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Original Article

Rabeprazole- and vonoprazan-based dual therapies for H pylori eradication: effective with low side effects, rabeprazole being more cost-effective

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Abstract: Objective: To evaluate the eradication effect of dual therapy based on rabeprazole or vonoprazan for *Helicobacter pylori* (Hp) infection. Methods: Data from 300 Hp-positive patients were retrospectively analyzed. Patients who received rabeprazole and amoxicillin were assigned to the rabeprazole group, those who received vonoprazan and amoxicillin were placed in the vonoprazan group, and those who underwent conventional quadruple therapy (omeprazole + amoxicillin + clarithromycin + bismuth potassium citrate) were included in the control group. Clinical medical records, including baseline characteristics, symptom manifestations, examination results, treatment regimens, and treatment costs, were collected. The Hp eradication rate, symptom relief, levels of inflammatory markers (interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF-α), and C-reactive protein (CRP)), incidence of adverse reactions, treatment compliance, and cost-effectiveness ratio (C/E) were compared among the three groups. Results: In both per-protocol (PP) and intention-to-treat (ITT) analyses, no statistically significant differences were observed in eradication rates among the three groups (P>0.05). Symptom relief was more pronounced at 44 days of treatment compared to 14 days across all groups (P<0.05). At both 14 and 44 days, significant differences were found in the relief of abdominal distension (14 days: Z=20.644, P<0.001; 44 days: Z=11.577, P=0.003) and belching (14 days: Z=23.234, P<0.001; 44 days: Z=20.194, P<0.001) among the three groups (P<0.05), with the rabeprazole group showing the best improvement, followed by the control group. After treatment, the IL-6, TNF-α, and CRP levels in the rabeprazole and vonoprazan groups were lower than those in the control group (all P<0.05). There was no significant difference in treatment compliance among the three groups (χ^2=0.224, P=0.894). The C/E was lowest in the rabeprazole group and highest in the vonoprazan group. Conclusion: Dual therapy based on rabeprazole or vonoprazan effectively improves symptoms in patients with Hp infection, with relatively few adverse reactions and good treatment compliance. Additionally, rabeprazole-based dual therapy had a lower cost.

Keywords: Helicobacter pylori, rabeprazole, vonoprazan, dual therapy, eradication effect

Introduction

Helicobacter pylori (Hp) infection is a significant global public health concern with a high incidence. According to statistics, approximately half of the world's population is infected with Hp [1]. In China, the infection rate remains relatively high. The health impact of Hp infection cannot be overlooked, as long-term infection, it significantly increases the risk of gastritis and peptic ulcers and is closely associated with the development of gastric cancer. Research [2] suggests that chronic inflammation caused by Hp infection may be a key initiating factor in gastric cancer.

At present, the primary treatment regimens for Hp infection include triple therapy and quadruple therapy, which involve different combinations of proton pump inhibitors (PPIs), bismuth agents, and antibiotics [3, 4]. However, the widespread use of antibiotics has led to increasing antibiotic resistance in Hp [5]. In recent years, the emergence of drug-resistant strains has gradually reduced the effectiveness of traditional treatment regimens. Additionally, these therapies may cause adverse reactions such as nausea, vomiting, diarrhea, and rash, affecting patient compliance [6]. To address these challenges in Hp treatment, it is crucial to explore more effective therapeutic approaches.

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As new PPIs, rabeprazole and vonoprazan offer unique advantages in inhibiting gastric acid secretion. The use of dual therapy based on rabeprazole or vonoprazan for Hp eradication has increasingly gained attention. Research by Han et al. [7, 8] highlights the potential application value of new PPIs in Hp treatment. Additionally, Kim et al. [9] emphasize the importance of optimizing treatment regimens to improve Hp eradication rates. This study aims to evaluate the clinical efficacy of dual therapy based on rabeprazole or vonoprazan for Hp eradication. By comparing the efficacy and safety of dual therapy with traditional treatment regimens, we seek to provide new therapeutic options for Hp infection, enhance eradication rates, and reduce antibiotic resistance and adverse reactions, so as to improve patient health outcomes.

