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ORIGINAL RESEARCH

Analysis of *Helicobacter pylori* Eradication Therapy Based on Drug Susceptibility Testing in Huairou District, Beijing: A Single-Arm Prospective Observational Study

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Objective: To assess the feasibility, effectiveness, and safety of susceptibility-guided individualised *H. pylori* therapy in a region without prior resistance data, using a single-arm prospective observational design.

Methods: This prospective study included patients with confirmed *H. pylori* infection undergoing gastroscopy at Beijing Huairou Hospital (April 2023–May 2024). Molecular testing targeted *23S rRNA* mutations (A2142G, A2142C, A2143G) for clarithromycin (CLA) and *gyrA* mutations (Asn87→Lys/Thr) for levofloxacin (LVX). Patients were assigned to three susceptibility-guided groups: CLA-sensitive, CLA-resistant+LVX-sensitive, and CLA-resistant+LVX-resistant, each receiving 14-day bismuth-containing quadruple therapy. Eradication was confirmed by ^{13}C urea breath test 4–8 weeks post-treatment.

Results: Intention-to-treat (ITT) eradication rate was 82.3% (per-protocol [PP]: 87.2%). ITT rates by group: CLA-S 81.8%, CLA-R-LVX-S 83.3%, CLA-R-LVX-R 85.0% (P=0.921). PP rates: 86.3%, 92.1%, 85.0% (P=0.602). No significant differences in compliance or safety (P=0.849; P=0.467).

Conclusion: Susceptibility-guided therapy achieved 85–90% eradication regardless of resistance profile. Although the ITT rate (82.3%) fell short of the 90% guideline threshold, it remains clinically acceptable in a moderate-to-high resistance setting (Huairou: CLA resistance 26.7%, LVX 28.8%, dual 8.6%), supporting the value of susceptibility testing.

Keywords: *Helicobacter pylori*, gastric carcinoma, drug resistance, treatment outcome

Introduction

China continues to have a comparatively high prevalence of *Helicobacter pylori* (*H. pylori*) infections. Reportedly, more than half of the mainland population is affected, with clear geographic heterogeneity. Residents in mountainous areas generally show higher infection rates than those living in urban districts.[1] This substantial burden of *H. pylori* infections remains a major driver of gastric diseases throughout the country. Although only 1–3% of infected individuals will ultimately develop malignant conditions, roughly 15% of all malignancies, and nearly 89% of gastric cancers worldwide, are associated with *H. pylori*.[2] According to the Kyoto consensus, *H. pylori* eradication should be prioritised for patients who suffer from gastric disorders and dyspeptic symptoms.[3] In addition to symptomatic relief, successful eradication can reduce gastric mucosal inflammation, facilitate ulcer healing, and may help lower the long-term risk of gastric cancer.[4]

With the steady rise of *H. pylori* resistance to antibiotics, the efficacy of the conventional standard triple therapy has declined markedly, and even empiric quadruple therapy is increasingly unable to deliver satisfactory eradication rates. Contemporary guidelines now emphasise that antibiotic selection should be informed by local resistance profiles.[5] Recent surveillance data underscore the escalating challenge of antimicrobial resistance in China. A 2024 multicentre study across 9 provinces reported that primary resistance rates to clarithromycin (CLA) and levofloxacin (LVX) among urban

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residents reached 50.83% and 47.17%, respectively.[6] A meta-analysis tracking resistance trends from 2000 to 2023 documented a substantial increase in CLA resistance of 32.6% (5071/15,555, 95% confidence interval [CI]: 27.7–37.9) and in levofloxacin, resistance of 13.2% (1091/8271, 95% CI: 9.3–18.4) over the same period.[7] More recent data from 2024 to 2025 indicate that resistance rates in certain regions have exceeded these national averages: a study conducted in Dongying, Shandong, reported CLA and LVX resistance rates of 60.25% and 46.15%, respectively,[8] while data from Nanjing, Jiangsu, showed rates of 41.65% for CLA and 42.68% for levofloxacin.[9] In northern China, a 2024 study encompassing Beijing and its surrounding areas documented CLA resistance at 36.9% and LVX resistance at 29.2%.[10] Notably, a 2025 study from Beijing Chao-Yang Hospital reported that susceptibility-guided therapy achieved significantly higher eradication rates than empirical therapy (intention-to-treat [ITT]: 94.4% vs 86.1%, P = 0.012), particularly for levofloxacin-resistant strains (per-protocol [PP]: 95.7% vs 50.0%, P = 0.049),[11] highlighting the potential clinical value of resistance testing. Against this backdrop, individualised treatment guided by antimicrobial susceptibility testing, that is, assessing whether a patient's strain is sensitive or resistant to specific agents, is gaining recognition as a practical approach in clinical practice. Data released by the Japanese Society for *H. pylori* indicate that, in regions with high CLA resistance or in patients who have failed eradication therapy, susceptibility-guided management is recommended to improve treatment outcomes.[6] Clinically, resistance testing provides precise guidance for antibiotic selection, but the added value of susceptibility-guided individualised therapy over empirical bismuth-containing quadruple therapy, particularly in regions with limited local resistance data, warrants further investigation.

