ORIGINAL ARTICLE

Study of The Safety and Efficacy of Different Esomeprazole Containing Regimens for Eradication of Helicobacter Pylori Infection

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Abstract

Background: ***One of the most prevalent chronic bacterial illnesses affecting humans is Helicobacter pylori (H. pylori). Helicobacter pylori has colonized more than 50% of the global population. Infection with Helicobacter pylori can affect as many as 80% of the population in some nations, such as Egypt; however, this number varies widely around the globe.***

Aim and objectives: ***To determine which esomeprazole-containing regimens are safest and most effective in eliminating H. pylori infection.***

Patients and methods: ***This is a prospective observational study carried out on 120-patients. The material of the present study included H. Pylori patients who were recruited form Al-Hussein Hospital, internal medicine outpatient clinics from April 2023 and April2024.***

Results: ***H. pylori eradication rate after esomeprazole-based regimen was 70.8%. Eradication rate did not significantly differ between different esomeprazole-based regimens. Also, patients reported adverse events had significantly lower eradication rate of H. pylori.***

Conclusion: ***The overall eradication rate of H. pylori using esomeprazole-based regimens was 70.8%, indicating moderate efficacy across different treatment protocols. The eradication rates were similar across all five esomeprazole-based regimens, suggesting that the efficiency of the antibiotic combinations used was not significantly different.***

Keywords: Esomeprazole; H. pylori; Eradication; Infection; Regimens

1. Introduction

The spiral-shaped, gram-negative, flagellated bacterium known as Helicobacter pylori (H. pylori) often inhabits the gastrointestinal mucosa. Roughly half of the global population is impacted, with that number rising to as high as 80% in nations with lower or medium outcomes. Transmission from person to person is the most common mode of transmission and typically happens within the first five years of a person's life.[1]

H. pylori infection risk factors include low socioeconomic status, promiscuity, a personal or familial history of gastritis or H. pylori infection, heavy alcohol use, and cigarette smoking.[2]

Fast urease tests, breath tests, serology tests, and stool antigen tests are noninvasive ways to diagnose H. pylori. On the other hand, there are three invasive procedures that rely on biopsy samples: culture and histology. Histology is still the be-all and end-all, although new techniques utilizing HD endoscopy have emerged.[1]

The first positive proton pump inhibitor (PPI) to be created as an optical isomer (L-isomer) was esomeprazole.5 Compared to omeprazole, its oral bioavailability is higher, leading to a more effective suppression of acid levels. When compared to omeprazole, esomeprazole exhibits stronger antibacterial action against Helicobacter pylori in vitro.[3]

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Most antibiotics' actions are pH-dependent, and PPIs' effectiveness has been demonstrated beyond a reasonable doubt. When it comes to treating H. pylori, proton pump inhibitors can work in two ways. Their antibacterial action against Helicobacter pylori and inhibition of stomach acid output have been studied in vitro.[4]

This study aims to evaluate several regimens that contain esomeprazole for the purpose of eradicating H. pylori infections, taking safety and effectiveness into consideration.

2. Patients and methods

A total of 120 participants were included in this prospective observational study. Participants in this study were recruited from the internal medicine outpatient clinics at Al-Hussein Hospital between April 2023 and April 2024. The patients tested positive for H. Pylori.

Inclusion criteria:

Aged above 18-years, both sexes, H. pylori infection was confirmed by positive H. pylori stool antigen test, naïve to treatment of H. pylori, and accepted to participate in the study and signed the written informed consent.

Exclusion criteria:

Patients receiving PPI other than esomeprazole, patients previously treated for H. pylori (previous attempts for eradication), pregnant females, and patients refusing to be enrolled in the study.

