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ORIGINAL ARTICLE

Comparison of Vonoprazan Based H Pylori Eradication Regimen and Omeprazole Based H Pylori Eradication Regimen: A Novel Option

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ABSTRACT

Background: H Pylori causes a number of conditions related to gastric mucosa. Owing to emerging antibiotic resistance, more treatment options are needed. Vonoprazan (VPZ) is potassium based acid inhibitor and showing promise in H Pylori eradication regimens.

Results: The study comprise of total 300. Mean Age of study population was 33.04 + 13.01 years and mean age of VPZ based H. Pylori eradication regimen group was 31.78 + 12.384 and mean age of PPI based H. Pylori eradication regimen group was 34.30 + 13.535 (P-Value 0.428) given in table 1. Gender distribution in study population was 54.3% females and 48% males. Gender Distribution in VPZ based H. Pylori eradication regimen group was 52% females and 48% males and in PPI based H. Pylori eradication regimen group, females were 56.7% and males were 43.3% (P-Value 0.487). Comparison of efficacy of VPZ based H. Pylori eradication regimen and PPI based eradication regimen shows that vonoprazan is more effective in H Pylori eradication as compared to PPI based H.Pylori eradication regimen (P-Value 0.028)

Conclusion: Vonoprazan is equally superior as first line therapy H.pylori eradication regimes as PPIs based regime. Eradication rate was higher as compared to PPI. More studies with large sample size in multiple ethnicities are required to establish more effective vonoprazan based regimens against H. Pylori.

Keywords: H. Pylori, Omeprazole, Proton Pump inhibitor (PPI), Vonoprazan (VPZ), H. Pylori eradication

INTRODUCTION

H. Pylori infection causes gastritis by infecting gastric mucosa[1]. Atrophic gastritis, gastro-duodenal ulcer, gastric adeno-carcinoma, mucosa-associated lymphoid tissue (MALT) lymphoma and even idiopathic thrombocytopenic purpura[2] can all be induced by H. pylori's chronic inflammation in gastric mucosa. H. pylori eradication can prevent or treat these disorders. Hence to prevent diseases in all infected people eradication therapy is suggested to treat [3].

Recently antibiotic-resistant H. pylori strains have risen whereas eradication rate is decreased[4]. Resistance to Clarithromycin exacerbates the H. pylori eradication failure. For addressing this problem, multiple drug type eradication regimens (quadruple therapy), higher doses of drug and increase in durations of treatment (10-14 days) is recommended[4].

As compared to proton pump inhibitors (PPIs), Vonoprazan (VPZ) and potassium-competitive acid blocker (P-CAB) triple therapy is found more effective in eradicating H. pylori. Eradication of H. pylori has progressed quite far. VPZ fumarate is a P-CAB that suppresses stomach acid secretion by inhibiting sodium potassium adenosine tri-phosphatase (ATPase) via reversible K+-competitive ionic binding [5]. VPZ might accumulate in acidic section of gastric parietal cells because of its high pKa value, stability in acidic environment unlike PPIs. VPZ, unlike PPIs, doesn't need to be activated by acid. As a result, vonoprazan suppresses stomach acid secretion more effectively and for longer duration than PPIs[5].

In phase 1 clinical trials in Japan and the UK, VPZ suppressed stomach acid output for more than 24 hours in healthy volunteers. Jenkins et al. found that after 4 hours of VPZ, mean intra-gastric pH was greater than 4, and acid-suppressing activity remained up-to 24 hours. pH greater than 5 holding time ratio was nearly 100.0 percent among participants in Japan and the UK after taking vonoprazan (40 mg) for 7 days[6].

PPI/amoxicillin/clarithromycin (PAC) or VPZ/amoxicillin/clarithromycin (VAC) as first-line therapy and PPI/amoxicillin/metronidazole (PAM) or VPZ/amoxicillin/metronidazole (VAM) as second-line therapy is most common H. pylori eradication regimens in Japan[7]. Consequently, all of evaluated study findings are relevant to these triple regimens.

