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SHORT REPORT

14-Day Vonoprazan-Based Bismuth Quadruple Therapy for Treatment-Naïve Patients with *Helicobacter pylori* Infection: A Retrospective Comparative Study

Feifei Lu[1,2,*], Wentao Xu[2,*], Xiaoye Shi[2,*], Honglu Yu[2,*], Xingshun Qi[1,2]

[1]College of Medicine and Biological Information Engineering, Northeastern University, Shenyang, Liaoning, 110167, People's Republic of China; [2]Department of Gastroenterology, General Hospital of Northern Theater Command, Shenyang, Liaoning, 110840, People's Republic of China

*These authors contributed equally to this work

Correspondence: Xingshun Qi, Department of Gastroenterology, General Hospital of Northern Theater Command, Shenyang, Liaoning Province, 110840, People's Republic of China, Email xingshunqi@126.com

Background: Until now, there is little evidence regarding clinical efficacy of 14-day vonoprazan-based bismuth quadruple therapy (BQT) for *Helicobacter pylori* (*H. pylori*) eradication.

Methods: Overall, 65 treatment-naïve patients with H. pylori infection who received 14-day vonoprazan-based BQT regimen (VBCA, n=17) or pantoprazole-based BQT regimen (PBCA, n=48) for H. pylori eradication were retrospectively included.

Results: Neither successful H. pylori eradication (88.2% versus 91.7%, p=1.000) nor adverse event (52.9% versus 64.6%, p=0.397) was significantly different between VBCA and PBCA groups.

Conclusion: Vonoprazan seems to be as effective and safe as pantoprazole during a 14-day BQT regimen in treatment-naïve patients with *H. pylori* infection.

Keywords: *Helicobacter pylori*, vonoprazan, pantoprazole, bismuth quadruple therapy, efficacy

Introduction

Helicobacter pylori (*H. pylori*), which infects more than half of the world's population,[1] can cause chronic gastritis, even peptic ulcer, gastric mucosa-associated lymphoid tissue lymphoma, and gastric adenocarcinoma.[2] *H. pylori*-positive individuals, especially symptomatic individuals, should consider to receive *H. pylori* eradication therapy.[2]

Vonoprazan, a potassium-competitive acid blocker, is a highly potent drug for *H. pylori* eradication.[3] Recently, a growing number of studies have shown a good efficacy of vonoprazan-amoxicillin dual therapy on eradicating *H. pylori*, but the duration of dual therapy and the optimal dose and frequency of amoxicillin have not been determined.[4,5] A 14-day bismuth quadruple therapy (BQT) remains the preferred regimen for *H. pylori* eradication.[6] However, there is little evidence regarding clinical efficacy of 14-day vonoprazan-based BQT for *H. pylori* eradication.[7,8] Therefore, we conducted a single-center retrospective study to evaluate the efficacy and safety of 14-day BQT with vonoprazan versus pantoprazole for treatment-naïve patients with *H. pylori* infection.

Materials and Methods

This retrospective observational study has been approved by the Medical Ethical Committee of the General Hospital of Northern Theater Command and complies with the Declaration of Helsinki. Considering the nature of this retrospective study, the patients' written informed consents were waived. The patient data was kept confidential. We retrospectively analyzed the data of treatment-naïve patients with *H. pylori* infection at the Department of Gastroenterology of the

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General Hospital of Northern Theater Command from November 2020 to April 2023. Adult patients who received a 14-day BQT regimen for *H. pylori* eradication and voluntarily added contact information were considered. The exclusion criteria were as follows: 1) patients with prior *H. pylori* eradication therapy; 2) patients who were allergic to amoxicillin; 3) patients who took probiotics during a 14-day BQT regimen; 4) patients who discontinued *H. pylori* eradication therapy due to the occurrence of drug-related adverse events; 5) patients who had poor medication adherence, which refers to over-dose, misuse, or forgetfulness of any medication; 6) patients who did not repeat urea breath test (UBT); and 7) patients who lost follow-up.

