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

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Background: There is limited information regarding the best approach for *Helicobacter pylori (H.pylori)* management in Latin America. The aim was to describe the *H. pylori* diagnostic tests and indications of treatment in Latin America. **Methods:** A multicenter, retrospective, international registry (Hp-LATAMReg) was conducted. Information about therapies used by gastroenterologists in six countries (Argentina, Chile, Colombia, Costa Rica, Mexico, and Peru) from 2015 to 2023 was registered in an e-CRF AEG-REDCap database. The most frequent indications for treatment and diagnostic tests before and after eradication treatment were described. **Results:** 1,378 patients were registered, of which 933 (68%) were female. The mean (SD) age of the patients was 53 (14) years. 524 patients (38%) were from Mexico, 210 patients (15%) from Argentina, 210 (15%) from Chile, 200 (14%) from Colombia, 176 (13%) from Peru and 58 (4.2%) from Costa Rica. 1218 (89%) were treatment naïve. The most frequent indication for treatment were non-investigated dyspepsia (n=526, 38%) and dyspepsia with normal endoscopy (n=334, 24%). The main *H. pylori* diagnostic methods before the eradication treatment were: histology (n=905, 67%), rapid urease test (RUT) (n= 196, 14%) and ^{13}C urea breath test (UBT) (n=180, 13%). To assess post-treatment eradication, the most frequent *H. pylori* diagnostics test used were: stool antigen (SA) monoclonal test (n=530, 39%), ^{13}C UBT (n=400, 29%) and ^{14}C UBT (n=215, 16%). There were statistical differences between the countries regarding the indication for treatment and the diagnostics methods before and after the eradication therapy (Table 1). **Conclusions:** In Latin America, there was marked heterogeneity between the countries regarding the main indications of treatment and the most frequently used diagnostics tests for *H. pylori* infection. It is necessary a consensus on the management of *H. pylori* infection in Latin America.