Materials and methods

Case selection

A total of 300 Hp-positive patients who visited the First Affiliated Hospital of Hebei North University between January and October 2023 were retrospectively included. This study was approved by the Ethics Committee of the First Affiliated Hospital of Hebei North University.

Inclusion criteria: Aged ≥18 years; diagnosed with Hp infection through relevant examinations, such as the urea breath test or gastroscopy; agreed to receive dual therapy based on rabeprazole or vonoprazan; had complete clinical medical records, including symptom manifestations, examination results, treatment drugs, and associated costs; had not received systemic treatment for Hp, or at least three months had passed since the last treatment.

Exclusion criteria: History of allergy to rabeprazole, vonoprazan, or other components of study drugs; severe dysfunction of major organs such as the heart, liver, or kidneys; presence of systemic diseases, including malignant tumors and autoimmune disorders, that could affect study outcomes; pregnant or lactating women; patients unable to cooperate with treatment and follow-up.

Intervention methods

Patients in the rabeprazole group were prescribed oral rabeprazole sodium enteric-coated tablets (20 mg twice daily) plus amoxicillin capsules (1 g three times daily) for 14 consecutive days. Patients in the vonoprazan group were given oral vonoprazan fumarate tablets (20 mg twice daily) plus amoxicillin capsules (1 g three times daily) for 14 consecutive days. Patients in the control group received oral omeprazole enteric-coated capsules (20 mg twice daily), amoxicillin capsules (1 g twice daily), clarithromycin tablets (0.5 g twice daily), and bismuth potassium citrate capsules (0.6 g twice daily) for 14 consecutive days. All patients underwent a C13-urea breath test 44 days after the start of treatment, and those with negative results were considered to have achieved successful Hp eradication.

The manufacturers of the study drugs are as follows: rabeprazole sodium enteric-coated tablets (Hunan Mingrui Pharmaceutical Co., Ltd.; National Drug Approval No. H20080125; specification: 20 mg × 14 tablets), amoxicillin capsules (CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.; National Drug Approval No. H13023964; specification: 0.25 g × 24 capsules), vonoprazan fumarate tablets (Tianjin Takeda Pharmaceutical Co., Ltd.; National Drug Approval No. J20200011; specification: 20 mg × 7 tablets), omeprazole enteric-coated capsules (Jinan Mingxin Pharmaceutical Co., Ltd.; National Drug Approval No. H20084393; specification: 20 mg × 28 capsules/bottle), clarithromycin tablets (Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.; National Drug Approval No. H10970216; specification: 0.25 g × 14 tablets), and bismuth potassium citrate capsules (YUEKANG Pharmaceutical Group Co., Ltd.; National Drug Approval No. H20056577; specification: 20 mg × 14 capsules).

Data collection and outcome measurements

Primary indicators: The eradication rate was defined as the proportion of patients who achieve successful Hp eradication, analyzed using per-protocol (PP) and intention-to-treat (ITT) methods [10]. PP analysis included patients with treatment compliance of ≥80% who underwent a follow-up C13 or C14 urea breath test. In ITT analysis, patients lost to follow-up, those who did not take medications as prescribed, or those who did not undergo the follow-up C13 or C14 urea breath test were considered treatment failures.

Symptom scores were assigned based on four clinical symptoms - abdominal distension, belching, upper abdominal pain, and anorexia - using a four-tier scale of 0, 3, 6, and 9 points, ranging from mild to severe. Symptom scores were recorded before treatment, at 14 days, and at 44 days after treatment. The symptom improvement score was calculated as the difference between the symptom score before treatment and the score at either 14 or 44 days post-treatment [11].

