International Journal of Medical Arts

Volume 5, Issue 1, January 2023

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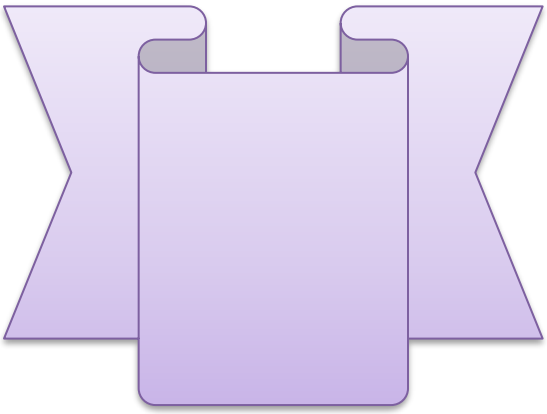

Print ISSN: 2636-4174

Online ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Internal Medicine]

Original Article

Comparative Study Between the Efficacies of Vonoprazan Versus Omeprazole in Patients with Gastroesophageal Reflux Disease

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Article information

Received: 25-01-2023

Accepted: 25-03-2023

DOI: 10.21608/IJMA.2023.189701.1607.

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Citation: Mahdi MAE, Al-Zhaby AAA, Abdel-Halim MM, Hassan MA. Comparative Study Between the Efficacies of Vonoprazan Versus Omeprazole in Patients with Gastroesophageal Reflux Disease. IJMA 2023 January; 5 [1]: 2958-2966. doi: 10.21608/IJMA.2023.189701.1607.

ABSTRACT

Background: The most commonly known abnormality of gastric acidity is gastroesophageal reflux disease [GERD] which is treated by proton pump inhibitors [PPIs]. One of the new family of gastric acid-suppressing medications is vonoprazan that works as a potassium-competitive acid blocker [P-CABs].

Aim of the Work: To compare the effectiveness of 20 mg vonoprazan versus omeprazole 40 mg once daily half an hour before breakfast as a treatment of symptoms and mucosal healing in GERD patients.

Patients and Methods: Sixty cases, proven to have GERD, were enrolled in a comparative clinical trial after having upper endoscopes. Cases were classified into two groups, 30 patients each; group [A] received omeprazole 40 mg once daily, whereas group [B] received vonoprazan 20 mg once daily for 8 weeks, then reevaluation of both groups by symptoms relief using GERD Q score, frequency scale of the symptoms of gastroesophageal reflux disease questionnaire [FSSG] and upper endoscopy was done for all patients after 8 weeks. For each patient, medical history taking, clinical examination, routine laboratory investigations, and upper endoscopy with GERD classification according to LA classification were done.

Results: No detected differences between the included groups regarding GERD Q Score and FSSG score. Our data showed that complete symptoms resolution was somewhat higher among the omeprazole group compared to the vonoprazan group without a statistically significant difference. There is a significant decrease in reflux score, and total score in both groups however, the drop in FSSG scores was more significant in group A in comparison to group B.

Conclusion: Vonoprazan showed no superiority over omeprazole in relief of typical symptoms and mucosal healing in patients with GERD; the drop in FSSG scores was more significant in omeprazole group compared to vonoprazan group.

Keywords: GERD; Vonoprazan; Omeprazole.

INTRODUCTION

The most common acid-related condition in Western nations today is gastroesophageal reflux disease [GERD] [1]. One of the main GERD complaints about heartburn that adversely affect a patient's life quality. Therefore, the aim of treatment to improve the quality of life by quickly alleviating their symptoms [2].

Endoscopy is used to identify GERD, as well as clinical signs including heartburn and acid regurgitation. The two types of GERD either erosive or non-erosive reflux disease [NERD] [3].

The endoscopic grading method that is now most frequently used for determining reflux esophagitis is the Los Angeles [LA] classification. According to the esophageal mucosal breaks' sizes, the LA classifies reflux esophagitis into four types [A-D]. LA-D is reflux esophagitis grade that is least commonly seen [4].

