 | NS |
| **After 4 weeks** | Complete resolution | 25 | 62.5 | 27 | 67.5 | 0.64 |
| | Sufficient relief | 15 | 37.5 | 13 | 32.5 | NS |
| **After 8 weeks** | Complete resolution | 33 | 82.5 | 35 | 87.5 | 0.53 |
| | Sufficient relief | 7 | 17.5 | 5 | 12.5 | NS |

SD: standard deviation, #: Independent t-test, §: Mann Whitney test, †: Paired Wilixocon test, ¶: chi-square test, NS: Not significant (P value >0.05), **: highly significant. (p-value <0.001)

**Table (3): Distribution of FSSG scores before and after treatment among examined groups**

| Score | | Group A (Vonoprazan) (N=40) | Group B (Dexlansoprazole) (N=40) | P# |
|---|---|---|---|---|
| | | **Mean±SD** | **Mean±SD** | |
| **Reflux score** | **Baseline:** | 11.44±2.10 | 10.93±2.25 | 0.30 NS |
| | **After 8 weeks:** | 3.33±0.91 | 2.50±0.78 | **<0.001**** |
| **P ‡** | | **<0.001**** | **<0.001**** | |
| **% of reduction** | | **70.77%** | **77.87%** | |
| **Dysmotility score** | **Baseline:** | 6.71±2.48 | 7.24±1.86 | 0.27 NS |
| | **After 8 weeks:** | 2.26±0.75 | 2.20±0.50 | 0.68 NS |
| **P‡** | | **<0.001**** | **<0.001**** | |
| **% of reduction** | | **63.56%** | **62.79%** | |

SD: standard deviation, #: Independent t-test, ‡: Paired t-test, NS: Not significant (P value >0.05), **: highly significant. (p-value <0.001)


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**Table (4): Distribution of LA classification among examined groups**

| LA classification | | Group A (Vonoprazan) (N=40) | | Group B (Dexlansoprazole) (N=40) | | P¶ |
|---|---|---|---|---|---|---|
| | | N | % | N | % | |
| **Baseline:** | **Grade A** | 12 | 30 | 13 | 32.5 | |
| | **Grade B** | 15 | 37.5 | 15 | 37.5 | 0.56 |
| | **Grade C** | 9 | 22.5 | 11 | 27.5 | NS |
| | **Grade D** | 4 | 10 | 1 | 2.5 | |
| **After 8 weeks** | **Grade A** | 21 | 52.5 | 20 | 50 | |
| | **Grade B** | 11 | 27.5 | 12 | 30 | 0.71 |
| | **Grade C** | 5 | 12.5 | 7 | 17.5 | NS |
| | **Grade D** | 3 | 7.5 | 1 | 2.5 | |
| P‡‡ | | **0.002*** | | **0.004*** | | |

¶: chi-square test, ‡‡: McNemar Bowker test, NS: Not significant (P value >0.05), *: Significant (P value ≤0.05)

