Microb Health Dis 2025; 7: e1442

Microbiota in Health and Disease
A Journal of the European Helicobacter & Microbiota Study Group

European Helicobacter & Microbiota Study Group

TREATMENT OF *HELICOBACTER PYLORI* INFECTION

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Abstract – *Helicobacter pylori* eradication strategies continue to adapt in response to increasing antimicrobial resistance. Among traditional regimens, bismuth-based quadruple therapy remains the most consistently effective first-line treatment, with registry data and randomized trials demonstrating eradication rates of over 90%, particularly when delivered as a single-capsule formulation. Clarithromycin-based triple therapy remains viable in select cases with confirmed susceptibility but underperforms in empirical use. The emergence of potassium-competitive acid blockers, notably vonoprazan, offers a compelling alternative to proton pump inhibitors, showing high efficacy when combined with dual, triple and quadruple regimens. These combinations frequently demonstrate non-inferiority to longer or more complex therapies. Adjunctive probiotic use continues to improve treatment tolerability and microbiota recovery. Overall, bismuth-based quadruple therapy and potassium-competitive acid blocker-containing regimens represent the most robust empiric options, with regional resistance patterns and tailored approaches remaining critical to optimizing patient outcomes.

Keywords: Treatment, *Helicobacter pylori*.

INTRODUCTION

Helicobacter pylori remains a major global pathogen implicated in peptic ulcer disease, gastric cancer, and MALT lymphoma. Rising antimicrobial resistance continues to compromise eradication success, driving the need for optimised, evidence-based treatment strategies. Over the past year, substantial progress has been made across traditional regimens, with updated guidelines endorsing bismuth-based quadruple therapy and tailored approaches in high-resistance settings. Potassium-competitive acid blockers (PCABs), particularly vonoprazan, have further reshaped first-line and rescue therapies. Concurrently, emerging data support the use of adjunctive probiotics, novel antibacterial agents, and pre-clinical innovations targeting biofilms and resistance mechanisms. This review synthesises recent clinical and translational research to guide contemporary *H. pylori* management.

METHODS

A systematic literature search was conducted to identify studies published between March 2024 and March 2025 reporting on treatment strategies for *Helicobacter pylori* infection. PubMed was searched using the following predefined search terms:

((((*Helicobacter pylori*[Title]) OR (*H. pylori*[Title])) AND ((Quadruple[Title]) OR (Dual[Title]) OR (Triple[Title]) OR (Treatment[Title]) OR (Outcome[Title]) OR (vonoprazan[Title]) OR (trial[Title]) OR (sequential[Title]) OR (Concomitant[Title]) OR (individualized[Title]) OR (rescue[Title]) OR

(refractory[Title]) OR (failure[Title]) OR (probiotic[Title]) OR (therapy[Title]) OR (compliance[Title]) OR (PROTON PUMP INHIBITOR[Title]) OR (COMPETITIVE ACID BLOCKERS[Title]) OR (Hybrid[Title]))))).

The search returned a total of 229 articles. All titles and abstracts were independently screened for relevance using Covidence systematic review management software. Following this initial screening, 212 articles were deemed appropriate to the topic and progressed to full-text review. After full-text assessment, 107 studies were approved by the authors for final inclusion in this review.

RECENT CLINICAL GUIDELINES FOR THE MANAGEMENT OF *HELICOBACTER PYLORI* INFECTION

Several updated clinical guidelines published in the past year reflect a global shift towards more tailored, evidence-based management of *Helicobacter pylori* infection, driven by rising antimicrobial resistance. The 2024 American College of Gastroenterology (ACG) guideline recommends 14-day bismuth quadruple therapy (BQT) as first-line treatment, with rifabutin triple therapy or PCAB-amoxicillin dual therapy as alternatives where available, while also discouraging clarithromycin- or levofloxacin-containing regimens unless susceptibility is confirmed[1]. The Second Irish *Helicobacter pylori* Working Group Consensus[2] similarly advises restricting clarithromycin triple therapy to cases with confirmed susceptibility, recommending 14-day BQT as first-line treatment. With Levofloxacin, amoxicillin -based quadruple therapy regimens suggested as second line, and rifabutin triple therapy for rescue, with non-invasive testing preferred for diagnosis and eradication confirmation[2]. In children, updated ESPGHAN/NASPGHAN guidelines discourage routine testing except for peptic ulcer disease or refractory iron deficiency anaemia, recommend endoscopy with biopsy for diagnosis to support susceptibility-guided therapy or BQT in the absence of susceptibility data[3].