In a randomized trial, Murakami et al. compared rate of eradication of H. pylori by VPZ versus PPIs in gastro-duodenal ulcers patientss [8]. The 20 mg Vonoprazan regimen (with 750mg amoxicillin and 200 0r 400mg clarithromycin, twice daily for 7 days) and 30mg lansoprazole regimen (combination with 750mg amoxicillin plus 200 or 400mg clarithromycin twice a day for 7 days) groups had eradication rates of 92.6% and 75.9% respectively ($p<0.0001$). These findings indicated that VPZ is not lesser to lansoprazole in terms of H. pylori eradication therapy. VPZ showed to have a greater eradication rate compared to PPIs in almost all studies. [8,9,10]

Objective: To compare efficacy Vonoprazan (VPZ) versus PPI therapy for eradication of H. pylori infection.

SUBJECTS & METHODS

It was a quasi-experimental study conducted in outdoor patient clinic, gastroenterology department, Ghulam Muhammadabad General hospital, Faisalabad from January, 2021 to June, 2021. A total 300 patients were eincluded in study after taking their consent using a non-probability consecutive sampling. Patients of both genders above 18 years age having symptoms of acid peptic disease and positive H pylori status were included in the study. Patients with history of prior stomach surgery like partial gastrectomy, allergic reaction to antibiotics used during study, antibiotics, cortico-steroids, PPIs or NSAID intake in last 2 weeks, Females that were pregnant or lactating, Alcoholism or addiction to drug, Severe neurological or psychiatric illness were excluded. Patients were allocated to group A and Group D randomly. 1 gm Amoxicillin y, 500mg Clarithromycin 500 mg, 20mg Capsule Omeprazole 20 mg twice a day was given to Group A for 2 weeks. 1 mg Amoxicillin, 500mg clarithromycin and 20 mg Vonoprazan was given to group B twice daily for 2 weeks. 4 weeks after therapy, antigen test for H Pylori was used to confirm H Pylori eradication in stools. Infection of H. Pylori was labeled if H. Pylori stool Antigen was positive.

RESULTS

This study comprise of total of 300 patients. Mean Age of study population was 33.04 + 13.01 years and mean age of vonoprazan based H. Pylori eradication regimen group was 31.78 + 12.384 and mean age of PPI based H. Pylori eradication regimen group was

34.30 + 13.535 (P-Value 0.428) given in table 1. Gender distribution in study population was 54.3% females and 48% males. Gender Distribution in Vonoprazan based H. Pylori eradication regimen group was 52% females and 48% males and in PPI based H. Pylori eradication regimen group, females were 56.7% and males were 43.3% (P-Value 0.487). Comparison of vonoprazan based H. Pylori eradication regimen efficacy and PPI based eradication regimen shows that vonoprazan is more effective in H Pylori eradication compared to PPI based H.Pylori eradication regimen (P-Value 0.028)

Table 1: Demographic Characteristics of study population

Parameter	Total Population	Vonoprazan Group	PPI Group	p-value
Age	33.04 + 13.012	31.78 + 12.384	34.30 + 13.535	0.428
Gender				
Female	163 (54.3%	78 (52%)	85 (56.7%)	0.487
Male	137 (45.7%)	72 (48%)	65 (43.3%)	

Table 2: Comparison of efficacy of Vonoprazan and omeprazole based H pylori eradication regimen

		Group		Total	p-value
		Vonoprazan Group	PPI Group		
Efficacy	Yes	128	114	242	0.028
		85.3%	76.0%	80.7%	
	No	22	36	58	
		14.7%	24.0%	19.3%	
Total		150	150	300	
		100.0%	100.0%	100.0%	

DISCUSSION

Murakami et al in a randomized trial on patients of gastro-duodenal ulcers evaluated the eradication H. pylori with vonoprazan compared to of PPIs. Vonoprazan displayed rate of first-line eradication as was 92.6% compared with with lansoprazole which showed eradication rate of 75.9%. VPZ showed more efficacies of 16.7% showing that it is not inferior. VPZ based therapy for eradication of H. Pylori has equal efficacy as of lansoprazole therapy in terms of eradication of H. pylori [8].

First-line eradication rates (ER) were 84.9% for vonoprazan-based amoxicillin and clarithromycin (VAC) and 78.8% for proton pump inhibitor (PPI)-based (PAC). Higher rate of eradication was noted for VAC compared to PAC (p=0.0013)[11]. In our study vonoprazan has also shown superiority to omeprazole in H. Pylori eradication.

Kajihara Y et al demonstrated that eradication rate of 94.6% for Vonoprazan based H. Pylori eradication therapy and 86.7% for Rabeprazole based eradication regimen[12]. VPZ based H.Prylori eradication therapy was more cost-effective than rabeprazole based H. Pylori eradication therapy as first-line therapy for H. pylori eradication.