The main therapeutic option for GERD and NERD is proton pump inhibitors [PPIs], which are superior to other medications in terms of symptom alleviation and mucosal healing [5]. PPIs are known as first-line treatments in individuals with GERD and NERD [6].

Vonoprazan is known as a new family in the suppression of gastric acid which is potassium-competitive acid blockers [P-CABs]. In comparison to PPIs, P-CABs reversibly inhibit H+ and K+ ATPase, resulting in a great and long-term suppression of acid secretion [7]. As reported in some studies, the rate of healing of reflux esophagitis was superior to that of a PPI [lansoprazole], with a greater effect seen in cases with greater severity [8].

P-CABs act faster than PPIs and reach their peak in acid inhibition impact post-treatment, whereas PPIs take three to five days. However, few researchers have looked at whether vonoprazan's faster affects the clinical impact on GERD symptoms of acid regurgitation as weak as heartburn [7].

Thus, our goal was to assess and compare any effectiveness of omeprazole 40 mg versus vonoprazan 20 mg as first-line therapies for the alleviation of classic symptoms and mucosal healing in patients with GERD.

PATIENTS AND METHODS

This prospective randomized open-labeled clinical trial was done on 60 patients aged ≥18 years old diagnosed with GERD by symptoms and confirmed by endoscopy who attend at Hepatology, Gastroenterology and Infectious Diseases Department at Al-Azhar university hospitals in Egypt.

This research was performed after the ethical committee at Al-Azhar university hospital's approval from January 2022 to August 2022. All the cases obtained informed consent.

Patients were classified randomly into two main groups including 30 patients each. group[A]`s patients received omeprazole 40 mg once daily half an hour before breakfast for 8 weeks, and group[B] was given vonoprazan 20 mg every day for 8 weeks then reevaluation of both groups by symptoms relief and endoscopy after 8 weeks has been performed.

We excluded patients with: esophageal problems, acute upper gastrointestinal hemorrhage, gastric or duodenal ulcers, hypersecretion syndromes, such as Zollinger Ellison syndrome, scleroderma, infection, and esophageal stenosis, severe pulmonary, hepatic, cardiovascular, neurological conditions, elevated serum glutamic oxaloacetic trans-aminase [SGOT] and Glutamic Pyruvic trans-aminase [SGPT] > 2.5 × the upper range in limit of normal [ULN]], diseases of the kidneys [serum creatinine of more than 2 mg/dL], metabolism, the GIT, endocrinology, or hematology; the necessity for surgery; a history of alcohol addiction; hepatitis or HIV; a history of cancer; and, in women, pregnancy or breastfeeding. PPIs, M3 receptor antagonism, H2RAs, improver of gastrointestinal motility, anticholinergics, prostaglandins, antacids, anti-gastrin medications, mucosal protectives, H. pylori eradicators medications, atazanavir sulfate, or any added medications that were excluded.

A computer-generated randomization was created through an independent randomization team assigned patients and treatment groups in a 1:1 ratio. The randomization procedure was overseen by separate randomization professionals, who also kept the randomization schedule in a safe location. The LA system subdivides into four classes [A-D] depending on

the extent mucosal breaks through in cases of esophagitis. LA grade A [LA-A] known to be the presence of one or more mucosal breaks do not extend 5 mm or beyond the tops of at least two mucosal folds. LA-D esophagitis is the extension of one or more mucosal breaks more than 75%. LA-D is a rare and late stage reflux esophagitis [table 1] [9].

