Evaluation of Prescription Patterns of *Helicobacter pylori* Drugs in Out-Patient Department, Meru Teaching and Referral Hospital

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Abstract

BACKGROUND

Helicobacter pylori infects up to half of the world's population. Infection with *Helicobacter pylori* is a major contributing factor for gastric ulcers, gastric carcinoma, and extra gastric disease. The main aim of this study was to observe the prescription patterns of *Helicobacter pylori* drugs at Meru Teaching and Referral Hospital, Meru. This infection is mostly treated by a triple-drug regimen for successful eradication. The available regimens are a combination of proton pump inhibitors, antibiotics, bismuth sulfate, and histamine blockers.

METHODOLOGY

A cross-sectional retrospective review of the patient files for *Helicobacter pylori* was done at Meru Teaching and Referral Hospital (MeTRH). Systematic random sampling was used to select 262 medical records for review. Data was collected using the pre-tested abstraction forms and was coded and analyzed for descriptive statistics.

RESULTS

Out of the 262 medical records that were reviewed, 147 (56.4%) were males prescribed the *Helicobacter pylori* drug regimen. Among all the young adults (age: 12-39 years) were more likely to get *Helicobacter pylori* infection. The medication regimens that were highly preferred at MeTRH were 14-day and 7-day clarithromycin triple-based therapy. The 14-day triple therapy accounted for 74.5% of all patient files. The most administered drug class for *Helicobacter pylori* were proton pump inhibitors at 45.3% followed by antibiotics at 38.8% and the least prescribed drugs were the H2 blockers with 15.9%.

CONCLUSION

Regarding the most prescribed drug, the proton pump inhibitors while the most preferred regimen was the 14-day clarithromycin triple-based therapy. This data will certainly be important for the pharmaceutical management chain to manage the stock of analyzed drugs and also can spread awareness regards the appropriate handling of drugs which can improve adherence and reduce the rate of treatment failure and the emergence of antibiotic drug resistance.

Keywords: *Helicobacter pylori, Triple therapy, Retrospective Data Analysis, Prescription Pattern, Antibiotic Drug Resistance*

Introduction

The prevalence of *Helicobacter pylori* infection is a global concern, with a substantial impact on public health. The correct management of *Helicobacter pylori* infection is imperative for proper drug use to avoid complications, resistance, and good quality of life. This study aims to examine prescription patterns for *Helicobacter pylori* treatment to contribute to effective management strategies. Approximately 50% of the globe's population is known to be infected with *Helicobacter pylori,* most of these

infections are mainly in developing countries(1). However, there has been a positive trend in the Western world toward reducing the prevalence of the infection. Despite this, the infection is still a burden to developing countries. *Helicobacter pylori* can lead to various disorders such as peptic ulcer disease, chronic gastritis, and mucosa-associated lymphoid tissue(2). This knowledge is vital in sharing insight into the management of this infection. The infection can be diagnosed and treated effectively using antibiotics. Unfortunately, the increase in antibiotic resistance is a hindrance to the management of this infection. Having a better understanding of the prescription patterns of *Helicobacter pylori* can enable proper management of the infection.

According to the Ministry of Health in Kenya, for the last 2 decades, the approved treatment for *Helicobacter pylori* eradication by using various drug regimens, such as Triple Drugs regimen, Bismuth Quadrapol therapy, Concomitant therapy, and Sequential therapy. These regimens have one or two proton pump inhibitors (PPIs) and different antibiotics like clarithromycin, amoxicillin, metronidazole, and bismuth sulfate in bismuth-based therapy. Triple drug therapy has increased the risk of clarithromycin resistance hence it is replaced with metronidazole which has increased the efficacy of triple therapy (3). Triple therapy and bismuth quadruple therapy have similar efficacy and compliance. Concomitant therapy consists of PPI, amoxicillin, clarithromycin, and nitroimidazole (tinidazole or metronidazole) administered together for 3-10 days and it is as effective as clarithromycin triple therapy with identical tolerability (4). Sequential therapy is an alternative therapy to a triple-drug regimen of PPI with amoxicillin for 5 days after which a PPI, clarithromycin administered for another 5 days.

The treatment of *Helicobacter pylori* is varied in Kenya and needs perceptive data finding. The research findings will open up the knowledge on the prescription patterns of *Helicobacter pylori* used in Meru Teaching and Referral Hospital thereby informing future research studies on the prescription patterns and agents used in treating *Helicobacter pylori.* The main aim of this study is to evaluate the current trend in the usage of drugs in the treatment of confirmed cases of *Helicobacter pylori* in Meru Teaching and Referral Hospital.

Methodology
Study design

A cross-sectional retrospective study was conducted to examine the prescription patterns for the treatment of *Helicobacter pylori* infections.

The study took place at Meru Teaching and Referral Hospital (MeTRH), located in Imenti North Constituency in Meru, Kenya, with a population of approximately 1.57 million people.

The target population consisted of patients presenting with gastrointestinal tract (GIT) complaints, including gastritis and duodenal ulcers. Both outpatient and inpatient clinical records of patients of all age groups with GIT complaints who were undergoing treatment for *Helicobacter pylori* infection were included in the study. Prescriptions that did not include the *Helicobacter pylori* drug regimen were excluded.

