

Clinical Outcomes of Standard Triple Therapy among H. Pylori Infection in Tripoli.

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ABSTRACT:

The *Helicobacter Pylori* commonly called H. Pylori infection is one of the common diseases and spread widely among the different classes of society, so that it infects and develops in the stomach and small intestine, and it is a Gram-negative bacillus. The efficacy of standard triple therapy (STT) in treating *Helicobacter pylori* infection has decreased. Many investigators have tried to increase the suppression rate. The study aimed to discover the clinical results of the usage of triple therapy to eliminate H. Pylori. Methods: this study has been carried between 2nd of May and 25th of August on 110 of people have H. Pylori bacteria and treatment with triple therapy aged between 14-60 years, who have applied to Tripoli Medical Centre in Tripoli city, Libya. This study was conducted by Cross Sectional Study. A standard interview-based questionnaire was used to obtain data on personal information such as (age, sex and income level), medical and drug information such as (use triple therapy, duration and side effect of drug). Results: it was discovered that about 75% of patients recovered and improved from H. Pylori after using the triple therapy, and the recent study establish that the meals and females are infected at approximately the same rates, these bacteria can infect at any age, and in this study was also presented about 61.8% of the cases who were infected with H. Pylori depended on fast food, and therefore there is a direct relationship between the type of food and infection with bacteria. Conclusion: From this point view, the triple therapy is a first line of defense, which doctors recommend to treat H. Pylori by Triple therapy (STT= clarithromycin, and amoxicillin or metronidazole). and must be spread health awareness among people by avoiding fast and unhealthy foods, avoiding stress, anxiety, doing excessive, use of non-steroidal pain-killers, maintaining general and personal hygiene. Further research in Libya is needed to establish the potential role of standard triple therapy and food in H. pylori treatments.

Key words: *Helicobacter pylori, treatment, standard triple therapy, Libya.*

INTRODUCTION:

The “*Helicobacter Pylori*” commonly called H. Pylori infection is one of the common diseases and spread widely among the different classes of society, so that it infects and develops in the stomach and small intestine, and it is a Gram-negative bacillus. The efficacy of standard triple therapy (STT) in treating *Helicobacter pylori* infection has decreased. Many investigators have tried to increase the suppression rate. The study aims to discover the clinical results of the usage of triple therapy to eliminate H. Pylori and the relationship between food type and prevalence of bacterial infection (1,2). The prevalence rates can reach (90%) and is higher among individuals going to low socioeconomic status group. It occurs especially due to failure of treatment and emergence of drug resistance. Most studies recommend that males and females are infected at approximately the same rates, the infection occurs in the childhood, and children are often infected by a strain with a genetic impression identical to that of their parents (3).

Numerous antibiotics are used to treat H. pylori and in order to reduce the opportunity of bacteria developing resistance; the doctor usually starts to prescribe at least two different types of antibiotics; such as Amoxicillin and Clarithromycin. In addition to a type of acid-suppressing drug such as Omeprazole which are used to help the stomach lining to heal, as these constitute the three drugs initial treatment for H. pylori, which takes approximately from one to two weeks to start after the patient feel better, and can be added to the conformation of bismuth subsalicylate (4). There are at least two different types of antibiotics are used, with the aim of removing bacteria, like other medication, taking antibiotics can cause some side effect to seem in some people and among these antibiotics are following and can be mentioned as;

Amoxicillin: By taking amoxicillin may cause diarrhea and nausea and these side effects appear in 1 to 10 people.

Clarithromycin: the use of clarithromycin can cause some side effects, such as: diarrhea, vomiting, nausea, stomach pain and heartburn, headache in addition to change in the sense of taste and abdominal gas

Metronidazole: By taking this kind of drug it can cause some side effects, such as: a feeling of metallic taste in the mouth, nausea, vomiting and diarrhea (12).