Sample size:

The G-power program was used to compute the sample size with the α parameter. There were 120 patients divided into 4 groups based on their cure rate following an esomeprazole-based regimen in an earlier trial, with an error of 0.05 and a power of 80%.5

Population and grouping:

The study included 120 patients who received 5-esomeprazole-based regimens:

Group-1 included 24-patients who received a regimen composed of(Amoxicillin 1gm BD+clarithromycin 500mg BD+esomeprazole 40mg BD) for 14-days; Group-2 included 24-patients(Amoxicillin 1gm BD+Metronidazole 500mg TDS+Clarithromycin 500mg BD+esomeprazole 40mg BD) for 14-days; Group-3 included 24-patients(Amoxicillin 1gm BD+Levofloxacin 500mg OD+esomeprazole 40mg BD) for 14-days; Group-4 included 24-patients(Doxycycline 100mg OD+Levofloxacin 250mg OD+Esomeprazole 40mg BD+Nitazoxanide 500mg BD) for 14-days; Group-5 included 24-patients(Bismuth sub citrate 240mg BD+Amoxicillin 1gm BD+Levofloxacin 500mg OD+Esomeprazole 40mg BD) for 14-days.

History taking:

Personal history: age, sex, residence, smoking, coffee or tea drinking. Medical history of associated comorbidities, such as hypertension, diabetes, chronic liver disease, and cardiac diseases. Surgical history of previous interventions. History of present illness: disease duration, presenting symptoms as epigastric pain, vomiting, GERD, method of diagnosis of H. pylori, and previous treatment for H. pylori.

Clinical examination:

General examination: weight, height, BMI, vital signs: blood pressure, heart rate, respiratory rate, and abdominal examination: for pain, tenderness, organomegaly, complete blood picture, liver function tests as alanine aminotransferase, aspartate aminotransferase, bilirubin and albumin, renal function tests as s. creatinine and urea, and a stool antigen test.

Stool antigen test:

Frequency of the test: the test was done twice, before and 4-6 weeks after completion of the therapy using Faecal H. pylori Antigen ELISA kits.

Interpretation:

Any sample well that was noticeably more yellow than the negative control well was interpreted in one of two ways: positively or reactively. Any sample well that did not visibly show more yellowing than the negative control well was considered negative or non-reactive.

Using the ELISA Reader, take the mean absorbance of both sets of test results and average them. The following formula will be used to determine both the positive and negative cut-offs. The positive cut-off is equal to 1.1 times the mean extinction of the negative control plus 0.10. Cutoff for negative data is 0.9 times the mean extinction of the negative control plus 0.10.

Interpret test result:

Extinction of patient samples is higher than the positive threshold, indicating a favorable outcome. Extinction of patient samples is lower than the negative threshold, which is negative. Questionable: the extinction of patient samples falls somewhere in the middle of the positive and negative thresholds.

Assay quality control:

Positive control showed an average OD reading greater than 0.8. Negative control showed an average OD reading less than 0.18.

Upper GIT endoscopy results:

The results of gastro-duodenal endoscopy were obtained from the patients' sheets if present. The recorded data included gastritis, duodenitis, gastric ulcer, duodenal ulcer or both.

Cure rate for Helicobacter pylori was the main result, whereas symptoms such as diarrhea, constipation, abdominal discomfort, anorexia, nausea, vomiting, skin rash, vertigo, headache, taste aversion, and exhaustion were the secondary outcomes.

Ethical considerations:

Institutional review boards (IRBs) and ethical committees at Al-Azhar University's Faculty of Medicine gave their stamp of approval before the study could begin. Prior to taking part in the study, all participants were required to sign written informed consent forms.

Statistical analysis:

All data were organized in SPSS version 27. Categorical data were presented as counts and percentages. Continuous data were assessed for normalcy with the Kolmogorov test. Data that follow a normal distribution were presented as mean ± standard deviation. Non-parametric continuous data were presented as median and range. Statistical tests were appropriately selected based on the data type. The Chi-square test was employed to analyze categorical data. The Student's t-test was employed to compare continuous data that follows a normal distribution. Binary logistic regression for multivariate analysis of factors influencing responsiveness to an esomeprazole-based regimen. A p-value below 0.05 was deemed statistically significant.

3. Results

Table 1. Baseline features and demographics.

	TOTAL COHORT (N= 120) NO. (%)
AGE (YEARS) MEAN ± SD	36.1 ± 10.3
SEX NO. (%)	
MALE	56 (46.7%)
FEMALE	64 (53.3%)
DIABETES NO. (%)	6 (5%)
HYPERTENSION NO. (%)	5 (4.2%)

The study included 120-H. Pylori patients who received esomeprazole-based treatment regimen with mean age 36.1 ± 10.3 years. Most of included patients were females (53.3%). Diabetes was present in 5% of patients and hypertension was present in 4.2% of patients, (Table 1; Figure 1).

