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EFFICACY OF POTASSIUM-COMPETITIVE ACID BLOCKER (P-CAB)-BASED THERAPEUTIC REGIMENS IN THE ERADICATION OF RESISTANT HELICOBACTER PYLORI STRAINS

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ABSTRACT

Helicobacter pylori infection is a severe public health issue, characterized by high prevalence in Latin America and a strong association with the development of gastric cancer. Given the growing bacterial resistance to conventional therapy based on proton pump inhibitors (PPIs), potassium-competitive acid blockers (P-CABs) emerge as a promising alternative. The present study aims to evaluate the efficacy of P-CABs, focusing on vonoprazan and tegoprazan, in the eradication of resistant H. pylori strains compared to PPIs. To this end, a literature review was conducted in the PubMed/MEDLINE, Embase, Cochrane, and Web of Science databases, encompassing publications particularly from the last 10 years. The results indicate that P-CABs promote faster, more potent, and sustained acid suppression without being subjected to interference from CYP2C19 polymorphisms. Vonoprazan-based regimens achieve overall eradication rates of 86% to 94%, outperforming PPIs, especially in clarithromycin-resistant strains (66% to 81% efficacy against 32% to 40% for PPIs). High-dose vonoprazan dual therapy stood out for its high efficacy and lower incidence of adverse events. Thus, it is concluded that P-CABs represent a significant therapeutic advance, offering greater reliability in combating antimicrobial resistance. However, due to the scarcity of robust data on Latin American populations, future regional clinical trials and cost-effectiveness evaluations tailored to the reality of the Brazilian healthcare system become essential to substantiate new clinical guidelines.

Keywords: Anti-Bacterial agents, Drug therapy, Combination, Helicobacter pylori, Retrospective studies, Treatment Outcome.

INTRODUCTION

Helicobacter pylori (H. pylori) infection represents a global public health issue, affecting more than half of the world's population and constituting the main risk factor for the development of chronic gastritis, peptic ulcer disease, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric

adenocarcinoma.[1,2] In Brazil and other Latin American countries, the prevalence of infection remains high, affecting more than 70% of populations living under unfavorable socioeconomic and sanitary conditions. Gastric cancer, the main clinical sequela of H. pylori infection, has an average incidence rate of 14 cases per 100,000 inhabitants in Latin America, particularly in Chile, Colombia, and Brazil.[3,4]

Effective eradication of H. pylori is essential for the treatment and prevention of these conditions. Traditionally, triple therapy based on proton pump inhibitors (PPIs)—consisting of a PPI, amoxicillin, and clarithromycin—has been the most widely used therapeutic regimen.[3] However, increasing bacterial resistance to antibiotics, particularly clarithromycin and metronidazole, has significantly compromised the efficacy of conventional regimens.[5] Clarithromycin resistance rates range from 2% to 26.7% in Latin American countries, while globally, resistance to clarithromycin and levofloxacin exceeds 15% in 24 of 31 countries and 18 of 31 countries, respectively.[3,6,7]

In this context of increasing antimicrobial resistance, potassium-competitive acid blockers (P-CABs) have emerged as a promising alternative to traditional PPIs. P-CABs, including vonoprazan and tegoprazan, represent a new class of gastric acid suppressants that act through a mechanism distinct from that of PPIs, binding reversibly and competitively to the potassium exchange site of gastric H+/K+-ATPase.[8,9] Furthermore, unlike PPIs, P-CABs are stable in acidic environments, do not require conversion to an active form, do not require preprandial administration, and exhibit a faster onset of action and more potent and sustained acid suppression. In addition, they are not metabolized by CYP2C19, thereby avoiding pharmacological variability associated with genetic polymorphisms.[8,9,10]

Vonoprazan was approved by the United States Food and Drug Administration (FDA) in 2022 for the treatment of H. pylori infection in adults, both as dual therapy (vonoprazan-amoxicillin) and triple therapy (vonoprazan-clarithromycin-amoxicillin).[9,11] Recent studies demonstrate that P-CAB-based regimens, particularly those containing vonoprazan, exhibit superior efficacy compared with PPI-based regimens, especially in patients infected with clarithromycin-resistant strains.[8,12] The 2022 Maastricht VI/Florence Consensus established, with 100% agreement among experts, that P-CAB-based regimens are "superior, or non-inferior, to conventional PPI-based triple therapies... and superior in patients with evidence of antimicrobial-resistant infections."[8]

However, despite the growing body of evidence regarding the efficacy of P-CABs, gaps in knowledge remain concerning their applicability in different geographic contexts, particularly in Brazil, where antimicrobial resistance patterns and access to these new therapies may differ from those in other regions. Furthermore, comparisons between different P-CABs (vonoprazan versus tegoprazan), different therapeutic regimens (dual, triple, or quadruple therapy), and different treatment durations require a thorough systematic analysis. Thus, against this background of new developments, uncertainties, and future prospects, the present article aims to define our perspectives and analyses on the subject.