TRADITIONAL THERAPIES FOR *HELICOBACTER PYLORI* INFECTION

Quadruple Therapy

Bismuth-based quadruple therapy (BQT) is now recommended as first-line therapy in regions with high or unknown clarithromycin resistance, as outlined in the Maastricht VI/Florence consensus. Data from the Hp-EuReg (n=15,582) confirmed that only single-capsule BQT consistently achieved eradication rates >90% across all European regions, emphasizing the importance of simplified regimens[4]. An Italian RCT (n=84) found no significant difference between single capsule Bismuth Quadruple Therapy and concomitant therapy (95.6% *vs.* 100%, p=0.56)[5]. In Belgium, a multicentre RCT (n=250) comparing BQT and 14-day Triple therapy showed no significant difference in eradication (73% *vs.* 68%, p=0.54)[6].

Multiple randomized controlled trials (RCTs) support the efficacy of BQT. In a Chinese multicenter RCT (n=1300), vonoprazan-based BQT regimens achieved eradication rates of more than 91[7]. A Taiwanese RCT showed that traditional BQT achieved 92.4-92.9% eradication by ITT and >97% by PP analyses, confirming non-inferiority between 10- and 14-day courses[8]. Another Chinese RCT comparing cefuroxime-tetracycline to cefuroxime-levofloxacin BQT regimens found superior efficacy with tetracycline (90.3% *vs.* 81.5%, p=0.045)[9]. High-dose amoxicillin did not improve outcomes in a Tunisian trial[10], and reduced tetracycline dosing schedules were confirmed non-inferior in additional studies[11-13]. Two meta-analyses concluded that 14-day BQT regimens are most effective, though 10-day regimens may offer comparable efficacy depending on the antibiotic combination[14,15]. Retrospective studies from Asia have demonstrated eradication rates of 87-94% using modified BQT protocols incorporating minocycline, levofloxacin, amoxicillin, or doxycycline[16-18]. Dispersible clarithromycin also demonstrated superior eradication compared to sustained-release formulations[19]. Retrospective LEGACy registry data from South America (n=772) demonstrated significantly higher eradication with quadruple therapies (88.7-91.3%) compared to triple therapies (75.2%)[20]. Romanian and Saudi Arabian studies also confirmed higher eradication with BQT compared to levofloxacin-based triple ther-

apy, particularly with 14-day durations[21,22]. Slovenian registry data showed improvements in triple therapy efficacy with high-dose PPI and extended durations (94% eradication with 14-day triple therapy) and excellent results with BQT (up to 100% eradication)[23]. In Alberta, Canada, first-line BQT consistently outperformed other regimens, while rifabutin-based rescue therapy achieved 50-57% success rates[24]. These data confirm BQT as an effective and adaptable regimen, with duration, antibiotic selection, and simplicity as key factors for success.

Triple Therapy

Although current guidelines favor quadruple therapy, clarithromycin-containing triple therapy remains in use in many regions. An observational study in Colombia (n=67) reported an overall eradication rate of 81.2%, which significantly increased to 95.6% in clarithromycin-susceptible strains and fell to 42.8% in resistant strains (p=0.001), demonstrating the critical impact of resistance profiling on treatment outcomes in high resistance regions[25]. Similar eradication rates were noted in retrospective studies from Ethiopia, Saudi Arabia, and the USA, ranging from 77.4% to 85.5%[26-28]. Historical data from Latin America support these findings, with a meta-analysis of 11 studies (1995-2013) reporting eradication rates between 78.3% and 90.6%, though these are likely no longer reflective of current resistance patterns[29]. Comparative studies of triple therapy included an Iranian RCT that compared omeprazole-amoxicillin-clarithromycin, omeprazole-amoxicillin-levofloxacin, and omeprazole-amoxicillin-metronidazole-bismuth, reporting eradication rates of 82.2%, 91.3%, and 97.3%[30]. Notably, a novel 7-day triple therapy regimen using amoxicillin 1 g BID, gemifloxacin 320 mg OD, and rabeprazole 20 mg BID achieved 88.7% eradication in a Turkish cohort[31]. However, except in clarithromycin-susceptible subgroups, no triple therapy regimen reliably surpasses the 90% eradication benchmark, supporting the recommendation for the widespread usage of bismuth-based quadruple therapies.