All patients were subjected to careful history taking with the evaluation of the GERD-Q questionnaire [Table 2] [10], the score has been performed before and after the treatment. A score of 8 or more is highly suggested to be GERD. It is expected to be improved after treatment. Also, the patients evaluated by [FSSG] scale is a validated questionnaire used in the evaluation of esophageal symptoms of GERD depending upon the results of endoscopic esophagitis. It consists of 7 acid-reflux related and 5 symptoms of dysmotility [No. 2, 3, 5, 8, 11] of GERD the higher scores the more directive to GERD [Table 3] [11]. Patients were examined clinically and the basic laboratory investigations were done [CBC, ESR, S. creatinine, S. Urea, ALT, AST, S. Albumin, S. Bilirubin, PT, PTT, INR] and Upper endoscopy with biopsy to exclude Barrett's esophagus before the start of treatment.

Table [1]: Los Angeles [LA] classification of GERD [9]

LA grade	Description
A	≥ 1 mucosal breaks ≤ 5 mm, and not extending between the tops of two mucosal folds
B	≥ 1 mucosal breaks ≥ 5 mm long that does not extend between the tops of two mucosal folds
C	≥ 1 mucosal breaks that is continuous between the tops of two or more mucosal folds, but that involves < 75% of the esophageal circumference
D	one or more mucosal breaks involving 75% or more of the esophageal circumference

Table [2]: GERD-Q questionnaire [10]

	Symptoms in the previous week	Symptom presence			
	Question	**0 days**	**1 day**	**2-3 days**	**4-7 days**
1	How often did you have a burning feeling behind your breastbone [heartburn]?	0	1	2	3
2	How often did you have stomach contents [liquid or food] moving upwards to your throat or mouth [regurgitation]?	0	1	2	3
3	How often did you have pain in the center of the upper stomach?	3	2	1	0
4	How often did you have nausea?	3	2	1	0
5	How often did you have difficulty getting a good night's sleep because of your heartburn and/or regurgitation?	0	1	2	3
6	ow often did you take additional medication for your heartburn and/or regurgitation, other than what the physician told you to take] [such as Maalox?]	0	1	2	3

Table [3]: FSSG disease questionnaire [11]

Question		Frequency				
		Never	**Occasionally**	**Sometimes**	**Often**	**Always**
1	Do you get heartburn?	0	1	2	3	4
2	Does your stomach get bloated?	0	1	2	3	4
3	Does your stomach ever feel heavy after meals?	0	1	2	3	4
4	Do you sometimes subconsciously rub your chest with your hand?	0	1	2	3	4
5	Do you ever feel sick after meals?	0	1	2	3	4
6	Do you get heartburn after meals?	0	1	2	3	4
7	Do you have an unusual [e.g. burning] sensation in your throat?	0	1	2	3	4
8	Do you feel full while eating meals?	0	1	2	3	4
9	Do some things get stuck when you swallow?	0	1	2	3	4
10	Do you get bitter liquid coming up into your throat?	0	1	2	3	4
11	Do you burp a lot?	0	1	2	3	4
12	Do you get heartburn if you bend over?	0	1	2	3	4

