https://doi.org/10.48047/AFJBS.6.2.2024.1925-1931

AfricanJournalofBiological Sciences

ResearchPaper OpenAccess

Efficacy of Triple therapy in Treatment of Helicobacter Pylori infection

Ayaat M Zedan[a] and Dina H Edrees[b]

a Internal Medicine Department, Faculty of Medicine, Helwan University, Egypt

b Clinical Pathology Department, Faculty of Medicine, Helwan University, Egypt.

Email:ayaat.zedan@med.helwan.edu.eg

Article History

Volume 6, Issue 2, April-July

Received: 10July2024

Accepted: 31 July 2024

Published: 31July 2024

doi:

10.48047/AFJBS.6.2.2024.1925-1931

Abstract:Background: Helicobacter pylori infection is a common health problem in Egypt with multiple treatment modalities.

Aim: to evaluate efficacy of triple therapy in treating patients with H. Pylori infection.

Patient and Methods: Twenty- Nine patients with positive helicobacter pylori antigen in stool were selected from Internal Medicine Department Outpatient Clinic, Badr University Hospital to be included in the study. Patients were included if they were 18 years old, both gender and those who are naïve to treatment. Patients with previous history of experience for treatment of Helicobacter pylori infection were excluded from the study. Patient's files were revised to get basic demographic, clinical and biochemical data. Patients were interviewed and interrogated about current and past history and were examined thoroughly.Patients received triple therapy for helicobacter pylori for 14 days (Prevpac that includes proton pump inhibitor as omeprazole 20mg/bid, clarithromycin 500mg/bid and amoxicilline1g/bid) and H.Pylori rapid stool Ag test was repeated one month after the end of treatment. Patients with negative H.pylori Ag stool test one month after treatment were considered responsive to the triple therapy and the efficacy of the triple therapy was calculated.

Results: 24 patients (82.8%) were responsive to triple therapy of helicobacter pylori infection and 5 patients (17.2%) were not responding to triple therapy of H. pylori. There is no statistically significant association between responders and non-responders to triple therapy of H. pylori regarding demographic data, risk factors and co-morbid diseases.

Conclusion: Efficacy of tripe therapy in treatment of helicobacter pylori infection was 82.8%, thus triple therapy is an effective modality in treatment of helicobacter pylori infection.

Keywords: Helicobacter pylori antigen, Triple therapy.

Introduction

Based on the American College of Gastroenterology Guideline (ACG), proton pump inhibitor (PPI)-based triple therapy is the mainstay remedy for H. pylori infection treatment and eradication (**Bjorkman DJ; et al, 2017**). Specifically, PPI-based triple therapy, usually consisting of a PPI, clarithromycin, and amoxicillin, is a widely recommended regimen for H. pylori treatment in areas with low levels of clarithromycin resistance (**Prasertpetmanee S; et al, 2013)**. Unfortunately, due to the wide use of antibiotics, the incidence of antibiotic-resistant strains is rapidly increasing, which can decrease the likelihood of H. pylori infection eradication **(Zou Y; et al, 2020).**The first-line for management of confirmed *H. pylori* infections utilizes a PPI, alongside 2–3 antibiotics for periods ranging from 3 to 14 days **(Guevara and Cogdill, 2020**). A full breakdown of the available first- and second-line treatment modalities can be found in this table.

Table (1): Treatment options for *H.p*ylori.

Regimen	Dosing Frequency	Duration	Indications
Triple PPI (variable dose) [a] CA (500 mg) AM [b] (1 g) OR MZ (500 mg)	BID BID BID	14 days	First-line treatment in regions where CA resistance is low (<15%) or with high proven local eradication rates (>85%) and in patients with no previous macrolide exposure.
Concomitant PPI (variable dose) [a] CA (500 mg) AM (1 g) MZ (500 mg)	BID BID BID BID	10–14 days	First-line treatment, especially in regions where CA resistance is high (>15%) and metronidazole resistance is low.
Quadruple Bismuth PPI (variable dose) [a] Bismuth (variable dose and preparation) [c] AM MZ	QID BID TID or QID	10–14 days	First-line treatment, especially in regions where CA and MZ resistances are high.
Quadruple Bismuth PPI (high dose) [a] Bismuth (variable dose and preparation) [c] TZ (500 mg) MZ (500 mg)	BID QID QID TID to QID	10–14 days	Can be used as a first-line treatment. Used as a second-line treatment if: 1. Triple or concomitant treatment failed; or 2. Earlier bismuth quadruple treatment failed (two different antibiotics need to be used).
Levofloxacin Regimens Levofloxacin (500 mg) Amoxicillin (1 g) PPI (high dose) [a]	QD BID BID	10–14 days	Potential first-line treatment in areas with low fluroquinolone resistance (reference to ACG). Second-line treatment after failure of a bismuth regimen.
High-dose dual PPI (high dose) [a] AM (750 mg or 1 g)	BID QID or TID respectively	14 days	Salvage therapy after two eradication failures.
Rifabutin-based triple Rifabutin	QD TID	14 days	Salvage therapy after two (Malfertheimer) or three (fallone) eradication failures. AGA guidelines suggest use as a second-line treatment after failed Bismuth therapy.