Dual Therapy

High-dose dual therapy (HDDT), consisting of a high dose combination of an antibiotic, most often amoxicillin, and a proton pump inhibitor, has re-gained attention due to its simplicity and favorable safety profile, although its efficacy remains widely varied. A Vietnamese observational study (n=82) showed ITT and PP eradication rates of 76.8% and 81.8%, with first-line therapy performing better than rescue therapy (86.0% *vs.* 70.0%)[32]. A meta-analysis of 16 studies (n=6255) found eradication rates comparable to other regimens (OR = 0.92, 95% CI: 0.67-1.26), but with significantly fewer adverse events (OR = 0.42, p = 0.00004)[33]. A large Southeast Asian network meta-analysis (79 studies, 29,903 patients) ranked rifabutin- or hybrid therapies as the most effective regimens, while it ranked HDDT the safest and associated with the lowest incidence of serious adverse events[12]. First-line comparisons of dual *vs.* quadruple therapy further confirm this trend. A 223-patient RCT reported significantly higher eradication with 12-day concomitant quadruple therapy *vs.* 14-day HDDT (90.4% *vs.* 79.1%, p=0.02), though HDDT had fewer adverse events[34]. Similarly, a multicenter Chinese RCT found higher eradication rates with quadruple therapy (91.2% PP) compared to cefuroxime-VPZ dual therapy (80.2% PP), although dual therapy was associated with fewer side effects. 13 A Chinese RCT reported 95.8% eradication with HDDT compared to 100% with BQT and noted that HDDT induced less gut microbiota disruption[35]. However, in an Irish cohort, HDDT achieved a low overall eradication rate of 56%, indicating potential regional limitations[36].

TAILORED *VS.* EMPIRICAL THERAPY FOR *HELICOBACTER PYLORI* INFECTION

Recent studies reinforce the strengths of tailored therapy over empirical regimens for *H. pylori* eradication, particularly in regions with high antibiotic resistance. Randomized trials from Korea and China show that tailoring treatment based on clarithromycin resistance, using molecular or culture-based methods, significantly improves eradication rates[37-39]. Non-invasive approaches,

including fecal molecular testing and antibiotic exposure history, have also proven effective for guiding therapy[40]. Antimicrobial susceptibility testing (AST)-guided bismuth quadruple therapy achieves eradication rates exceeding 90%, even in highly resistant populations[41,42]. Shorter, 7- to 10-day tailored regimens may offer comparable efficacy to longer courses with better compliance and lower costs[41,43]. However, a multicenter Korean trial found no overall superiority of tailored culture-based therapy over empirical concomitant therapy, although tailored regimens were more effective in dual-resistant strains and were associated with fewer adverse events[44]. Although these findings show improved eradication following tailored therapy in regions of high resistance, widespread adaptation should be limited, considering BQT as a first-line therapy and resource availability when selecting tailored AST treatment.