OBJECTIVES

To evaluate the efficacy of therapeutic regimens based on potassium-competitive acid blockers (P-CABs), specifically vonoprazan and tegoprazan, in the eradication of antibiotic-resistant Helicobacter pylori strains, comparing them with conventional regimens based on proton pump inhibitors (PPIs), through a literature review of scientific publications from 2016 to 2026. Specifically, the study aims to:
1. Analyze the eradication rates of H. pylori achieved with P-CAB-based regimens compared with PPI-based regimens, both in the general population and in subgroups with strains resistant to clarithromycin and other antibiotics;

2. Identify the P-CAB-based therapeutic regimens (dual, triple, or quadruple therapy) with the greatest efficacy in eradicating resistant strains;
3. Describe the safety and tolerability profile of P-CAB-based regimens compared with conventional regimens;
4. Discuss the applicability of the findings to the Brazilian context, considering local antimicrobial resistance patterns and national treatment guidelines.

METHODS

The present literature review was conducted through a systematic search of the PubMed/MEDLINE, Embase, Cochrane Library, and Web of Science databases, covering the period from January 2016 to May 2026. The search strategy used the following terms in combination: ("Helicobacter pylori" OR "H. pylori") AND ("vonoprazan" OR "tegoprazan" OR "potassium-competitive acid blocker" OR "P-CAB" OR "PCAB") AND ("eradication" OR "treatment" OR "therapy") AND ("resistance" OR "resistant" OR "clarithromycin" OR "antibiotic"). Additionally, the reference lists of the selected articles were consulted to identify relevant complementary studies.

The eligibility criteria were as follows:

(a) randomized controlled trials (RCTs), observational studies, systematic reviews, and meta-analyses published between 2016 and 2026;
(b) studies comparing P-CAB-based regimens with PPI-based regimens for H. pylori eradication; (c) studies evaluating efficacy against antibiotic-resistant strains, particularly clarithromycin-resistant strains;
(d) publications in English, Portuguese, or Spanish;
(e) studies reporting data on eradication rates, adverse events, and/or treatment adherence, regardless of publication date.

The following were excluded:

(a) case reports, case series, and conference abstracts without complete data;
(b) studies without a comparator group;
(c) studies with inadequate methodology or incomplete data that prevented the extraction of relevant information;
(d) duplicate publications or retracted studies.

Study selection was conducted in two stages:

(1) screening of titles and abstracts to identify potentially eligible studies;
(2) full-text review of the selected articles to confirm the eligibility criteria.

Data extraction included study characteristics (author, year, country, design), population characteristics (sample size, previous treatment status, resistance pattern), interventions (type of P-CAB, therapeutic regimen, duration), outcomes (eradication rates according to intention-to-treat [ITT] and per-protocol [PP] analyses, adverse events, adherence), and main conclusions.

The assessment of the methodological quality of the included studies was based on information reported in the selected meta-analyses and systematic reviews themselves, which used validated tools such as the Cochrane Risk of Bias Tool for RCTs and AMSTAR-2 for systematic reviews. This

methodological approach is appropriate for the proposed objective of synthesizing the current state of knowledge regarding P-CABs in the eradication of resistant H. pylori, providing a comprehensive and clinically relevant overview of the available literature.

RESULTS AND DISCUSSION

• Mechanism of Action and Pharmacodynamic Properties of P-CABs

P-CABs represent a significant advance in gastric acid suppression compared with conventional PPIs. While PPIs are prodrugs that require activation in an acidic environment and bind irreversibly to H+/K+-ATPase through covalent bonds, P-CABs bind reversibly and competitively to the potassium-binding site of the proton pump.[8,9,10] This fundamental difference gives P-CABs superior pharmacokinetic and pharmacodynamic properties: faster onset of action, more potent and sustained acid suppression, the ability to maintain intragastric pH above 6 for longer periods, and no requirement for preprandial administration.[8,9] Their main pharmacological representatives are vonoprazan and tegoprazan.

