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P01.09.

BRAZILIAN REGISTRY ON H. PYLORI MANAGEMENT (HP-BRAZILREG) ANALYSIS OF 835 FIRST-LINE EMPIRIC TREATMENTS

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Objective: The aim of this study was to evaluate the effectiveness of empirical first-line eradication treatments.

Materials and Methods: Hp-BrazilReg (partner of Hp-WorldReg) is a multicenter-prospective real-life registry of outcomes of *H. pylori* management by Brazilian gastroenterologists. Data were registered at e-CRF AEG-REDCap from March 2022 to September 2023. Effectiveness was evaluated by modified intention-to-treat (mITT) analysis. Data were subject to quality review.

Results: There were 1,133 patients in first-line empiric treatments, mean age 53 years, 62% wom- en. The main treatment indications were dyspepsia (58%), gastroduodenal ulcers (12%), and premalig- nant gastric lesions (3%). Diagnostic endoscopy was performed in 97% of the cases, and no pre-treat- ment resistance test was performed. 835 patients were included in the mITT analysis. Low, standard, and high-dose PPIs or vonoprazan (VPZ) were used in 31%, 34%, 23%, and 11% of the cases, respec- tively. The main first-line regimens were triple-clarithromycin+amoxicillin (92% of the cases), with PPI or VPZ (14-day prescription), and dual-VPZ+amoxicillin (4%), 10-day prescription. Eradication was con- firmed by endoscopic methods (86%) and 14C-UBT (14%). Overall, mITT effectiveness was 87%, and the triple-PPI+clarithromycin+amoxicillin reported better results, although non-significant, than the same drug combination with VPZ (87% *vs.* 82%, *p*=0.34) (Table 1). Dual VPZ+amoxicillin effectiveness was 100%, with a short sample. Overall, 25% of patients presented mild adverse events; compliance was 99%..

Conclusions: Triple-PPI+clarithromycin+amoxicillin is the most used first-line treatment in Brazil, with an acceptable eradication rate (87%). Dual VPZ+amoxicillin therapy shows initial promising results.

TABLE 1. RESULTS OF FIRST-LINE *H. PYLORI* EMPIRICAL TREATMENTS IN BRAZIL (N-835).

First-line treatment	N	Duration days Mean (SD)	% Use	% Eradication (mITT)
PPI+A+C	719	13.9 (1.1)	86.1	86.5 (*)
VPZ+A+C	49	13.9 (0.9)	5.9	81.6 (*)
VPZ+A	33	10.4 (3.6)	4.0	100.0
PPI+M+T+Bi	2	14.0 (0.0)	0.2	100.0
VPZ+M+T+Bi	1	14.0 (0.0)	0.1	100.0
Others	31	14.0 (2.8)	3.7	87.1
TOTAL	835	13.7 (1.4)	100.0	86.8

PPI-proton pump inhibitor; C – clarithromycin; A –amoxicillin; Bi - bismuth salts; VPZ – vonoprazan; T – tetracycline; M – metronidazole; SD - standard deviation; CI - confidence interval; mITT -modified intention-to-treat.
(*) PPI+A+C versus VPZ+A+C □ *p*-value = 0.34

Conflict of Interest: S.R. Chaves: None. O.P. Nyssen: None. J.C.S. Veloso: None. H.P. Breyer: None. H. Okamoto: None. J.R. Marinho: None. L.S. Silva: None. G. Couto: None. L.A.S. Sousa: None. C.S. Alencar: None. L.F. Pena: None. H.O. Galizzi: None. B.S. Sanches: None. G.G.L. Cançado: None. L.T. Ribeiro: None. P.P. Parra: None. A. Cano-Català: None. L. Moreira: None. J.P. Gisbert: None. L.G.V. Coelho: None.

P01.10.

BRAZILIAN REGISTRY ON H. PYLORI MANAGEMENT (HP-BRAZILREG) ANALYSIS OF 300 EMPIRIC SECOND-LINE AND RESCUE TREATMENTS

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Objective: Eradication treatment effectiveness decreases as therapy failure accumulates. The objec- tive of the study was to evaluate the effectiveness of empirical retreatments in Brazil.

Materials and Methods: Hp-BrazilReg (partner of Hp-WorldReg) is a multicenter-prospective real-life registry of outcomes of H. pylori management by Brazilian gastroenterologists. Data were registered at e-CRF AEG-REDCap from March 2022 to September 2023. The effectiveness was evaluated by modified intention-to-treat (mITT) analysis. Data were subject to quality review.

