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REVIEW ARTICLE

EFFICACY OF PROTON PUMP INHIBITORS-BASED REGIMENS FOR THE THERAPY OF HELICOBACTERIA PYLORI INFECTION: CURRENT STATUS IN THE MIDDLE EAST REGION: A REVIEW

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ABSTRACT

Helicobacter pylori (*H. pylori*) infection affects millions of people worldwide, including Middle East. There are several treatment regimens available to treat the illness caused by this organism. In order to eradicate the *H. pylori* infection in the Middle East, proton pump inhibitor (PPI)-based regimens are increasingly being reported in the literature, which was the focus of this study. We studied the regimens used in various nations to identify the most effective and widely used (PPI)-based regimen in clinical settings. Although a PPI and two antibiotics for 10- to 14-day course of treatment have traditionally been used to treat such infections, there are now several alternatives. Quadruple therapies like bismuth have demonstrated improved *H. pylori* eradication. Thus, they are suggested as primary treatments in Middle Eastern regions where resistance rates are lower. Quadruple therapy that includes bismuth has shown superior *H. pylori* eradication over traditional triple regimens. As a result, it has been recommended as first-line treatment in Middle Eastern countries where resistance is less common.

Keywords: Efficacy; *Helicobacter pylori;* Middle East; Proton Pump Inhibitors; Peptic Ulcer Disease.

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1. INTRODUCTION

Due to its widespread prevalence and contribution to the etiology of peptic ulcer disease, infection with Helicobacter pylori (*H. pylori*) is a serious public health issue. Gastrin release is stimulated by *H. pylori*, and acid output is increased. High levels of non-steroidal anti-inflammatory drugs (NSAID) intake and *H. pylori* increases the risk of peptic ulcer disease (PUD). NSAIDs do not affect acid secretion, although they may weaken mucosal resilience and impede healing.[1]

PPIs are prescribed under the premises of therapeutic equivalency, similarity in structure, and mechanism of action. However, because of the size of the population, lax limits on formulary practices have been economically inefficient.[2] Due to their effectiveness, safety, and tolerability, PPIs are recommended on a long-term basis around the world.[3-5]

This study aimed to provide a summary synthesis of the emerging literature reporting the use of PPI-based on treatment plans for *H. pylori* infection in the Middle East region.

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2. MATERIAL AND METHODS

Academic databases including Google Scholar, PubMed, and a grey Google, were searched. Relevant studies that reported using PPIs-based regimens to treat *H. pylori* infection in the Middle East region were extracted and synthesized. The search terms used include Efficacy, Proton Pump Inhibitors, Peptic Ulcer Disease, *Helicobacter pylori*, and Middle East.

The search findings were discussed in detail in the following sections.

3. RESULTS

3.1 Helicobacter pylori

The bacterium *H. pylori*, is a microaerophilic, spi-

ral-shaped, gram-negative, flagellated with a fundamental adaption trait that enables it to live and remain in the stomach. Even when residing near persons who are already afflicted, *H. pylori* usually spread via person-to-person infection.[6, 7]

Complex microbial-epithelial interactions and evasion of human defense systems are linked to the pathophysiology of *H. pylori* infections and enable sustained colonization. Many underdeveloped nations have high incidences of *H. pylori* disease, with Africa having the greatest overall incidence (70.1%).[8] Due to *H. pylori* DNA presence in human feces and saliva, fecal-oral and oral-oral pathways are the most common person-to-person transmission techniques. Infection from one person to another is the predominant mode of transmission.[9] Rarely, especially in places with poor sanitation, the bacteria has been found in untreated water, raw vegetables, and undercooked meals. The capacity of *H. pylori* to generate ammonia to keep the an advantageous neutral cytoplasmic and periplasmic pH, is the key adaptation that enables it to thrive and remain in the stomach.[10]

