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EMPIRICAL ERADICATION THERAPY FOR *HELICOBACTER PYLORI* INFECTION IN SECOND AND SUBSEQUENT TREATMENT LINES: EXPERIENCE FROM 500 CASES OF THE BRAZILIAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-BRAZILREG)

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Objective*:* The aim of the study was to evaluate the effectiveness of empirical therapy in the sec- ondline and rescue therapy in Brazil.

Patients and Methods: A prospective registry of the Brazilian gastroenterologists on *H. pylori* management (Hp-BrazilReg, Hp-WorldReg's partner) registered infected adult patients from March 2022 to October 2024. Modified intention-to-treat (mITT) analyses were performed.

Results: We evaluated 572 patients (mean age 52 years; 64% women). 386 (67%) patients received a second-line and 186 (33%) received rescue therapy (third-line and subsequent). Low-, standard-, high-dose proton pump inhibitors (PPIs) and vonoprazan (VPZ) were used in 40%, 10%, 24%, and 26% of cases, respectively. With second-line, the overall eradication rate was 74%. The most frequently used regimen was PPI+amoxicillin+levofloxacin for 10-14 days, with 55% eradication for 10 days and 84% for

14 days. Adding bismuth to this same 14-day regimen increased the effectiveness to 100% (p=0.016). In third-line, the main scheme was PPI-bismuth-tetracycline-metronidazole (PPI-BTM), used in 24%, with 87% mITT cure. Within fourth-line, dual therapy VPZ-amoxicillin (VA) was the most commonly prescribed (33%), followed by PPI+bismuth+amoxicillin+rifabutin (14%), both showing 100% effectiveness. The therapy VA was the most used in the fifth-line treatment or more, encompassing 43% of the cases with 100% effectiveness. Overall, 23% presented mild adverse events, being nausea the most frequent (14%) and compliance was 99%.

Conclusions: In Brazil, the overall effectiveness of second-line therapy showed a suboptimal (≤90%) cure rate; however, the combination of PPI-bismuth-amoxicillin-levofloxacin prescribed for 14 days reported successful effectiveness. In the third-line, PPI-BTM provided encouraging results (87%). Alternatively, therapy with VA and rifabutin-based therapy showed promising results in rescue treatment.

Conflict of interest disclosure:

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VONOPRAZAN IS HIGHLY EFFECTIVE AND SAFE AS AN ADJUVANT IN DIFFERENT REGIMES IN FIRST- AND RESCUE-LINE THERAPIES FOR *H. PYLORI* INFECTION IN BRAZIL

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Objective: The aim of the study was to evaluate the effectiveness of vonoprazan (VPZ) as adjuvant in eradication therapy for *H. pylori* (ETHP) in Brazil.

Patients and Methods: We performed a real-life registry, assessing outcomes of ETHP by Brazilian gastroenterologists (Hp-BrazilReg, WorldHpReg's partner), and data were registered at AEG-REDCap from March 2022-October 2024. Effectiveness was evaluated by modified intention-to-treat (mITT).

Results: 2,132 Brazilian patients, mean age 52 years, 61% women, were included. First-line treatments were administered to 73% (n=1,560) of cases, second-line to 18% (n=386), and rescue to 9% (n=186), with 94% of patients receiving 14-day prescriptions. Low-, standard-, and high-dose of proton pump inhibitors (PPIs), as well as 20mg BID of vonoprazan (VPZ) were used in 39%, 38%, 23%, and 15% of treatments, respectively. Compliance (>90% drug intake) was reported in 99% of the patients. At least

one adverse event was reported by 25% of patients, mainly nausea (13%). The regimens reaching ≥ 90% eradication were: dual-VPZ+amoxicillin for first-line and rescue treatments (96% and 100%, respectively), VPZ+bismuth+tetracycline+metronidazole for second- and third-line treatments (92% and 90%, respectively), and PPI+bismuth+levofloxacin+amoxicillin (100%) for second-line treatment. Prescribing VPZ (*vs.* PPI) was an independent factor associated with higher effectiveness both in first-line (OR 2.95; IC 95%: 1.71-5.09) and in second-line and rescue treatments (OR 2.87; IC 95%: 1.69-5.13), with no difference in adverse effects (p<0.01).

Conclusions: VPZ, when prescribed as an adjuvant for treating *H. pylori* infection, shows highly effective results as part of dual therapy with amoxicillin for first-line and rescue treatments, as well as in quadruple therapy with bismuth+metronidazole+tetracycline or bismuth+amoxicillin and rifabutin for rescue treatments.