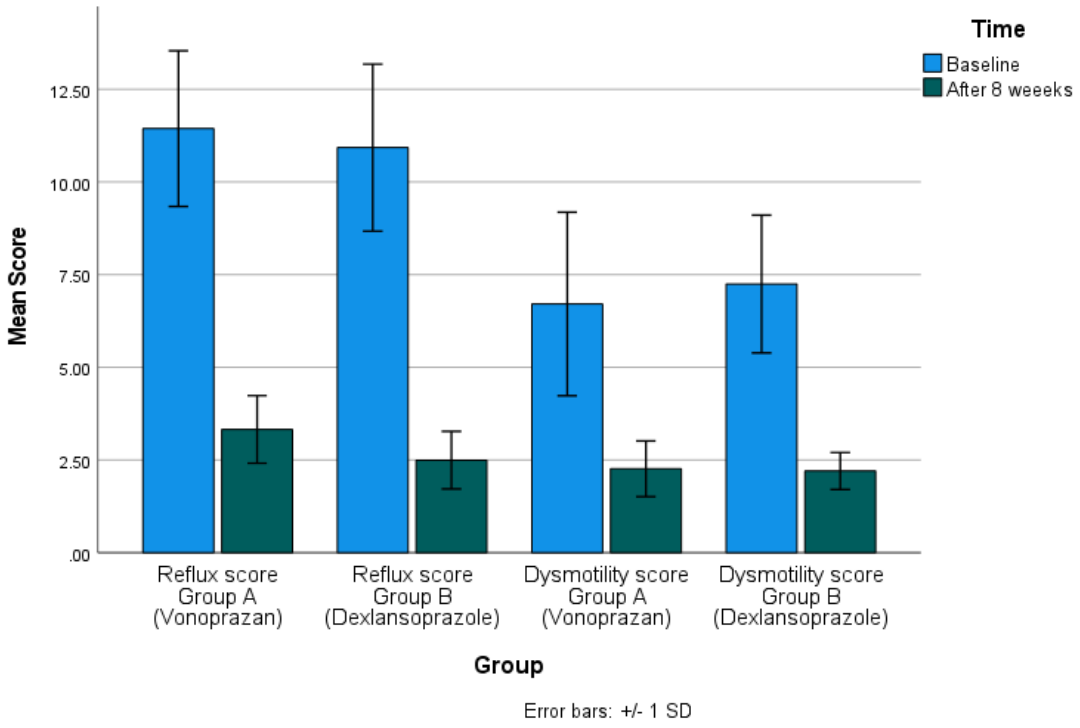


**Figure (1): Reflux & Dysmotility scores before and after treatment among examined groups**

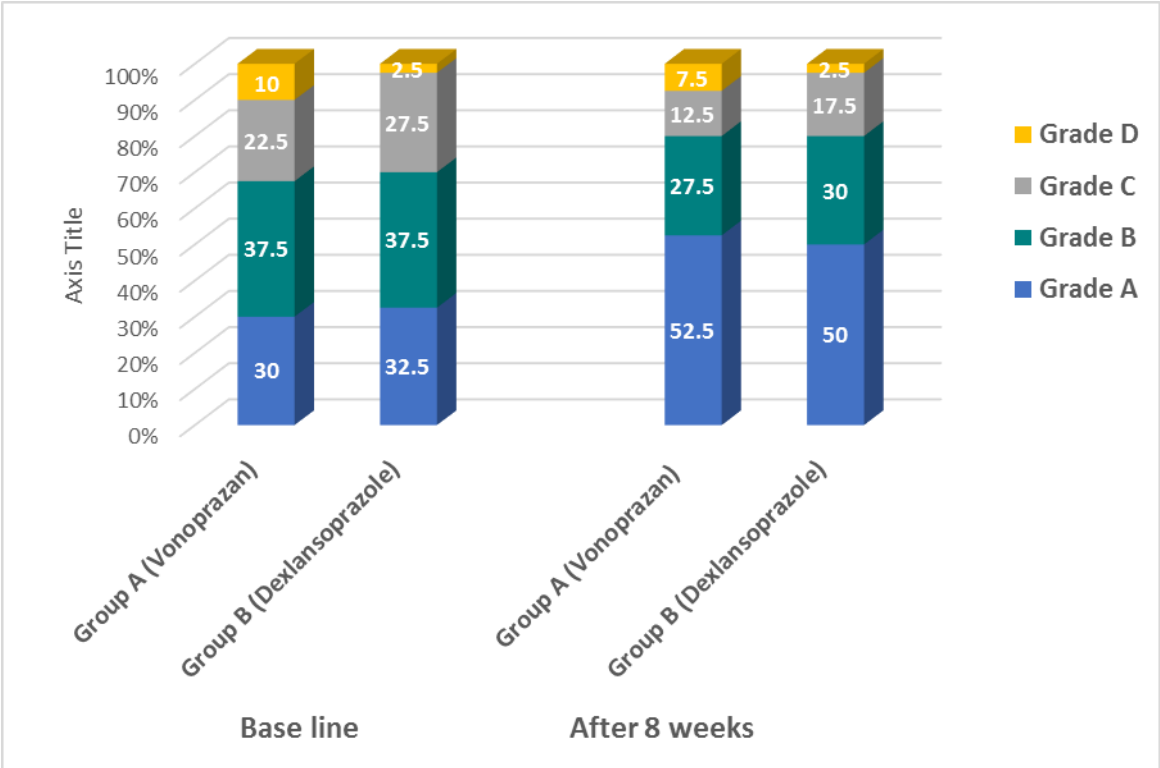


**Figure (2): Distribution of LA classification among examined groups**

## DISCUSSION

Gastroesophageal reflux disease (GERD) is a prevalent disorder, typically managed with proton-pump inhibitors (PPIs) as the initial treatment of choice. The recent introduction of potassium-competitive acid blockers such as vonoprazan necessitates a comparative analysis. Therefore, this study evaluates the efficacy of Vonoprazan against Dexlansoprazole in patients diagnosed with GERD.