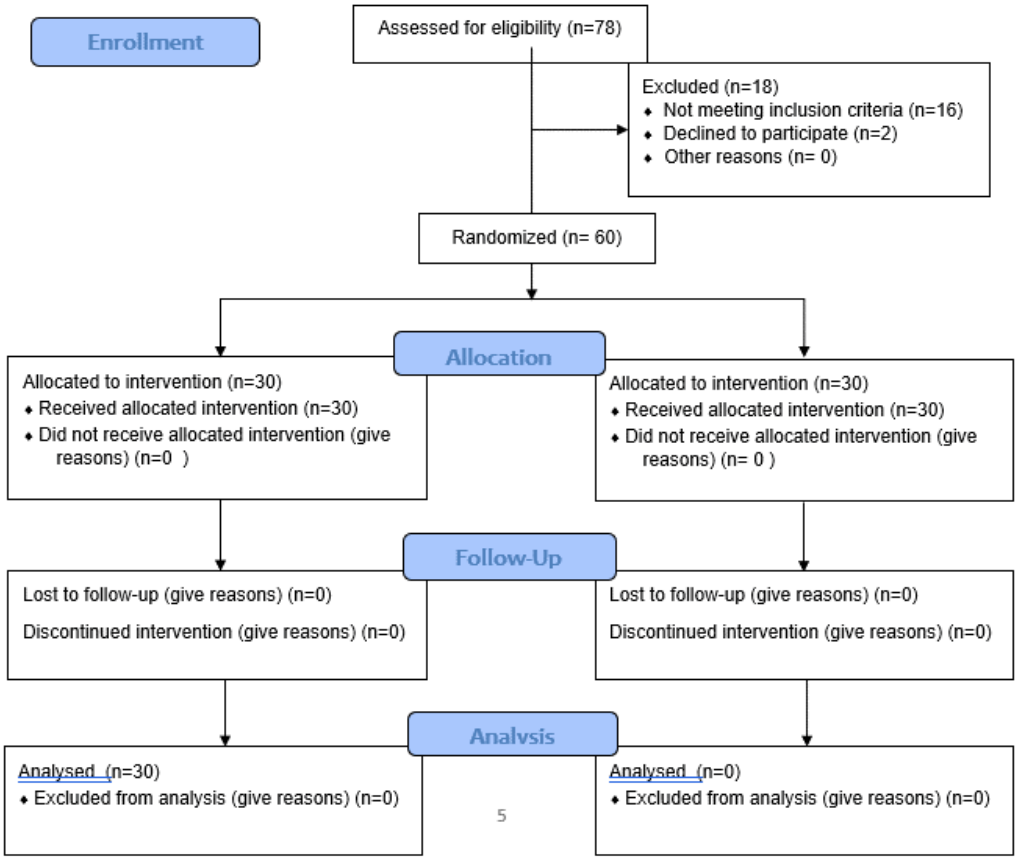

Figure [1]: Consort flow chart of the enrolled patients

Statistical analysis

Analysis of included data by SPSS 24.0 for windows [SPSS Inc., Chicago, IL, USA]. The Shapiro Walk test for normal distribution use. For qualitative data we used frequencies and percent. If there were any differences in qualitative variables, we used Chi-square test [χ^2] and Fisher exact were used. For quantitative data, we used to mean and SD [Standard deviation] in parametric and we used median in non-parametric data. If there were any differences in quantitative variables independent T-test and Mann-Whitney test were used. If P-value ≤ 0.05 means significant level, if $p < 0.001$ showed highly significant difference on the other hand, $P > 0.05$ indicates a non-significant difference.

RESULTS

We found no statistically significant difference in both groups regarding age, gender, and residence. There was no significant difference between both groups regarding clinical presentation. No significant difference between both groups regarding red flag symptoms [table 4].

We found no significant difference between both groups in routine laboratory parameters [table 5].

There was no significant difference between both groups regarding GERD Q Score before treatment. After therapy, the score improved in both groups, but with no significant difference; complete symptoms resolution was a little higher in group A compared to group B without statistically significant difference [table 6].

There was significant decrease in reflux score, and total score in both groups however, the drop in FSSG scores was more significant in group A. Also, patients in group A had significant decrease of after-treatment scores [table 7].

There was no significant difference between both groups regarding LA classification before and after treatment [table 8].

Table [4]: Demographic data, clinical presentations and red flag symptoms of the studied cases