Regimen	Dosing Frequency	Duration	Indications
Amoxicillin PPI (high dose) [a]	BID		
Statins Atorvastatin (40 mg) Simvastatin (20 mg)	 QD BID	14 days	Experimental use
Probiotics [e]		14 days	Experimental use

Notes: Abbreviations: PPI—proton pump inhibitor; CA—clarithromycin; AM—amoxicillin; MZ—metronidazole; BID—bidaily; QID—quad daily; TID—tridaily; TZ—tetracycline; QD—once daily; [a] dose varies depending on PPI used. Standard doses include esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20 mg. High dose implies double the standard dose. [b] In patients with a penicillin allergy, amoxicillin should be substituted for metronidazole. [c] Bismuth can come in multiple preparations; the most common preparations are: Bismuth subsalicylate (262 mg), two tablets QID; colloidal bismuth subcitrate (120 mg), one tablet QID; bismuth biskalcitrate (140 mg), three tablets QID; bismuth subcitrate potassium (140 mg), three tablets QID. [d] Alternative antibiotics that can be used in rescue treatments include sitafloxacin, tinidazole, and furazolidone. [e] Lactobacillus and Bifidobacterium are supported by a growing body of evidence, whereas the benefits of Lactiplantibacillus and Saccharomyces are supported by a limited number of studies.

2. Subject, Material and Methods:

We carried out this study in the period from April 2023 to June 2023 in Internal Medicine Department outpatient Clinic and Clinical Pathology Lab, Badr University Hospital, Faculty of Medicine, Helwan University, Egypt. Twenty -Nine patients with positive helicobacter pylori antigen in stool with age ≥ 18 years and of both sex were included in the study.We excluded patients with previous history of treatment for Helicobacter pylori infections. Written Informed consent from patients and Approval from the Research Ethics Committee were obtained. We performed full history taking and thorough clinical examination. We revised the initial data of the patients including age, sex, associated co-morbidities and risk factors. Specific investigation includes detection of H. pylori Ag in stool by H.pylori rapid chromatographic stool Ag test which is an immune-chromatographic assay with 97% specificity and 91.3% sensitivity **(Nicolas et al; 2017).** Patients with positive H.pylori Ag in stool received triple therapy for 14 days (Prevpac that includes proton pump inhibitor as omeprazole 20mg/bid, clarithromycin 500mg/bid and amoxicilline1g/bid) and H.Pylori rapid stool Ag test was repeated one month after the end of treatment. Patients with negative H.pylori Ag stool test one month after treatment were considered responsive to the triple therapy and the efficacy of the triple therapy was calculated.

3. Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard deviation and ranges. Also qualitative variables were presented as number and percentages. The following tests were done:

- The Comparison between groups with qualitative data was done by using ***Chi-square test*** and ***Fisher's exact test*** instead of Chi-square test only when the expected count in any cell less than 5.
- ***The confidence interval was set to 95%*** and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
  - P-value $\leq$0.05 was considered significant.
  - P-value $\leq$0.001 was considered as highly significant.
  - P-value >0.05 was considered insignificant.

4. RESULTS:

24 patients **(82.8%)** were responsive to triple therapy of helicobacter pylori infection and 5 patients **(17.2%)** were not responding to triple therapy of H. pylori. There is no statistically significant association between responders and non-responders to triple therapy of H. pylori regarding demographic data, risk factors and co-morbid diseases. The results of the present study are demonstrated in the following tables and figures.

Table (2) : Association between Response to triple therapy and Demographic data.