Detection of inflammatory factors: Six milliliters of fasting venous blood were collected from patients before treatment and 14 days after the start of treatment (referred to as "after treatment" hereinafter). The levels of interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF-α), and C-reactive protein (CRP) were measured by the enzyme-linked immunosorbent assay (ELISA) using a Varioskan LUX multifunction microplate reader (Thermo Fisher Scientific (China) Co., Ltd.). The detection kits were purchased from Shanghai Kanglang Biotechnology Co., Ltd., and all procedures were carried out strictly following the instructions provided by the kit.

Secondary indicators: The occurrence of adverse reactions, such as nausea, abdominal pain, abdominal distension, diarrhea, constipation, dry mouth, bitter taste, belching, etc., were collected from patients. Treatment compliance was assessed by the number of tablets taken by the patient 3 days after the end of treatment. The treatment compliance index was calculated as: actual number of tablets taken by the patient/total number of tablets required for the entire course of treatment × 100%. A compliance rate >80% was considered good compliance, while <80% was considered poor compliance [12].

Cost-effectiveness analysis: The total cost of the drugs used by patients for 14 days of treatment is considered the cost (C), and the Hp eradication rate is the effect (E). Based on these, the cost-effectiveness ratio (C/E) was calculated according to the PP analysis [13]. A smaller value indicates higher benefit. The drug price for each medication is based on the drug supply catalog of our hospital in 2023.

Statistical analysis

SPSS 23.0 software was used for statistical analysis. Measurement data conforming to a normal distribution are expressed as mean ± standard deviation, with variance analysis used for comparisons among the three groups. Qualitative data are described using rates and frequencies. For the analysis of differences between groups, the chi-square test or exact test was used for unordered categorical data, and the rank sum test was used for ordered categorical data. The statistics for the improvement in patients' symptoms were calculated after excluding patients without relevant symptoms before treatment. The differences between symptom score reductions before and after treatment were analyzed using both ITT and PP methods to assess the efficacy of Hp eradication. A two-sided test was applied with a significance level of $\alpha=0.05$.

Results

Basic characteristics of patients

There were no statistically significant differences in age, BMI, gender distribution, chronic gastritis, living city, education level, smoking, or drinking history among the three groups (P> 0.05) (**Table 1**).

Hp eradication rate

Both PP and ITT analyses showed no statistically significant differences in the eradication rate among the three groups (P>0.05) (**Table 2**).

Degree of symptom relief

The degrees of symptom relief for abdominal distension, belching, upper abdominal pain, and anorexia were significantly greater at 44 days of treatment than at 14 days in all the three groups (P<0.05) (**Table 3**). At both 14 days and 44 days of treatment, there were statistically significant differences in the degree of symptom relief for abdominal distension (14 days: Z=20.644, P<0.001; 44 days: Z=11.577, P=0.003) and belching (14 days: Z=23.234, P<0.001; 44 days: Z=20.194, P<0.001) among the three groups (P<0.05). Furthermore, the rabeprazole group showed the best results, followed by the control group.

Changes in inflammatory factor levels

Before treatment, there were no statistically significant differences in the levels of IL-6, TNF-α, and CRP among the three groups (P>0.05).

Table 1. Basic characteristics of patients

Characteristics	Rabeprazole group (n=120)	Vonoprazan group (n=116)	Control group (n=64)	χ^2/F	*P*
Gender (male/female)	63/57	59/57	38/26	1.257	0.533
Age (years)	46.58±10.39	45.55±11.20	46.18±10.74	0.272	0.762
BMI (kg/m^2)	22.86±1.52	22.67±1.65	22.71±1.62	0.452	0.637
Chronic gastritis (n)	99/21	92/24	54/10	0.799	0.671
Residential city (n)	72/48	74/42	40/24	0.369	0.832
Education above junior high school (n)	98/22	94/22	49/15	0.747	0.688
Smoking (n)	40/80	38/78	19/45	0.269	0.874
Drinking (n)	21/99	16/100	7/57	1.552	0.460