The vacA and cagA genes are the two main virulence components of *H. pylori* gene subtypes. The cagA gene is triggered by a repeating motif made up of glutamine (E), proline (P), isoleucine (I), tyrosine (Y), and alanine (A), whereas the vacA gene often has a mosaic structure.[11] The most frequent virulence gene in the *H. pylori* genotypes identified from Iranian patients was vacA (89%). The resistance to metronidazole (55.5%) and clarithromycin (37%) were detected in 63 *H. pylori* isolates observed. In the research, there was no evidence of furazolidone resistance.[11] In the past, diarrheal infections have been treated with a broad-spectrum antibacterial medication called furazolidone.[12] Furazolidone, in conjunction with bismuth, has eradicated *H. pylori* in nations like China.[13, 14] Furazolidone is clinically accessible in Iran, but has several adverse effects that make it harder for patients to follow their treatment plans.[15, 16]

The Eastern Mediterranean region has a high rate of infection with *H. pylori*. The high prevalence is responsible for several conditions affecting the upper digestive system. These conditions are peptic ulcer, dyspepsia, gastric adenocarcinoma, and iron deficiency anemia brought on by bleeding, among others.[17-21] According to studies, *H. pylori* infections are more prevalent at younger ages in underdeveloped nations. Therefore, eradication of *H. pylori* from the foregut remains the primary objective of the treatment. The majority of children infected by *H. pylori* present with chronic gastritis, which may be asymptomatic.[22-24]

H. pylori is present in the majority of people with peptic ulcer disease unrelated to NSAIDs, especially as they age.[25] According to studies, between 60 and 80 percent of Iranians are infected with this bacteria.[26] Proton pump inhibitors and antibiotics have been used in combination to treat this gram-negative microaerophile infection.[27]

3.2 Proton pump inhibitors

It is crucial to treat *H. pylori* related ulcer using PPIs such omeprazole, lansoprazole, pantoprazole, rabeprazole, and esomeprazole. They are effective acid-suppressing substances and permanent proton pump inhibitors on the parietal cell surface. In the final common mechanism in the process of acid release, the proton pump is the enzyme H+/ K+-adenosine triphosphatase (H+/ K+-ATPase), that secretes hydrogen ions into the stomach lumen. In the end, inhibiting this enzyme will completely stop the production of stomach acid in response to any stimulus, even food.[28]

PPIs are prescribed for the short-term management of duodenal ulcers (DU), gastric ulcers (GU), and the treatment and prophylaxis of NSAID-induced ulcers in conjunction with antibiotics, to eradicate *H. pylori* and treat Zollinger-Ellison syndrome. GERD and esophagitis are also treated with PPIs. Although they are very successful as preventative measures in patients at high risk for gastrointestinal hemorrhage or PUD from NSAIDs, they are typically overprescribed and misused in more than 80% of both hospitalized and out-patients[29-31], putting a heavy strain on the healthcare system. According to Lebanese epidemiological research, several unsuitable PPI indications, doses, and durations are still used in practice, most notably for gastroprotection. However, there is no connection between the research participants' demographics and overuse. The abuse of PPI is reported to result in annual losses of over 40 million dollars.[32]

PPIs are considered as well-tolerated, safe, and reasonably priced as both original and generic medications, despite the rare side effects associated with their usage that have been documented, such as diarrhea, stomach discomfort, flatulence, gastritis, nausea, skin rash, and headache, which are often moderate and uncommon. Increased risk of infection with *Clostridium difficile*, osteoporosis and community-acquired pneumonia are not unusual with long-term, high-dose treatment.[33] Using PPI and taking antibiotics for an extended time have been linked to an increase in the incidence of risk factors for *Clostridium difficile* infection. A major nosocomial infection with a high risk of morbidity, death, and higher healthcare costs is *Clostridium difficile* infection.[34-36]

Given *H. pylori* as a primary responsible pathogen for PUD and stomach cancer, diagnosing and treating it in primary care settings is of essential.[37] Once *H. pylori* is found, treatment is started. The combination of a PPI and two antibacterial medications (triple

therapy) is a successful therapeutic approach. According to research by Al-Badriyeh *et al*., rabeprazole and esomeprazole are the two PPIs most frequently used as primary treatments at a Qatari government hospital.[38] A 14-day three-drug therapy utilizing a PPI, amoxicillin or metronidazole and clarithromycin, is effective in earlier trials for the management of PUD, with or without bismuth. Then, for Iranian children, quadruple treatments were recommended as a second-line eradication regimen after PPI, amoxicillin, and clarithromycin triple therapy. However, the quadruple regimen is currently only permitted to be used if the organism strains are sensitive to the particular antimicrobials.[39, 40]