NON-TRADITIONAL AND NOVEL THERAPIES

Potassium-Competitive Acid Blockers (PCABs) in *H. pylori* Treatment

Potassium-competitive acid blockers (PCABs) have emerged as an effective alternative to proton pump inhibitors (PPIs) in *Helicobacter pylori* treatment due to their potent and sustained acid suppression. Numerous Asian RCTs confirm that vonoprazan-amoxicillin (VA) dual therapy achieves eradication rates exceeding 90% with 10- or 14-day regimens, offering a simplified first-line option with fewer adverse events and better compliance compared to bismuth quadruple therapy (BQT)[45-53]. Adjunctive strategies, including *Saccharomyces boulardii*[47] and amoxicillin dose adjustments[50,54], further optimize outcomes. VPZ-based triple and quadruple regimens demonstrate high efficacy even in resistant infections[55-58]. Other PCABs, such as tegoprazan and keverprazan, show comparable or superior efficacy to PPI-based regimens, with improved tolerability[58-62]. Real-world studies support PCAB effectiveness across diverse populations, including elderly and penicillin-allergic patients, while simplified VPZ dual therapy shows favorable cost-effectiveness[63-67]. However, long-term VPZ use may increase gastric cancer risk, warranting post-treatment surveillance[68]. Systematic reviews and meta-analyses consistently report superior eradication rates and safety for VPZ-based regimens, particularly in antibiotic-resistant populations[69-74], with tegoprazan showing similar benefits[75]. These findings support PCABs, especially vonoprazan, as key components of modern *H. pylori* treatment, with further research continuing to optimize regimens.

Rifasutenizol

Rifasutenizol is a novel dual-targeted antibacterial agent with potent activity against *H. pylori*, representing a promising addition to the diminishing arsenal of effective therapies amid rising antibiotic resistance. Structurally derived from nitroimidazole compounds, rifasutenizol exerts its antibacterial effect through a dual mechanism of action, combining DNA damage induction with interference in bacterial protein synthesis pathways. This dual-targeting approach enhances bactericidal efficacy while mitigating the risk of resistance development, a common issue with monotherapeutic agents. Li et al[76] reported the first series of clinical trials evaluating rifasutenizol, comprising four randomized studies conducted in healthy participants and *H. pylori*-infected patients in China. The phase 1 trials established the safety, tolerability, and pharmacokinetic profile of rifasutenizol, demonstrating linear pharmacokinetics across doses, with a half-life supporting once-daily administration and no serious adverse events reported. Notably, food intake modestly enhanced systemic drug exposure. Subsequently, two phase 2 trials assessed the efficacy of rifasutenizol-containing triple therapy regimens compared to established standard therapies. In the treatment arm receiving rifasutenizol (400-600 mg) combined with rabeprazole and amoxicillin, *H. pylori* eradication rates reached 95-100%, significantly exceeding the predefined efficacy threshold and outperforming standard comparators. Across all trials, rifasutenizol demonstrated a favorable safety profile, with minimal adverse events, primarily limited to mild, transient gastrointestinal symptoms. Importantly, microbiological analyses confirmed the eradication efficacy of rifasutenizol against both antibiotic-sensitive and resistant *H. pylori* strains, supporting its utility in overcoming current therapeutic limitations.

These findings position rifasutenizol as a leading candidate for inclusion in future first-line or rescue regimens for *H. pylori* infection, warranting further large-scale, multinational studies to validate its global applicability.

THE ROLE OF PROBIOTICS AND PREBIOTICS AS ADJUNCTS TO *H. PYLORI* ERADICATION THERAPY

A growing body of evidence supports the adjunctive use of probiotics and prebiotics alongside *H. pylori* eradication therapy to improve tolerability, preserve gut microbiota, and, in limited cases, enhance eradication success. Randomized trials and meta-analyses demonstrate that supplementation with *Saccharomyces boulardii*, *Lactobacillus* spp., and *Bifidobacterium* spp. reduces treatment-related adverse events and modestly improves eradication rates[77-85]. Large-scale real-world data from the European Hp-EuReg registry confirm probiotic co-administration improves both safety and effectiveness, with *Lactobacillus* enhancing efficacy and *Bifidobacterium/Saccharomyces* improving tolerability[86]. Novel delivery systems, such as hydrogel-based *L. reuteri* formulations, show promise for improving probiotic survival and targeted gastric action[87]. Prebiotics (e.g., fucoidan) and synbiotics also demonstrate potential to mitigate treatment-induced dysbiosis, even when eradication rates are unaffected[88]. Probiotic use post-eradication improves symptom control and microbiota recovery[89]. However, benefits may depend on treatment duration, with *S. boulardii* improving eradication rates in 10-day but not 14-day triple therapy[90]. Overall, probiotics are safe, well-tolerated adjuncts that can enhance tolerability and, in selected regimens, improve eradication success, though optimal strains, formulations, and timing require further investigation. However, the additional costs borne by patients and the increased complexity of the probiotic regimen must be considered when assessing the proposed benefits.