In this context, pharmacodynamic studies have demonstrated that vonoprazan maintains target intragastric pH levels for longer proportions of a 24-hour period compared with PPIs.[8] Furthermore, P-CABs are not metabolized by CYP2C19, avoiding the therapeutic variability associated with genetic polymorphisms that affect some PPIs.[8],[10] These characteristics are particularly relevant to H. pylori eradication, as potent and sustained acid suppression promotes active bacterial replication (making the bacteria more susceptible to bactericidal antibiotics), increases the stability of acid-labile antibiotics such as clarithromycin and amoxicillin, and increases their intragastric concentrations.[9]

Tegoprazan, in turn, has been shown to inhibit porcine, canine, and human H+/K+-ATPase in vitro, with IC50 values ranging from 0.29 to 0.52 μM, whereas inhibition of canine renal Na+/K+-ATPase occurred at concentrations above 100 μM, thus demonstrating high selectivity.[13] Kinetic analysis revealed that tegoprazan inhibits H+/K+-ATPase through a potassium-competitive mechanism with reversible binding.[13]

• Comparative Efficacy: P-CABs versus PPIs in the General Population

At the top of the evidence hierarchy, multiple meta-analyses and systematic reviews published between 2022 and 2025 have consistently demonstrated the superiority of vonoprazan-based regimens over PPI-based regimens for H. pylori eradication. The meta-analysis by Kanu and Soldera (2024), which included 15 studies (7 RCTs, 7 retrospective observational studies, and 1 comparative study) involving a total of 8,049 patients, revealed a significant difference in eradication rates between vonoprazan-based triple therapy and PPI-based triple therapy, both in RCTs (RR = 1.17; 95% CI: 1.11–1.22; P 0.0001) and observational studies (RR = 1.13; 95% CI: 1.09–1.17; P 0.0001).[1]

The systematic review and meta-analysis by Benito et al. (2024) analyzed 77 studies (24 RCTs) involving 44,162 patients (22,297 receiving vonoprazan and 21,865 receiving PPIs).[14] The overall efficacy of vonoprazan was 88% (95% CI: 87%–90%), with rates of 86%, 88%, and 94% for vonoprazan-containing dual, triple, and quadruple therapies, respectively.[14] In treatment-naive patients, vonoprazan demonstrated superior performance compared with PPIs (87% versus 70%; risk difference = 0.13; 95% CI: 0.11–0.15).[14]

Liu et al. (2024) conducted a meta-analysis of RCTs comparing vonoprazan-based therapies with PPI-based therapies, reporting pooled eradication rates of 82.8% for vonoprazan-amoxicillin dual therapy (VA), 89.1% for vonoprazan-amoxicillin-clarithromycin triple therapy (VAC), and 91.8% for vonoprazan-based bismuth-containing quadruple therapy (VBQT).[15] Eradication rates increased with more frequent amoxicillin administration and extended treatment duration within each regimen.[15]

Regarding tegoprazan, the results are less consistent. The meta-analysis by Kanu and Soldera (2024) found no significant difference between tegoprazan-based triple therapy and PPI-based triple therapy, either in RCTs (RR = 1.04; 95% CI: 0.93–1.16; P = 0.5) or observational studies (RR = 1.03; 95% CI: 0.97–1.10; P = 0.3).[1] Cho et al. (2025) confirmed these findings in a meta-analysis of 7 studies involving 3,200 patients, demonstrating that eradication rates did not differ significantly between tegoprazan-based and PPI-based therapies in the ITT analysis (77.3% versus 76.4%; P = 0.68; pooled RR = 1.01) or PP analysis (84.3% versus 84.2%; P = 0.69; pooled RR = 1.01).[1,8,16]

However, more recent studies suggest the non-inferiority of tegoprazan. Park et al. (2025) conducted a multicenter, double-blind, phase III RCT at 19 hospitals in South Korea, randomizing 382 patients to receive 14-day triple therapy with tegoprazan 50 mg (TAC1), tegoprazan 100 mg (TAC2), or lansoprazole 30 mg (LAC), each combined with amoxicillin 1,000 mg and clarithromycin 500 mg, twice daily.[17] In the modified ITT analysis, eradication rates were 86.0%, 85.5%, and 78.7% for TAC1, TAC2, and LAC, respectively, with both tegoprazan-based regimens meeting the non-inferiority criteria.[17] Song et al. (2025), in turn, reported results from a multicenter, double-blind RCT conducted at 41 centers in China, demonstrating that tegoprazan-based bismuth-containing triple therapy (TACB) was non-inferior to esomeprazole-based therapy (EACB), with eradication rates of 93.5% (95% CI: 89.9–96.1%) versus 86.4% (95% CI: 81.9–90.2%), a difference of 7.0% (95% CI: 2.1–12.0%). The superiority test demonstrated a significantly higher rate in the tegoprazan group (P = 0.006).[18]

• Efficacy Against Clarithromycin-Resistant Strains

The most pronounced advantage of P-CABs is observed in patients infected with clarithromycin-resistant strains, representing a crucial advance given that clarithromycin resistance exceeds 15% in many regions, making conventional triple therapy unsuitable.[2,5]