This study focuses on Huairou, a mountainous district in the northern outskirts of Beijing, where epidemiological data on *H. pylori* resistance patterns and eradication efficacy have not yet been reported. As noted above, the prevalence of *H. pylori* infection in China exhibits significant geographic heterogeneity, with mountainous areas generally showing higher infection rates than urban districts.[1] Huairou's distinct demographic composition, limited access to specialised gastroenterology services, and differences in antibiotic prescribing practices compared with urban centres may contribute to region-specific resistance profiles. Moreover, previous large-scale surveillance studies in China have predominantly drawn samples from provincial capitals or urban hospitals, leaving rural and mountainous regions underrepresented.[11–20] Given that antimicrobial resistance patterns directly influence the selection of empirical eradication regimens, the absence of local data may compromise treatment success rates in this area. Therefore, characterising the resistance landscape in Huairou is essential to guide evidence-based, region-adapted clinical decision-making and to determine whether susceptibility-guided therapy offers added value in such settings. Using molecular methods, we developed individualised bismuth-containing quadruple regimens based on each patient's CLA and LVX resistance levels. Moreover, eradication rates, safety profiles, and treatment adherence were compared across different resistance groups, aiming to characterise the local resistance landscape in Huairou and to assess the clinical utility of individualised treatment in this context. This study was designed as a single-arm observational investigation without a concurrent empirical therapy control group; therefore, the primary focus was on evaluating the feasibility and clinical outcomes of susceptibility-guided therapy, rather than establishing comparative effectiveness. Accordingly, we formulated the following primary hypothesis: In a region with no prior data on antibiotic resistance, susceptibility-guided individualised therapy would achieve an overall eradication rate exceeding 80%—a clinically acceptable threshold—while demonstrating favourable safety and adherence profiles across resistance-defined subgroups. A secondary hypothesis was that eradication rates would not differ significantly between patients with susceptible strains and those with single- or dual-resistant strains when therapy was tailored to resistance patterns. By testing these hypotheses in a prospective, single-arm design, this study seeks to provide the first region-specific evidence base to inform *H. pylori* management in the northern suburbs of Beijing. This study represents the first investigation of *H. pylori* resistance patterns and susceptibility-guided eradication therapy in Huairou District, a mountainous suburban region in northern Beijing that has been underrepresented in previous national surveillance studies. The dataset presented herein has not been previously published, and the findings provide region-specific evidence to inform clinical decision-making in this area.

Participants and Methods

Study Population

Patients were recruited from Beijing Huairou Hospital between April 2023 and May 2024. Individuals who underwent a gastroscopy for dyspeptic symptoms or as part of routine health examinations and tested positive for both the rapid urease test (RUT) and *H. pylori* quantitative real-time polymerase chain reaction (QRT-PCR) were deemed eligible for the study. The inclusion criteria were as follows: (1) receiving a gastroscopy at Beijing Huairou Hospital either for routine physical examination or evaluation of dyspepsia; (2) dual positivity on RUT and QRT-PCR; (3) aged 18–75 years; (4) no prior history of *H. pylori* eradication therapy.

The exclusion criteria were as follows: (1) the use of proton pump inhibitors (PPIs), H2 receptor antagonists, antibiotics, bismuth, or related medications within the previous 4 weeks; (2) known malignancies of the digestive tract; (3) Zollinger–Ellison syndrome; (4) a history of gastric or oesophageal surgery; (5) significant comorbidities affecting the cardiovascular, cerebrovascular, pulmonary, hepatic, renal, haematologic, neurological, endocrine, or psychiatric systems; (6) documented allergy to any medication included in this study; (7) pregnancy or lactation; (8) any additional medical condition that could increase the risk of treatment-related adverse effects. This study was supported by the Scientific Research Backbone Fund of Beijing Huairou Hospital. The study protocol was approved by the hospital's ethics committee (Approval No. J.H.L.K.Zi[2023]No.[004]-01). Written informed consent was obtained from all participants.

Study Procedures

This study was designed as a single-arm, prospective observational study. All enrolled patients received susceptibility-guided individualised therapy; no concurrent empirical therapy control group was included. (1) During gastroscopy, one biopsy specimen was taken from the gastric antrum for RUT. Additional samples, obtained from the antrum and the lesser curvature of the gastric body, were submitted for QRT-PCR. Patients were considered *H. pylori*-positive only when both the RUT and QRT-PCR results were positive. (2) After confirming that no exclusion criteria or contraindications to eradication therapy were present, physicians recorded baseline demographic and clinical information. Genomic DNA of *H. pylori* was extracted from gastric mucosal tissue using a commercial nucleic acid extraction kit (R0017M, Beyotime Biotechnology, Shanghai). Resistance testing was performed with a commercially available assay (GW0210, CoWin Biotech Co., Ltd., Taizhou, Jiangsu). This assay had previously been validated in Chinese populations, with reported sensitivity and specificity exceeding 90% for both CLA and LVX resistance detection, compared with culture-based phenotypic methods.[7] Clarithromycin resistance was determined by identifying point mutations at positions 2142 and 2143 of the 23S rRNA gene (eg A2142G, A2142C, A2143G); the detection of any of these mutations was considered indicative of resistance. Levofloxacin resistance was evaluated by screening for mutations within the quinolone resistance-determining region of the gyrA gene, such as substitutions at codon Asn87 (eg Asn87→Lys/Thr); the presence of any such mutation was classified as resistance. Individualised eradication regimens were administered based on the CLA and LVX resistance profiles. Detailed instructions were provided regarding medication use and precautions. (3) Follow-up was conducted 1–3 days after the completion of eradication therapy to document adverse events and assess medication adherence. Between 4 and 8 weeks after treatment, patients were contacted via telephone and asked to undergo an RUT for eradication efficacy evaluation.

