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Research Article

Efficacy of Helicobacter pylori Eradication Regimens in Romanian Patients - A Single-Center Experience

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ABSTRACT

Background: Helicobacter pylori infection affects nearly 50% of the global population and is associated with various gastrointestinal and systemic disorders. Rising antibiotic resistance, particularly to clarithromycin and metronidazole, has reduced the efficacy of standard eradication therapies. Limited local resistance data in Romania necessitate evaluation of current treatment regimens.

Methods: This prospective study enrolled 100 consecutive H. pylori-positive patients (70 females, 30 males; mean age ~53 years) at Valahia Medical Center, Romania (2023–2025). Diagnosis was confirmed via breath test, rapid urease test or stool antigen test. Patients received one of 17 treatment regimens, including clarithromycin-based triple therapy, levofloxacin-based regimens and adjunctive therapies (e.g., bismuth, herbal supplements like GastriSan). Eradication was assessed post-treatment using the HELIC® ABT breath test, rapid urease test or stool antigen test.

Results: Overall eradication rate was 49% (42.85% in females, 63.33% in males). High eradication rates (100%) were observed in small cohorts receiving levofloxacin-amoxicillin-PPI (10 days) or clarithromycin-amoxicillin-PPI (10 days). The clarithromycin-amoxicillin-PPI-GastriSan regimen (14 days, n=16) achieved 75% efficacy. Levofloxacin-tinidazole-PPI (10 days, n=10) and clarithromycin-amoxicillin-PPI (14 days, n=47) showed moderate efficacy (50% and 48.9%, respectively). Bismuth-containing regimens had low success (33.33%). Herbal adjuncts improved eradication (68.42% overall, 76.47% with GastriSan). First-attempt treatments had higher success (51.94%) than second attempts (31.57%).

Conclusion: Eradication rates for standard therapies in Romania are suboptimal, reflecting antibiotic resistance. Levofloxacin-based regimens and GastriSan supplementation show promise but require further validation. Personalized treatment strategies, susceptibility testing and larger studies are needed to optimize outcomes. Non-invasive breath testing may enhance patient compliance and monitoring.

Keywords: Helicobacter pylori; Antibiotic resistance; Eradication therapy; GastriSan; Romania; Levofloxacin; Clarithromycin

Introduction

H. pylori infects nearly 50% of the global population and is implicated in a range of gastrointestinal and extra-gastrointestinal disorders including peptic ulcer disease, gastric adenocarcinoma and MALT lymphoma[1,2]. In addition, H. pylori have been linked with iron deficiency anaemia, idiopathic thrombocytopenic purpura and vitamin B12 deficiency[3].

Rising antibiotic resistance, particularly to clarithromycin and metronidazole, has significantly reduced the efficacy of traditional eradication therapies[4]. The World Health Organization (WHO) has even designated clarithromycin-resistant H. pylori a high-priority target for new antibiotic development[5]. In Romania, where limited local resistance data exist[6,7], evaluating the performance of current treatment regimens is critical to guide clinical practice.

Methods

Study design and patient selection

In this prospective study, 100 consecutive patients diagnosed with H. pylori infection at Valahia Medical Center in Ploiești, Romania were enrolled between March 1, 2023 and January 10, 2025. The group had 70 females and 30 males, with a medium age of 53.06 years for females and 53,47 years for men **(Table 1)**.

Table 1: Descriptive data.

	Age	
	female	**male**
Valid	70	30
Mean	53.06 years	53.47 years
Std. Deviation	14.08	18.43
Minimum	18.00	20.00
Maximum	78.00	85.00

Diagnosis was confirmed using one of the following methods described in **(Table 2)**.

Table 2: Diagnostic tests used.

Diagnostic Test	Invasiveness	Target	Reference
HELIC® ABT Test	Non-invasive	Urease activity (breath test) measured in mm (Delta value)	[8,9]
Gastric Biopsy Rapid Urease Test	Invasive	Urease enzyme in gastric biopsies	[3]
Stool Fecal Antigen Test	Non-invasive	H. pylori antigens in stool	[10]

The HELIC® ABT test measures the variation of breath ammonia after the ingestion of a standardised sample of urea provided by the manufacturer. The patient has to keep a probe in the mouth and the test measure variation of ammonia in the breath in the first 7 minutes. An increase over 3 mm on the test is considered positive with a sensitivity of 95% and a specificity of 97%[8,9].

Treatment regimens

Patients were assigned one of 17 treatment regimens according to clinical guidelines and individual profiles. The regimens are detailed in **(Table 3)**.

