

Original Article

Study Demonstrating Simple, Cheap and Effective Regimen for Helicobacter Pylori Eradication at a Teaching Hospital of Sindh

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Abstract

Objective: Without or partial treatment of Helicobacter pylori infection is associated with chronic gastritis and gastric malignancies in our setup. The aim of this study is to plan a simple, cheap and effective regimen for eradication of H. pylori infection at a teaching hospital of Sindh.

Methods: We performed a retrospective study comprising of 185 stool antigen test positive patients at Medicine Department of Suleiman Roshan Medical College Hospital Tando-Adam Sanghar Sindh from 01 January to 30th October 2023. These treatment naïve patients were prescribed seven days triple therapy regimen containing vonoprazan 20 mg bid, amoxicillin 1.0 gm bid and tinidazole 500 mg bid daily. The eradication of H. pylori was confirmed via stool antigen test performed four weeks after completion of therapy.

Results: Intention-to-treat and per-protocol analyses discovered that our regimen showed better eradication rate 88.2% (95% CI, 80-95%) and 91.89% (95% CI, 84-97%) respectively. Major adverse effects were noted in 15 (8.82%) of patients and only 05 (2.94%) still remained positive after completion of therapy.

Conclusion: Seven days vonoprazan-based triple therapy is a potential first line H. pylori eradication regimen in developing countries as it is simple (low pills burden), cheap, shorter duration of treatment and fewer major adverse effects.

Keywords: Helicobacter Pylori (H. pylori), Simple, cheap and effective regimen, Vonoprazan-based triple therapy, Major adverse effects.

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Introduction

About half of world's population is affected by a common global bacterium known as Helicobacter Pylori (H. Pylori) which typically resides in mucosae of lower stomach and upper duodenum.¹ Untreated or partially treated H. pylori infection can lead to acid-peptic disease, chronic gastritis, gastric-adenocarcinoma and mucosa-associated lymphoid tissue lymphoma (MALT oma).^{1,2} H. pylori also causes 75% of duodenal and 17% of gastric ulcers cases. It is now thought to be human precursor of gastric cancers. It sometimes presents as iron deficiency anemia, vitamin B12 deficiency and idiopathic thrombocytopenic purpura.³ Hence one study demonstrated that successful eradication of H. pylori was associated with 50% reduction in sporadic gastric

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cancers.⁴ Vonoprazan, a potassium-competitive acid blocker (P-CAB) has longer lasting acid suppression effect and higher potency as compared to conventional proton pump inhibitors (PPIs) hence vonoprazan-based eradication therapy seems to have better efficacy with shorter duration of treatment.^{5,6}

Presently available medical literature found one systemic review meta-analysis in which vonoprazan-based triple therapy had significantly higher eradication rate than conventional PPI-based triple regimen of seven days duration (87.9% Vs 72.8% by intention-to-treat analysis).⁷

The objective of our study is to offer simple, easily available and better treatment option via vonoprazan-based triple regimen which has cheaper cost and excellent patient compliance in our setup. Until now pub-

lished studies showed only few of them have treatment efficacy around 90%.

Methods

This descriptive, case-series retrospective study was conducted at Medicine Department of Suleiman Roshan Medical College Hospital Tando-Adam Sindh from 01 January to 30th October 2023. All participants gave informed and written consent and detailed medical history was also taken.

We enrolled 185 patients of either sex and ages from 18 to 78 years for evaluation of possible *H. pylori* infection. All patients with definite diagnosis of *H. pylori* infection via stool antigen test (ICA), urea breath test (UBT), rapid urease test or pathology specimen showing organisms in biopsied tissues were recruited. Those patients without diagnostic laboratory tests and only positive for anti-*H. pylori* IgG antibodies were excluded. In order to be adherent to treatment protocol, patients were clearly advised about route and timings of drugs used in our regimen. These treatment-naïve patients were prescribed seven-days triple therapy regimen comprising of vonoprazan 20mg bid, amoxicillin 1.0gm bid and tinidazole 500mg bid. After seven days therapy period, patients were instructed not to take any antibiotics and PPI/P-CAB drugs for four weeks. The primary end-point of our study was eradication of *H. pylori* (evaluated by stool antigen test performed four weeks after completion of therapy) on an intention-to-treat basis and secondary end-point was rate of major adverse effects. During this study, eradication was confirmed via stool antigen test (ICA) performed at our hospital pathology laboratory.

Basic characteristics, eradication rate and major adverse effects were noted by using Chi-square test.

Results

We evaluated 185 *H. pylori* positive patients during this study. Out of them, 15 patients were removed as they lost follow-ups or very poor and uneducated to purchase medications hence 170 patients fell into an intention-to-treat group. The age of our patients ranged from 18-78 years (mean age SD 32.6 ± 10.42) and males 130(76.47%) were predominantly affected gender showing M: F ratio (3.25:1). The intention-to-treat group include all those patients having completely negative stool antigen test results and those who do not tolerate treatment regimen. The eradication rate in this group was 88.2% (95% CI: 80-95%). In this group, 150 patients (88.2%) showed complete eradication of *H. pylori* infection as revealed by negative stool antigen test. Moreover, 15 patients (8.82%) were found intolerant to this treatment regimen and 05 patients (2.94%) still remained positive on stool antigen test who requires quadruple

bismuth therapy for 14 days. All 15 patients who were intolerant to this regimen, they offered just symptomatic treatment and reassurance. The most frequent major adverse effects were nausea, metallic taste in mouth, abdominal pain, diarrhea, dryness of mouth and headache.