The bacteria select to live in an acidic environment, as they need an acidic environment to increase their competence in the stomach and the role of these drugs is to increase the effectiveness of the antibiotic in eliminating bacteria and dropping stomach acidity, and these drugs are divided into two groups as following;

1-Histamine H₂-Receptor Antagonist “H₂RA” antagonist; whose mechanism of action is block the activity of the compound histamine, which has a role in increasing acid secretion in the stomach, and one of the drugs belonging to this group; Cimetidine, Ranitidine, Nizatidine and Famotidine (5).

2- Proton Pump Inhibitors drugs “PPIs”; these drugs block the proton pumps inside the stomach, thus reducing the amount of acid secreted inside them, and these drugs have a rapid effect in relieving pain, controlling the stomach’s PH, as well as possessing it has an antimicrobial effect, so it is preferable to use it instead of histamine receptor blockers in the treatment especially in people with peptic ulcers and include; Omeprazole, Lansoprazole, Pantoprazole, Esomeprazole and Rabprazole. (6). This study was aimed to evaluate clinical outcomes of standard triple therapy on H. pylori patients in Tripoli, Libya.

Materials and Methods:

A Cross-sectional study has been carried between 2nd of May and 25th of August on group of individuals have H. Pylori bacteria and treatment with triple therapy aged between 14 and 60 years, who have applied to government hospital named “University hospital center” in Tripoli city, Libya. Throughout the study a total number of 110 subjects who complied with the study.

Study Design:

This study was conducted by “Cross Sectional Study”. A standard interview-based questionnaire was used to obtain data on efficacy of triple drug regimen for the eradication of Helicobacter Pylori. The questionnaire consists from 2 sections each section including many questions, Section I: including personal information. Section II: including Medical information (use triple therapy, duration and side effect of drug).

Statistical analysis:

Data of the questionnaire were analyzed using software program statistical satrapies (version,24.0, N=110) Descriptive and qi square were used Our findings were

given in tables as percentage, arithmetic mean and standard deviation. Our findings were given in tables as arithmetic mean and standard deviation.

Literature review:

A study conducted by Hind H. Khalifallah & Aisha Mohamed A.et.al (2019). It was about Helicobacter pylori infection in healthy dyspeptic adult population resident in Tripoli and Sabha of Libya cities and this study was aimed to correlate with the risk factors associated with H. pylori seropositivity in such two populations. Results: In Sabha region, the overall prevalence of H. pylori was 57% in healthy & 37% in Dyspeptic patients respectively. In Tripoli region, the Healthy was 85.1%, dyspeptic patients were 83.2%. Conclusions: - In the two cities, H. pylori detection in healthy and dyspeptic was high of individuals of aged 25-35 years. (15) .

A study was written by Malik Hassan and Farah Assis, September, (2018). It was about Eradication rate of Helicobacter Pylori by classic triple therapy in Lebanon: Is it still effective? The purpose of this research is to determine the eradication rate of H. pylori in patients initially treated with classic triple therapy. The secondary objectives are to determine the association of the eradication rate with multiple demographic variables such as; gender, smoking, obesity, past medical history and medication history, to identify a relation between the eradication rate and either the different types of triple therapy or the methods of diagnosis. The results were showed that 61.9% = 104 patients were found to be sensitive to triple therapy and whereas 38.1% = 64 patients were resistant. There was no statistical significance between gender, age and smoking history method of diagnosis type of triple therapy with $p > 0.05$ (16).

Another study in Germany published by Bluemal *et al.* in January (2019). It was study the antimicrobial resistance of Helicobacter pylori in Germany. Aim of this study; National and international guidelines recommend empiric first-line treatments of individuals infected with H. pylori without prior antimicrobial susceptibility testing and assessed the primary resistance of H. pylori in Germany to antibiotics by molecular genetic methods and evaluated risk factors for the development of resistance. Result:-Overall primary resistances were 11.3% (210/1851) to Clarithromycin female sex and prior antimicrobial therapies owing to unrelated bacterial infections were risk factors for Clarithromycin resistance. (18). A research conducted by Nvakil, Flanza in July (2014). It was about Seven-day therapy for Helicobacter Pylori in the United States of America (USA). Aim of this is study compared the efficacy of 3.7 and 10-day triple therapies with Rabprazole to a 10-day Omeprazole control triple therapy for the eradication of H. pylori in patients with and without peptic ulcer disease in the United States. Results: In intent- to- treat patients, the