Table 2. Hp eradication rate

Group	PP analysis		ITT analysis	
	Cases	Eradication Rate (cases, %)	Cases	Eradication Rate (cases, %)
Rabeprazole group (n=120)	117	105 (89.74%)	120	105 (87.50%)
Vonoprazan group (n=116)	111	98 (88.29%)	116	98 (84.48%)
Control group (n=64)	59	53 (89.83%)	64	53 (82.81%)
χ^2		0.156		0.842
P		0.925		0.656

PP, per-protocol; ITT, intention-to-treat.

After treatment, the levels of IL-6, TNF-α, and CRP in the rabeprazole group and vonoprazan group were lower than those in the control group (F=74.320, 129.800, 74.020, all P< 0.001) (**Figure 1**).

Incidence of adverse reactions

There was a statistically significant difference in the incidence of adverse reactions among the rabeprazole group, vonoprazan group, and control group. The incidence was lower in the rabeprazole and vonoprazan groups than that in the control group (all P<0.05) (**Table 4**).

Treatment compliance

In the rabeprazole group, 4 patients (3.33%) had poor compliance; in the vonoprazan group, 5 patients (4.31%) had poor compliance; and in the control group, 2 patients (3.13%) had poor compliance. There was no statistically significant difference in treatment compliance among the rabeprazole group, vonoprazan group, and control group (χ^2=0.224, P=0.894) (**Figure 2**).

Cost-benefit analysis

The rabeprazole group had the lowest C/E, while the vonoprazan group had the highest (**Table 5**).

Discussion

Hp infection is closely associated with the development of various gastrointestinal conditions, including chronic gastritis, peptic ulcers, and gastric cancer. Currently, conventional quadruple therapy is the primary approach to treating Hp infection. However, the rise in antibiotic resistance and the occurrence of adverse drug reactions highlight the need for a more effective, safe, and cost-efficient treatment strategies. This study aims to evaluate the clinical efficacy of dual therapy, utilizing either rabeprazole or vonoprazan, in eradicating Hp infection, and to provide evidence for optimizing treatment protocols for Hp infection.

Our research findings revealed no statistically significant difference in the eradication rates between the rabeprazole group, vonoprazan group, and the control group in both the PP and ITT analyses. This suggests that dual therapy based on rabeprazole or vonoprazan is as effective as conventional quadruple therapy in eradicating Hp. Although dual therapy involves fewer medications than quadruple therapy, it does not demonstrate a significant disadvantage in eradication rates, thus offering the potential to simplify treatment protocols. Based on these results, we conclude that dual

Table 3. Degree of symptom relief

Symptom	Rabeprazole group (n=120)		Vonoprazan group (n=116)		Control group (n=64)	
	14 d	44 d	14 d	44 d	14 d	44 d
Abdominal distension						
-3	1	0	0	2	2	0
0	0	30	28	40	20	25
3	10	20	20	8	11	20
6	10	25	15	13	5	24
9	6	3	2	2	3	3
Z	-3.302		-2.031		-2.169	
P	0.001		0.042		0.030	
Belching						
-3	1	0	2	0	1	0
0	25	13	58	46	22	24
3	21	31	10	16	22	24
6	15	26	5	14	3	23
9	3	2	1	2	2	0
Z	-2.325		-2.916		-2.236	
P	0.020		0.004		0.025	
Upper abdominal pain						
-3	2	0	1	0	2	0
0	14	9	25	22	18	11
3	16	23	6	3	10	21
6	3	18	18	13	5	12
9	1	1	3	20	4	4
Z	-3.252		-2.562		-2.219	
P	0.001		0.010		0.026	
Poor appetite						
-3	0	1	1	0	1	0
0	8	7	8	10	6	7
3	10	12	3	18	12	1
6	1	20	3	16	7	5
9	3	3	0	1	1	11
Z	-2.066		-2.386		-2.354	
P	0.039		0.017		0.019	

therapy with rabeprazole or vonoprazan is comparable to conventional quadruple therapy in terms of Hp eradication efficacy.