Demographic data	Response to triple therapy				Test value	P-value
	Respond		Not Respond & Died			
	No.	%	No.	%		
Age (years)						
18 to 25 years	7	29.2%	0	0.0%		
>25 to 35 years	5	20.8%	1	20.0%		
>35 to 45 years	7	29.2%	1	20.0%	6.749	0.150
>45 to 55 years	4	16.7%	1	20.0%		
>55 to 65 years	1	4.2%	2	40.0%		
Sex						
Female	17	70.8%	3	60.0%	0.227	0.634
Male	7	29.2%	2	40.0%		

Using: x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
p-value >0.05 is insignificant

There is no statistically significant association between response to triple therapy and demographic data, regarding age "years" and sex, with p-value (**p=0.150 and p=0.634**) respectively.

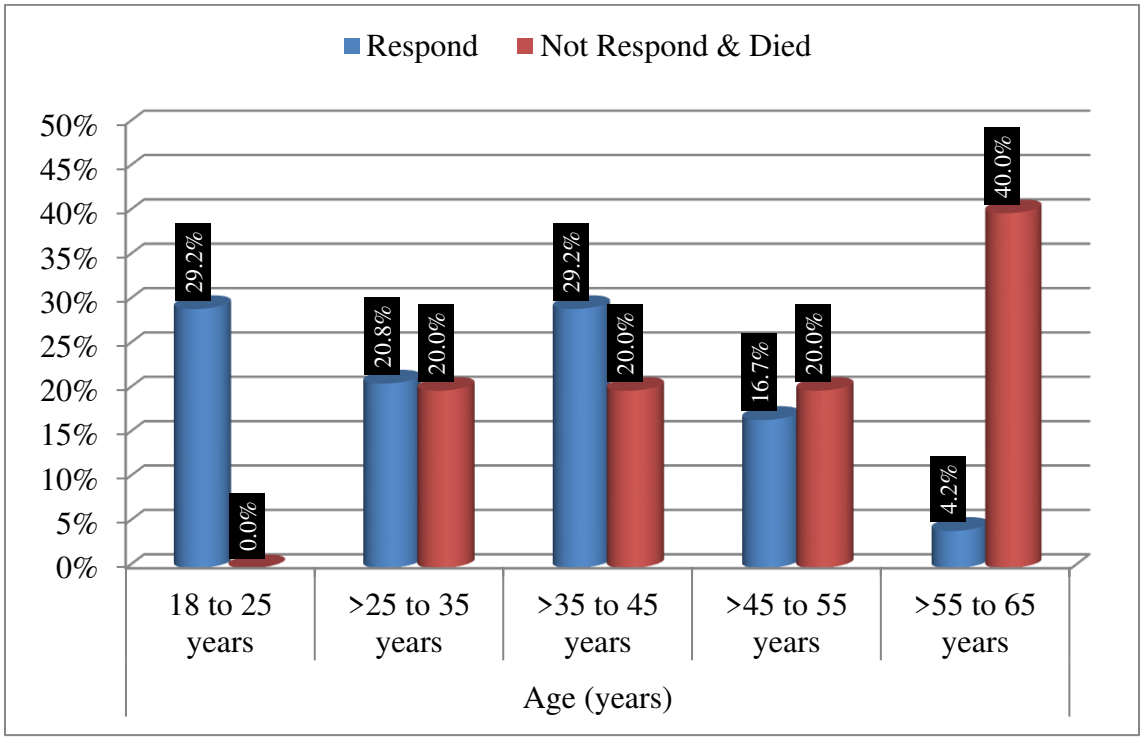

Fig . (1): Association between response to triple therapy and Age (years).