The pivotal study by Chey et al. (2022), a phase 3 RCT conducted in the United States and Europe involving 1,046 patients, demonstrated marked superiority of vonoprazan-based regimens in clarithromycin-resistant infections.[12] Eradication rates in clarithromycin-resistant infections were 65.8% for vonoprazan triple therapy and 69.6% for vonoprazan dual therapy, compared with 31.9% for lansoprazole triple therapy (both superior; difference of 33.9%; 95% CI: 17.7–48.1; P = 0.001 for triple therapy; difference of 37.7%; 95% CI: 20.5–52.6; P = 0.001 for dual therapy).[12] These results represent more than a doubling of eradication rates in clarithromycin-resistant strains.

The meta-analysis by Benito et al. (2024) confirmed these findings on a larger scale: in patients with clarithromycin-resistant infections, vonoprazan-based therapies demonstrated an efficacy of 81% (95% CI: 76%–85%), outperforming PPIs (76% versus 40%; risk difference = 0.33; 95% CI: 0.24–0.43).[14] For clarithromycin-susceptible strains, vonoprazan efficacy was 92% (95% CI: 89%–95%), similar to that of PPIs.[14]

Clinical guidelines corroborate these findings. The 2024 American College of Gastroenterology (ACG) guideline reports that, in prespecified superiority analyses, vonoprazan-clarithromycin triple therapy was superior to lansoprazole-clarithromycin triple therapy in patients with clarithromycin-resistant strains (eradication rates according to modified ITT analysis: 66% versus 32%, P = 0.0001).[9] Similarly, vonoprazan-amoxicillin dual therapy was superior to lansoprazole-clarithromycin triple therapy in patients with clarithromycin-resistant strains (70% versus 32%, P = 0.0001).[9]

The 2024 American Gastroenterological Association (AGA) guideline highlights that, when subpopulations of patients with clarithromycin-resistant strains within randomized trials are evaluated, P-CABs administered twice daily showed an even greater incremental benefit over PPI-based regimens, presumably because

enhanced acid suppression improves the efficacy of other antibiotics, such as amoxicillin.[8] A cited Japanese study demonstrated higher eradication rates with one week of vonoprazan dual therapy compared with vonoprazan-based triple therapy in patients with clarithromycin-resistant strains (92% versus 76%).[8]

Zhang et al. (2023) conducted a meta-analysis of 5 studies involving 1,852 patients comparing vonoprazan-amoxicillin dual therapy with triple therapies.[19] For clarithromycin-resistant strains, vonoprazan-amoxicillin dual therapy demonstrated superiority over vonoprazan-based triple therapy (86.7% versus 71.4%; RR = 1.20; 95% CI: 1.03–1.39; P = 0.02).[19] However, for clarithromycin-susceptible strains, vonoprazan-amoxicillin dual therapy was significantly inferior to vonoprazan-based triple therapy (83.0% versus 92.8%; RR = 0.90; 95% CI: 0.85–0.95; P = 0.0002).[19]

• Comparison of Different P-CAB-Based Therapeutic Regimens

The network meta-analysis by Rokkas et al. (2025) compared the efficacy and safety of P-CAB-based regimens (dual, triple, and quadruple therapy) versus PPI-based regimens for the first-line treatment of H. pylori infection.[20] Twenty-five eligible RCTs were included, involving 7,605 patients randomized to 6 first-line regimens. The surface under the cumulative ranking curve (SUCRA) values for these 6 regimens were as follows: P-CAB dual therapy, 92.7%; P-CAB triple therapy, 62.5%; P-CAB quadruple therapy, 33.9%; PPI dual therapy, 75.1%; PPI triple therapy, 19.4%; and PPI quadruple therapy, 16.3%.[20] The comparative effectiveness ranking showed that P-CAB dual therapy ranked first for efficacy and last for adverse events, demonstrating the best combined efficacy-safety profile.[20]

Ouyang et al. (2024) conducted a network meta-analysis of 54 RCTs involving 15,320 patients (74.9% male, mean age 30.2 years).[21] In the ITT analysis, high-dose vonoprazan dual therapy (VPZ-HD-dual), vonoprazan triple therapy (VPZ-triple), and vonoprazan quadruple therapy (VPZ-quadruple) demonstrated significantly higher eradication rates than PPI triple therapy, PPI quadruple therapy, and vonoprazan dual therapy regimens.[21] Subgroup analysis indicated that poor patient adherence significantly reduced eradication rates. Resistance to clarithromycin and metronidazole significantly weakened the eradication effects of PPI triple therapy, tegoprazan triple therapy, and vonoprazan triple therapy.[21] Notably, the risk of adverse events with VPZ-HD-dual was significantly lower than with VPZ-quadruple.[21]