Country	Argentina (n=210)	Chile (n=210)	Colombia (n=200)	Costa Rica (n=58)	Mexico (n=524)	Peru (n=176)	Overall (n=1,378)
Indication of Helicobacter pylori eradication							**p<0.001***
Non-investigated dyspepsia	20 (9.5%)	8 (3.8%)	36 (18%)	0 (0%)	322 (61%)	140 (80%)	526 (38%)
Dyspepsia with normal endoscopy	153 (73%)	117 (56%)	20 (10%)	0 (0%)	19 (3.6%)	25 (14%)	334 (24%)
Duodenal Ulcer	11 (5%)	2 (1%)	5 (2.5%)	1 (1.7%)	24 (4.6%)	1 (0.6%)	44 (3.2%)
Gastric Ulcer	12 (5.5%)	2 (1%)	13 (6.5%)	6 (10%)	38 (7.3%)	5 (2.8%)	76 (5.5%)
Preneoplastic lesions	0 (0%)	2 (1%)	0 (0%)	10 (17.2%)	29 (5.5%)	0 (0%)	41 (3%)
MALT Lymphoma	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	0 (0%)	3 (0.2%)
First-degree relatives of patients with gastric cancer	0 (0%)	12 (5.7%)	9 (4.5%)	8 (14%)	8 (1.5%)	4 (2.3%)	41 (3%)
Unexplained iron deficiency anaemia	2 (0.9%)	2 (1%)	14 (7%)	0 (0%)	2 (0.4%)	0 (0%)	20 (1.5%)
Other	11 (5%)	65 (31%)	103 (52%)	33 (57%)	80 (15%)	1 (0.6%)	293 (21%)
Diagnostic test before eradication							
^{13}C UBT	6 (2.9%)	0 (0%)	0 (0%)	0 (0%)	94 (17%)	80 (46%)	180 (13%, **p<0.001***)
^{14}C UBT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	41 (7.8%)	10 (5.7%)	51 (3.7%, **p<0.001***)
Serology	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.2%)	0 (0%)	3 (0.2%, p=0.428)
SA Monoclonal Test	3 (1.4%)	13 (6.2%)	4 (2%)	3 (5.2%)	5 (1%)	0 (0%)	28 (2%, **p<0.001***)
SA Polyclonal Test	2 (0.1%)	0 (0%)	0 (0%)	0 (0%)	18 (3.4%)	0 (0%)	20 (1.5%, **p<0.001***)
Histology	199 (95%)	25 (12%)	196 (98%)	42 (72%)	357 (68%)	86 (49%)	905 (66%, **p<0.001***)
RUT	0 (0%)	179 (85%)	0 (0%)	13 (22%)	4 (0.8%)	0 (0%)	196 (14%, **p<0.001***)
Culture	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)	0 (0%)	0 (0%)	1 (0.1%, **p<0.001***)
Stool PCR test	0 (0%)	0 (0%)	0 (0%)	2 (3.4%)	0 (0%)	0 (0%)	2 (0.1%, **p<0.001***)
Diagnostic test after eradication							
^{13}C UBT	58 (28%)	69 (33%)	0 (0%)	0 (0%)	171 (33%)	102 (58%)	400 (29%, **p<0.001***)
^{14}C UBT	4 (1.9%)	1 (0.5%)	0 (0%)	0 (0%)	138 (26%)	72 (41%)	215 (16%, **p<0.001***)
SA Monoclonal Test	143 (68%)	85 (41%)	198 (99%)	52 (90%)	52 (9.9%)	0 (0%)	530 (39%, **p<0.001***)
SA Polyclonal Test	1 (0.5%)	3 (1.4%)	0 (0%)	0 (0%)	124 (24%)	0 (0%)	128 (9.3%, **p<0.001***)
Histology	8 (3.8%)	16 (7.6%)	2 (1%)	4 (6.9%)	35 (6.7%)	1 (0.6%)	66 (4.8%, **p<0.001***)
RUT	0 (0%)	41 (20%)	0 (0%)	2 (3.4%)	0 (0%)	0 (0%)	43 (3.1, **p<0.001***)
Stool PCR test	0 (0%)	0 (0%)	0 (0%)	2 (3.4%)	0 (0%)	0 (0%)	2 (0.1%, **p<0.001***)

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.

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

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QUADRUPLE AND DUAL THERAPIES ARE SUPERIOR TO STANDARD CLARITHROMYCIN-BASED TRIPLE THERAPY FOR HELICOBACTER PYLORI FIRST-LINE ERADICATION THERAPY USED IN THE LATIN AMERICAN REGISTRY ON THE MANAGEMENT OF HELICOBACTER PYLORI INFECTION (HP-LATAMREG).

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Background: *Helicobacter pylori* infection is a public health problem in Latin America. The aim was to describe and evaluate the main *Helicobacter pylori* eradication therapies, their eradication rates, adherence, and side effects. **Methods:** A multicenter, retrospective, international registry (Hp-LATAMReg) was conducted. Information about therapies used by gastroenterologists in six countries (Argentina, Chile, Colombia, Costa Rica, Mexico, and Peru) from 2015 to 2023 was registered in an e-CRF AEG-REDCap database. The modified intention-to-treat (mITT) effectiveness, safety, and adherence was analyzed for the first-line regimens. The mITT and the side effects rate of the schemes were compared by a Poisson multivariate regression, adjusted by sex, age, proton pump inhibitor (PPI) dose used in the schemes and the length of the treatment. **Results:** 1,378 patients were registered, of which 1,218 (88%) were treatment-naïve. The most commonly prescribed first-line therapies (n= 1,117, 81%) were analyzed: standard clarithromycin-based triple therapy (SCTT) (PPI-amoxicillin (A)-clarithromycin (C); n=405, 29%), PPI-C-A-Metronidazole (M) (n=219, 16%), dual therapy (DT) (PPI-A; n=139, 10%), PPI-M-Tetracycline (Tc)-Bismuth (B) (n=133, 9.7%), PPI-C-A-B (n=70, 5.1%), PPI-A-M-B (n=41, 3%), PPI-A-Levofloxacin (L) (n=39, 2.8%), PPI-M-Doxycycline (D)-B (n=37, 2.7%) and PPI-A-D-B (n=34, 2.5%). Most of the regimes were 14-day long (n=1,051, 96%), and administered high-dose PPIs (54 to 128 mg omeprazole equivalents b.i.d.) (n=548, 50%). The first-line mITT overall effectiveness ranged from 72% to 100%, being the DT, PPI-A-M-B, PPI-M-Tc-B, PPI-C-A-M and PPI-A-D-B significantly more effective than SCTT. Moreover, the DT, PPI-M-Tc-B, PPI-C-A-B and PPI-A-D-B schemes had significantly fewer side effects compared with SCTT. Good adherence, defined as >90% of drug intake, was observed in 98% (n=1,090), without differences between the schemes (p=0.16) (Table 1). **Conclusions:** In Latin America, quadruple and dual therapies were superior to SCTT and were safer than standard triple therapy. SCTT should not be considered as a first-line eradication treatment in Latin America.