At 44 days of treatment, symptom relief - measured by improvements in abdominal distension, belching, upper abdominal pain, and anorexia - was greater in the rabeprazole group, vonoprazan group, and control group compared to 14 days. This indicates that prolonged treatment leads to gradual symptom improvement, likely due to the sustained effects of the medications, which inhibit Hp growth and reduce inflammation. At both 14 and 44 days, statistically significant differences were observed in the relief of abdominal distension and belching among the three groups, with the rabeprazole group showing the greatest improvement, followed by the control group. As PPIs and P-CABs, rabeprazole and vonoprazan effectively suppress gastric acid secretion, thereby reducing gastric mucosal irritation and alleviating symptoms such as abdominal distension and belching. Additionally, amoxicillin's antibacterial properties aid in Hp eradication, further mitigating inflammation and contributing to symptom relief [14]. Following treatment, the levels of inflammatory markers - including IL-6, TNF-α,

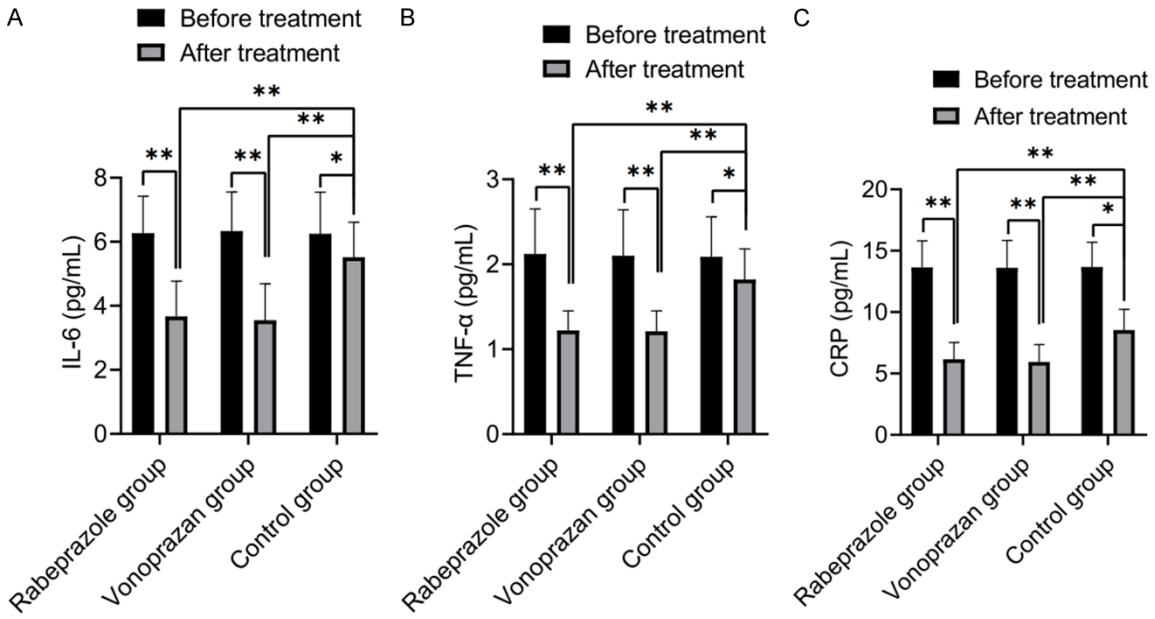

Figure 1. Changes in inflammatory factor levels. IL-6: interleukin-6; TNF-α: tumor necrosis factor-alpha; CRP: C-reactive protein. *P<0.05, **P<0.001.