Zhang et al. (2024) conducted a meta-analysis of 11 RCTs and 2 retrospective clinical studies involving 4,570 samples, comparing high-dose vonoprazan-amoxicillin dual therapy (VHA) with other therapies.[22] VHA dual therapy demonstrated higher H. pylori eradication rates (ITT: 86.0% versus 80.7%; OR = 1.36; 95% CI: 1.07–1.73; P = 0.01; PP: 90.6% versus 85.7%; OR = 1.42; 95% CI: 1.07–1.88; P = 0.02), fewer adverse events (15.4% versus 27.7%; OR = 0.49; 95% CI: 0.35–0.68; P 0.0001), and similar treatment adherence (94.6% versus 93.2%; OR = 1.27; 95% CI: 0.98–1.64; P = 0.07) compared with other guideline-recommended therapies.[22] According to subgroup analysis using PP data, VHA dual therapy was more effective than PPI-based bismuth quadruple therapy (P-BQT) (93.5% versus 89.3%; OR = 1.76; 95% CI: 1.03–3.00; P = 0.04).[22] Eradication rates for 7-, 10-, and 14-day VHA dual therapy were 65% (95% CI: 0.55–0.75), 92% (95% CI: 0.91–0.94), and 93% (95% CI: 0.90–0.97), respectively.[22]

Qian et al. (2023) compared 10-day vonoprazan-amoxicillin dual therapy with bismuth quadruple therapy in 375 treatment-naive patients infected with H. pylori.[23] The eradication rates of bismuth quadruple therapy (B-quadruple), VHA dual therapy (vonoprazan 20 mg twice daily + amoxicillin 750 mg 4 times daily), and VA dual therapy (vonoprazan 20 mg + amoxicillin 1,000 mg twice daily) were 90.9%, 93.4%, and 85.1%, respectively, according to PP analysis.[23] The efficacy of the VHA-

dual group was non-inferior to that of the B-quadruple group (P = 0.001), whereas VA-dual did not meet the non-inferiority margin of -10%.[23] Adverse event rates in the B-quadruple group were significantly higher than those in the VHA-dual (P = 0.012) and VA-dual (P = 0.001) groups.[23]

• Efficacy in Salvage Therapy

The efficacy of P-CABs has also been evaluated in second-line and salvage therapies. The meta-analysis by Benito et al. (2024) reported a vonoprazan efficacy rate of 90% (95% CI: 87%–93%) in salvage therapy.[14] However, no significant differences were observed between vonoprazan and PPIs in salvage therapy and quadruple therapies.[14]

Data from the Brazilian registry on H. pylori management (Hp-BrazilReg) provide an important perspective on salvage therapy in the Brazilian context.[25] Sanches et al. (2025) evaluated 572 patients (mean age 52 years, 64% women) who underwent empirical salvage therapy as second-line and subsequent treatments.[25] The overall eradication rate for second-line treatment was 74%, with the most common regimen being triple therapy (PPI + amoxicillin + levofloxacin), achieving eradication rates of 73% with a 14-day regimen and 57% with a 10-day regimen.[25] The addition of bismuth to the 14-day regimen increased effectiveness to 100% (P = 0.016).[25] In third-line therapy, the PPI-bismuth-tetracycline-metronidazole regimen achieved a cure rate of 87%.[25] Fourth-line dual therapy with amoxicillin-vonoprazan achieved 100% eradication, while bismuth quadruple therapy showed similar results.[25] Vonoprazan-amoxicillin dual therapy was also effective as fifth-line treatment, achieving 100% effectiveness.[25]

Safety and Tolerability Profile

The safety profile of P-CAB-based regimens is comparable or superior to that of PPI-based regimens. The meta-analysis by Benito et al. (2024) reported an adverse event rate of 19% (95% CI: 16%–21%) with vonoprazan, comparable to PPI-based regimens (18% versus 13%, respectively; risk difference = 0.00; 95% CI: -0.01 to 0.02; P = 0.57).[14]

The study by Chey et al. (2022) demonstrated that the overall frequency of treatment-emergent adverse events was similar between vonoprazan- and lansoprazole-based regimens (P > 0.05).[12] The 2024 ACG guideline reports that vonoprazan-clarithromycin triple therapy was generally well tolerated, with diarrhea (4%) and dysgeusia (4%) being the most commonly reported adverse events, at rates comparable to those observed with PPI-clarithromycin triple therapy.[9] Vonoprazan-amoxicillin dual therapy was generally well tolerated, with a safety profile comparable to that of lansoprazole-clarithromycin triple therapy and low discontinuation rates due to adverse events.[9]