3.3 Eradication of H. pylori

Appropriate regimens are chosen into account the widespread infection by *H. pylori* in the area, antibiotic resistance, and the eradication rates of particular regions, as well as consensus reports and clinical observations of reliable results.[41] Worldwide, there is concern over the rising risk of antibiotic resistance with traditional triple therapy for PUD, low adherence, and rising *H. pylori* eradication failure, necessitating the quest for new therapeutic regimens with increased efficacy.[42, 43] Due to their ability to tackle antimicrobial resistance, bismuth-based quadruple treatments have lately been chosen as the first-line regimen for PUD.[44] As a first-line treatment, 14 days of bismuth-based four-drug therapy results in higher than 80% of patients being successfully cured.[45, 46] Should bismuth quadruple therapy fail, other relevant therapies could be developed. In the absence of bismuth, another alternative is a regimen of high-dose of PPI, metronidazole, and amoxicillin.[47, 48]

3.4 H. pylori infection eradication in the Middle East using PPI-based regimens

Because in vitro sensitivity does not necessarily correspond to in vivo efficacy for the pathogen, treatments are recommended somewhat experimentally.[49] Studies in the Middle East have discovered that using a triple treatment with clarithromycin, PPI and amoxicillin in Turkey significantly reduced the *H. pylori* eradication.[50] According to the Maastricht IV study, antibiotic resistance and poor compliance are the major reasons why attempts to eradicate *H. pylori* have failed, and therapies including clarithromycin are advised as a first-line empirical therapy, particularly in regions having high clarithromycin sensitivity.[51]

Contrary to traditional triple therapy, therapies incorporating bismuth have a higher eradication rate. An alternate first-line empirical treatment for locations with substantial clarithromycin resistance is bismuth-containing triple therapy for a duration of 10–14 days.[52, 53] However, studies have linked the increased number of tablets the patient had to take as well as adverse effects that led to treatment cessation to decreased patient compliance and the highest incidence of lost-to-follow-up instances among patients receiving this quadruple therapy.[54, 55]

The most successful *H. pylori* treatment plans for children have the fewest side effects and are the least expensive for the patient. Even for young patients, choosing the right treatment is crucial. In Iran, children treated with a 10-day three-drug regimen comprising omeprazole, clarithromycin and amoxicillin, had a higher eradication rate than the quadruple regimen of omeprazole, amoxicillin, metronidazole and bismuth citrate.[56, 57] This study supports earlier findings and recommendations that three-drug and four-drug therapies be regarded as first- and second-line therapies, respectively, by the Canadian Helicobacter Study Group, the North American Society for Paediatric Gastroenterology Hepatology and Nutrition (NASPGHAN), and the Japanese Paediatric Helicobacter Study Group.[57-60]

When compared to traditional triple treatment as a first-line regimen, the combination of levofloxacin, clarithromycin, and esomeprazole can yield a higher eradication rate with the same level of safety.[61] Concomitant levofloxacin triple treatment has a 3% greater overall eradication rate than doxycycline-based therapy, according to a prospective randomized controlled experiment. When levofloxacin, tinidazole, amoxicillin, and esomeprazole were compared to bismuth subsalicylate, doxycycline, tinidazole, and esomeprazole for two weeks of therapy, the doxycycline group had a higher incidence of successful eradication.[62] A safe and effective secondary course of treatment for the eradication of *H. pylori* is the combination of ofloxacin, azithromycin, omeprazole, and bismuth.[63] Table 1 and 2 below showed a summary of studies on PPI-based regimens used in treatment of PUD and documentation of country specific studies in Middle East region respectively.