Table 4. Incidence of adverse reactions

Adverse reactions	Rabeprazole group (n=120)	Vonoprazan group (n=116)	Control group (n=64)
Nausea	4 (3.33%)	2 (1.72%)	2 (3.13%)
Abdominal pain	2 (1.67%)	2 (1.72%)	0 (%)
Abdominal distension	2 (1.67%)	1 (0.86%)	3 (4.69%)
Diarrhea	0 (0%)	0 (%)	5 (7.81%)
Constipation	0 (0%)	2 (1.72%)	0 (%)
Dry mouth	0 (0%)	0 (%)	1 (1.56%)
Bitter taste	0 (0%)	0 (%)	1 (1.56%)
Belching	00 (%)	0 (%)	1 (1.56%)
Total	8 (6.67%)*	7 (6.03%)*	13 (20.31%)
χ^2		11.617	
P		0.003	

Note: *Compared with control group, P<0.05.

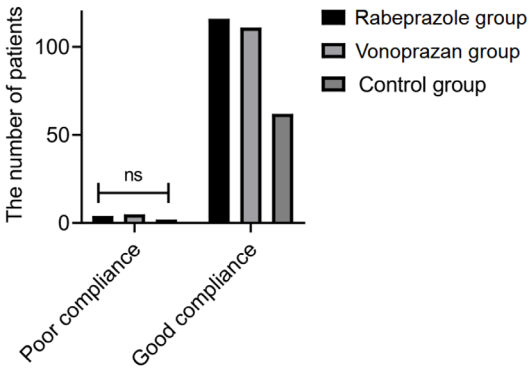

Figure 2. Treatment compliance. ns P>0.05.

and CRP - were lower in the rabeprazole and vonoprazan groups compared to the control group. This may be explained by two mechanisms: first, Hp infection triggers an inflammatory response in the gastric mucosa, increasing the release of inflammatory cytokines [15]; second, by inhibiting gastric acid secretion, rabeprazole and vonoprazan help reduce mucosal irritation and inflammatory factor release. Furthermore, the antibacterial effect of amoxicillin aids in reducing inflammation, reinforcing the overall therapeutic benefit. Together, the acid suppression and antibacterial action con-

Table 5. Cost-benefit analysis

Group	Medicine	Specification	Dosage	Unit Price (yuan/box)	Total Cost (yuan)	Hp eradication rate (%)	C/E
Rabeprazole group (n=120)	Rabeprazole sodium enteric-coated tablets	14 tablets/box	2 tablets/d	29.00	107	89.74	1.19
	Amoxicillin capsules	24 capsules/box	12 capsules/d	7.00			
Vonoprazan group (n=116)	Vonoprazan fumarate tablets	7 tablets/box	2 tablets/d	75.0	349	88.29	3.95
	Amoxicillin capsules	24 capsules/box	12 capsules/d	7.00			
Control group (n=64)	Omeprazole enteric-coated capsules	14 tablets/box	2 tablets/d	29.00	349	89.83	3.26
	Amoxicillin capsules	24 capsules/box	8 capsules/d	7.00			
	Clarithromycin tablets	14 tablets/box	4 tablets/d	48.50			
	Bismuth potassium citrate capsules	40 capsules/box	4 capsules/d	31.00			

tribute to a significant reduction in inflammatory markers in the rabeprazole and vonoprazan groups.