Jin et al. (2025) conducted a comprehensive meta-analysis of 28 RCTs comprising 37 studies and 8,818 patients.[25] The incidence of adverse events with P-CAB-based therapy was significantly lower than with PPI-based treatments (RR = 0.73; 95% CI: 0.63–0.86; P 0.0001).[25] Zhang et al. (2024) confirmed that VHA dual therapy was associated with fewer adverse events than other therapies (15.4% versus 27.7%; OR = 0.49; 95% CI: 0.35–0.68; P 0.0001).[22]

Regarding tegoprazan, Cho et al. (2025) observed no significant difference in adverse events between tegoprazan-based and PPI-based therapies (27.2% versus 30.8%; P = 0.26; pooled RR = 0.91).[9],[16] Park et al. (2025) reported comparable safety profiles between the tegoprazan- and lansoprazole-treated groups, with no serious drug-related adverse events.[17]

• Cost-Effectiveness

Yunusa and Love (2023) conducted a cost-effectiveness analysis of vonoprazan- and rifabutin-based regimens versus other prepackaged first-line treatment options for H. pylori infection in the United States, using a state-transition Markov model.[26] The study evaluated five regimens: clarithromycin triple therapy, bismuth quadruple therapy, vonoprazan dual therapy, vonoprazan triple therapy, and rifabutin triple therapy.[26]

The results demonstrated that rifabutin triple therapy had a lower expected cost and was more effective than clarithromycin triple therapy, bismuth quadruple therapy, and vonoprazan dual therapy, thus dominating these regimens.[26] Vonoprazan triple therapy had a higher expected cost (US$1,172 versus US$1,048) and higher expected quality-adjusted life years (QALYs) (14.262 versus 14.256) than rifabutin triple therapy, resulting in an estimated incremental cost-effectiveness ratio of US$22,573/QALY.[26] The study suggested that vonoprazan triple therapy had the highest expected net monetary benefit and was the most cost-effective option at willingness-to-pay thresholds ranging from US$50,000 to US$150,000 per QALY, followed by rifabutin triple therapy.[26] The authors concluded that eradication of H. pylori infection with vonoprazan triple therapy would provide the greatest net health and monetary benefit from the perspective of US healthcare payers.[26]

No studies conducted in the Brazilian context were identified. However, regarding vonoprazan, an average price range of R$200.00 to R$300.00 per box containing 30 tablets should be considered. Tegoprazan, in turn, has not yet been approved by ANVISA and is currently undergoing the commercial authorization process, with approval expected next year, according to its pharmaceutical manufacturer.

• Specific Considerations in the Brazilian and Latin American Context

The applicability of P-CABs in the Brazilian and Latin American context requires careful consideration of multiple factors, including local antimicrobial resistance patterns, drug availability, costs, and national treatment guidelines.

Regarding availability, vonoprazan was approved by the US Food and Drug Administration (FDA) in 2022 and is available in most countries in North, Central, and South America.[10,27] Tegoprazan is marketed in some Latin American countries and is awaiting approval in others, as is the case in Brazil.[27,28] This regional availability represents an important opportunity for implementing P-CAB-based therapies in Latin America.

Antimicrobial resistance patterns in Latin America have specific characteristics that influence treatment selection. Although the data are relatively old, the study by Camargo et al. (2014) is noteworthy. In a systematic review of H. pylori antibiotic resistance in Latin America, analyzing 59 independent studies published up to October 2013,[29] the authors found the following pooled prevalences of primary resistance among adults by antibiotic: 12% for clarithromycin (35 studies), 53% for metronidazole (34 studies), 4% for amoxicillin (28 studies), 6% for tetracycline (20 studies), 3% for furazolidone (6 studies), 15% for fluoroquinolones (5 studies), and 8% for dual clarithromycin-metronidazole resistance (10 studies).[29] Resistance prevalence varied significantly by country but not by year of sample collection.[29] The authors concluded that resistance to first-line antibiotics used against H. pylori is high in Latin American populations and that, in some countries, the empirical use of clarithromycin without susceptibility testing may not be appropriate.[29]

Coelho and Coelho (2014) reached similar findings in the same year when describing the Latin American perspective on the clinical management of H. pylori,[3] reporting clarithromycin resistance rates ranging from 2% to 24%.[3] In view of this, they observed that, because of the high rates

of primary metronidazole resistance in Latin American countries, quadruple therapy in which metronidazole is replaced with furazolidone is frequently used as an alternative.[3]

Recent data from the Brazilian registry on H. pylori management (Hp-BrazilReg) provide a contemporary perspective on clinical practice in Brazil.[24] Sanches et al. (2025) reported that vonoprazan was used in 26% of salvage therapy cases, demonstrating the growing adoption of this new therapeutic class in Brazilian clinical practice.[24] Notably, fourth-line dual therapy with amoxicillin-vonoprazan achieved 100% eradication, and vonoprazan-amoxicillin dual therapy was also effective as fifth-line treatment, achieving 100% effectiveness.[24] These results suggest that vonoprazan-based regimens may be particularly valuable in cases of multiple treatment failures in the Brazilian context.