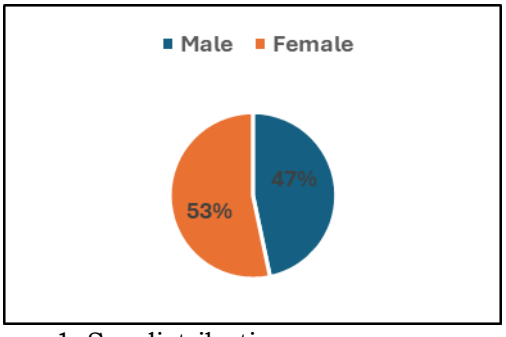

Figure 1. Sex distribution.

Table 2. Treatment response.

	TOTAL COHORT (N= 120) NO. (%)
RESPONDERS (NEGATIVE ANTIGEN)	85 (70.8%)
NON-RESPONDERS (POSITIVE ANTIGEN)	35 (29.2%)

After treatment, 70.8% of patients had negative antigen test and 29.2% of patients had positive antigen test, (Table 2; Figure 2).

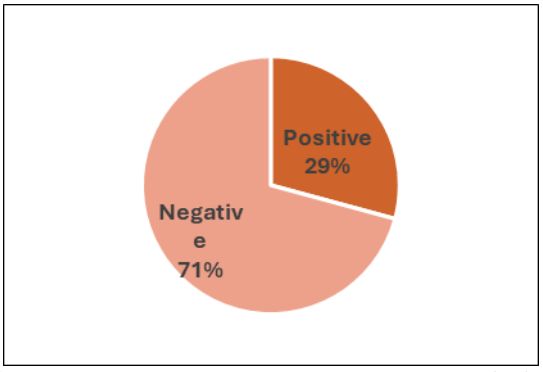

Figure 2. Response rate to esomeprazole-based regimens.

Table 3. Response rate among different regimens.

	GROUP-1 (N= 24) NO. (%)	GROUP-2 (N= 24) NO. (%)	GROUP-3 (N= 24) NO. (%)	GROUP-4 (N= 24) NO. (%)	GROUP-5 (N= 24) NO. (%)	P-VALUE
ERADICATION RATE	15 (62.5%)	16 (66.7%)	18 (75%)	17 (70.8%)	19 (76%)	0.7

Chi square test; Level of significance<0.05

The eradication rate did not differ statistically significantly among the groups under study, (Table 3; Figure 3).

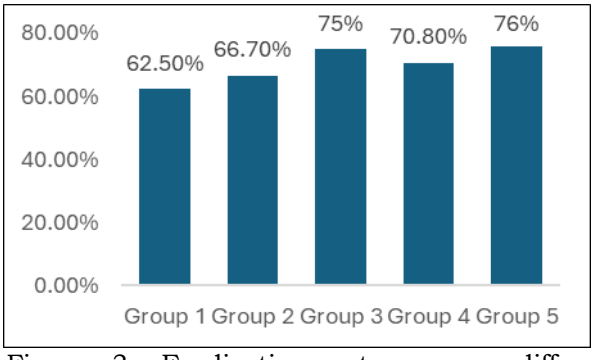

Figure 3. Eradication rate among different treatment regimens.

Table 4. Adverse events.

	TOTAL COHORT (N= 120) NO. (%)
NAUSEA	18 (15%)
DIARRHEA	19 (15.8%)
VOMITING	6 (5%)
BLOATING	22 (18.3%)
ABDOMINAL PAIN	9 (7.5%)

Adverse events occurred in about 25% of participants (30 persons). Bloating (18.3%) was the most common adverse event, followed by diarrhea (15.8%) and nausea (15%), while 7.5% of patients complained stomach pain, and 5% reported vomiting (Table 4; Figure 4).