Treatment Regimens

All patients received an individualised bismuth-containing quadruple regimen for 14 days. Group allocation was strictly based on the results of molecular resistance testing, without physician discretion. Treatment groups were assigned according to *H. pylori* susceptibility to CLA and LVX. (1) The CLA-susceptible (CLA-S) group received: rabeprazole sodium enteric-coated capsules (20 mg, Hubei Jumpcan Pharmaceutical Co., Ltd.), 20 mg twice daily; compound bismuth aluminate granules (1.3 g per sachet, Liaoning Aoda Pharmaceutical Co., Ltd.), 1.3 g (1 sachet) 3 times daily; amoxicillin capsules (0.25 g, Zhejiang Jinhua CONBA Bio-Pharm Co., Ltd.), 1000 mg twice daily; CLA tablets (0.25 g, Shanghai Abbott Pharmaceutical Co., Ltd.), 500 mg twice daily. (2) The CLA-resistant and LVX-susceptible

(CLA-R-LVX-S) group received: rabeprazole sodium enteric-coated capsules (20 mg, Hubei Jumpcan Pharmaceutical Co., Ltd.), 20 mg twice daily; compound bismuth aluminate granules (1.3 g per sachet, Liaoning Aoda Pharmaceutical Co., Ltd.), 1.3 g (1 sachet) 3 times daily; amoxicillin capsules (0.25 g, Zhejiang Jinhua CONBA Bio-Pharm Co., Ltd.), 1000 mg twice daily; LVX tablets (0.25 g, Zhejiang Poly Pharm Co., Ltd.), 500 mg once daily. (3) The CLA-resistant and LVX-resistant (CLA-R-LVX-R) group received: rabeprazole sodium enteric-coated capsules (20 mg, Hubei Jumpcan Pharmaceutical Co., Ltd.), 20 mg twice daily; compound bismuth aluminate granules (1.3 g per sachet, Liaoning Aoda Pharmaceutical Co., Ltd.), 1.3 g (1 sachet), 3 times daily; amoxicillin capsules (0.25 g, Zhejiang Jinhua CONBA Bio-Pharm Co., Ltd.), 1000 mg twice daily; minocycline hydrochloride capsules (50 mg, HanHui Pharmaceuticals Co., Ltd.), 100 mg twice daily. The dosage of compound bismuth aluminate granules follows the product labelling and is consistent with the recommendations of the Chinese national consensus guidelines for *H. pylori* eradication.[17,21] In this group, minocycline was selected instead of tetracycline or furazolidone, which are recommended by the latest Chinese national consensus guidelines for multidrug-resistant *H. pylori* infection.[17,21] This choice was based on several considerations. First, recent studies have shown that minocycline maintains a low resistance rate and achieves favourable eradication efficacy in both treatment-naïve and rescue settings, as well as in multidrug-resistant cases. Second, compared with tetracycline, minocycline offers practical advantages, including broader availability, lower cost, and a more favourable adverse effect profile. However, it is important to note that minocycline is primarily bacteriostatic, and its widespread use carries the potential risk of inducing antimicrobial resistance. Therefore, in alignment with current evidence, minocycline-based regimens were reserved for patients with dual resistance to CLA and LVX in this study, and such an approach is generally more appropriate for rescue therapy, multidrug-resistant infections, or patients with an amoxicillin allergy, rather than as a routine first-line option.

Efficacy Evaluation

(1) Outcome measures: The primary endpoint was the *H. pylori* eradication rate. Both ITT and PP analyses were used to calculate eradication outcomes. (2) Calculation methods: The ITT eradication rate (%) was calculated as the number of patients with a negative ^{13}C-urea breath test divided by the total number of patients assigned to each treatment group × 100%. The PP eradication rate (%) was calculated as the number of patients with a negative ^{13}C-urea breath test divided by the number of patients who completed eradication therapy with at least 80% adherence and underwent post-treatment ^{13}C-urea breath testing × 100%. Patients who were lost to follow-up or withdrew before post-treatment testing were considered treatment failures in the ITT analysis. (3) Assessment of adherence was calculated as the percentage of medication actually taken relative to the prescribed dose. Adherence of ≥80% was considered acceptable; patients with adherence <80% were classified as poorly adherent and were excluded from the PP analysis.

Safety Assessment

Adverse events were monitored throughout the treatment period and at the follow-up visit (1–3 days post-treatment). All adverse events were recorded and graded according to the following criteria:

Mild

Symptoms (eg, transient nausea, bloating, diarrhoea, bitter taste) that were easily tolerated, caused no disruption of daily activities, and required no medical intervention.

Moderate

Symptoms (eg, persistent gastrointestinal discomfort, mild rash) that interfered with some daily activities and required symptomatic treatment (eg, antidiarrhoeals, antihistamines) but did not necessitate discontinuation of eradication therapy.

Severe

Symptoms that caused significant impairment of daily activities required specific medical treatment, or led to premature withdrawal from the study regimen.

Serious

Any adverse event that resulted in hospitalisation, life-threatening condition, persistent disability, or death (defined in accordance with ICH E6 Good Clinical Practice guidelines). The relationship of each adverse event to study medications was assessed by the attending physicians. The proportion of patients experiencing any adverse event, as well as the distribution by severity grade, was compared across the three treatment groups.

Statistical Analysis

All analyses were performed using SPSS 24.0 (IBM, Armonk, NY, USA). Data distribution was assessed using the Kolmogorov–Smirnov test for sample sizes ≥50. Normally distributed continuous data were presented as mean ± standard deviation ($\bar{x} \pm s$) and compared across groups using one-way analysis of variance. Categorical data were expressed as counts and percentages (n[%]), and intergroup comparisons were examined using the chi-square (χ^2) test. A P-value <0.05 was considered statistically significant. Sample size estimation was based on the study design involving 3 resistance-defined groups, namely, CLA-S, CLA-R-LVX-S, and CLA-R-LVX-R, and the primary endpoint of *H. pylori* eradication. Drawing on previous comparable clinical studies and local resistance patterns, we assumed expected eradication rates of approximately 85% in the CLA-S group, 80% in the CLA-R-LVX-S group, and 75% in the CLA-R-LVX-R group. A difference of 15% in eradication rates between any 2 groups was considered clinically meaningful. We set $\alpha = 0.05$ (two-sided) and statistical power at 80%. Allowing for an anticipated attrition rate of approximately 10%, the required total sample size was calculated to be no fewer than 220 participants.