Our study included 80 patients, 40 patients selected randomly in each group, the study reported that a statistically insignificant distinction has been observed among examined groups according to age, BMI, sex, residence, clinical presentation, and red flag symptoms.

This investigation was confirmed by Mahdi et al. [21] found statistically insignificant distinctions between the groups regarding age, sex, residence, clinical presentation, and red flag symptoms.

Our analysis revealed no statistically significant difference in GERD Q scores among the study groups before treatment. Post-treatment, both groups showed improvement, with no statistically significant difference in the change observed.

Similarly, Our results corroborated those of Mahdi et al. [21] who revealed that a statistically insignificant distinction has been observed among both groups regarding GERD Q Score before treatment. After therapy, the score improved in both groups, but with insignificant differences; complete symptom resolution was a little greater in group B (Dexlansoprazole) than in group A (Vonoprazan) without statistically significant variance.

Also, this study agreed with Sakurai et al. [22] reported that there was no apparent change in the groups' GERD Q scores pre-to therapy. After 4 weeks, 88.0% with a mean 95% [confidence interval = 68.8-97.5%] of the esomeprazole group and 81.8% [95 percent confidence interval 59.7-94.8%] of the vonoprazan group reported experiencing enough relief without any significant variance among both groups' treatment.

Our study revealed no statistically significant difference in dysmotility scores between the groups before and after treatment. However, post-treatment reflux scores showed a statistically significant decrease in the

Dexlansoprazole group (Group B) compared to the Vonoprazan group (Group A.(

Our results aligned with those of Mahdi et al. [21] who found a significant reduction in reflux scores and overall scores in both groups; nevertheless, the decline in FSSG values was greater in Dexlansoprazole.

In agreement with this, the systematic review by Miyazaki et al. [23] conducted a comparative effectiveness analysis of Vonoprazan versus other proton pump inhibitors (PPIs) in the treatment of GERD. In the primary analysis of healing effects at eight weeks, the odds ratios (ORs) for vonoprazan (twenty milligrams daily) compared to Esomeprazole (twenty milligrams), Rabeprazole (twenty milligrams), Lansoprazole (thirty milligrams), and Omeprazole (twenty milligrams) were 2.29 (95% CI 0.79–7.06), 3.94 (1.15–14.03), 2.40 (0.90–6.77), and 2.71 (0.98–7.90), correspondingly. They indicated that the gastrointestinal tract infection healing efficacy of Vonoprazan surpasses that of Rabeprazole (twenty milligrams) but does not exceed that of other proton pump inhibitors. Subgroup analysis revealed that Vonoprazan demonstrates greater effectiveness compared to most proton pump inhibitors in cases with severe erosive esophagitis.

On the other hand, a meta-analysis by Cheng et al. [24] directly compared the therapeutic benefits and side events of Vonoprazan twenty milligrams with proton pump inhibitors. The risk ratios (RR) for effectiveness & adverse events comparing Vonoprazan to proton pump inhibitors were 1.06 (0.99–1.13) and 1.08 (0.96–1.22), correspondingly. Subgroup analysis for cases with severe esophagitis at baseline demonstrated significantly superior outcomes for Vonoprazan compared to Lansoprazole, with a relative risk of 1.14 (1.06–1.22). Subgroup analysis demonstrates that Vonoprazan exhibits superior efficacy compared to PPIs in cases with severe erosive esophagitis .

Multicenter research by Xiao et al. [25] demonstrated the non-inferior efficacy of vonoprazan relative to lansoprazole in the treatment of erosive esophagitis (EO) in Asian patients. They indicated that eosinophilic esophagitis healing rates were superior with Vonoprazan compared to Lansoprazole. The incidence of treatment-emergent adverse events (TEAEs) was 38.1 percent for the Vonoprazan group and 36.6 percent for the Lansoprazole group.

This study's strength lies in its head-to-head, randomized controlled trial design, comparing Vonoprazan (P-CABs) and Dexlansoprazole (PPIs) for treating gastroesophageal reflux disease (GERD) in two groups of Egyptian patients .