		Group A [n=30]	Group B [n=30]	Test	p
Age [years], Mean ± SD		52.85 ± 11.65	51.64 ± 12.72	0.384	0.702
Gender	Female Male	8 [26.7%] 22 [73.3%]	9 [30%] 21 [70%]	0.082	0.775
Residence	Rural Urban	12 [40%] 18 [60%]	14 [47.7%] 16 [53.3%]	0.272	0.602
Clinical presentation	Heartburn	17 [%]	15 [%]	0.268	0.605
	Regurgitation	11 [%]	10 [%]	0.073	0.787
	Chest pain	12 [%]	13 [%]	0.069	0.793
	Cough	8 [%]	7 [%]	0.089	0.766
	Dysphagia	5 [16.7%]	4 [%]	0.131	0.718
	Vomiting	4 [%]	6 [%]	0.480	0.488
	Nausea	9 [%]	11 [%]	0.300	0.584
	Epigastric pain	16 [%]	17 [%]	0.067	0.795
Red flag symptoms	Persistent vomiting	2 [6.7%]	2 [6.7%]	--	1
	Weight loss	3 [10%]	4 [13.3%]	0.162	0.688
	Esophageal bleeding	1 [3.3%]	2 [6.7%]	0.351	0.554
	Dysphagia	5 [16.7%]	4 [13.3%]	0.131	0.718
	Odynophagia	4 [13.3%]	2 [6.7%]	0.741	0.389

Table [5]: Routine laboratory investigations of both groups

	Group A [n=30]	Group B [n=30]	T	P
Hemoglobin [G/dL], mean ± SD	11.56 ± 1.55	11.69 ± 1.46	0.546	0.586
TLC [10^3 /µL], mean ± SD	10.91 ± 2.38	11.64 ± 2.51	1.89	0.061
PLT [10^3 /µL], mean ± SD	327.15 ± 67.41	316.95 ± 52.72	1.07	0.288
Albumin [g/dL], mean ± SD	3.95 ± 0.355	4.05 ± .444	1.57	0.118
ALT [U/L], mean ± SD	30.48 ± 7.18	28.55 ± 6.38	1.8	0.074
AST [U/L], mean ± SD	31.65 ± 6.57	30.54 ± 6.71	1.06	0.292
Serum creatinine [mg/dL], mean ± SD	0.853 ± .064	0.847 ± .072	0.557	0.578
BUN [mg/dL], mean ± SD	21.78 ± 4.18	20.63 ± 4.21	1.73	0.085

Table [6]: GERD Q Score before and after treatment

	Group A [n=30]	Group B [n=30]	χ^2	P
GERD Q Score, mean ± SD	15.68 ± 1.43	15.73 ± 1.25	0.144	0.886
After 1 week				
Complete resolution** Sufficient relief*	15 [50%] 15 [50%]	11 [36.7%] 19 [63.3%]	1.05	0.591
After 2 weeks				
Complete resolution** Sufficient relief*	16 [53.3%] 14 [46.7%]	15 [50%] 15 [50%]	2.59	0.274
After 4 weeks				
Complete resolution** Sufficient relief*	20 [66.7%] 10 [33.3%]	19 [63.3%] 11 [36.7%]	1.19	0.55
After 8 weeks				
Complete resolution** Sufficient relief*	26 [86.7%] 4 [13.3%]	25 [83.3%] 5 [16.7%]	0.18	1.5

* Sufficient relief was achieved when the score ≤ 1 question [1, 2, 5, and 6] on the GERD Q.
** Complete resolution was achieved when the score is 0 in all questions.