Results

Baseline Data

A total of 232 patients were enrolled in the study (Figure 1). Based strictly on the results of molecular testing for CLA and LVX resistance, without clinician discretion, these participants were assigned to 3 treatment groups, namely, CLA-S, CLA-R-LVX-S, and CLA-R-LVX-R. All patients received an individualised 14-day bismuth-containing quadruple regimen according to susceptibility results. In the CLA-S group, 170 patients were included in the ITT analysis. In the

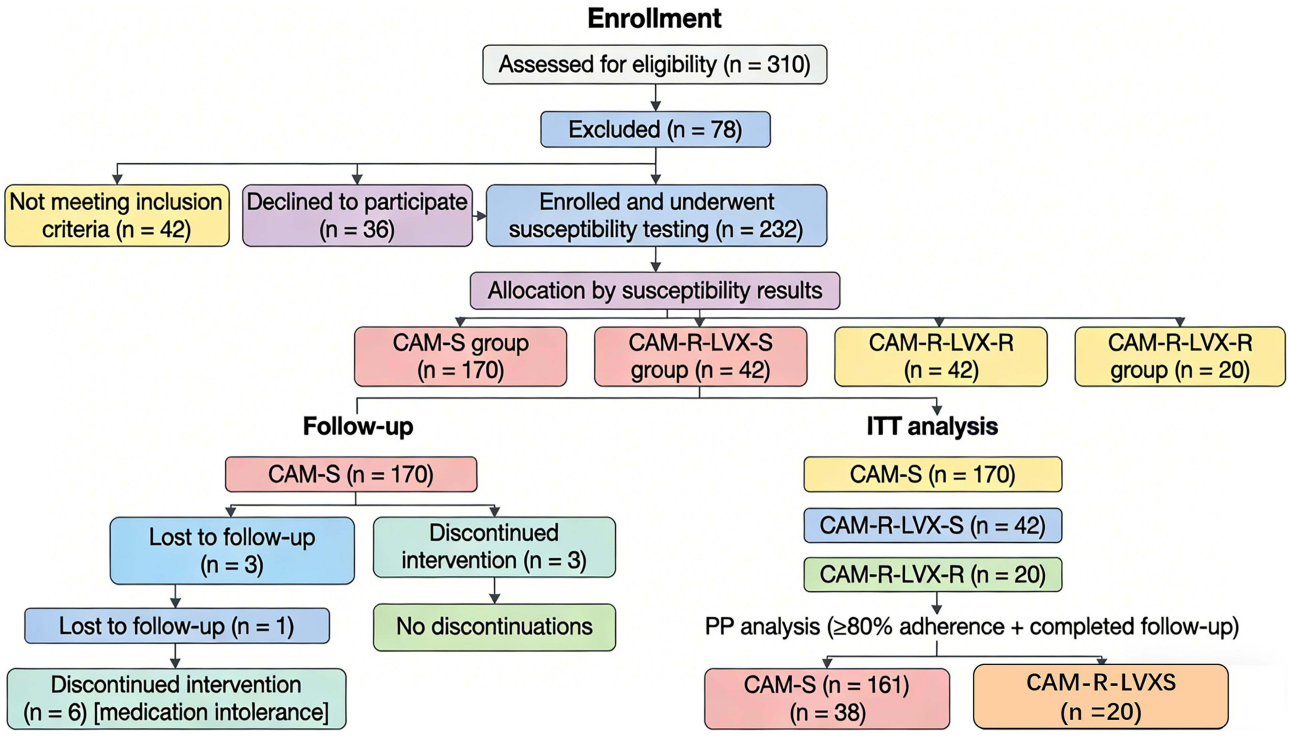

Figure 1 Patient enrollment, allocation, follow-up, and analysis flow diagram.

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CLA-R group, 62 patients underwent ITT analysis; 42 were classified as CLA-R-LVX-S and 20 as CLA-R-LVX-R. After treatment initiation, 9 patients in the CLA-S group were lost to analysis (3 lost to follow-up and 6 withdrawals, including medication intolerance cases), leaving 161 patients for PP analysis. In the CLA-R-LVX-S group, 4 patients dropped out (1 lost to follow-up and 3 withdrawals), and 38 were included in the PP analysis. No patients in the CLA-R-LVX-R group discontinued therapy; all 20 were included in the PP analysis. Across the 3 groups, there were no statistically significant differences in age (P = 0.307), sex composition (P = 0.791), smoking habits (P = 0.830), alcohol consumption (P = 0.517), or endoscopic diagnosis (peptic ulcer disease vs non-ulcer dyspepsia) (P = 0.775). Detailed baseline characteristics are presented in Table 1.

Comparison of Helicobacter pylori Eradication Rates

A total of 232 patients were included in the trial, and individualised eradication regimens were administered according to antimicrobial susceptibility results. Overall, 191 patients achieved successful eradication. Based on the ITT analysis, the overall *H. pylori* eradication rate was 82.3% (95% CI: 79.6–85.7%), with all patients lost to follow-up or withdrawn before efficacy assessment counted as eradication failures. In the PP analysis, 219 patients were evaluable, of whom 191 had eradicated results, yielding an eradication rate of 87.2% (95% CI: 82.1–91.2%). Eradication outcomes for the 3 groups are summarised in Table 2. In the ITT analysis, eradication rates were 81.8% (95% CI: 75.9–87.6%) for the CLA-S group, 83.3% (95% CI: 71.6–95.1%) for the CLA-R-LVX-S group, and 85.0% (95% CI: 67.9–96.4%) for the CLA-R-LVX-R group. Differences among groups were

Table 1 Comparison of Baseline Characteristics Among the Three Groups

Baseline Characteristics	CLA-S (n=170)	CLA-R-LEV-S (n=42)	CLA-R-LEV-R (n=20)	Statistic	*P*-value
Age (years, $\bar{x} \pm s$)	52.56±11.067	52.90±10.626	56.45±6.21	*F*: 1.187	0.307
Sex (male/female, n)	106/64	27/15	14/6	χ^2: 0.470	0.791
Smoking habits (yes/no, n)	32/138	11/31	3/17	χ^2: 0.373	0.830
Alcohol consumption (yes/no, n)	22/148	4/38	4/16	χ^2: 1.321	0.517
PUD/NUD (n)	52/118	11/31	5/15	χ^2: 0.511	0.775

Abbreviations: CLA-S, clarithromycin-susceptible group; CLA-R-LEV-S, clarithromycin-resistant and levofloxacin-susceptible group; CLA-R-LEV-R, clarithromycin-resistant and levofloxacin-resistant group; n, number of patients in each group; PUD, peptic ulcer disease; NUD, non-ulcer dyspepsia.