3.5 Efficacy and tolerability of PPI-based H. pylori regimens

The effectiveness and tolerability of five different regimens were compared in patients tested positive for *H. pylori*, and present with dyspepsia. The five different treatment regimens were pantoprazole, amoxicillin, and clarithromycin for 14 days; pantoprazole, metronidazole and amoxicillin given for 14 days; pantoprazole, metronidazole, tetracycline and bismuth subsalicylate given for14 days; a five-day pantoprazole and amoxicillin, followed by pantoprazole, metronidazole, tetracycline given for 10 days (concomitant therapy).[64, 65] With concurrent and subsequent medications, eradication rates were higher.[64,66] Sequential regimens and “non-bismuth four-drug” or “concurrent” regimens are therefore viable therapeutic modalities and sequential treatment with added bismuth can also be recommended to overcome resistance.[67, 68]

Table 1. Summary of studies on PPI-based regimens used in treatment of PUD in middle east region

PPIs	Antibiotics/Added drugs	Regimen	Duration	Eradication rate (ITT, PPA)	Reference
Omeprazole	Clar, Amo	Triple	10 days	75.5%, 92%	81
Omeprazole	Amo, Met, Bis	Quadruple	10 days	68.8%, 84%	81
Omeprazole	Amo, Met, Bis	Quadruple	14 days	91.9%	82
Omeprazole	Amo and Clar	Triple	14 days	82.1%	82
Omeprazole	Amo-clav, Met	Triple	14 days	80.5%	82
Esomeprazole	Clar, Amo	Triple	7 days.	78.6%	83
Esomeprazole	Lev Amo	Triple	7 days.	84.7%	83
Esomeprazole	Lev, Clar	Triple	7 days.	90.6%	83
Omeprazole	Azi, Ofl, Bis	Quadruple	14 days	77.3%, 86.7%	83
Omeprazole	Amo, Clar, and Bis	Quadruple	14 days	64.5%, 74.7%	83
Omeprazole	Amo, and Clar	Triple	10 days	68.6%,	84
Omeprazole	Tet, Met and Bis	Quadruple	10 days.	88%	84
Pantoprazole	Amo, Clar	Triple	14 days	42%, 48.3%	85
Pantoprazole	Amo, Met	Triple	14 days.	52%, 54.2%	85
Pantoprazole,	Tet, Met and Bis	Quadruple	14 days.	62%, 77.5%	85
Pantoprazole	Amo, Tet, Met	Sequential	5 days (PPI+ Amo) 5 days (PPI+ Tet+ Met)	71%, 80.7%	85
Pantoprazole	Amo, Tet, Met	Concomitant	10 days	72%, 83.7%	85
Pantoprazole	Tet, Met, and Bis	Quadruple	14 days	74.6%, 75.6%	86
Pantoprazole	Amo, Clar, Met	Sequential	5 days (PPI+ Amo) 5 days (PPI+ Clar+ Met)	70.2%, 70.4%	86
Pantoprazole	Amo, Clar, Met and Bis	Bismuth Sequential	5 days (PPI+ Amo+ Bis) 5 days (PPI+Clar+Met+ Bis)	88.5%, 90.3%	86
Lansoprazole	Amo, Lev, Met	Sequential	5 days (PPI+ Amo) 5 days (PPI+ Lev +Met)	77.9%, 78.5%	86
Pantoprazole	Amo, Tet, Met	Hybrid sequential	5 days (PPI+ Amo) 5 days (PPI+Amo+Tet+ Met)	76.1%, 76.2%	86
Omeprazole	Amo, Bis, Clar, Tin	Quadruple	7 days	75.5%, 76%	87
Omeprazole	Tet, Bis, Met, Oflo	Quadruple	7-days	86.5%, 86.7%	87
Omeprazole	Fur, Bis, Amo, Tet	Quadruple	14 days.	80%, 87%	87
Omeprazole	Bis, Met, Tet	Quadruple	10 days	78.3%, 87.8%	88
Esomeprazole	Dox, Tin and Bis	Quadruple	14 days.	76.9%, 82.1%	88
Esomeprazole	Lev, Tin, Amo	Concomitant	14 days.	78.9%, 82.1%	62

PPI (Proton pump inhibitor). Amo (Amoxicillin). Amo-clav (Amoxicillin-clavulanic acid). Azi (Azithromycin), Bis (Bismuth), Clar (clarithromycin), Dox (Doxycycline), Fur (Furazolidone), Lev (Levofloxacin), Met (metronidazole), Ofl (Ofloxacin), Tet (tetracycline), Tin (Tinidazole), ITT (intention-to-treat) and PPA (per-protocol analysis)