Our research findings also indicate that the incidence of adverse reactions in the rabeprazole and vonoprazan groups was lower than that in the control group. In conventional quadruple therapy, clarithromycin and bismuth potassium citrate may lead to adverse effects such as gastrointestinal discomfort and skin rashes. In contrast, dual therapy, which involves fewer medications, was associated with a lower incidence of adverse reactions. This reduction can significantly improve patient quality of life [16]. Han et al. [17] investigated the efficacy and safety of vonoprazan-based dual therapy for Hp eradication, providing a reference for the vonoprazan treatment. Notably, there was no statistically significant difference in treatment compliance among the three groups, suggesting that patient adherence to the three regimens was comparable. Since treatment compliance plays a crucial role in Hp eradication success, healthcare providers should emphasize patient education to improve adherence. Additionally, our results showed that the C/E of the rabeprazole group was the lowest, while that of the vonoprazan group was the highest, indicating that rabeprazole-based dual therapy is the more cost-efficient option. When selecting a treatment regimen, factors such as efficacy, adverse reactions, and cost should be taken into account. For patients with financial constraints, rabeprazole-based dual therapy may be a more suitable choice. Previous studies support our findings. Han et al. [18] compared vonoprazan- and PPI-based regimens for Hp eradication, helping contextualize the differences among treatment groups. Tai et al. [19] evaluated the efficacy and safety of rabeprazole-based dual therapy, corroborating the results observed in our rabeprazole group. Additionally, Zhang et al. [20] conducted a systematic review and meta-analysis of vonoprazan-based dual therapy, providing broader evidence to support our study's conclusions.

The mechanisms of action of rabeprazole and vonoprazan are as follows. (1) Inhibition of gastric acid secretion. Rabeprazole and vonoprazan function as PPIs and P-CABs, respectively. They specifically target the H^+/K^+-ATPase or potassium ion channels on gastric parietal cells, effectively inhibiting gastric acid secretion [21]. By reducing gastric acid levels, these drugs help minimize gastric mucosal irritation, promote mucosal repair, and create an unfavorable environment for Hp survival, thereby enhancing eradication rates. (2) Regulation of immune response. The reduction in gastric acid secretion also plays a role in modulating the immune response of the gastric mucosa. Hp infection induces an inflammatory reaction, increasing the release of pro-inflammatory cytokines such as IL-6, TNF-α, and CRP [22]. These cytokines activate immune cells, triggering an immune response that exacerbates gastric mucosal damage. By suppressing gastric acid secretion, rabeprazole and vonoprazan help regulate immune activity, reduce inflammatory cytokine release, and mitigate mucosal damage.

The antibacterial action of amoxicillin further aids in suppressing the inflammatory response. Amoxicillin is a broad-spectrum penicillin antibiotic, and it exerts strong antibacterial activity against Hp. It primarily works by disrupting the bacterial cell wall, leading to bacterial death. Additionally, amoxicillin inhibits bacterial protein synthesis and interferes with other bacte-

rial survival pathways, further contributing to Hp eradication. Additionally, the regulation of inflammatory factors may involve other mechanisms, such as immune modulation and cell signaling pathways [23]. Understanding the mechanisms of action of rabeprazole, vonoprazan, and amoxicillin in acid suppression, immune response regulation, and inflammation control can provide a solid foundation for evaluating the effectiveness of the treatment regimens examined in this study.

This study has several limitations. As a retrospective analysis, it may be subject to selection bias and information bias, affecting the accuracy of the results. The relatively small sample size of 300 patients may not fully represent the general population, potentially impacting the reliability of statistical conclusions. Additionally, the study only compared dual therapy with rabeprazole or vonoprazan against conventional quadruple therapy, without evaluating other potential treatment regimens. The focus was primarily on Hp eradication rate, symptom relief, and inflammatory marker levels, which may not encompass all critical aspects of Hp treatment. Furthermore, the short follow-up duration limits the assessment of long-term efficacy and recurrence rates.

Despite these limitations, the study demonstrates that dual therapy with rabeprazole or vonoprazan is effective in Hp eradication, improving patient symptoms with fewer adverse reactions and good treatment compliance. Among the two dual therapies, rabeprazole-based treatment offers a more cost-effective option. These findings provide valuable insights for optimizing Hp treatment strategies. In clinical practice, physicians should tailor treatment plans based on individual patient conditions to maximize eradication rates while minimizing adverse effects. Further large-scale clinical trials are necessary to confirm the long-term efficacy and safety of the dual therapies for Hp infection.

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Disclosure of conflict of interest

None.

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