eradication percentages achieved for the Rabprazole – based treatment were: 3-day, 27% (95% confidence interval: 21% - 34%).*7-day, 77% (95% confidence interval: 72% - 84%).The eradication percentage with the 10 day Omeprazole based on treatment was 73% (95% confidence interval: 67% - 79%). There was no statistically significant difference between the 7 day Rabprazole based on regimen and the 10 day Rabprazole and Omeprazole based regimens (19)

Results:

In table (1) it found that 18.2% of cases aged from 14-29 years old, 24.5% of cases aged from 30-39 years old, 30.9% of cases aged from 40-49 years old, 14.5% of cases aged from 50-59 years old, 11.8% of cases aged above of 60 years old. it established that the most of cases were females and represents 52.7% from the

patients and 47.3% of cases were males.). The majority of cases were un-married and it represented 74.5% from the participants and 25.5% cases were married. The most of participants (69.2%) of cases were income level between 400-1000 LD, 24% of cases were income level between 1000-1500 LD and 6.7% of cases were income level 1500 and more. From data analysis it was found that the most of participants had helicobacter infection and it represents 87.3% from the patients and 12.7% of cases did not have H. Pylori infection before. it found 83.3% of cases, the doctor prescribed the Triple therapy, 15.6% of cases the doctor prescribed the Quad therapy and 1% of cases do not take any drugs. It also found 36.5% of cases duration of treatment period lasted for weeks, 47.9% of cases duration of treatment period lasted for months and 15.6% of cases duration of treatment period lasted for years (table 2).

Table (1): Distribution of the patients regarding to personal information.

Age	No. of cases	Percent%
14 - 29 yr.	20	18.2%
30 - 39 yr.	27	24.5%
40 – 49 yr.	34	30.9%
50 - 59 yr.	16	14.5%
+ 60 yr.	13	11.8%
Gender		
Male	52	47.3%
Female	58	52.7%
Marital status		
Married	28	25.5%
Un-Married	82	74.5%
Income level		
400-1000LD	72	69.2%
1000-1500 LD	25	24.0%
1500 and more	11	10%
Total	110	100%

Table 2: Presentation of medical information

Type of treatment	No. of cases	Percent%
Triple treatment	90	81.8%
Quad therapy	15	13.6%
Do not take any drugs	5	4.5%
Patients had H.pylori		
Yes	96	87.3%
No	14	12.7%
Duration of treatment		
Weeks	35	36.5%
Months	46	47.9%
Years	15	15.6%
Total	96	100.0

Table 3: The relationship between kind of treatment and successful rate of each other.

			Is the treatment was successful?			Pearson Chi-Square		
			Yes	No	Total	Value	df	P-Value
What the kind of treatment did the doctor prescribed?	Triple treatment	Count	60	20	80	5.053	2	0.080
		Percent %	75.0	25.0	100.0			
	Quad therapy	Count	15	0	15			
		Percent %	100.0	0.0	100.0			
	Do not take any drugs	Count	1	0	1			
		Percent %	100.0	0.0	100.0			
	Total	Count	76	20	96			
		Percent %	79.2	20.8	100.0			

In table 3, it was found that 75% of patients improved and the triple treatment was successful with them, while the quadruple treatment achieved 100% of successful rate and there were a high significance differences between Quadruple treatment and successful recovery from H. Pylori. From data analysis, there were 72.7% of patients do not infected again after finish of Triple Treatment Course which was the higher proportion, while 27.27% of patients infected again after finish of Triple treatment course (table 4). There were the majority of patients (87.5%) had no side effects from the triple therapy which were the higher percentage, while only 12% of the patients had side effects (figure 1).

Table 4: Distribution of infected again after finish of Triple treatment course.