Table 2 Comparison of *H. pylori* Eradication Rates Among the Three Groups

Parameter	CLAS	CLA-R-LEV-S	CLA-R-LEV-R
ITT analysis			
Total cases	170	42	20
Successful eradication cases	139	35	17
Eradication rate (%)	81.8	83.3	85.0
95% CI	75.9–87.6%	71.6–95.1%	67.9–96.4%
Statistic	χ^2 = 0.164		
P-value	0.921		
PP analysis			
Total cases	161	38	20
Successful eradication cases	139	35	17

(*Continued*)

Table 2 (Continued).

Parameter	CLAS	CLA-R-LEV-S	CLA-R-LEV-R
Eradication rate (%)	86.3	92.1	85.0
95% CI	81.0–91.7%	83.1–97.8%	62.1–96.4%
Statistic	χ^2 = 1.015		
P-value	0.602		

Abbreviations: CLAS, clarithromycin-susceptible group; CLA-R-LEV-S, clarithromycin-resistant and levofloxacin-susceptible group; CLA-R-LEV-R, clarithromycin-resistant and levofloxacin-resistant group; ITT, intention-to-treat; PP, per-protocol; 95% CI, 95% confidence interval.

not statistically significant (χ^2 = 0.164, P = 0.921). In the PP analysis, eradication rates were 86.3% (95% CI: 81.0–91.7%) (CLA-S), 92.1% (95% CI: 83.1–97.8%) (CLA-R-LVX-S), and 85.0% (95% CI: 62.1–96.4%) (CLA-R-LVX-R), respectively, again without statistically significant differences (χ^2 = 1.015, P = 0.602). The 95% CIs for the CLA-R-LVX-R group were substantially wider than those for the other 2 groups, reflecting the limited sample size (n = 20) and reduced precision of the eradication rate estimate in this subgroup. As noted in the sample size estimation, the study was primarily powered to estimate overall eradication rates and to allow comparisons across groups under balanced allocation. Due to the small sample size of the dual-resistant subgroup (n = 20), however, the subgroup comparisons were underpowered. Consequently, the absence of statistically significant differences should not be interpreted as evidence of equivalence among the 3 treatment groups.

To explore whether clinical or demographic factors influenced eradication success, we performed multivariable logistic regression analysis within each treatment group. Variables included age, sex, smoking habits, alcohol consumption, and endoscopic diagnosis (peptic ulcer disease vs non-ulcer dyspepsia). In the CLA-S group, none of these factors were significantly associated with eradication success (all P > 0.05). Similarly, in the CLA-R-LVX-S and CLA-R-LVX-R groups, no independent predictors were identified, likely due to the limited sample size and the high eradication rates achieved. These findings suggest that within the context of susceptibility-guided therapy, eradication outcomes were primarily driven by the appropriateness of antibiotic selection rather than by baseline demographic or clinical characteristics.

Safety and Adherence

The safety and adherence results are shown in Tables 3 and 4. The adverse reaction rate was comparable across the 3 groups: 19.9% in the CLA-S group, 21.1% in the CLA-R-LVX-S group, and 15.0% in the CLA-R-LVX-R group. These differences were not statistically significant (χ^2 = 0.327, P = 0.849). A detailed breakdown of adverse events by type and severity is presented in Table 4. In terms of severity, mild adverse events occurred in 26 patients (16.1%) in the CLA-S group, 6 patients (15.8%) in the CLA-R-LVX-S group, and 3 patients (15.0%) in the CLA-R-LVX-R group. Moderate adverse events were observed in 6 patients (3.7%) in the CLA-S group and 2 patients (5.3%) in the CLA-R-LVX-S group, with none in the CLA-R-LVX-R group. No severe or serious adverse events were reported across any treatment group. Most of the reported adverse reactions were mild gastrointestinal symptoms, such as nausea, bloating, diarrhoea, or a bitter taste in the mouth. Occasional cases of headache or rash were observed. No serious adverse events were observed. Treatment adherence was also similar across groups. The proportion of patients achieving adequate adherence was 93.2% in the CLA-S group, 94.7% in the CLA-R-LVX-S group, and 100% in the CLA-R-LVX-R group, with no statistically significant differences (χ^2 = 1.525, P = 0.467).

Antibiotic Resistance Rates

Among the 232 patients included in the study, 62 harboured CLA-R strains (62/232), and 67 carried LVX-R strains (67/232). Dual resistance to both CLA and LVX was detected in 20 patients (20/232). The corresponding resistance rates were 26.7%, 28.8%, and 8.6%, respectively.

Table 3 Comparison of Treatment Safety and Adherence Among the Three Groups

Parameter	CLA-S	CLA-R-LEV-S	CLA-R-LEV-R
Safety			
Total cases	161	38	20
Adverse reaction cases	32	8	3
ARR (%)	19.9%	21.1%	15.0%
95% CI	0.136–0.261	0.075–0.346	0.021–0.321
Statistic	$\chi^2 = 0.327$		
P-value	0.849		
Adherence			
Total cases	161	38	20
Low adherence cases	11	2	0
Adherence rate (%)	93.2	94.7	100
95% CI	89.2%-97.1%	87.3%-99.2%	99.0%-100%
Statistic	$\chi^2 = 1.525$		
P-value	0.467		

Abbreviations: CLAS, clarithromycin-susceptible group; CLA-R-LEV-S, clarithromycin-resistant and levofloxacin-susceptible group; CLA-R-LEV-R, clarithromycin-resistant and levofloxacin-resistant group; ARR, adverse reaction rate; 95% CI, 95% confidence interval.