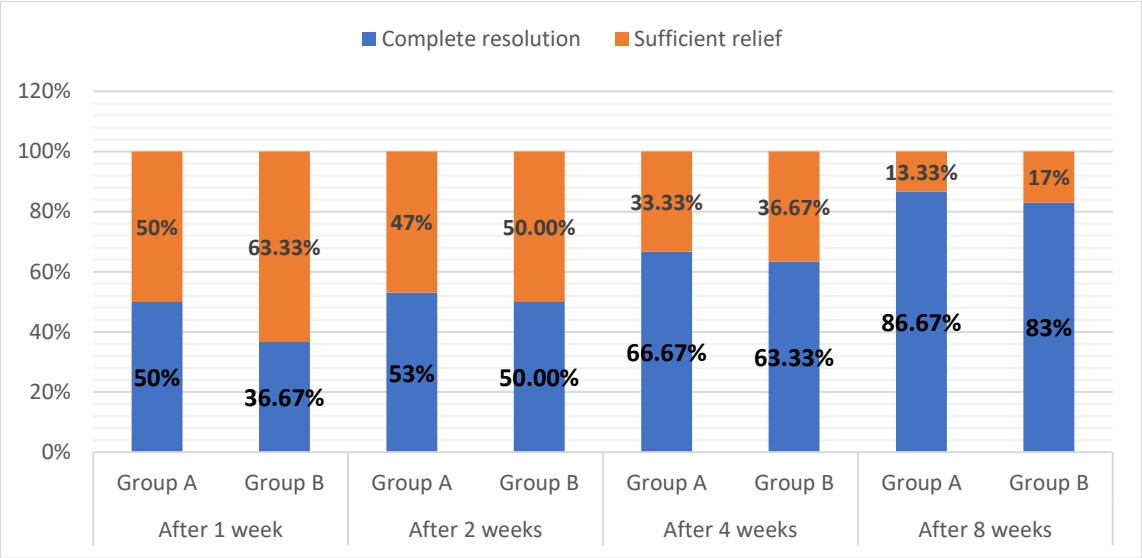

Figure [2]: GERD Q Score results in evaluation treatment between the two studied groups

Table [7]: FSSG scores of both studied group

	Group [A] [n=30]	Group [B] [n=30]	t	P
Reflux score				
Before treatment Mean ± SD	10.62 ± 2.78	11.86 ± 2.64	2.29	**0.024**
After treatment Mean ± SD	2.35 ± 0.523	3.1 ± 0.614	6.57	**<0.001**
Dysmotility score				
Before treatment, Mean ± SD	6.83 ± 1.37	7.16 ± 2.12	0.716	0.477
After treatment, Mean ± SD	2.13 ± 0.379	2.38 ± 0.411	1.47	0.147
Total score				
Before treatment, Mean ± SD	16.42 ± 3.18	19.36 ± 4.21	3.94	**<0.001**
After treatment, Mean ± SD	4.31 ± 0.876	5.51 ± 1.06	6.17	**<0.001**