Results: 298 patients, with a mean age of 52 years, 66% women, were evaluated. Overall, the main treatment indications were dyspepsia (60%) and gastroduodenal ulcer (12%). 196 (66%) patients re- ceived a second-line therapy, and 102 (34%) received a further 3rd-, 4th-, and 5th-line treatment. Low-, standard-, and high-dose PPIs, as well as vonoprazan (VPZ), were used in 39%, 13%, 27%, and 27% of cases, respectively. No pre-treatment resistance test was performed. Overall, the mean inten-tion-to-treat (mITT) effectiveness of second-line therapy was 83%. The two most common regimens were a 10-day triple therapy of PPI + amoxicillin + levofloxacin with 80% effectiveness in 54% of the patients and dual therapy with VPZ + amoxicillin with 89% effectiveness in 9% of cases. In subsequent rescue regimens, classical bismuth quadruple was the most used regimen with 91% effectiveness (Ta-ble 1). Overall, 27% of the patients presented mild adverse events; compliance was at 99%.

Conclusions: In Brazil, the overall effectiveness of second-line therapy achieved 83%. From the 3rd to the 5th rescue treatment line, empirical bismuth quadruple therapy was the most used regimen, providing ≥90% effectiveness. Dual VPZ+amoxicillin therapy showed promising results in second and subsequent rescue therapies.

TABLE 1. ANTI-*H. PYLORI* SECOND-LINE AND RESCUE REGIMENS AND THEIR EFFICACIES (N=298).

	Retreatment regimens (2nd-line)			
	N	Duration days Mean (SD)	% use	% eradication (mITT)
PPI+A+L	105	11.8 (2.0)	53.6	79
PPI+A+C	28	14 (0.0)	14.3	89
VNZ +A	18	11.7 (3.5)	9.2	89
PPI+A+L+Bi	12	13.7 (1.2)	6	100
PPI+M+T+Bi	7	14 (0.0)	3.6	57
VNZ+A+L	6	14 (0.0)	3.1	100
VNZ+A+C	5	14 (0.0)	2.6	80
VNZ+M+T+Bi	4	14 (0.0)	2.0	80
Others	11	13.8 (1.2)	6	90
TOTAL	196	12.6 (2.0)	100.0	83
	Rescue regimens (3rd-line and more)			
	N	Duration days Mean (SD)	% use	% eradication (mITT)
PPI+M+T+Bi	22	12.9 (0.38)	22	91
VNZ +A	17	14.4 (1.6)	17	100
PPI+M+D+Bi	11	14.08 (0.27)	11	100
PPI+A+C	8	14.0 (0.0)	7.8	75
VNZ+A+L	7	13.4 (1.5)	7	57
VNZ+M+T+Bi	7	14.0 (0.0)	7	100
PPI+ A+D+Bi	5	14.0 (0.0)	5	100
R + A + Bi + [PPI (1) / VNZ (3)]	4	14.0 (0.0)	4	100
PPI+A+L	4	14.0 (14.0)	4	75
VNZ+A+C	3	14.0 (0.0)	3	100
Others	14	13.5 (1.4)	14	86
TOTAL	102	13.7 (1.3)	100.0	90

PPI – proton pump inhibitor; A – amoxicillin; L – levofloxacin; VPZ – vonoprazan; M – metronidazole; T – tetracycline; C – clarithromycin; Bi – bismuth salts; D – doxycycline; R -rifabutin; SD – standard deviation; CI – confidence interval; mITT – modified intention to Treat.

Retreatment regimens (2nd-line)

Conflict of Interest: B.S. Sanches: None. O.P. Nyssen: None. S.R. Chaves: None. J.C.S. Veloso: None. H.P. Breyer: None. H. Okamoto: None. J.R. Marinho: None. L.S. Silva: None. G. Couto: None. L.A.S. Sousa: None. C.S. Alen car: None. L.F. Pena: None. H.O. Galizzi: None. G.G.L. Cançado: None. M.J.G. Massote: None. P.P. Parra: None. A. Cano-Català: None. L. Moreira: None. J.P. Gisbert: None. L.G.V. Coelho: None.

P06.06.

AN UPDATE OF THE HELICOBACTER PYLORI DIAGNOSTIC TESTS AND INDICATIONS FOR TREATMENT FROM THE LATIN AMERICAN REGISTRY ON HELICOBACTER PYLORI MANAGEMENT (HP-LATAMREG)

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Objective: There is limited information regarding the best approach for *Helicobacter pylori (H. pylori)* infection management in Latin America. Our aim was to describe the *H. pylori* diagnostic tests and treatment indications in Latin America.