Prescription (%, n)	SCTT (29%, n=405)	PPI-C-A-M (16%, n=219)	DT (10%, n=139)	PPI-M-Tc-B (9.7%, n=133)	PPI-C-A-B (5.1%, n=70)	PPI-A-M-B (3%, n=41)	PPI-A-L (2.8%, n=39)	PPI-M-D-B (2.7%, n=37)	PPI-A-D-B (2.5%, n=34)
mITT eradication rate (%, n) (p<0.01*)	75%, n=301	93%, n=201	90%, n=125	89%, n=118	81%, n=57	100%, n=41	72%, n=28	81%, n=30	94%, n=32
Side effects rate (%, n) (p<0.01*)	39%, n=156	37%, n=82	10%, n=14	6.8%, n=9	16%, n=11	40%, n=16	21%, n=8	43%, n=16	2.9%, n=1
Good adherence rate (%, n) (p=0.16*)	97%, n=391	99%, n=215	99%, n=138	98%, n=130	99%, n=69	98%, n=40	100%, n=39	92%, n=34	100%, n=34

Poisson multivariate model of the eradication rates per scheme

Scheme	RR eradication (95% CI)	p-value
SCTT	Reference	-
PPI-A-L	0.97 (0.79-1.20)	0.78
DT	1.13 (1.03-1.23)	0.01
PPI-A-M-B	1.25 (1.16-1.34)	<0.01
PPI-M-Tc-B	1.15 (1.05-1.26)	<0.01
PPI-M-D-B	1.05 (0.88-1.26)	0.60
PPI-C-A-M	1.21 (1.13-1.30)	<0.01
PPI-C-A-B	1.07 (0.95-1.22)	0.27
PPI-A-D-B	1.15 (1.03-1.29)	<0.01

Poisson multivariate model of the side effects rates per scheme

Scheme	RR side effects (95% CI)	p-value
SCTT	Reference	-
PPI-A-L	0.53 (0.27-1.04)	0.07
DT	0.36 (0.21-0.63)	<0.01
PPI-A-M-B	1.33 (0.87-2.03)	0.18
PPI-M-Tc-B	0.24 (0.12-0.46)	<0.01
PPI-M-D-B	1.27 (0.82-1.95)	0.28
PPI-C-A-M	0.91 (0.73-1.12)	0.37
PPI-C-A-B	0.35 (0.19-0.65)	<0.01
PPI-A-D-B	0.11 (0.02-0.74)	0.02

Table 1. Eradication, side effects and acceptable adherence rates of the different schemes and the Poisson multivariate models (adjusted by sex, age, PPI dose used in the schemes and the length of the treatment) for eradication per scheme and side effects per scheme. *Chi square test. mITT = modified intention to treat; SCTT = Standard clarithromycin-based triple therapy; DT = Dual therapy; PPI = Proton pump inhibitor; C = Clarithromycin; A = Amoxicillin; B = Bismuth salts; M = Metronidazole; L = Levofloxacin; T = Tetracycline; D = Doxycycline.