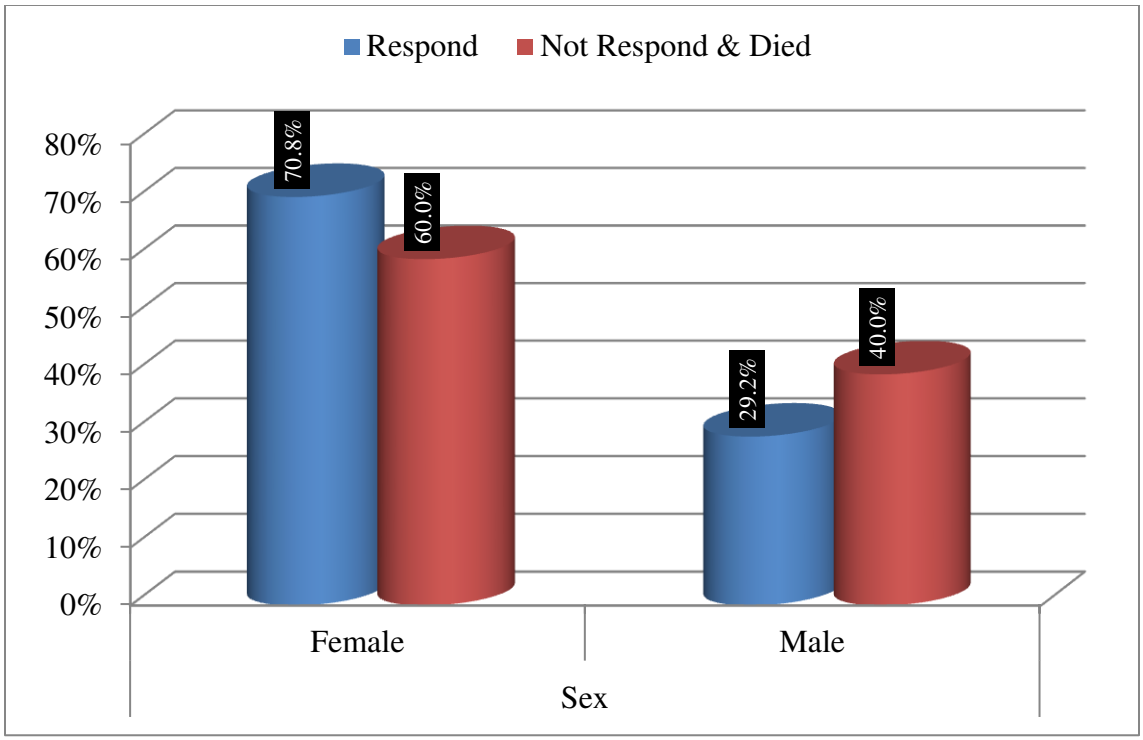

Fig . (2): Association between response to triple therapy and Sex.

Table (3): Association between Response to triple therapy and smoking

Risk factors	Response to triple therapy				Test value	P-value
	Respond		Not Respond & Died			
	No.	%	No.	%		
Smoking	1	4.2%	1	20.0%	1.616	0.204

Using: x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
p-value >0.05 is insignificant

No statistically significant association between response to triple therapy and Smoking with p-value (**P=0.204**).

Table (4): Association between Response to triple therapy and Gastrointestinal presentations.

Gastrointestinal presentations	Response to triple therapy				Test value	P-value
	Respond		Not Respond & Died			
	No.	%	No.	%		
Epigastric pain	14	58.3%	3	60.0%	0.005	0.945
Heart burn	3	12.5%	1	20.0%	0.196	0.658
Abdominal distention	9	37.5%	2	40.0%	0.011	0.917
Regurgitation	1	4.2%	0	0.0%	0.216	0.642
Vomiting	3	12.5%	1	20.0%	0.196	0.658
Nausea	6	25.0%	0	0.0%	1.576	0.209
Constipation	0	0.0%	0	0.0%	0.000	1.000
Melena	1	4.2%	0	0.0%	0.216	0.642
Anemia	1	4.2%	0	0.0%	0.216	0.642

Using: x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

p-value >0.05 is insignificant

There is no statistically significant association between response to triple therapy and gastrointestinal presentations including Epigastric pain, Heart burn, Abdominal distention, Regurgitation, Vomiting, Nausea, Constipation, Melena and Anemia, with p-value (**p>0.05)**.