Table 4 Adverse Events by Type and Severity Among the Three Groups

Adverse Event	CLA-S (n = 161)	CLA-R-LEV-S (n = 38)	CLA-R-LEV-R (n = 20)
Mild	26 (16.1%)	6 (15.8%)	3 (15.0%)
–Nausea	12	3	2
–Bloating	8	2	1
–Diarrhea	4	1	0
–Bitter taste	2	0	0
Moderate	6 (3.7%)	2 (5.3%)	0 (0%)
–Persistent GI discomfort	4	1	0
–Rash	2	1	0
Severe	0 (0%)	0 (0%)	0 (0%)

Notes: Severity grading: mild = symptoms that did not require medical intervention; moderate = symptoms that required symptomatic treatment; severe = symptoms that required treatment discontinuation or hospitalization.
Abbreviations: CLAS, clarithromycin-susceptible group; CLA-R-LEV-S, clarithromycin-resistant and levofloxacin-susceptible group; CLA-R-LEV-R, clarithromycin-resistant and levofloxacin-resistant group; ARR, adverse reaction rate; 95% CI, 95% confidence interval; GI, gastrointestinal.

Discussion

Helicobacter pylori infection has emerged as a major global public health concern. Epidemiological surveys in China indicate an infection rate of approximately 56.22% among the general population.[11] Although combination regimens for *H. pylori* eradication have been refined over recent years, clinical eradication rates have not improved to the degree once anticipated. Multiple studies have documented a steady rise in resistance to CLA, metronidazole, and quinolones. This

increase has markedly undermined the efficacy of empirical regimens. A surveillance study and systematic review involving 14 hospitals across 9 provinces reported that CLA resistance could lower the eradication rate of triple therapy by nearly 40%; in cases with dual resistance, eradication rates fell below 40%. Extending treatment duration offered only limited compensation for the loss of efficacy associated with resistance.[12] Domestic clinical data show that the guideline-recommended empirical bismuth-containing or non-bismuth quadruple regimens achieve eradication rates of roughly 79.8–86.67% in treatment-naïve *H. pylori*-positive cases.[13]

The eradication rate of CLA-containing quadruple therapy has declined from 95% to 80% globally and from 89% to 78% in China.[14] In 2017, the World Health Organization designated CLA-R *H. pylori* as a high-priority pathogen requiring new antibiotic development. Given the protracted timeline and substantial costs associated with launching new agents, it is particularly important to ensure a high first-line eradication rate.[15] Against this backdrop, susceptibility-guided individualised therapy has gained broad consensus as a rational and effective strategy. Malfertheiner et al[16] along with the Fifth Chinese National Consensus Report on the Management of *Helicobacter pylori* Infection,[17] advocate for precision treatment with improved eradication outcomes.

Resistance of *H. pylori* to commonly prescribed antibiotics in China has shown a consistent upward trend in recent years.[18–20] Therefore, current clinical guidelines recommend prioritising the assessment of CLA susceptibility in regions where resistance rates exceed 15%. The Maastricht VI/Florence consensus further stipulates that, even in treatment-naïve patients, CLA-containing eradication therapy should only be initiated after confirming *H. pylori* susceptibility through molecular diagnostics or susceptibility testing.[16] Additionally, LVX, a representative quinolone, also plays a crucial role in *H. pylori* eradication therapy. Resistance to LVX is strongly associated with mutations in the gyrA gene, whereas CLA resistance is primarily driven by point mutations in the 23S rRNA gene. Notably, there is a high level of concordance between genotypic alterations and phenotypic resistance for both agents.[22] Drawing on this relationship, the detection of resistance-associated mutations can reliably predict antimicrobial susceptibility and thereby inform individualised treatment strategies for patients with an *H. pylori* infection. The Sixth Chinese National Consensus Report on Management of *Helicobacter pylori* Infection (Treatment Excluded)[21] explicitly recognises the clinical value of testing for CLA- and LVX-resistance genes in guiding eradication therapy.[21] Commercially available assays for detecting these resistance-conferring mutations demonstrate sensitivities and specificities exceeding 90% for both CLA and LVX resistance.[23]

In the present study, molecular diagnostic techniques were employed to detect *H. pylori* infection and associated antibiotic resistance. Following that, patients were administered individualised eradication regimens. The overall eradication rate was 82.3% in the ITT analysis and 87.2% in the PP analysis. Among patients harbouring CLA-susceptible strains, the eradication rate reached 86.3%. In contrast, within the CLA-resistant cohort, eradication rates were 92.1% for the CLA-R-LVX-S subgroup and 85.0% for the CLA-R-LVX-R subgroup. Across patient groups demonstrating full susceptibility, single-drug resistance, or dual-drug resistance, eradication rates consistently exceeded 85%, with no statistically significant differences between groups. These findings suggest that susceptibility testing offers tangible advantages in clinical practice. A clinical study conducted in South Korea evaluated the effectiveness of susceptibility-guided individualised therapy as a first-line treatment for *H. pylori* infection in regions with substantial antibiotic resistance. The reported eradication rates were 93.1% in the ITT analysis and 100.0% in the PP analysis, significantly outperforming those achieved with sequential therapy.[24] In addition to its impressive performance in eradicating resistant strains, susceptibility testing has also demonstrated value in rescue therapy. In a retrospective analysis of 361 patients with an *H. pylori* infection, 111 received initial treatment, while 150 underwent rescue therapy. Individualised antibiotic selection within bismuth-containing quadruple regimens was guided by the molecular detection of resistance-associated gene mutations. Eradication rates exceeded 90% in both primary and rescue settings, confirming the reliability of resistance gene testing in terms of informing individualised treatment strategies in the clinical context.[25] Consistent with these observations, a randomised controlled trial conducted by Chen et al[26] showed no significant difference in efficacy between molecular testing- and susceptibility-guided precision treatment as either a first-line or rescue therapy. In first-line eradication, *H. pylori* infection was successfully cleared in 241 of 280 patients (86%) in the molecular testing-guided group and in 243 of 280 patients (87%) in the susceptibility-guided group (P = 0.81).