This study has limitations, including a small sample size and an open-label design, which could introduce bias. However, we mitigated this risk through sample randomization, blinding of outcome assessors, and frequent monitoring of patient medication adherence. While GERD diagnosis was based on endoscopic findings and symptoms, PH monitoring was not performed, and a placebo comparison group was unavailable. Further researches are recommended in multiple centers, involving large numbers of participants to validate these findings.

## CONCLUSION

This study concluded that Vonoprazan exhibited no superiority over Dexlansoprazole in terms of symptomatic relief effect and healing effect of mucosal in cases with gastroesophageal reflux disease according to all GERD scores and endoscopic evaluation except for reflux score where the Dexlansoprazole had superior effect than Vonoprazan regarding reflux score.

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**Authors' contributions**

Conceptualization, A.G.; Data curation, A.G, S.S., A.M.E.M.S and A.A.; Formal analysis, H.A.N., and D.S.; Investigation, A.G., A.A. and S.S., A.M.E.M.S; Methodology, H.A.N., and D.S., Resources, A.G, S.S. and A.A., A.M.E.M.S; Supervision, A.A., A.G.; Validation, H.A.N., and D.S.; Writing – original draft, A.G, S.S. and A.A.; Writing – review & editing, H.A.N., A.M.E.M.S and D.S.

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**Ethics approval**

The Zagazig University Institutional Review Board approved this study (IRB No: 745/5-Nov-2024). All participants provided written informed consent after a thorough explanation of the study's aims and objectives. Participants were assured of their right to withdraw at any time and that their privacy and data confidentiality would be maintained. All procedures adhered to relevant guidelines and regulations, ensuring participants were not exposed to harm or adverse effects .

**Conflict of interests**

The authors declare that they have no competing interests.

## HIGHLIGHTS

- Vonoprazan (PCABs) is a new pharmacological option in the management of gastroesophageal reflux disease (GERD), although proton pump inhibitors (PPIs) represent the gold standard in the current treatment of GERD.
- The study found that the therapeutic efficacy of Vonoprazan is equal to Dexlansoprazole in symptom relief and mucosal healing in GERD cases through outcome measures: GERD scores and endoscopic evaluation.
- This study is the first randomized controlled, open-label trial to be done on two groups of Egyptian patients with GERD to compare the therapeutic efficacy of Vonoprazan versus Dexlansoprazole. Further researches are recommended in multiple centers, involving large numbers of participants to validate these findings.

## REFERENCES


1. Clarrett DM, Hachem C. Gastroesophageal reflux disease (GERD). *Missouri medicine* 2018 May,115(3), 214.
2. Dent J, Jones R, Vakil N, Halling K, Junghard O, Wernersson B, et al. A management strategy for GERD based on the Gastroesophageal Reflux Disease Questionnaire (GerdQ). Scandinavian Journal of Gastroenterology. 2008 Jan;43, 34-35.
3. Nirwan JS, Hasan SS, Babar ZUD. Global prevalence and risk factors of gastro-oesophageal reflux disease (GORD): systematic review with meta-analysis; *Sci Rep*. 2020 Apr 2;10(1):5814.
4. Peery AF, Crockett SD, Murphy CC. Burden and cost of gastrointestinal, liver, and pancreatic diseases in the United States. *Gastroenterology*. 2022 Feb;162(2):621-644.
5. El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastroesophageal reflux disease: a systematic review. *Gut*. 2014 Jun;63(6):871-80
6. Ronkainen J, Aro P, Storskrubb T. High prevalence of gastroesophageal reflux symptoms and esophagitis with or without symptoms in the general adult Swedish population: a Kalixanda study report, *Scand J Gastroenterol.* 2005 Mar;40(3):275-85.
7. Katz PO, Dunbar KB, Schnoll-Sussman FH, Greer KB, Yadlapati R, Spechler SJ. A clinical guideline for the diagnosis and management of gastroesophageal reflux disease. *Official journal of the American College of Gastroenterology| ACG*. 2022 Jan 1,117(1), 27-56.
8. Kazakova T, Danoff R, Esteva I, Shchurin A. Gastro-esophageal reflux disease in primary care practice: a narrative review. *Ann Esophagus* 2023;6:25.
9. Yadlapati R, DeLay K. Proton pump inhibitor–refractory gastroesophageal reflux disease. *Medical Clinics.* 2019 Jan 1,103(1),15-27.
10. Maradey-Romero C, Fass R. New and future drug development for gastroesophageal reflux disease. *Journal of Neurogastroenterology and Motility*. 2014 Jan;20(1):6-16.
11. Scarpignato C, Hunt RH. The potential role of potassium-competitive acid blockers in the treatment of gastroesophageal reflux disease. *Curr Opin Gastroenterol.* 2019 Jul;35(4):344-355.
12. Oshima T, Miwa H. Potent potassium-competitive acid blockers: a new era for the treatment of acid-related diseases. *Journal of neurogastroenterology and motility*. 2018 Jul 30;24(3):334-344.
13. Laine L, DeVault K, Katz P, Mitev S, Lowe J, Hunt B, et al. Vonoprazan versus lansoprazole for healing and maintenance of healing of erosive esophagitis: a randomized trial. *Gastroenterology*. 2023 Jan 1,164(1), 61-71.
14. Oshima T, Arai E, Taki M, Kondo T, Tomita T, Fukui H, et al. Randomized clinical trial: vonoprazan versus lansoprazole for the initial relief of heartburn in patients with erosive oesophagitis. *Aliment Pharmacol Ther.* 2019 Jan;49(2):140-146.