Follow-up and efficacy assessment

Two weeks after treatment completion, patients underwent a repeat HELIC® ABT test. Eradication was defined as the absence of detectable H. pylori.

Table 3: Treatment Regime and Outcomes.

Treatment No.	Regimen Description	Duration	Sample Size	Eradication Rate
1	Levofloxacin + Amoxicillin + PPI	10 days	2	100%
2	Clarithromycin + Amoxicillin + PPI + GastriSan11	14 days	16	75%
3	Clarithromycin + Amoxicillin + Bismuth Oxide + PPI + Pylorix	10 days	1	0 %
4	Tetracycline + Metronidazole + Bismuth Oxide + PPI	10 days	1	0%
5	Clarithromycin + Amoxicillin + PPI	10 days	2	100%
6	Clarithromycin + Amoxicillin + PPI	14 days	47	48,90%
7	Clarithromycin + Amoxicillin + PPI + Bismuth oxide	14 days	3	33,33%
8	Clarithromycin + Amoxicillin + PPI + Helicostop	10 days	1	0%
9	Clarithromycin + Metronidazole + PPI	14 days	2	0%
10	Clarithromycin + Tinidazole + PPI	14 days	1	0%
11	Clarithromycin + Tinidazole + PPI + Trimethoprim/ Sulfamethoxazole + Bismuth Oxide + PPI	10 days	1	0%
12	Levofloxacin + Amoxicillin + PPI	14 days	3	33,33 %
13	Levofloxacin + Doxycycline + PPI	10 days	1	100%
14	Levofloxacin + Metronidazole + PPI	10 days	1	0%
15	Levofloxacin + Tinidazole + PPI	10 days	10	50,00 %
16	Levofloxacin + Tinidazole + PPI + GastriSan	10 days	1	100%
17	Tetracycline + Metronidazole + Bismuth Oxide + PPI	10 Days	7	42,85%

***Note:** Treatments 1,3,4,5,7, 8, 9,10,11, 12, 13, 14, 16 and 17 had very small sample sizes, reported as a range.

Results

The study revealed considerable variability in the eradication rates across the regimens. To facilitate comparison, **(Tables 4, 5 and 6)** ranks the treatment options by efficacy and provides commentary on each.

The overall efficacy of all the treatments was 49% (42,85% for females and 63,33% for men).

Table 4: Ranking of Treatment Options.

Treatment No.	Regimen Description	Sample Size	Eradication Rate	Comments
5	Clarithromycin + Amoxicillin + PPI 10 Days	2	100%	Promising; however, based on two patients
1	Levofloxacin + Amoxicillin + PPI 10 Days	2	100%	Promising; however, based on two patients

Treatment No.	Regimen Description	Sample Size	Eradication Rate	Comments
13	Levofloxacin + Doxycycline + PPI 10 days	1	100%	Promising; however, based on a single patient
16	Levofloxacin + Tinidazole + PPI + GastriSan 10 days	1	100%	Promising; however, based on a single patient
2	Clarithromycin + Amoxicillin + PPI + GastriSan 10 days[11]	16	75%	Best option among regimens with multiple patients
10	Levofloxacin + Tinidazole + PPI 14 Days	10	50%	Most common regimen; moderate efficacy
6	Clarithromycin + Amoxicillin + PPI 14 days	47	48%	Most common regimen; moderate efficacy
17	Tetracicline + Metronidazole + Bismuth + PPI 10 days	7	42,85%	Most common regimen; moderate efficacy
7	Clarithromycin + Amoxicillin + PPI + Bismuth oxide 14 days	3	33,33%	Least effective among those with reported data
12	Levofloxacin + Amoxicillin + PPI 14 days	3	33,33%	Least effective among those with reported data
3,4, 8, 9,10,11, 12, 13, 15	Various regimens with 0% eradication	1–3	0%	Not effective

Table 5: Efficacy of different pharmaceutical agents used.