About 170 patients were showed as per-protocol group because they have completed prescribed regimen successfully for 07 days. The eradication rate in this group was 91.89% (95% CI: 84-97%).

Table 1: Basic Characteristics in our patients (n=170)

Variables	No. of Patients	Percentage
Age (years) mean ± SD	32.6 ± 10.42	-
Gender (Male)	130	76.47%
M: F ratio (3.25:1)	130:40	76.47%: 23.52%
Lab. Diagnostic Tests	-	-
A) Non-invasive tests	-	-
Stool antigen test (ICA) n (%)	80	47.05%
Urea breath test (UBT) n (%)	3	1.76%
B) Invasive tests	-	-
Rapid urease test n (%)	70	41.17%
Endoscopic biopsy for <i>H. Pylori</i>	15	8.82%
<i>H. Pylori</i> positive for both rapid urease test and endoscopic biopsy	2	1.17%
Endoscopy showing active gastric/ duodenal ulcers n (%)	-	-
Active gastric ulcers	40	45.97%
Active duodenal ulcers	45	51.72%
Both active gastric and duodenal ulcers	2	2.29%

Discussion

H. Pylori infections affect more than 50% of the world's population. In impoverished countries, it is relatively frequent and substantially more prevalent in younger peoples and those with poor socioeconomic status.⁸ A recent local study from Peshawar Pakistan demonstrated high prevalence (57.6%) of *H. pylori* among paramedical students and it predominantly affects males (86.3%) belonging to rural areas.⁹ This is in accordance to results of our study showing major affection of males (76.47%) with younger age (mean age SD 32.6±10.42) groups. It may be probable that majority of males are careless at younger age and remain outside home during maximum time of the day and they don't wash their hands especially before taking meals. Another latest study by Mori et al¹⁰ reported higher prevalence (28.4%)

of *H. pylori* among males between ages 30 and 39 years. Our community-based practice study showed remarkable results via vonoprazan-based triple therapy for eradication of *H. pylori*, 88.2% intention-to-treat and 91.89% per-protocol groups. This is comparable to study results by Lia Goldberg and Thomas J. Amrick¹¹ who demonstrated *H. pylori* eradication rates 83% for intention-to-treat and 88% for per-protocol groups respectively. Another recent study by Yu-Tse Chiu from Taiwan¹² also showed 83% rate of eradication following vonoprazan-based triple therapy for seven days. About 8.82% patients reported major adverse effects on our treatment protocol. The most common major adverse effects were nausea, metallic taste in mouth, diarrhea, abdominal pain and headache which were quite similar to study by Lia Goldberg and Thomas J. Amrick¹¹ but these were more prevalent (30%) in their patients. This may probably be due to larger sample size of our study. Our drug regimen on average cost about PKR: 1000-1100 (3-4 US dollars) per week in order to eradicate *H. pylori* infection. This is in contrast to study by Lia Goldberg and Thomas J. Amrick¹¹ who showed average wholesale cost of their drug regimen 72.00 US dollars for five days in order to provide *H. pylori* eradication.

In addition, our drug regimen is simple, convenient and more effective due to least chances of drug resistance as most of GPs, specialist doctors and even patients do not utilize amoxicillin and tinidazole frequently. They usually focus on broad spectrum antibiotics like fluoroquinolones, macrolides and third-generation cephalosporins for routine infections hence leading to maximum chances of serious drug resistance in our setup. Therefore, this regimen will get more attention to researchers and specialist doctors for prescription in developing countries of world to eradicate *H. pylori* infection.

Conclusion

On conclusion, seven days vonoprazan-based triple therapy is a potential first line *H. pylori* eradication regimen in developing countries as it is simple (low pill burden), cheaper, shorter duration of treatment and fewer major adverse effects.

Recommendation

Our study provides an open message and recommendation to all healthcare profession personnel that:

- Give general public awareness about proper hand-washing methods especially before food taking via electronic and print media.
- Early detection and screening of *H. pylori* infection especially in lower socio-economic status population.
- Application of preventive measures for *H. pylori*

infection at schools, hostels and local community centers in order to avoid its spread.

- Further large-scale randomized control trials will be needed in future to compare its efficacy with extended PPI-based sequential therapies.

Ethical Approval: This study was approved by Ethical Review Committee of Suleiman Roshan Medical College, Tando-Adam, Sindh (vide letter no. SRMC/PRINCIPAL/322, Dated: 17-07-2023) and in accordance with ethical standards as laid in Declaration of Helsinki.

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Conflict of Interest: *None*

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