Patients and Methods: A multicenter, prospective, international registry (Hp-LATAMReg; Hp-WorldReg partner) was conducted. Data were collected from seven Latin American countries from 2015 to 2024 and registered at the e-CRF AEG-REDCap platform. The most frequent indications for treatment and diagnostic tests before and after eradication treatment were evaluated.
Results: 2,497 patients were registered, of which 1,680 (67%) were female. The mean (SD) age of the patients was 53 (14) years. Most of the patients were from Mexico (n=446, 18%), Peru (n=343, 14%), and Chile (n=274, 11%). Among those, 2,186 (88%) were treatment-naïve cases. The most frequent in- dications for treatment were non-investigated dyspepsia (n=995, 40%) and dyspepsia with normal en- doscopy (n=690, 28%). The main *H. pylori* diagnostic methods before the eradication treatment were histology (n=1,642, 66%) and rapid urease test (n=354, 14%). To assess post-treatment eradication, the most frequent *H. pylori* diagnostics tests used were stool antigen monoclonal test (n=1,016, 41%) and ^{13}C-UBT (n=635, 25%). There were statistically significant differences between the countries in the diagnostic methods used, both pre- and post-treatment (Table 1).
Conclusions: In Latin America, there is a marked heterogeneity between the countries regarding the main treatment indications and the most frequently used diagnostic tests for *H. pylori* infection.

TABLE 1. **MAIN INDICATIONS OF *H. PYLORI* ERADICATION AND DIAGNOSTIC TESTS BEFORE AND AFTER THE TREATMENT IN LATIN AMERICA. THE NUMBER OF TESTS IS NOT EQUAL AS THE NUMBER OF PATIENTS BECAUSE MORE THAN ONE TEST COULD BE CONDUCTED.**

Country	Argentina (n=274)	Chile (n=343)	Colombia (n=200)	Costa Rica (n=104)	Ecuador (n=43)	Mexico (n=1,087)	Peru (n=446)	Overall (n=2,497)
Indication of *Helicobacter pylori* eradication								*p*<0.001*
Non-investigated dyspepsia	27 (9.9%)	45 (4.5%)	36 (18%)	2 (1.9%)	0 (0%)	700 (65%)	185 (42%)	995 (40%)
Dyspepsia with normal endoscopy	201 (74%)	202 (58%)	16 (8%)	15 (14%)	1 (2.3%)	33 (3%)	176 (39%)	644 (26%)
Duodenal Ulcer	13 (4.8%)	8 (2.3%)	5 (2.5%)	8 (7.7%)	1 (2.3%)	45(4.1%)	9 (2%)	89 (3.6%)
Gastric Ulcer	13 (4.8%)	7 (5.1%)	13 (6.5%)	8 (7.7%)	7 (16%)	75 (6.9%)	14 (3.1%)	137 (5.5%)
Preneoplastic lesions	0 (0%)	2 (0.6%)	0 (0%)	19 (18%)	31 (67%)	67(6.1%)	33 (7.4%)	152 (6.1%)
NSAIDs or Aspirin treatment	10 (3.7%)	0 (0%)	5 (2.5%)	0 (0%)	0 (0%)	5 (0.5%)	0 (0%)	20 (0.8%)
MALT Lymphoma	1 (0.3%)	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	0 (0%)	4 (0.2%)
First-degree relatives of patients with gastric cancer	2 (0.7%)	12 (3.5%)	9 (4.5%)	10 (9.6%)	2 (4.7%)	19 (1.8%)	16 (3.6%)	70 (2.8%)
Unexplained iron deficiency anemia	1 (0.4%)	2 (0.6%)	7 (3.5%)	0 (0%)	0 (0%)	3 (0.3%)	1 (0.2%)	14 (0.6%)
Screening to prevent gastric cancer	0 (0%)	0 (0%)	0 (0%)	1 (1%)	1 (2.3%)	17 (1.6%)	10 (2.2%)	29 (1.2%)
Other	6 (2.2%)	64 (19%)	109 (54%)	41 (39%)	0 (0%)	121 (11%)	2 (0.4%)	343 (14%)
Diagnostic test before eradication								
13C-UBT	6 (2.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	166 (15%)	126 (28%)	298 (12%, p<0.001*)
14C-UBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	75 (6.9%)	37 (8.3%)	112 (4.5%, p<0.001*)
Serology	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)	1 (0.2%)	5 (0.2%, p=0.7)
SA Monoclonal Test	10 (3.6%)	15 (4.4%)	4 (2%)	15 (14%)	6 (14%)	29 (2.7%)	0 (0%)	79 (3.2%, p<0.001*)
SA Polyclonal Test	2 (0.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	18(1.7%)	0 (0%)	20 (0.8%, p=0.01*)
Histology	256 (93%)	25 (7.3%)	196 (98%)	65 (63%)	37 (86%)	788 (73%)	275 (62%)	1,642 (66%, p<0.001*)
RUT	0 (0%)	310 (90%)	0 (0%)	29 (28%)	0 (0%)	7 (0.6%)	8 (1.8%)	354 (14%, p<0.001*)
Culture	0 (0%)	0 (0%)	0 (0%)	3(0.1%)	0 (0%)	0 (0%)	0 (0%)	3 (0.1%, p<0.001*)
Stool PCR test	0 (0%)	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	0 (0%)	0 (0%)	2 (0.1%, p<0.001*)
Diagnostic test after eradication								
13C-UBT	83 (30%)	69 (20%)	0 (0%)	0 (0%)	0 (0%)	307 (28%)	176 (40%)	635 (25%, p<0.001*)
14C-UBT	4 (1.5%)	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)	262 (24%)	249 (56%)	516 (21%, p<0.001*)
Serology	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.3%)	0 (0%)	0 (0%)	1 (0.1%, p<0.001*)
SA Monoclonal Test	178 (65%)	207 (60%)	198 (99%)	96 (92%)	43 (100%)	292 (27%)	2 (0.4%)	1,016 (41%, p<0.001*)
SA Polyclonal Test	5 (1.8%)	4 (1.2%)	0 (0%)	0 (0%)	0 (0%)	139 (13%)	0 (0%)	148 (5.9%, p<0.001*)
Histology	8 (2.9%)	16 (4.7%)	2 (1%)	6 (5.8%)	0 (0%)	68 (6.3%)	12 (2.7%)	112 (4.5%, p<0.001*)
RUT	0 (0%)	46 (13%)	0 (0%)	2 (1.9%)	0 (0%)	0 (0%)	1 (0.2%)	49 (2%, p<0.001*)
Stool PCR test	0 (0%)	1 (0.3%)	0 (0%)	3 (2.9%)	0 (0%)	0 (0%)	0 (0%)	4 (0.2%, p<0.001*)