Table 2. Documentation of country specific studies and on PPI-based regimen for *H. pylori* in the Middle East

Country	Major Findings/Recommendations	Reference
Iran	Triple therapy superior to quadruple therapies in children. Recommended PPI, Amoxicillin and Clarithromycin as first line regimen.	89
Iran	Bismuth-based quadruple therapy recommended as the first line of therapy for eradication of *H. pylori* infection in children in Iran geographic area	56
Saudi Arabia	The combined Levofloxacin, Clarithromycin and Esomeprazole based regimen can give more significant eradication rate as first line triple therapy for *H. pylori* eradication	90
Iran	Two weeks treatment with ofloxacin, azithromycin, omeprazole, and bismuth are an effective and safe regimen for *H. pylori* eradication as second-line therapy	91
Kuwait	Bismuth-based quadruple therapy is more effective as a first-line therapy in Kuwait	92
Turkey	Concomitant and sequential therapies are effective treatments for *H. pylori*. Bismuth-containing therapy is superior to conventional triple therapies Concomitant and sequential	65
Turkey	Bismuth-enhanced sequential therapy is recommended to overcome resistance	93
Iran	Quintuple therapy with Omeprazole Tetracycline, Bismuth, Metronidazole, Ofloxacin regimen is an alternative second-line rescue therapy for Iranian patients who failed first-line eradication treatment of *H. pylori*	94
Israel	Recommended clarithromycin-based triple therapy as first-line treatment, and levofloxacin or bismuth-based protocols for second-line treatment	95
Qatar	Rabeprazole and esomeprazole are two (2) PPIs most preferred for first line use in the main Qatari government hospital health service	2
Iran	Furazolidone-bismuth quadruple therapy had proven to be relatively effective in Iran, however, these regimens need to be optimized.	96
Saudi Arabia	Recommended that bismuthbased quadruple therapy for 10 days as firstline treatment or as secondline therapy.	97
Syria	Levofloxacin concomitant therapy provide a slight superiority to doxycycline-based quadruple therapy.	62
PPI (Proton pump inhibitor), Amo (Amoxicillin), Clar (Clarithromycin)		

Adherence of primary care physicians (PCPs) to the guidelines on the treatment of PUD and gastroesophageal reflux disease (GERD) remains very necessary to achieve high eradication rates. A cross-sectional study involving a questionnaire shared on the Maccabi Healthcare Services (MHS) platform in Israel revealed sub-optimal adherence to Maastricht/Florence guidelines on *H. pylori* infection management in adult patients. Adherence to the American College of Gastroenterology guidelines on the management of GERD was relatively satisfactory.[69, 70] Compliance with guidelines among Lebanese pediatricians was also generally poor.[71-73]

Additionally, patients and a number of healthcare professionals rely on the details in the package inserts as convenient resources for quick drug information. Therefore, it is crucial to guarantee the accuracy and comprehensiveness of information on, among other things, indications, dosage, warnings/contraindications, adverse effects, and drug interactions. The national authorities should take the necessary action to eliminate false and inaccurate information from package inserts while upholding shared quality standards.[74, 75]

Contrary to prescriptions from doctors, the majority of patients take their drugs whenever it is convenient for them. Furthermore, it's no longer necessary to have a prescription to get these drugs.[76-78] To lower

the financial risk for the patient's unfavorable health outcomes, clinical practice needs to be improved with reference to rational prescription.[48, 79, 80]

CONCLUSION

Studies from the Middle East region have demonstrated the effectiveness of PPI-based regimens in the treatment of *H. pylori* eradication, with bismuth-based quadruple therapies gaining more recommendations as the initial treatment of choice. The most common proton inhibitors are omeprazole, rabeprazole, and esomeprazole. The most-included antibiotics are amoxicillin, metronidazole, clarithromycin, levofloxacin, and ofloxacin. There were also reports that concomitant and sequential therapies provide effective alternative regimens to achieve better eradication of *H. pylori* infections.

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CONFLICT OF INTEREST
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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

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All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.