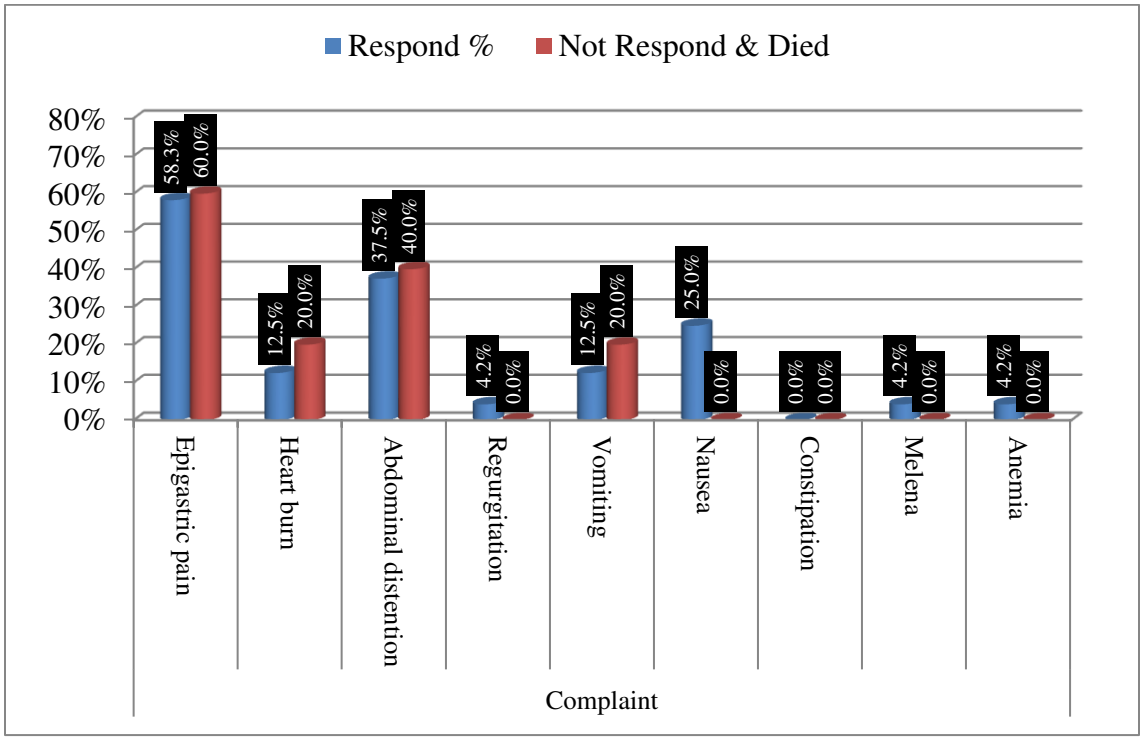

Fig .(3): Association between response to triple therapy and gastrointestinal presentations.

Table (5): Association between Response to triple therapy and Co-morbid diseases.

Co-morbid diseases	Response to triple therapy				Test value	P-value
	Respond		Not Respond & Died			
	No.	%	No.	%		
Hypertension	1	4.2%	1	20.0%	1.616	0.204
Diabetes mellitus	1	4.2%	0	0.0%	0.216	0.642
Hypotension	2	8.3%	0	0.0%	0.448	0.504
Bronchial Asthma	0	0.0%	0	0.0%	0.000	1.000
Cardiac diseases	1	4.2%	0	0.0%	0.216	0.642

Using: x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

p-value >0.05 is insignificant

No statistically significant association between response to triple therapy and co-morbid disease, with p-value (**p>0.05**).

Discussion

Due to the importance of H. pylori infection and its treatment, this study was conducted to asses efficacy of triple therapy in treatment of H. pylori infection and to investigate the factors related to the patient's response to this therapeutic protocol.

Our study showed that the triple therapy is an effective therapeutic modality in treatment of H.pylori infection with response rate (82.2%) this is consistent with **Maliheh S, 2016.**

There is no statistically significant association between response to triple therapy and age "years" or sex, with p-value (**p=0.150 and p=0.634**) respectively. This is in agreement with other studies conducted by **Broutet N; et al , 2003 &Boyanova L; et al ,2009**.

In line with **Akbarirad M, et al.2022,** our study revealed there isno statistically significant association between response to triple therapy and Smoking with p-value (**P=0.204**) respectively.and this was different from **Yu J; et al ,2021.**

No statistically significant association between response to triple therapy and diabetes mellitus, with p-value (**P=0.642**). This is similar to results of **Nam SJ, et al, 2019** and different from **Yao CC ; et al,2019.**

There is no statistically significant association between response to triple therapy and gastrointestinal presentations including Epigastric pain, Heart burn, Abdominal distention, Regurgitation, Vomiting, Nausea, Constipation, Melena and Anemia, with p-value (**p>0.05)**.

No statistically significant association between response to triple therapy according to co-morbid disease, with p-value (**p>0.05**).

This study faced a few limitations. One of the most obvious limitations was the small number of patients included in the study, so further studies are required on a large number of patients to confirm the results of this study.

Acknowledgments

We would like to acknowledge the Clinical Pathology Lab, Badr University Hospitals for supporting the practical work of this study.

Footnotes

Authors`contribution: study concept and design: AM. Performance of the practical work: DE. Interpretation of data: AM and DE. Drafting the manuscript: AM and DE.

Conflict of Interests: None.

Ethical Approval: Approval from the Research Ethics Committee was obtained.

Funding/Support: No

Informed Consent: Written Informed consent from patients.

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