*Chi-square test. MALT = mucosa-assisted lymphoid tissue; UBT = Urea Breath Test; SA= Stool Antigen; RUT= Rapid Urease Test.

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MOST FREQUENT HELICOBACTER PYLORI FIRST-LINE EMPIRICAL ERADICATION THERAPIES: DATA FROM THE LATIN AMERICAN REGISTRY ON H. PYLORI MANAGEMENT (HP-LATAMREG)

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***Objective**: Helicobacter pylori* infection is a public health problem in Latin America. Our aim was to describe the most frequent eradication therapies, their effectiveness, adherence, and safety.

Materials and Methods**:* A multicenter, prospective, international registry (Hp-LATAMReg; Hp- WorldReg partner) was conducted. Therapies used in seven countries of Latin America from 2015 to 2024 were registered at e-CRF AEG-REDCap platform. The modified intention-to-treat (mITT) effective- ness, safety, adherence, length of treatment, and the proton pump inhibitor (PPI) dose prescribed were analyzed for the first-line regimens. ***Results: 2,511 patients were registered, of which 2,323 (93%) were treatment-naïve. The most commonly prescribed first-line therapies (n=2,216, 88%) were PPI-amoxicillin-clarithromycin (n=801, 30%) and PPI-clarithromycin-amoxicillin-metronidazole (n=369, 14%). Most of these regimens (n=2,055, 93%) were prescribed for 14 days, and almost 50% of the patients were administered high-dose PPIs (54 to 128 mg omeprazole equivalents b.i.d.) (n=967, 46%) with significant differences between treat- ment schemes (p<0.01). The first-line mITT overall effectiveness ranged from 74% to 95%, wit the PPI-amoxicillin-metronidazole-bismuth the only therapy achieving optimal (90%) cure rates. However, when therapies were optimized (i.e. 14 days and high-dose PPIs), other quadruple therapies, such as the PPI-amoxicillin-clarithromycin-metronidazole and the PPI-metronidazole+tetracyclin+bismuth, also provided optimal (>90%) effectiveness. Good adherence, defined as >90% of drug intake, was observed in 98% (n=2,163) of cases (Table 1).

Conclusions: In Latin America, bismuth quadruple therapy with PPI-amoxicillin-metronidazole-bis- muth and optimized (14-day and high-dose PPIs) non-bismuth concomitant quadruple with PPI-amox- icillin-clarithromycin-metronidazole and bismuth quadruple with PPI-metronidazole-tetracycline-bis- muth provided optimal (>90%) effectiveness.