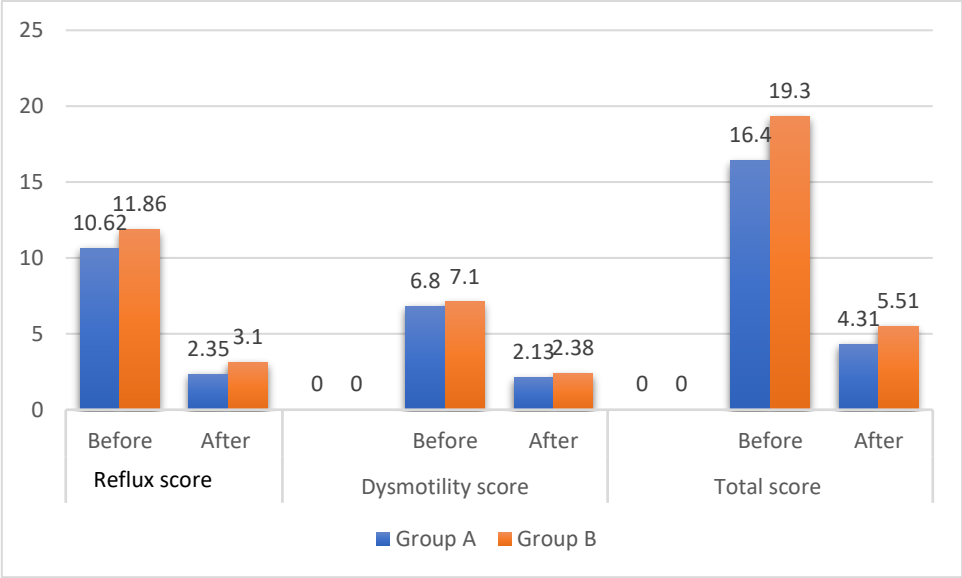

Figure [3]: FSSG scores on both studied groups

Table [8]: LA classification of the two studied groups

	Group A		χ^2	p	Group B		χ^2	p
	pre-treatment	post-treatment			Pre-treatment	post-treatment		
Grade A	10 [33.3%]	15 [50%]	1.12	0.772	9 [30%]	16 [53.3%]	1.13	0.57
Grade B	11 [36.7%]	9 [30%]			11 [36.7%]	8 [26.7%]		
Grade C	8 [26.7%]	5 [16.6%]			7 [23.3%]	4 [13.3%]		
Grade D	1 [3.3%]	1 [3.3%]			3 [10%]	2 [6.6%]		

DISCUSSION

The distressing disorder of GERD is presented mainly by heartburn and acid reflux brought on by stomach contents reflux. By endoscopy, GERD either non-erosive reflux disease [NERD] and erosive esophagitis [EE], however, the presences of symptoms and its severity is not always related mainly to the extent of mucosal damage [12].

PPIs have traditionally been one of top treatment option for GERD. PPIs are often used in clinical practice, however, due to pharmacological restrictions, the typical dose of a PPI does not always result in enough stomach acid suppression in all individuals. Even after continuous double-dose PPI medication for 8 weeks, in ten to twenty percent of patients with severe EE do not improve. Furthermore, it is widely known that total symptom alleviation by PPI is challenging to achieve than merely healing mucosal breakdowns, which leaves roughly one-third of GERD patients dissatisfied with their current course of treatment [12].

Vonoprazan a new potent drug for potassium-competitive acid blocking [P-CAB], is quicker and demonstrates a longer-lasting lowering of acid levels than standard PPIs [11].

Our study aimed to assess the effectiveness of 40 mg of Omeprazole versus 20 mg of Vonoprazan in the treatment of classic symptoms and improve the mucosal healing in GERD patients. The study was done on 60 patients who were subclassified into two groups, each consisting of 30 patients. Group[A] took omeprazole 40 mg once every day for 8 weeks, group [B] took Vonoprazan 20 mg once every day for 8 weeks then reevaluation of both groups by symptoms and endoscopy after 8 weeks has been performed.

Regarding demographic data, we found no statistically significant difference between the groups regarding age, sex, or residence.

Our results were marched to **Ashida *et al*.** [14] According to their findings, 607 patients above the age of 20 who had endoscopically verified cured EE after 8 weeks of vonoprazan 20 mg once/day and lansoprazole 15 mg [n = 201], vonoprazan 10 mg [n = 202], or vonoprazan 20 mg [n = 204], once daily. A similar demographic profile existed for all three groups. Whereas in **Sakurai *et al*.** [15] `s study sixty cases in total gave their informed permission before being randomly allocated to the vonoprazan or esomeprazole group [n = 30]. The trial was completed by 47 individuals [Esomeprazole group [n=25] and vonoprazan group [n=22]]. The body mass index [BMI] in vonoprazan groups was considerably greater than the esomeprazole groups. While mean age, sex, smoking habits, drinking alcohol, atrophy, and LA grade didn`t show statistically differ across the groups in a significant way.

In our study, we found no significant difference in both groups regarding the clinical presentation and red flag symptoms.

Whereas, in **Akiyama *et al*.** [17] `s study, the patients' switch from PPI to VPZ medication, reflux symptoms including heartburn and regurgitation significantly decreased for heartburn [P=0.003], regurgitation[P=0.005], and reflux dimension scores [P=0.001]. The GIT discomfort, indigestion, diarrhea, and constipation that are not related to reflux, however, remained constant before and after treatment.