Infected again after finish treatment	No. of cases	Percent%
Yes	30	27.27%
No	80	72.7%
Total	110	100.0%

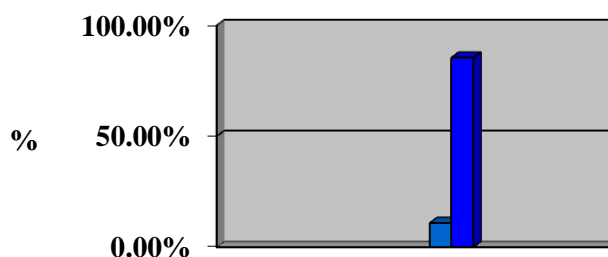


figure 1: Side effect of triple therapy

DISCUSSION:

H. pylori infections are toughly associated with serious upper gastrointestinal tract diseases like, peptic ulcers, gastric cancer, mucosa-associated lymphoid tissue (MALT) lymphoma as it is classified as a group I carcinogen. H. pylori resistance to antibiotics has reached alarming levels worldwide, which activated a serious search for more effective treatments. Despite recent introduction of new therapeutic programs to fighting *Helicobacter pylori* infection, the treatment still fails in more than 20% of patients, due to the increased emergence of antibiotic resistant strains so, a rational antimicrobial therapy is recommended to be susceptibility-based and regulatory to control this resistance. (7) Savoldi et al. stated that, since the year 2000, the H. pylori eradication rates have been decreasing because of increasing resistance to one or more of the antibiotics (8). In this study we found the higher percentage were aged 40-49 years (30.9%). As comparing with a study by by Hind H. Khalifallah & Aisha Mohamed A.et.al (2019), in Tripoli region, the Healthy was 85.1%, dyspeptic patients was 83.2% and In the two cities, H. pylori detection in healthy and dyspeptic was high of individuals of aged 25-35 years which not same as our results. In this research the most of cases were females (52.7%) and 74.5% were un-married. whereas the most of participants (69.2%) of patents had income level between 400-1000 LD which were the lowest level. In this study relegated that about (87.3%) of cases had H. Pylori infection and the doctor prescribed the Triple therapy of them for weeks or months, and the result was that about (75%) of these patients recovered and improved from H. Pylori after using the Triple therapy. while the quadruple treatment achieved 100% of successful rate and there were a high significance differences between Quadruple treatment and successful recovery from H. Pylori and most of the patients did not complain about the side effects of the Triple treatment. As comparing with study by Malak Hassan and Farah Assi (2018) The results were showed that 61.9% = 104 patients were found to be sensitive to triple therapy and whereas 38.1% = 64 patients were resistant. There was no statistical significance between gender, age and smoking history method of diagnosis type of triple therapy with $p > 0.05$. which were less than our percentage. Another study by: Bluemal,et.al (2019), the result was that clarithromycin might still be recommended in first-line eradication therapies in yet untreated patients which were the same as what we reached in my research.

CONCLUSION:

In conclusion, our results indicate positive association between Triple treatment and H. Pylori infection was found, and therefore the diagnosis of these infection is improved when use of Triple treatment with no or little

side effect. In this study, there was no significant difference in H. Pylori infection to sex and age. Relationship was found between kind of food and H. Pylori infection, that is quick meals have high risk prevalence to H. Pylori infection; the reason for this is due to a lack of awareness, low education and failure to adapt to diet programs. From this point view, the triple therapy is a first line of defense, which doctors recommend to treat H. Pylori, and must be spread health awareness among people by avoiding fast and unhealthy foods, avoiding stress, anxiety, doing excessive, use of non-steroidal pain-killers, maintaining general and personal hygiene. Further research in Libya is needed to establish the potential role of standard triple therapy and food in H. pylori treatments.

Recommendations:

- 1-In case of infection with H. Pylori infection, we recommend taking the Triple treatment, which is the first line of defense against these bacteria with no or little side effect.
- 2-Pay attention to personal and general hygiene with periodic hand washing.
- 3-Choosing and preparing healthy meals at home and avoiding fast food and unhealthy diet.
- 4-Spreading health awareness and education about H. Pylori infection.

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