Pharmaceutical used	**Length of the regimen**	**Sample Size**	**Medium Delta value before treatment, mm** (HELIC® ABT Test)	**Medium Delta value after treatment, mm** (HELIC® ABT Test)	**Eradication Rate**
Mixed	10 days	25	15 mm	8 mm	48%
Mixed	14 days	75	16 mm	8 mm	49,33%
Clarithromycin	Mixed	75	15 mm	8 mm	50,66%
Clarithromycin	10 days	3	7 mm	8 mm	66.66%
Clarithromycin	14 days	72	15 mm	8 mm	50%
Amoxicillin	mixed	79	16 mm	8 mm	49,36%
Amoxicillin	10 days	5	13 mm	8 mm	40%
Bismuth oxide	mixed	12	17 mm	10 mm	33,33%
Levofloxacin	mixed	18	17 mm	7 mm	44,44%
Levofloxacin	10 days	15	15 mm	7 mm	46,66%
Levofloxacin	14 days	4	29 mm	7 mm	50%
Metronidazole	mixed	11	16 mm	9 mm	27,27%
Tinidazole	mixed	13	15 mm	7 mm	46,15%
Tetracycline	10 days	7	17 mm	10 mm	42,85%
Herbal additives (Pilorix, Helicostop, Gastrisan)	mixed	19	15 mm	8 mm	68,42%
GastriSan	mixed	17	15 mm	8 mm	76,47%

Table 6: The efficacy of the treatment by cure attempt number.

The cure number	**Sample Size**	**Medium Delta value before treatment, mm** (HELIC® ABT Test)	**Medium Delta value after treatment, mm** (HELIC® ABT Test)	**Eradication Rate**
1	77	16 mm	8 mm	51,94%
2	19	17 mm	9 mm	31,57%
3	3	10 mm	3 mm	100%

Discussion

The declining eradication rates of standard clarithromycin-based triple therapy (Treatments 2,3, 5, 6, 7, 8, 9, 10 and 11) align with global trends and suggest a high prevalence of antibiotic resistance[12,4,13]. Treatments 1, 12, 13, 14, 15 and 16 which uses a levofloxacin-based regimen, achieved the highest eradication rate among treatments with more than one patient (50.00%) and may represent a viable alternative in the setting of clarithromycin resistance.

While Treatment 2, incorporating GastriSan, demonstrated a 75% eradication rate, the sample size of 16 patients limits the strength of this finding. Nevertheless, the adjunctive use of natural compounds such as kale cabbage powder is promising and merits further exploration in larger, controlled trials. Treatments 3,4, 8, 9,10,11 and 14, despite their inclusion in the study, showed no success, indicating that these regimens are not effective under current conditions.

The length of the regime influenced the result of the treatment. 25 patients (19 females and 6 males) were on a 10-day regimen (medium age 53 years). All the 10 days regimens had a 48% cure rate (12 patients, 9 females and 4 male, medium age49 years old). The rest of 75 patients were on a 14-day regimen and 37 patients (49,33%) were cured (22 females and 15 males, medium age 48 years).

The regimes that included clarithromycin cured 50,66% of patients and all the regimes that contained amoxicillin had a

49,36% cure rate. Also, the regimes that included levofloxacin had 44,44% rate and the regimes that included bismuth oxide a low rate of 33,33%.

The regimes that included an herbal additive had obtained a higher cure rate of 68,42%, mainly because of the GastriSan treatment arm that cured 76,47% of patients when added to the regimen.

In women the rate is slightly lower than men. The patients that were on the first cure attempt obtained a 51,49% rate, higher than the medium rate, as well as the patient on the 3rd cure attempt. A Medium age of the patients that responded to treatment was 49, lower than the medium age of the group.

The number of patients that were screened was 263 and only 100 returned for HP evaluation after treatment. Almost 62 % of patients didn't return for the final test.

Conclusion

Our findings underscore the need for personalized and region-specific H. pylori eradication strategies. Based on our data:

- Treatment 10 (Levofloxacin + Tinidazole + PPI for 10 days) appears to be the best option among regimens with multiple patients, with a 50.00% eradication rate.
- Treatment 2 (Clarithromycin + Amoxicillin + PPI + GastriSan) is highly promising, obtaining a 75% eradication rate; however, further investigation is required due to its extremely limited sample size.
- Adding herbal supplements – Gastrisan – to a regiment can increase the cure rate to 76,47%
- Routine antibiotic susceptibility testing, enhanced patient education and larger multicentre studies are recommended to optimize treatment selection and improve patient outcomes.
- Noninvasive breath tests like (HELIC® ABT Test) can increase the diagnostic and eradication rate in patients that are refusing upper digestive endoscopy.

Eradication rates for standard therapies in Romania are suboptimal, reflecting antibiotic resistance. Levofloxacin-based regimens and GastriSan supplementation show promise but require further validation. Personalized treatment strategies, susceptibility testing and larger studies are needed to optimize outcomes. Non-invasive breath testing may enhance patient compliance and monitoring.

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