INPLASY

Non-inferiority study of Ilaprazole combined with Amoxicillin dual therapy versus quadruple therapy for Helicobacter pylori eradication:a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Not applicable.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 August 2025 and was last updated on 25 August 2025.

INTRODUCTION

Review question / Objective To compare the efficacy and safety of Ilaprazole combined with Amoxicillin dual therapy (IA) and bismuth quadruple therapy (BQT) in eradicating Helicobacter pylori (H. pylori).

Condition being studied Helicobacter pylori (H. pylori) is a Gram-negative bacterium with a global prevalence of approximately 50%. H. pylori infection is closely associated with a spectrum of gastrointestinal disorders, including chronic gastritis, peptic ulcer disease (PUD), gastric mucosa-associated lymphoid tissue (MALT) lymphoma, and even gastric cancer. Eradication of H. pylori not only serves as a crucial strategy for preventing gastric cancer development but also represents a key therapeutic intervention for improving functional dyspepsia (FD) and preventing PUD recurrence. Currently, bismuth-containing quadruple therapy is the first-line treatment regimen for H. pylori infection. However, the requirement for multiple medications in this regimen leads to an increased incidence of adverse events and poor patient adherence. Ilaprazole, a new-generation proton-pump inhibitor (PPI), exhibits rapid onset of action, potent acid-suppressive effects, a long half-life, and minimal susceptibility to cytochrome CYP2C19 genetic polymorphism. Owing to these favorable pharmacokinetic and pharmacodynamic profiles, Ilaprazole has been recommended for H. pylori eradication therapy. Several studies have demonstrated the efficacy of Ilaprazole-amoxicillin dual therapy (IA dual therapy) in treating H. pylori infection. Nevertheless, controversies and uncertainties remain regarding its practical effectiveness as a first-line treatment option. Therefore, the present Meta-analysis was conducted to compare the efficacy and safety of the IA dual therapy regimen versus the bismuth-containing quadruple therapy regimen, with the aim of providing evidence-based references for clinical practice.

METHODS

Participant or population Study participants and treatment duration: Patients aged >14 years with

Helicobacter pylori (H. pylori) infection confirmed by 13C-urea breath test (13C-UBT), with a 14-day treatment course.

Intervention Ilaprazole-amoxicillin dual therapy regimen (IA dual therapy regimen).

Comparator Bismuth-containing quadruple therapy regimen (BQT regimen) recommended by current guidelines.

Study designs to be included Randomized controlled trial (RCT).

Eligibility criteria Duplicate publications.

Information sources The databases of China National Knowledge Infrastructure (CNKI), Wanfang Data, China Science and Technology Journal Database (VIP), Chinese biomedical literature service system (SinoMed), Pubmed, Embase, Cochrane Library and Web of Science.

Main outcome(s) The Ilaprazole-amoxicillin dual therapy regimen (IA dual therapy regimen) demonstrates superior efficacy and higher safety compared with the bismuth-containing quadruple therapy regimen (BQT regimen). Based on the current research evidence, the IA dual therapy regimen is supported for Helicobacter pylori (H. pylori) eradication therapy, with a recommended treatment course of 14 days.

Quality assessment / Risk of bias analysis In this study, the Cochrane Risk of Bias Assessment Tool was used to systematically evaluate the risk of bias of the included studies. The main evaluation items included: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, completeness of outcome data, selective reporting of results, and other potential sources of bias.

Strategy of data synthesis Meta-analysis was performed using RevMan 5.4. Heterogeneity testing was conducted for the included studies: if $P > 0.10$ and $I2 \leq 50\%$, low heterogeneity was indicated, and a fixed-effects model was selected; if $P \leq 0.10$ and $I2 > 50\%$, high heterogeneity was determined, and a random-effects model was chosen. The outcome measures were dichotomous variables, and statistical analysis was performed using relative risk (RR) and 95% confidence interval (CI), including Helicobacter pylori (H. pylori) eradication rate, adverse event rate, and adherence rate. $P < 0.05$ was considered statistically significant.

Subgroup analysis No subgroup analysis was performed.

Sensitivity analysis In this study, sensitivity analysis was performed using the one-by-one exclusion method, and all results showed good stability.

Country(ies) involved China.

Keywords Ilaprazole; Amoxicillin; Helicobacter pylori; Meta-analys.

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