While domestic and international studies have largely reported susceptibility-guided eradication rates exceeding 90%,[27,28] the overall rate in the present study was approximately 85%, which is lower than previously reported levels. This difference may be attributed to two main factors. First, the limited sample size—particularly for resistant strains (only 62 patients harboured CLA-R isolates, and just 20 exhibited dual resistance to CLA and LVX)—reduces the robustness of the observed eradication rates and precludes precise subgroup estimates or meaningful comparisons across resistance categories. Second, suboptimal treatment adherence may have contributed to the lower efficacy. Adequate adherence is a prerequisite for successful eradication; in this study, adherence rates were 93.2% in the CLA-S group, 94.7% in the CLA-R-LVX-S group, and 100% in the CLA-R-LVX-R group. The fact that adherence in the first two groups did not reach 95% may partly reflect local educational or sociocultural factors. Therefore, targeted patient education and structured follow-up could play a meaningful role in improving adherence.

Our findings indicate that in the Huairou district, resistance rates of *H. pylori* to CLA and LVX were 26.7% and 28.8%, respectively, and the dual resistance rate was 8.6%. A meta-analysis of antimicrobial resistance among Chinese adults carrying *H. pylori* has shown a sustained decline in eradication success over the past two decades, primarily attributable to the rising prevalence of antibiotic resistance. The increasing resistance is particularly evident to CLA and LVX, which are widely used in eradication regimens. Specifically, CLA resistance increased from 13.7% during 2000–2005 to 31.0% in 2016–2021, while LVX resistance rose from 8.0% to 33.1% over the same period.[29] The observed resistance rates in Huairou, while broadly consistent with national trends, warrant consideration of region-specific drivers. Several factors may contribute to these patterns. First, as a mountainous district in northern Beijing, Huairou has historically had a relatively high prevalence of *H. pylori* infection, which may be associated with lower socioeconomic status, crowded living conditions, and limited access to clean water sources in rural areas—factors that facilitate both infection transmission and repeated antibiotic exposures. Second, antibiotic prescribing patterns in community-based healthcare settings may differ from those in urban tertiary hospitals. In Huairou, primary care facilities often serve as the first point of contact for patients with upper gastrointestinal symptoms, and the empirical use of macrolides and fluoroquinolones for respiratory or urinary tract infections remains common. Such prior antibiotic exposure is a well-established risk factor for acquired resistance in *H. pylori*. Third, the availability of non-prescription antibiotics in retail pharmacies, although formally regulated, continues to be reported in some peri-urban and rural areas, potentially contributing to selective pressure on resistance. Fourth, patient-level factors, including lower health literacy and inconsistent treatment adherence in prior unrelated infections, may further shape the local resistance landscape. Collectively, these socioeconomic and healthcare delivery factors likely interact to produce the resistance profile observed in this study. Future research incorporating detailed antibiotic exposure histories and prescribing audits could help clarify the relative contributions of these drivers. In patients with a refractory *H. pylori* infection, antibiotic resistance is a principal determinant of eradication failure. Given the relatively high resistance rates to both CLA and LVX observed in the Huairou region, the empirical use of these agents should, in principle, be preceded by susceptibility testing to optimise eradication outcomes.

In summary, the eradication efficacy of conventional quadruple therapy comprising a PPI, 2 antibiotics, and bismuth is prone to fluctuations driven by antibiotic resistance. Eradication rates across resistance-defined subgroups in the per-protocol analysis ranged from 85.0% to 92.1%, with corresponding ITT rates ranging from 81.8% to 85.0%, and no significant intergroup differences were observed in either analysis. Susceptibility testing also reduces unnecessary drug exposure and repeat treatments, thereby alleviating the financial burden on patients. More importantly, susceptibility-guided antibiotic use can effectively reduce inappropriate prescribing and help slow the spread of resistant strains, aligning closely with the global public health strategy of rational antibiotic use. Nevertheless, the broader implementation of molecular susceptibility testing in primary care settings faces several practical challenges. First, the required real-time PCR instrumentation and dedicated laboratory space may not be readily available in many community-based or rural healthcare facilities, which constitute the frontline of dyspepsia management in regions such as Huairou. Second, the per-test cost in China currently ranges from approximately RMB300 to RMB500, which, while decreasing with technological advances, remains non-trivial compared with the cost of empirical quadruple therapy (typically from RMB200 to RMB300 per course). Although susceptibility-guided therapy may reduce the downstream costs associated with repeated treatment failures, the upfront expenditure poses a barrier in resource-limited settings. Third, reimbursement policies vary

considerably across regions, and in many areas, molecular resistance testing is not yet covered by basic medical insurance, limiting patient access. From a health system perspective, the cost-effectiveness of susceptibility-guided therapy depends on the local prevalence of antibiotic resistance: in settings where resistance to first-line agents exceeds the 15–20% threshold, the strategy becomes increasingly favourable. For regions with lower resistance rates, empirical therapy may remain a pragmatic and economically attractive option. Future implementation efforts should therefore consider tiered diagnostic algorithms, centralised testing models to reduce per-unit costs, and integration with routine gastroscopy services to streamline workflows. As molecular technologies continue to evolve toward point-of-care formats, their scalability in primary care is likely to improve, potentially enabling broader adoption in diverse healthcare settings. With ongoing advances in molecular susceptibility testing, particularly the detection of resistance-associated genetic mutations, such approaches are increasingly likely to become non-invasive, rapid, and cost-effective. From laboratory diagnostics to clinical application, and from individualised care to population-level management, susceptibility testing holds value across the entire continuum of *H. pylori* prevention and control. As technologies mature and clinical pathways evolve, susceptibility testing shows great promise to transition from a specialised option to a routine standard, offering a China-derived model for global gastric cancer prevention. Accordingly, healthcare institutions, if feasible, are encouraged to integrate testing for CLA and LVX resistance-associated genes with clinical decision-making to better inform eradication regimen selection.