However, significant challenges remain for the widespread implementation of P-CABs in Brazil and Latin America. First, the cost of these medications may be substantially higher than that of widely available generic PPIs, representing a potential barrier in resource-limited healthcare systems. Second, most studies on P-CABs have been conducted in Asian, North American, and European populations, with extremely limited data on Latin American populations. Third, CYP2C19 genetic polymorphisms, which affect PPI metabolism but not P-CAB metabolism, have different distributions across ethnic groups.[9,30,31] Caucasians, non-Hispanic African Americans, and Hispanics have a significantly higher prevalence (57%–71%) of rapid CYP2C19 metabolizer phenotypes compared with Asian American ethnic groups (45%).[31] This difference suggests that Latin American populations, characterized by extensive ethnic admixture, could particularly benefit from P-CABs, which are not metabolized by CYP2C19 and avoid the therapeutic variability associated with genetic polymorphisms.[8,10]

• Current Guidelines and Recommendations

The most recent international guidelines have incorporated recommendations on the use of P-CABs in the treatment of H. pylori infection. The 2024 American College of Gastroenterology (ACG) guideline provides specific recommendations regarding vonoprazan-based regimens.[9] For treatment-naive patients, the guideline suggests vonoprazan-clarithromycin-amoxicillin triple therapy or vonoprazan-amoxicillin dual therapy as first-line options, particularly in regions where clarithromycin resistance exceeds 15% or when bismuth is unavailable.[9]

The 2024 American Gastroenterological Association (AGA) guideline on the integration of P-CABs into clinical practice establishes that P-CAB-based regimens are superior or non-inferior to conventional PPI-based triple therapies and superior in patients with evidence of antimicrobial-resistant infections.[8] The guideline states that P-CABs administered twice daily provide an even greater incremental benefit over PPI-based regimens in patients with clarithromycin-resistant strains.[8]

The 2022 Maastricht VI/Florence Consensus established, with 100% agreement among experts, that P-CAB-based regimens are superior or non-inferior to conventional PPI-based triple therapies and superior in patients with evidence of antimicrobial-resistant infections.[8]

In the Brazilian context, during the 24th Brazilian Digestive Disease Week (XXIV Semana Brasileira do Aparelho Digestivo – SBAD),[32] held from November 13 to 15, 2025, in São Paulo, the Brazilian Research Group for the Study of H. pylori and Microbiota (Núcleo Brasileiro para Estudo do H. pylori e Microbiota) presented the guidelines of the new Brazilian consensus, whose official publication was expected in the first half of 2026. Although the consensus had not yet been published, the research group had already presented some of its recommendations during the event, emphasizing the use of P-CABs, when available, particularly vonoprazan, as a first-line treatment option, while acknowledging limitations related to cost and access.

• Limitations and Gaps in Knowledge

Despite the growing body of evidence on P-CABs, several limitations and gaps in knowledge deserve attention. First, most studies on vonoprazan have been conducted in Asian populations, particularly Japanese and Chinese populations, where antimicrobial resistance patterns, genetic characteristics (including CYP2C19 polymorphisms), and clinical practices may differ substantially from those in other regions.[1],[14] Studies involving Latin American populations remain scarce.

Second, long-term safety data for P-CABs are limited. Although short-term studies demonstrate a safety profile comparable to that of PPIs, theoretical concerns regarding more potent and prolonged acid suppression, including the potential for hypergastrinemia, alterations in the intestinal microbiota, nutritional deficiencies, and an increased risk of enteric infections, require monitoring in long-term studies.27,28,33

Third, the cost-effectiveness of P-CABs in different healthcare settings, particularly in middle-income countries such as Brazil, remains incompletely characterized. Although the analysis by Yunusa and Love (2023) demonstrated favorable cost-effectiveness in the United States, direct extrapolation to healthcare systems with different cost structures and resources may not be appropriate.[26]

A fourth consideration is that the comparative efficacy of different P-CABs (vonoprazan versus tegoprazan versus other agents under development) requires additional head-to-head comparative studies. To date, most evidence favors vonoprazan, with less robust data available for tegoprazan.[1,16,25]

Fifth, optimal strategies for selecting patients who would benefit most from P-CAB-based therapies versus conventional regimens remain incompletely defined. Although the benefit is clear in clarithromycin-resistant strains, the cost-benefit ratio in unselected populations requires further evaluation.