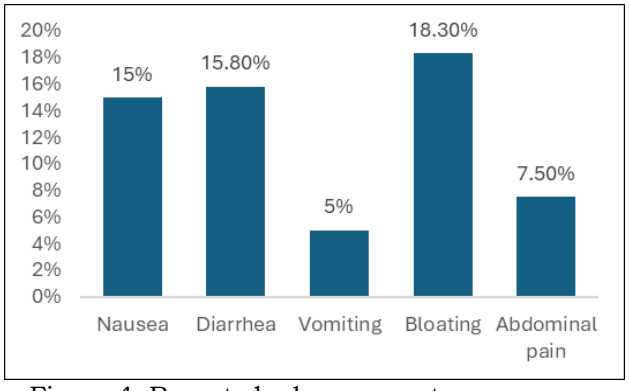

Figure 4. Reported adverse events.

Table 5. Eradication rate between patients with and without adverse events.

	ADVERSE EVENTS (N= 30) NO. (%)	NO ADVERSE EVENTS (N= 90) NO. (%)	P-VALUE
ERADICATION RATE	11 (36.7%)	74 (82.2%)	P<0.001

Chi square test; Level of significance<0.05

Eradication rate was significantly higher in patients who did not experience adverse events that patients experienced adverse events (p<0.001), (Table 5).

Table 6. Demographic differences between responders and non-responders.

	NON-RESPONDERS (N= 35)	RESPONDERS (N= 85)	P-VALUE
AGE (YEARS) MEAN ± SD	34.9 ± 11.2	36.5 ± 9.9	0.4
SEX NO. (%)			
MALE	15 (42.9%)	41 (48.2%)	0.59
FEMALE	20 (57.1%)	44 (51.8%)	
DIABETES NO. (%)	1 (2.9%)	5 (5.9%)	0.48
HYPERTENSION NO. (%)	1 (2.9%)	4 (4.7%)	0.65

t-test for students; chi square test; significance level <0.05

Respondents and non-respondents did not differ statistically significantly in terms of age, sex, diabetes, or hypertension, (Table 6; Figure 5).

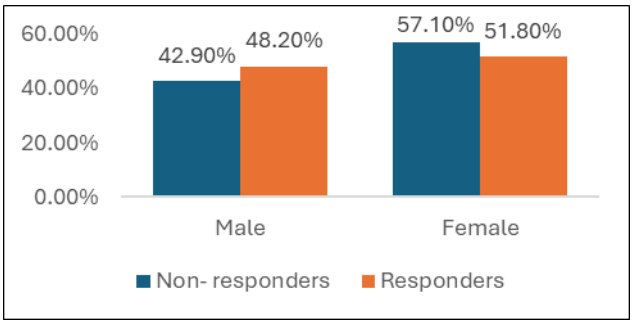

Figure 5. Sex distribution between responders and non-responders.

4. Discussion

Gastritis, gastroduodenal ulcer disease, and gastric cancer are all primarily caused by an infection with H. pylori. Triple therapy with a proton pump inhibitor (PPI) and two antibiotics is currently the gold standard for treating Helicobacter pylori infection; however, it is unclear if esomeprazole or an older PPI like omeprazole is more effective in this setting. [6]

The current study included 124-H. Pylori patients with a mean age of 36.1 ± 10.3 years. In agreement with the present study, Boltin et al.,[7] The previous research showed that the average age of the 120 patients with H. pylori was 39.2±9.3 years. In an earlier study conducted in Egypt, the average age of patients with H. pylori was 26.3±6.5 years.[8]

The present study showed that most of the included H. pylori patients were females (53.3%). In concordance with the present study, Boltin et al.,[7] in one study showed that most of the H. pylori patients were females (51.8%). In a previous study in Egypt, males represented 51% of H. pylori patients who received an esomeprazole-based regimen.[9]

According to the present study, diabetes was present in 5% of patients, and hypertension was present in 4.2% of patients. In agreement with the present study, Abd El-Wahab et al.,[8] reported that diabetes was present in 6.7% of H. pylori patients in Egypt, while hypertension was present in 16.7% of patients. On the other hand, a previous study exploring the efficacy of an esomeprazole-based regimen among 68 patients showed that 14.7% of patients were diabetic and 33.8% of patients were hypertensives.[10] Against the present study, a previous study in Egypt reported a higher prevalence of diabetes (24.5%) and hypertension (33.3%) among H. pylori patients. [9]

The present study showed that mean s. creatinine of the included patients was 0.8 ± 0.2mg/dL and mean urea level was 15.4 ± 5.01mg/dL. This result reflected that all patients

had normal renal functions. In agreement with the present study, Teima et al.,[11] in previous study showed that mean s. creatinine of the included patients was 0.9 ± 0.4 mg/dL which means that all included patients had normal renal functions.