TABLE 1. EFFECTIVENESS BY MODIFIED INTENTION-TO-TREAT, SAFETY, AND COMPLIANCE OF FIRST-LINE EMPIRICAL THERAPY IN LATIN AMERICA.

	PPI-C-A (27%, n=801)	PPI-C-A-M (15%, n=366)	PPI-A (11%, n=274)	PPI-M-Tc-B (7.3%, n=185)	PPI-C-A-B (4.2%, n=118)	PPI-A-M-B (6.7%, n=156)	PPI-A-L (3.7%, n=109)	PPI-M-D-B (7.9%, n=201)
mITT eradication rate (%, n) (p<0.01*)	75%, n=595	89%, n=327	88%, n=241	87%, n=160	79%, n=93	95%, n=148	74%, n=81	87%, n=172
Side effects rate (%, n) (p<0.01*)	35%, n=281	41%, n=151	7.3%, n=20	12%, n=23	18%, n=21	47%, n=72	20%, n=22	48%, n=97
Adherence rate (%, n) (p<0.01*)	98%, n=779	99%, n=363	98%, n=269	97%, n=181	98%, n=117	97%, n=152	99%, n=109	96%, n=193
High-dose PPIs use (%, n) (p<0.01*)	25%, n=192	31%, n=105	98%, n=267	73%, n=132	22%, n=25	65%, n=100	43%, n=44	52%, n=102
High-dose PPIs mITT cure rate (%, n) (p<0.01*)	69%, n=131	85%, n=88	88%, n=236	93%, n=123	72%, n=18	97%, n=97	77%, n=34	83%, n=85
14 days use (%, n) (p<0.01*)	89%, n=697	98%, n=358	99%, n=273	99%, n=184	95%, n=105	100%, n=156	90%, n=99	97%, n=195
14-days mITT cure rate (%, n) (p<0.01*)	77%, n=530	91%, n=322	88%, n=241	87%, n=159	78%, n=81	95%, n=148	77%, n=75	88%, n=171
14-days and high-dose PPIs use (%, n) (p<0.01*)	23%, n=185	26%, n=96	99%, n=266	71%, n=131	21%, n=25	64%, n=100	37%, n=40	49%, n=98
14-days and high-dose PPIs mITT cure rates (%, n) (p<0.01*)	74%, n=115	90%, n=84	89%, n=236	93%, n=122	72%, n=18	97%, n=97	80%, n=32	85%, n=83

*Chi-square test. mITT = modified intention to treat; PPI = Proton pump inhibitor; C = clarithromycin; A = amoxicillin; B = bismuth salts; M = metronidazole; L = levofloxacin; Tc= tetracycline; D = doxycycline; high-dose PPIs (54 to 128 mg omeprazole equivalents b.i.d.).

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HELICOBACTER PYLORI TREATMENT IN PAKISTAN: DATA FROM THE PAKISTAN REGISTRY ON H. PYLORI MANAGEMENT (HP-PAKISTANREG)

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***Objective**:* In Pakistan, there are several treatment options for *H. pylori* treatment. These include a combination of various antibiotics with proton pump inhibitors. The aim of this study was to investi- gate the effectiveness of first-line empirical treatment of *H. pylori* in Pakistan. ***Patients and Methods**:* Treatment-naïve patients from Hp-PakistanRegin 2021-2023 were analyzed *via*
modified intention-to-treat (MITT) and per-protocol (PP) for effectiveness.

Results: 123 patients were analyzed. Male (62%) and female (38%) patients were enrolled in the study. 79% of patients were treatment naïve, and 99% did not show any type of allergy. 24% received a con- current treatment (11% proton pump inhibitors). Diagnosis involved multiple tests, including serology, urea breath test, stool antigen tests, histology, rapid urease test, culture, and stool polymerase chain reaction (PCR), along with endoscopic confirmation as needed. Treatment regimens varied, with triple therapy being the most common (42%), followed by dual (7.2%), quadruple (3.1%), and hybrid therapy (1.0%). Duration was typically 10 (70%) or 14 days (24%). 13% of prescriptions included probiotics, whereas no patient was found to be on prebiotics. 96% of patients were adherent to therapy. Antibiotic resistance to clarithromycin, nitroimidazole, quinolone, amoxicillin, and tetracycline was not observed in any of the patients. According to PP analysis, the overall first-line therapy effectiveness was 91% in 2022 and 80% in 2023. According to mITT, in 2022, it was reported as 91%, and in 2023, it was 76%.

Conclusions: Our study sheds light on *H. pylori* management in Pakistan, highlighting effective strat- egies for treatment-naïve patients. Despite adherence and no bacterial resistance, declining efficacy underscores the need for ongoing monitoring and protocol adjustments.

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