H. pylori infection would be diagnosed by $^{13}C/^{14}C$-UBT, stool antigen test, and serum antibody test in our treatment-naïve patients. A BQT regimen consists of an acid suppressant, including vonoprazan (20mg twice daily) or pantoprazole (40mg twice daily), in combination with colloidal bismuth pectin (200mg twice daily), clarithromycin (500mg twice daily), and amoxicillin (1000mg twice daily) (VBCA or PBCA). The PBCA or VBCA regimen was chosen before and after November 2021, respectively. *H. pylori* status was re-evaluated by $^{13}C/^{14}C$-UBT at least four weeks after a 14-day BQT regimen. Successful *H. pylori* eradication would be considered if the repeated $^{13}C/^{14}C$-UBT result was negative.

Patients' demographics (ie, age and gender), height, weight, and current status of smoking and/or drinking alcohol were obtained at initial outpatient visits. Additionally, adverse events of *H. pylori* eradication therapy, medication situation, and results of *H. pylori* eradication therapy were obtained via WeChat or outpatient visits. The data were collected by three researchers (WX, XS, and XQ). Data accuracy was independently checked by two investigators (WX and XS).

Continuous variables were reported as mean ± standard deviation or median (range) and compared by the *t*-test or non-parametric Mann–Whitney *U*-test. Categorical variables were reported as frequency (percentage) and compared by the chi-square test. A two-sided $P < 0.05$ was considered statistically significant. All statistical analyses were performed using SPSS 22.0 software (IBM Corp, Armonk, NY, USA).

Results

During this study period, a total of 136 patients received *H. pylori* eradication therapy. Among them, 71 patients were excluded, because 9 patients had prior *H. pylori* eradication therapy, 5 were allergic to amoxicillin, one took probiotics during a 14-day BQT regimen, 5 discontinued *H. pylori* eradication therapy due to the occurrence of drug-related adverse events, 34 had poor medication adherence, 11 did not repeat UBT, and 6 were lost follow-up. Finally, 65 treatment-naïve patients were included, of whom 17 (26.2%) and 48 (73.8%) received VBCA and PBCA, respectively.

Patient characteristics are shown in Table 1. Age, gender, body mass index, current smoking, and current alcohol use were not significantly different between the two groups.

The rate of successful *H. pylori* eradication was not significantly different between VBCA and PBCA groups (88.2% [15/17] versus 91.7% [44/48], p=1.000).

Table 1 Baseline Characteristics of Included Patients

Variables	All Patients		VBCA Group		PBCA Group		P value
	No.Pts (n)	Mean±SD or Frequency (Percentage)	No.Pts (n)	Mean±SD or Median (Range) or Frequency (Percentage)	No.Pts (n)	Mean±SD or Frequency (Percentage)	
Age (years)	65	48.9±13.4	17	45.8±11.6	48	49.7±13.8	0.399
Gender (male)	65	32 (50.8)	17	9 (52.9)	48	24 (50.0)	0.835
BMI (kg/m^2)	64	23.8±4.3	16	22.6 (20.6–30.9)	48	24.1±3.0	0.659
Current smoking	64	12 (19.4)	16	3 (18.8)	48	9 (18.8)	1.000
Current alcohol use	64	7 (11.3)	16	1 (6.3)	48	6 (12.5)	0.817

Abbreviations: VBCA, a combination of vonoprazan, bismuth, clarithromycin, and amoxicillin; PBCA, a combination of pantoprazole, bismuth, clarithromycin, and amoxicillin.

The occurrence rate of adverse events was not significantly different between VBCA and PBCA groups (52.9% [9/17] versus 64.6% [31/48], p=0.397). Most adverse events were mild and resolved spontaneously after discontinuation of medication. No serious adverse events were seen. Among them, bitter taste and darkened stool were the most common adverse events in the two groups.

Conclusion

Vonoprazan seems to be as effective as pantoprazole during a 14-day BQT regimen in treatment-naïve patients with *H. pylori* infection. Notably, our study has shown a relatively rate of adverse events, primarily because all of our included patients could readily communicate with us via WeChat about any discomfort and its related instructions, and all complaints observed during their *H. pylori* eradication therapy had been recorded and regarded as adverse events.

Disclosure

Feifei Lu, Wentao Xu, Xiaoye Shi and Honglu Yu are co-first authors for this study. The authors report no conflicts of interest in this work.

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