The current study demonstrated that mean ALT was 25 ± 12 IU/L and mean AST was 28.9 ± 10.9 IU/L. These results reflected that all patients had normal liver functions. In concordance with the present study, a previous study included 240-H. pylori patients found that AST was 28.6 ± 5.8 IU/L and ALT was 28.2 ± 6.4 IU/L.[11]

According to the present study, the response rate to esomeprazole-based regimens was 70.8% (85 patients out of 124 patients). A prior study that involved 86 patients found that the eradication rate of H. Pylori using an esomeprazole-based regimen (with amoxicillin and clarithromycin) was 79%, which was considerably higher than the 64% of patients treated with a non-esomeprazole-based regimen. This finding is consistent with the current study. (p = 0.045).[10]

Eradication rate did not differ significantly between patients received different treatment regimens in the present study. In agreement with the present study, Tai et al.,[12] did not find significant differences between 2-esomeprazole-based regimens as regards eradication rate which was 91.7% in patients received esomeprazole and amoxicillin and 87.5% in patients received esomeprazole, amoxicillin, clarithromycin and metronidazole (p= 0.29).

In the present study, about 25% of patients experienced adverse events(30 patients). The most reported adverse events were bloating (18.3%), followed by diarrhea (15.8%) and nausea (15%), while abdominal pain was reported in 7.5% of patients, and vomiting was reported in 5% of patients. In concordance with the present study, Buitrago-Laguado et al.,[13] in a previous study, showed that 31.5% of patients who received an esomeprazole-based regimen for eradication of H. pylori experienced adverse events, and the most reported events were nausea and bloating.

Nausea and bloating were reported more frequently in patients who received either metronidazole or bismuth-containing regimens, while diarrhea was reported more frequently in patients who received amoxicillin and/or clarithromycin or levofloxacin. In line with the present study, Toosi et al.,[14] reported a higher rate of nausea with metronidazole and diarrhea with amoxicillin.

In the present study, the incidence of adverse events was associated with a significantly lower eradication rate (36.7% vs. 82.2%; p< 0.001). In agreement with the present study, a previous study reported a higher eradication rate among patients without adverse events than patients with adverse events(p= 0.04).[13]

To assess the predictors for response to esomeprazole-based regimens, patients were divided into responders and non-responders. No age differences were reported between responders and non-responders. In concordance with study by, Dal Lee et al.,[10] did not find significant age differences between responders and non-responders.

In the present study, sex distribution was comparable between responders and non-responders. In agreement with the present study, Boltin et al.,[7] in previous study did not report sex as a significant predictor for response to esomeprazole-based regimens (OR:0.99; p= 0.083).

The current investigation found that respondents and non-responders had similar linked co-morbidities. In concordance with the present study, Dal Lee et al.,[10] did not find significant differences between responders and non-responders as regards diabetes or hypertension frequency.

The current study showed that responders and non-responders were comparable to each other as regards CBC criteria (hemoglobin, WBCs and platelets), renal and liver function tests. In concordance with the present study, Aljahdli et al.,[15] did not report s. creatinine or BUN as significant predictors for H. pylori eradication.

The study had the advantages of being included different regimens containing esomeprazole and the eradication rate and adverse events were analyzed. Also, the study explored the predictors for eradication rate.

Limitations: Absence of control group consisting of patients received other types of PPIs could affect the reliability of the results. Relatively small sample size could affect generalizability of data. Absence of randomization expose the study for selection bias. Lastly, the study did not put in consideration the resistance to different antibiotics.

4. Conclusion

The overall eradication rate of H. pylori using Esomeprazole-based regimens was 70.8%, indicating moderate efficacy across different treatment protocols. The five distinct esomeprazole-based regimens' eradication rates did not differ significantly, indicating that they were all equally successful, independent of the antibiotic combinations utilized.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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