The overall ITT eradication rate of 82.3% observed in this study warrants further clinical interpretation. While the 90% eradication threshold is widely cited as a benchmark for acceptable empirical therapy in regions with low antimicrobial resistance, its applicability to settings with moderate-to-high resistance is less straightforward. In the present study, the local resistance rates to CLA and LVX were 26.7% and 28.8%, respectively—levels that would substantially compromise the efficacy of empirical regimens containing these agents. Indeed, previous studies have shown that CLA resistance can reduce the eradication rate of triple therapy by nearly 40%, and in cases with dual resistance, eradication rates fell below 40%.[12] Against this backdrop, the 82.3% ITT eradication rate achieved with susceptibility-guided therapy in this study represents a clinically meaningful outcome. Moreover, the PP eradication rates across all resistance-defined subgroups ranged from 85% to 92%, with no significant differences between groups, indicating that individualised treatment can stabilise eradication outcomes even in the presence of single or dual resistance. From a clinical perspective, achieving eradication rates consistently above 80% in a region with previously uncharacterised resistance patterns (and doing so while avoiding unnecessary antibiotic exposure) represents a valuable step towards evidence-based, region-adapted *H. pylori* management. Importantly, this study provides the first baseline data for Huairou, enabling future comparisons and guiding empirical choices when susceptibility testing is not available.

Several limitations of this study should be acknowledged. First, as a single-centre investigation, the findings may reflect regional characteristics and may not be fully generalisable. Second, this study employed a single-arm design without an empirical therapy control group. While we observed clinically acceptable eradication rates, based on established guideline benchmarks, this design does not permit direct comparative conclusions regarding the superiority or non-inferiority of susceptibility-guided therapy relative to empirical regimens. Third, while the total sample size (n = 232) met the prespecified requirement for overall eradication rate estimation, the modest sample size in the CLA-R cohort—particularly the dual-resistant subgroup (n = 20)—means that subgroup comparisons are underpowered. Therefore, the lack of statistically significant differences among the 3 resistance-defined groups should not be interpreted as evidence of therapeutic equivalence. Larger, multicentre studies with more balanced group allocation are needed to enhance the robustness of subgroup analyses. Fourth, while the molecular assay used for resistance detection had been validated in prior studies with high sensitivity and specificity, dedicated local validation against culture-based phenotypic susceptibility testing was not performed in this population. Future studies incorporating parallel culture-based testing would further strengthen the reliability of resistance detection in this region. Finally, given that all patients in this study underwent individualised treatment, future randomised controlled trials comparing empirical therapy with susceptibility-guided individualised regimens are warranted to better support *H. pylori* management in primary healthcare settings across the northern suburbs of Beijing. Additionally, while the molecular assay used in this study had previously been validated against culture-based phenotypic susceptibility testing in Chinese populations with reported sensitivity and specificity exceeding 90%,[23] no parallel comparison between genotypic resistance (based on 23S rRNA and gyrA

mutations) and phenotypic resistance (by culture-based drug susceptibility testing) was performed within the enrolled population of this study. Consequently, the concordance between genotype and phenotype in the specific Huairou cohort remains uncharacterised. Although the commercial assay employed is widely used in clinical practice in China and has demonstrated robust performance in prior multicentre evaluations, the absence of local validation may introduce a degree of uncertainty in resistance classification, particularly for cases with atypical mutation patterns or mixed infections. Future studies conducted in this region should consider incorporating parallel phenotypic susceptibility testing to further substantiate the accuracy of molecular resistance detection and to better characterise the genotype–phenotype concordance in local *H. pylori* isolates.

Conclusion

This single-arm, prospective observational study demonstrates that susceptibility-guided, individualised bismuth-containing quadruple therapy achieved clinically acceptable *H. pylori* eradication rates (ITT: 82.3%; PP: 87.2%) in Huairou District, Beijing, a region with moderate-to-high CLA (26.7%) and LVX (28.8%) resistance and no previously reported resistance data. Eradication rates across resistance-defined subgroups in the PP analysis ranged from 85.0% to 92.1%, with corresponding ITT rates ranging from 81.8% to 85.0%, and no significant intergroup differences were observed in either analysis. However, several important limitations constrain the interpretation and generalisability of these findings. Moreover, the study was not designed to assess the cost-effectiveness or operational feasibility of integrating molecular susceptibility testing into primary care settings, which remain critical considerations for broader implementation. Accordingly, while the findings support the utility of susceptibility-guided therapy as a viable strategy in regions with elevated antimicrobial resistance, they should not be interpreted as establishing superiority over empirical regimens or as evidence that such testing is ready for routine application across diverse healthcare contexts. Future randomised controlled trials with larger, more balanced cohorts and formal health economic evaluations are warranted to further inform evidence-based, region-adapted *H. pylori* management.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Beijing Huairou Hospital, Approval ID: J.H.L.K.Zi[2023]No.[004]-01. Written informed consent was obtained from all participants.

Consent for Publication

The manuscript is not submitted for publication or consideration elsewhere.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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