Furthermore, the impact of P-CABs on the intestinal microbiota and their potential to contribute to the development of antimicrobial resistance require further investigation. Although P-CAB-based dual therapies use fewer antibiotics than quadruple regimens, the long-term ecological impact of these therapies remains incompletely characterized.[21,22]

CONCLUSION

This literature review demonstrates that therapeutic regimens based on potassium-competitive acid blockers (P-CABs), particularly vonoprazan, are more effective than conventional proton pump inhibitor (PPI)-based regimens for the eradication of Helicobacter pylori, especially in resistant strains, particularly those resistant to clarithromycin. The accumulated evidence establishes that:

1. Overall Efficacy: Vonoprazan-based regimens demonstrate eradication rates ranging from 86% to 94%, depending on the therapeutic regimen (dual, triple, or quadruple therapy), exceeding those of PPI-based regimens (70% to 80%) in treatment-naive patients. High-dose vonoprazan-amoxicillin dual therapy has a particularly favorable profile, combining high efficacy (86% to 93%) with a lower incidence of adverse events (15.4% versus 27.7% for other therapies).[1,14,15,22]

2. Efficacy Against Resistant Strains: The most pronounced benefit of P-CABs is observed in clarithromycin-resistant infections, in which vonoprazan-based regimens achieve eradication rates of 66% to 81%, compared with only 32% to 40% with PPI-based regimens, representing more than a doubling of treatment success rates. This advantage is clinically crucial, given that clarithromycin resistance exceeds 15% in 24 of 31 countries worldwide, including several Latin American countries, where rates range from 2% to 24%.[3,6,9,12,14,29]

3. Mechanism Underlying Superiority: The superiority of P-CABs derives from their distinct pharmacodynamic properties: reversible and competitive binding to H+/K+-ATPase, stability in acidic environments, more potent and sustained acid suppression, and the absence of CYP2C19-mediated metabolism, thereby

avoiding therapeutic variability associated with genetic polymorphisms that disproportionately affect non-Asian populations. This last characteristic is particularly relevant to Latin American populations, where the prevalence of rapid CYP2C19 metabolizer phenotypes is high (57% to 71%).[8,9,10,31]

4. Safety Profile: P-CAB-based regimens have a safety profile comparable or superior to that of PPI-based regimens, with adverse event rates of 19% versus 13% to 18%, respectively, without a statistically significant difference. Vonoprazan dual therapies demonstrate particularly favorable tolerability, with a lower incidence of adverse events than quadruple therapies.[14,20–22,25]

5. Cost-Effectiveness: An economic analysis conducted in the United States demonstrates that vonoprazan triple therapy has the highest expected net monetary benefit at willingness-to-pay thresholds ranging from US50,000 to US150,000 per QALY, with an incremental cost-effectiveness ratio of US$22,573/QALY compared with rifabutin triple therapy.[26] However, further studies evaluating economic feasibility in Latin American countries are needed.

It should be emphasized that, despite their promising results, the current evidence on P-CABs has important limitations. These include the high concentration of studies involving Asian populations, the scarcity of long-term safety data—including effects on the microbiota—the lack of cost-effectiveness assessments in the Brazilian context, and the absence of well-established head-to-head comparisons between drugs in this class, such as vonoprazan and tegoprazan. Accordingly, future research should prioritize clinical and pharmacogenomic trials, particularly those investigating CYP2C19 polymorphisms, validated in Latin American populations, accompanied by cost-effectiveness analyses specifically adapted to the Brazilian Unified Health System (SUS) and the supplementary healthcare sector. In parallel, studies addressing barriers to clinical implementation, continuous monitoring of antimicrobial resistance and long-term safety, and direct comparative trials between available P-CABs are essential to establish a robust evidence base to support the development of new therapeutic guidelines by the Brazilian Ministry of Health.

In summary, potassium-competitive acid blockers, particularly vonoprazan, represent a significant advance in the therapeutic arsenal for Helicobacter pylori eradication, especially in the context of increasing antimicrobial resistance. The rational implementation of these therapies, particularly in Brazil, guided by local evidence, adapted guidelines, and cost-effectiveness considerations, has the potential to substantially improve H. pylori eradication rates and, consequently, reduce the burden of associated diseases, including peptic ulcer disease and gastric cancer, which remain significant public health concerns in Brazil and Latin America.

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