Jung et al. conducted a systematic evaluation of 10 trials with a total of 10,644 patients. Eradication rate of H. pylori was 88.1% in group with triple therapy based on vonoprazan and 72.8% in group based on PPI. As compared to PPI, was shown that for eradication of H. pylori eradication vonoprazan was superior (P-Value <0.05)[13].

In a meta-analysis of 14 trails involving 14,636 patients, odds ratio of vonoprazan eradication rate compared to PPIs was 2.44[14]. Vonoprazan was found more effective than PPIs.

In a meta-analysis, Li et al found that vonoprazan- and traditional PPI-based therapy are equally successful in eradicating H. pylori susceptible to clarithromycin. Vonoprazan was found to be superior to PPIs in the treatment of clarithromycin-resistant H. pylori [15].

Eradication rates of Vonoprazan based regimen in Clarithromycin susceptible H. pylori-infected patients were 87.3% and eradication rates of PPI based regimen were 76.5%. Questionnaire scores did not differ significantly between the groups[16]. Vonoprazan was found non inferior to PPI for H Pylori eradication therapy.

A retrospective study of 573 patient undergoing primary H. pylori eradication therapy, group based on Vonoprazan regimen showed significantly superior rate(83%) of eradication compared to Lansoprazole (66%) and Rabeprazole (67%) based regimens ($p < 0.01$)[17].

Results of another meta-analysis of total of 14 studies comprising of 14 636 patients displayed that when used as first line therapy, pooled rate of eradication of regimens containing Vonoprazan was considerablly higher as compared to regime containing PPI. The difference (85.1% vs 68.0%) was statistically significant (P < .00001). Furthermore, subgroup analysis revealed that VPZ was significantly superior to both patients with clarithromycin-resistant strains (81.5 percent vs 40.9 percent, P =.00001) and those with clarithromycin-susceptible strains (94.9 percent vs 89.6%, P =.006)[8].

Maruyama M et al compared the VPZ and conventional PPIs for eradication of H. Pylori. Eradication rate was significantly higher (95.8% versus 69.6%) in VPZ group than PPI group [19]. Efficacy of VPZ was more than conventional PPI bases therapies for eradication H. Pylori.

CONCLUSION

Vonoprazan is equally superior as first line therapy to eradication regimens based on PPIs.

In Pakistan, we evaluated at vonoprazan-based H. pylori eradication therapy. Its eradication rate is greater than that of PPI. More studies with large sample size in multiple ethnicities are required to establish more effective vonoprazan based regimens against H. Pylori.

REFERENCES

1. Asaka M, Kato M, Kudo M, et al. Atrophic changes of gastric mucosa are caused by Helicobacter pylori infection rather than ag- ing: studies in asymptomatic Japanese adults. Helicobacter 1: 52- 56, 1996.
2. Kusters JG, van Vliet AH, Kuipers EJ. Pathogenesis of Helicobacter pylori infection. Clin Microbiol Rev. 2006;19(3):449-490. doi:10.1128/CMR.00054-05
3. Malfertheiner P, Megraud F, O'Morain CA, et al. Management of Helicobacter pylori infection-the Maastricht V/Florence Consensus Report. Gut 66: 6-30, 2017.
4. Smith SM, O'Morain C, McNamara D. Antimicrobial susceptibil- ity testing for Helicobacter pylori in times of increasing antibiotic resistance. World J Gastroenterol 20: 9912-9921, 2014.
5. Scott DR, Munson KB, Marcus EA, Lambrecht NW, Sachs G. The binding selectivity of vonoprazan (TAK-438) to the gastric H+, K+ -ATPase. Aliment Pharmacol Ther 42: 1315-1326, 2015.
6. Jenkins H, Sakurai Y, Nishimura A, et al. Randomised clinical trial: safety, tolerability, pharmacokinetics and pharmacodynamics of repeated doses of TAK-438 (vonoprazan), a novel potassium-competitive acid blocker, in healthy male subjects. Aliment Pharmacol Ther 41: 636-648, 2015.
7. Lee SY. Current progress toward eradicating Helicobacter pylori in East Asian countries: differences in the 2013 revised guidelines between China, Japan, and South Korea. World J Gastroenterol 20: 1493-1502, 2014.
8. Murakami K, Sakurai Y, Shiino M, Funao N, Nishimura A, Asaka M. Vonoprazan, a novel potassium-competitive acid blocker, as a component of first-line and second-line triple therapy for Helicobacter pylori eradication: a phase III, randomised, double-blind study. Gut 65: 1439-1446, 2016.
9. Maruyama M, Tanaka N, Kubota D, et al. Vonoprazan-based regimen is more useful than PPI-based one as a first-line Helicobacter pylori eradication: a randomized controlled trial. Can J Gastroen- terol Hepatol 2017: 4385161, 2017.
10. Kajihara Y, Shimoyama T, Mizuki I. Analysis of the cost- effectiveness of using vonoprazan-amoxicillin-clarithromycin triple therapy for first-line Helicobacter pylori eradication. Scand J Gas- troenterol 52: 238-241, 2017.
11. Sue S, Kuwashima H, Iwata Y, et al. The Superiority of Vonoprazan-based First-line Triple Therapy with Clarithromycin: A Prospective Multi-center Cohort Study on Helicobacter pylori Eradication. Intern Med. 2017;56(11):1277-1285. doi:10.2169/internalmedicine.56.7833