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EFFECTIVENESS OF FIRST-LINE EMPIRICAL *HELICOBACTER PYLORI* TREATMENT OUTSIDE EUROPE: RESULTS OF 10,000 CASES FROM THE WORLD-WIDE REGISTRY ON *H. PYLORI* MANAGEMENT (WORLDHPREG)

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Objective*: Helicobacter pylori* infection is a global health concern, with treatment success varying due to regional differences in antibiotic resistance, clinical practices, and healthcare access. This study evaluated the effectiveness of empirical first-line therapies outside of Europe.

Patients and Methods: The WorldHpReg is a global, prospective registry capturing real-world *H. pylori* management and outcomes. Data were collected from March 2022 to April 2025 using AEG-REDCap e-CRF. Effectiveness was analysed by modified intention-to-treat (mITT).

Results: Of 9,973 cases, 7,738 (78%) first-line empirical treatments were analysed across non-European regions including LATAM, Brazil, Africa, Australia, Canada, Egypt, India, Jordan, Pakistan, and Saudi Arabia. Ninety different regimens were used, with overall mITT effectiveness of 84%. Optimal (≥90%) effectiveness was achieved in Australia (95%), India (99%), Jordan (96%), and Saudi Arabia (91%). In LATAM, high cure rates were observed with non-bismuth quadruple therapy (91%) and several bismuth-based combinations, like amoxicillin-metronidazole (94%), metronidazole-doxycycline (90%), and amoxicillin-doxycycline (97%). The single-capsule formulation (94%) and metronidazole-tetracycline (91%) were also highly effective in LATAM, with 97% in Brazil. Standard triple therapy with amoxicillin-clarithromycin surpassed 90% in select regions, though patient numbers were limited. Most other regimens yielded suboptimal results (Table 1).

Conclusions: First-line therapies for *H. pylori* yielded overall suboptimal results outside Europe but achieved optimal outcomes in some regions using adapted regimens, emphasizing the need for region-specific treatment protocols to improve eradication success globally.

TABLE 1. MODIFIED INTENTION-TO-TREAT EFFECTIVENESS OF MOST FREQUENT FIRST-LINE EMPIRICAL TREATMENTS WORLD-WIDE.

Country Treatment(a)	LATAM N (% mITT)	Brazil	Africa	Australia	Canada	Egypt	India	Jordan	Pakistan	Saudi Arabia
Triple-C+A	1,041(75%)	1,826(80%)	25(92%)	19(95%)	NA	4(100%)	61(100%)	14(100%)	53(59%)	7(86%)
Concomitant-C+A+M	613(91%)	1(100%)	NA	NA	6(83%)	NA	NA	29(86%)	NA	NA
Dual-A	340(86%)	116(89%)	NA	NA	NA	NA	NA	NA	NA	NA
Quadruple-A+M+B	259(94%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Quadruple-M+D+B	267(90%)	2(100%)	NA	NA	NA	NA	NA	NA	NA	1(100%)
Triple-A+L	126(82%)	16(69%)	NA	NA	NA	45(100%)	NA	NA	12(42%)	11(100%)
Quadruple-M+Tc+B	177(90%)	30(97%)	1(100%)	NA	1(100%)	NA	NA	NA	NA	2(100%)
Quadruple-C+A+B	187(78%)	6(100%)	NA	NA	NA	NA	NA	NA	NA	NA
Quadruple-A+D+B	177(97%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Single-capsule*	104(97%)	NA	NA	NA	NA	NA	NA	1(100%)	NA	40(88%)
Triple-C+T	NA	NA	43(67%)	NA	NA	NA	NA	NA	NA	NA
Other	483(89%)	85(79%)	3(100%)	NA	3(67%)	27(100%)	80(99%)	50(100%)	93(74%)	3(100%)
Overall	3,774(85%)	2,082(81%)	72(78%)	19(95%)	10(80%)	76(100%)	141(99%)	94(96%)	158(67%)	64(91%)

[a]Treatments were categorised in 11 categories encompassing over 90% of first-line prescriptions world-wide. LATAM: Latin America; ASEAN: Association of South-East Asian Nations; A: amoxicillin; B: bismuth salts; C: clarithromycin; D: doxycycline; L: levofloxacin; M: metronidazole; T: tinidazole; Tc: tetracycline; *Three-in-one single-capsule containing metronidazole, tetracycline and bismuth; N: total number of patients analysed; %: total number of patients with *H. pylori* eradicated; mITT: modified intention-to-treat.