In the study of **Ashida *et al*.** [14], vonoprazan was beneficial in severe symptomatic patients [LA grade C/D] and erosive esophagitis. Also, the healing rate showed greater results in vonoprazan at two weeks compared with lansoprazole. The healing process was supported by the finding as vonoprazan had a considerably greater 24-hour gastric pH > 4-time ratio on days one and seven compared to esomeprazole and rabeprazole [17]. However, the severity of the mucosal injury is not correlated with GERD symptoms. In light of this mismatch, we believe that esophageal hypersensitivity and acid exposure both have an impact on GERD symptoms.

Our results showed no significant difference between both groups regarding GERD Q Score. All the patients were confirmed GERD with a GERD Q score of 90% percent likelihood. Healing of GERD lesions and scoring of LA classification were assessed by upper endoscopy at 8 weeks and proved better among the omeprazole group compared to the vonoprazan group but without statistically significant difference, that complete symptoms resolution was somewhat higher in omeprazole group in comparison to vonoprazan group with no statistically significant difference.

Matching with our results, the results of **Sakurai *et al*. [18]**, said there was no apparent change in the groups' GERD Q scores pre to therapy. After 4 weeks, 88.0% with mean 95% [CI=68.8-97.5%] of esomeprazole group and 81.8% [95% CI 59.7-94.8%] of vonoprazan group reported experiencing enough relief without any significant difference between the two treatment groups.

Our results demonstrated that there is a significant decrease in reflux score, and total score in both groups however, the drop in FSSG scores was more significant in omeprazole group in comparison with vonoprazan group with high significant differences in both groups regarding after-treatment scores. However, the study of **Sakurai *et al*. [18]**, Before therapy, showed no discernible difference between their groups in FSSG scores. After starting the treatment by a day, the mean FSSG total score as well as the score of acid reflux symptom, and the score of motility disorder symptom. For all scores, the variations between days 14 and 28 were modest. The groups showed no significant difference in treatment effect.

In the systematic review conducted by **Miyazaki *et al*. [21]** of the 4001 papers included in the database were suitable, and 42 studies were among them. The analysis was supplemented with a hand search of one paper. Vonoprazan [20 mg daily] had odds ratios [ORs] compared to esomeprazole 20 mg, rabeprazole 20 mg, lansoprazole 30 mg, and omeprazole 20 mg of 2.29 [95% of CI=0.79-7.06], 3.94 [CI=1.15-14.03], 2.40 [CI=0.90-6.77], and 2.71 [CI=0.98-7.90], respectively, for the main analysis of healing effects at 8 weeks. When compared to the majority of the comparator PPIs, vonoprazan had relatively higher ORs in the patients' subgroups with severe esophagitis especially when the treatment started.

Whereas, in a meta-analysis conducted by **Miwa *et al*. [22]**, 22 RCTs out of the 4001 publications found were suitable for analysis. Hand-searching was done to find one research and upload it. The analysis did not refute the consistency hypothesis. ORs of the following vonoprazan 10 mg was 13.92 [with 95% CI=1.70-114.21], 5.75 [95% CI 0.59-51.57], 3.74 [with 95% CI 0.70-19.99], and 9.23 [95% CI 1.17-68.72], respectively. So, the treatment by Vonoprazan may be more effective than some PPIs at treating GERD over the long term.

The scope of our work has a set of limitations. Neither patients nor medical professionals were blinded. Second, there were no clear standards for stopping VPZ. FSSG score and the patient's desire were the key factors in our decision to cease the medication. To verify these findings, a case-controlled, double-blinded, multicenter investigation is needed.

Conclusions: From the findings of this study, we conclude that omeprazole 40 mg and vonoprazan 20 mg have a similar symptomatic relief effect and mucosal healing in patients with GERD except for FSSG score; there is a significant decrease in reflux score, and total score in both groups however, the drop in FSSG scores was more significant in omeprazole group compared to vonoprazan group.

Conflict of Interest and Financial Disclosure: None.

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International Journal of Medical Arts

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Print ISSN: 2636-4174
Online ISSN: 2682-3780