12. Kajihara Y, Shimoyama T, Mizuki I. Analysis of the cost-effectiveness of using vonoprazan-amoxicillin-clarithromycin triple therapy for first-line Helicobacter pylori eradication. Scand J Gastroenterol. 2017 Feb;52(2):238-241. doi: 10.1080/00365521.2016.1250157. Epub 2016 Nov 3. Erratum in: Scand J Gastroenterol. 2017 Feb;52(2):ii. PMID: 27806639.
13. Jung YS, Kim EH, Park CH. Systematic review with meta-analysis: the efficacy of vonoprazan-based triple therapy on Helicobacter pylori eradication. Aliment Pharmacol Ther 46: 106-114, 2017. [PubMed] [Google Scholar]
14. Dong SQ, Singh TP, Wei X, Yao H, Wang HL. Review: A Japanese population-based meta-analysis of vonoprazan versus PPI for Helicobacter pylori eradication therapy: Is superiority an illusion? Helicobacter. 2017 Dec;22(6). doi: 10.1111/hel.12438. Epub 2017 Sep 8. PMID: 28884937.
15. Li et al. showed through their meta-analysis that vonoprazan- and conventional PPI-based therapies are similarly effective for the eradication of clarithromycin-susceptible H. pylori strains. The superiority of VAC to PPI-AC was emphasized against clarithromycin-resistant H. pylori
16. Li M, Oshima T, Horikawa T, et al. . Systematic review with meta-analysis: vonoprazan, a potent acid blocker, is superior to proton-pump inhibitors for eradication of clarithromycin-resistant strains of Helicobacter pylori. Helicobacter 23: e12495, 2018. [PubMed] [Google Scholar]
17. Sue S, Ogushi M, Arima I, Kuwashima H, Nakao S, Naito M, Komatsu K, Kaneko H, Tamura T, Sasaki T, Kondo M, Shibata W, Maeda S. Vonoprazan- vs proton-pump inhibitor-based first-line 7-day triple therapy for clarithromycin-susceptible Helicobacter pylori: A multicenter, prospective, randomized trial. Helicobacter. 2018 Apr;23(2):e12456. doi: 10.1111/hel.12456. Epub 2017 Dec 21. PMID: 29271026.
18. Dong SQ, Singh TP, Wei X, Yao H, Wang HL. Review: A Japanese population-based meta-analysis of vonoprazan versus PPI for Helicobacter pylori eradication therapy: Is superiority an illusion? Helicobacter. 2017 Dec;22(6). doi: 10.1111/hel.12438. Epub 2017 Sep 8. PMID: 28884937.
19. Maruyama M, Tanaka N, Kubota D, Miyajima M, Kimura T, Tokutake K, Imai R, Fujisawa T, Mori H, Matsuda Y, Wada S, Horiuchi A, Kiyosawa K. Vonoprazan-Based Regimen Is More Useful than PPI-Based One as a First-Line Helicobacter pylori Eradication: A Randomized Controlled Trial. Can J Gastroenterol Hepatol. 2017;2017:4385161. doi: 10.1155/2017/4385161. Epub 2017 Feb 28. PMID: 28349044; PMCID: PMC5350398.