H. PYLORI ERADICATION STRATEGIES IN PEDIATRIC POPULATIONS

Eradication of *H. pylori* in children remains challenging, especially in regions with high antibiotic resistance. Recent studies highlight the potential of alternative regimens, with an Egyptian trial showing ciprofloxacin-based triple therapy significantly outperforms clarithromycin triple therapy (90% *vs*. 70%) in high-resistance settings[91]. Bismuth-based quadruple therapy and colloidal bismuth subcitrate-containing regimens also demonstrate high eradication rates (86-94%) with good tolerability, even in children with dual-resistant strains[92,93]. In contrast, a Chinese study reported poor outcomes with both clarithromycin triple therapy and quadruple therapies, likely due to high clarithromycin resistance[94]. Adjunctive vitamin D supplementation showed no significant benefit[95] in this population. Overall, bismuth-based regimens appear effective and well-tolerated in pediatric populations, though tailored approaches in areas of high clarithromycin resistance may be justified where access to BQT is limited or unavailable.

PRE-CLINICAL AND *IN VITRO* RESEARCH

A wide range of innovative pre-clinical and *in vitro* approaches for *H. pylori* eradication have emerged over the past year, focusing on nanotechnology, targeted molecular inhibitors, bioactive natural compounds, and passive immunotherapy. Nanoparticle-based strategies show promise for overcoming treatment barriers, such as gastric acidity, mucus penetration, and biofilms, with antibody-coated systems, sonodynamic nanoparticles, and cascade nanozymes demonstrating targeted, effective anti-*H. pylori* activity *in vitro* and *in vivo* models[96-98]. Benzofuran- and benzothiophene-based urease inhibitors showed nanomolar potency and selectivity[99]. Biocompatible polymer systems, including gastroretentive plant mucilage formulations, chitosan-modified molybdenum selenide nanomaterials, liposomal furazolidone-N-acetylcysteine combinations, and ultrasound-activated fucoidan platforms, offer enhanced drug delivery, biofilm disruption, and mucosal protection[100-103]. Antimicrobial peptides and food-derived bioactives also show potential, including pH-responsive hydrogels, lunasin-enriched soybean extracts, and dual-func-

tional corn peptides that inhibit bacterial adhesion[104-106]. Finally, nanomaterial-based strategies to target *H. pylori* biofilms represent a major area of progress[107]. Collectively, these findings highlight significant advances in antibiotic-sparing, targeted therapies for *H. pylori*, with several candidates showing potential for clinical translation.

CONCLUSIONS

Optimizing *Helicobacter pylori* eradication remains essential to reducing the global burden of peptic ulcer disease and gastric cancer. Recent clinical evidence reinforces bismuth-based quadruple therapy as the preferred first-line regimen in regions with high resistance, while tailored, susceptibility-guided approaches consistently improve eradication rates. Potassium-competitive acid blockers, particularly vonoprazan, have emerged as effective, well-tolerated alternatives to traditional PPI-based therapies across both first-line and rescue settings. Adjunctive probiotics demonstrate benefit in improving treatment tolerability and, in select regimens, eradication success. As the role of *H. pylori* eradication in gastric cancer prevention becomes increasingly clear, incorporating evidence-based, regionally adapted, and patient-centered strategies into routine clinical practice is critical to improving outcomes.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

No new data were created or analyzed in this study. More information is available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization, Deirdre McNamara, Conor Costigan, and Thomas J. Butler; investigation, Conor Costigan and Thomas J. Butler; writing—original draft preparation, Conor Costigan and Thomas J. Butler; writing—review and editing, Deirdre McNamara, Conor Costigan, and Thomas J. Butler. All authors have read and agreed to the published version of the manuscript.

AI Statement

No artificial intelligence has been used for this article.

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