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PRESCRIPTION OF FIRST-LINE EMPIRICAL TREATMENTS FOR *HELICOBACTER PYLORI* INFECTION OUTSIDE EUROPE: RESULTS OF 10,000 CASES FROM THE WORLD-WIDE REGISTRY ON *H. PYLORI* MANAGEMENT (WORLDHPREG)

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***Objective**: Helicobacter pylori* remains a significant global health concern. While effective treatments exist, variations in clinical practices and regional contexts necessitate continuous evaluation. This study assessed first-line empirical therapies for *H. pylori* infection outside Europe.

Patiens and Methods: The WorldHpReg is a global, prospective registry capturing real-world *H. pylori* management and outcomes. Data were collected from March 2022 to April 2025 using AEG-REDCap e-CRF. Descriptive analyses and Chi-square tests were applied.

Results: Among 9,973 cases from non-European countries, 7,738 (78%) involved first-line empirical therapies. Patients were predominantly women (62%) with a mean age of 50. Diagnosis was primarily by histology (75%), while urea breath tests and stool antigen tests were less common. Ninety different first-line regimens were identified (Table 1). The most used was triple therapy (PPI or P-CAB plus amoxicillin-clarithromycin, 41%), especially in Brazil, India, and Latin America. Concomitant quadruple therapy (PPI-amoxicillin-clarithromycin-metronidazole) followed (9%), notably in Canada, Jordan, and Latin America. Bismuth quadruple therapy was infrequent, except in Saudi Arabia and Latin America. Alternative or region-specific therapies included levofloxacin or tinidazole-based regimens and dual therapy with PPI/P-CAB-amoxicillin. Most regimens lasted 14 days, with varying PPI doses. Use of newer acid blockers like vonoprazan remained limited.

Conclusions: WorldHpReg highlights wide variability in *H. pylori* treatment across regions, with triple therapy predominating and limited adoption of quadruple regimens. Region-specific guidelines are essential to improve eradication outcomes globally.

TABLE 1. MOST FREQUENT FIRST-LINE EMPIRICAL TREATMENTS WORLDWIDE.

Country Treatment[a]	N (%)	LATAM	Brazil	Africa	ASEAN	Australia	Canada	Egypt	India	Jordan	Pakistan	Saudi Arabia
Triple-C+A	3,187(41%)	1,069(27%)	1,907(87%)	39(17%)	NA	19(100%)	1(3.2%)	4(5.1%)	69(45%)	15(14%)	53(34%)	11(14%)
Concomitant-C+A+M	692(8.9%)	635(16%)	1(0%)	NA	1(0.1%)	NA	24(77%)	NA	NA	31(30%)	NA	NA
Dual-A	476(6.2%)	360(9.2%)	116(5.3%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Quadruple-A+M+B	273(3.5%)	273(7%)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Quadruple-M+D+B	272(3.5%)	269(6.9%)	2(0.1%)	NA	NA	NA	NA	NA	NA	NA	NA	1(1.3%)
Triple-A+L	221(2.9%)	133(3.4%)	16(0.7%)	NA	NA	NA	NA	46(59%)	NA	1(1%)	12(7.6%)	13(16.3%)
Quadruple-M+Tc+B	221(2.9%)	178(4.5%)	38(1.7%)	1(0.4%)	NA	NA	1(3.2%)	NA	NA	NA	NA	3(3.8%)
Quadruple-C+A+B	204(2.6%)	197(5%)	6(0.3%)	NA	NA	NA	NA	NA	1(0.7%)	NA	NA	NA

Continued

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Country Treatment[a]	N (%)	LATAM	Brazil	Africa	ASEAN	Australia	Canada	Egypt	India	Jordan	Pakistan	Saudi Arabia
Quadruple-A+D+B	177(2.3%)	177(4.5%)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Single-capsule*	153(2%)	104(2.7%)	NA	NA	NA	NA	NA	NA	NA	1(1%)	NA	48(60%)
Triple-C+T	128(1.7%)	NA	NA	128(57%)	NA	NA	NA	NA	NA	NA	NA	NA
Overall	7,736 (100%)	3,916 (51%)	2,183 (28%)	224 (2.9%)	791** (10%)	19 (0.2%)	31 (0.4%)	78 (1%)	152 (2%)	104 (1.3%)	158 (2%)	80 (1%)

[a]Treatments were categorised in 11 categories encompassing over 90% of first-line prescriptions world-wide; LATAM: Latin America; ASEAN: Association of South-East Asian Nations; A: amoxicillin; B: bismuth salts; C: clarithromycin; D: doxycycline; L: levofloxacin; M: metronidazole; T: tinidazole; Tc: tetracycline. *Three-in-one single-capsule containing metronidazole, tetracycline and bismuth; N: number of prescriptions; NA: non-available. **From other treatment combinations.

Conflict of interest disclosure:

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