15. Sealed Envelope Ltd. 2024. Create a blocked randomization list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists.
16. Jones R, Junghard O, Dent J, Vakil N, Halling K, Wernersson B, et al. Development of the GerdQ, a tool for the diagnosis and management of gastro-oesophageal reflux disease in primary care. *Aliment Pharmacol Ther*. 2009 Nov 15;30(10):1030-8.
17. Kusano M, Shimoyama Y, Sugimoto S, Kawamura O, Maeda M, Minashi K, et al. Development and evaluation of FSSG: frequency scale for the symptoms of GERD. *Journal of Gastroenterology*. 2004 Sep;39(9):888-91 .
18. Uchiyama K, Ando T, Kishimoto E, Nishimura T, Imamoto E, Takagi T, et al. Correlation of gastrointestinal symptom rating scale and frequency scale for the symptoms of gastroesophageal reflux disease with endoscopic findings. *Scand J Gastroenterol*. 2024 Nov;59(11):1220-1228.
19. Yuming T, Jia H, Ying Z, Aihua Q, Bin X, Weiyan Y. Comparison of esophageal motility in gastroesophageal reflux disease with and without Globus sensation. *Revista Española de Enfermedades Digestivas* 2017 Dec;109(12),850-5 .
20. Tolia V, Youssef NN, Gilger MA, Traxler B, Illueca M. Esomeprazole for the Treatment of Erosive Esophagitis in Children: An International, Multicenter, Randomized, Parallel-Group, Double-Blind (for Dose) Study. *J Pediatr Gastroenterol Nutr*. 2015 Jul;60, S24-30.
21. Mahdi MA, Al-Zhaby AA, Abdel-Halim MM, Hassan MA. Comparative Study Between the Efficacies of Vonoprazan Versus Omeprazole in Patients with Gastroesophageal Reflux Disease. *International Journal of Medical Arts*. 2023 Jan 1,5(1), 2958-66.
22. Sakurai Y, Mori Y, Okamoto H, Nishimura A, Komura E, Araki T, et al. Acid-inhibitory effects of vonoprazan 20 mg compared with esomeprazole 20 mg or rabeprazole 10 mg in healthy adult male subjects randomized open-label cross-over study. *Alimentary pharmacology & therapeutics*. 2015 Sep, 42(6), 719-30.
23. Miyazaki H, Igarashi A, Takeuchi T, Teng L, Uda A, Deguchi H, et al. Vonoprazan versus proton-pump inhibitors for healing gastroesophageal reflux disease: a systematic review. *Journal of Gastroenterology and Hepatology* 2019 Aug,34(8),1316-28 .
24. Cheng Y, Liu J, Tan X, Dai Y, Xie C, Li X, et al. Direct Comparison of the Efficacy and Safety of Vonoprazan Versus Proton-Pump Inhibitors for Gastroesophageal Reflux Disease: A Systematic Review and Meta-Analysis. *Dig Dis Sci*. 2021 Jan;66(1):19-28.
25. Xiao Y, Zhang S, Dai N, Fei G, Goh KL, Chun HJ, Sheu BS, Chong CF, Funao N, Zhou W, Chen M. Phase III, randomized, double-blind, multicentre study to evaluate the efficacy and safety of vonoprazan compared with lansoprazole in Asian patients with erosive oesophagitis. *Gut*. 2020 Feb;69(2):224-230.

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