Sample size

The sample size was calculated using Fisher's formula: $N = z^2 pq/D^2$

Where:

N= the desired sample size

Z = the standard normal deviation of 1.96 at a 95% confidence interval.

P = estimated prevalence of *Helicobacter pylori* in Kenya =75.4% (according to the Ministry of Health)

q= 1-p (0.3)

D= 0.05 (the level of significance at 95% or acceptable margin of error)

Although the calculated sample size was 285, the available patient records were only 3260.

Therefore, the sample size was adjusted and 262 files were evaluated.

Systematic random sampling was employed to select the patients whose medical records were reviewed between January 2019 and December 2020. Data were recorded on a pre-tested data abstraction form.

Ethical approval

Ethical approval was granted by the Kenya Methodist University Ethics and Research Review Committee, approval number (KeMU/SERC/BPH/31/2021 and permission to collect data provided by the Meru Teaching and Referral Hospital (MeTRH) administration, approval number (MRU/MED/GEN/R.14).

Data analysis

Data on the proportion of patients receiving various types of regimens were analyzed using descriptive statistics. The data were organized, encoded, and entered into Microsoft Excel 2016 to summarize and present the study findings. Quantitative variables such as age, gender, various classes of drugs, and specific agents were described as frequencies and percentages.

Results

A total of 262 patient files were observed and data abstracted. The social demographic information obtained was as indicated in Table 1. The age was stratified into 10 age group ranges.

Table 1:
Socio-demographic Characteristics of *H. Pylori*-infected Patients

Characteristics		Frequency (Percentage) of patients
Age group (years)	20-29	10 (3.8%)
	30-39	40 (15.3%)
	40-49	46 (17.6%)
	50-59	43(16.4%)
	60-69	41(15.6%)
	70-80	32(12.2%)
	80-90	31(11.8%)
	90-100	18(6.9%)
	Total	100
Gender	Males	147 (56%)
	Females	115 (44%)
	Total	100
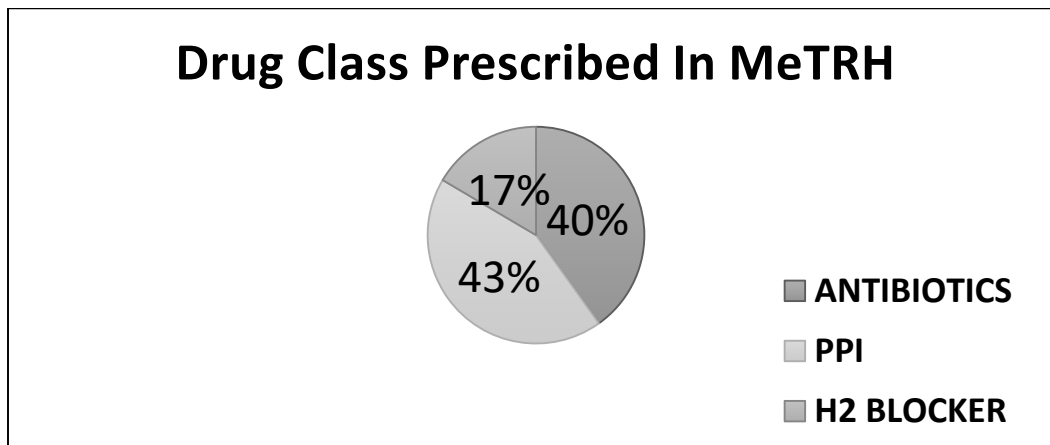
Figure 1:
Drug Classes Prescribed for the Treatment of *H. pylori* Infection

The maximum age of Helicobacter pylori patients was 99 years, with no patients aged below 20. The majority of patients were male (56.0%), while females comprised 44.0% of cases.

Frequently prescribed drug class

These included antibiotics, proton pump inhibitors (43.30%), and histamine 2 receptor blockers (16.50%). Proton pump inhibitors were the most administered, followed by antibiotics (40.10%). These drugs were used in fixed-dose combinations (Figure 1).

Frequently prescribed *H. pylori* infection regimen kit

The most used regimen at MeTRH was the 14-day clarithromycin triple-based therapy (66.03%), followed by the 7-day regimen (23.30%). The 10-day regimen was the least prescribed (10.69%), as shown in Table 2.

Drugs prescribed for *H. pylori* treatment

Figure 2 shows the most prescribed drugs were omeprazole (23.23%), amoxicillin (21.25%), and clarithromycin (20.79%). The least prescribed were pantoprazole (1.16%), lansoprazole (0.58%), relcer gel (0.46%), rabeprazole (0.35%), uligicid acid (0.23%), and lactulose (0.12%).

Discussion

The study elucidates the prescription patterns for *Helicobacter pylori* treatment among MeTRH patients and the results will contribute to future reviews of patients, therefore ensuring clinical practice is aligned with the best standards of patient care.

The results of the study indicate that elders (80%) are more affected than the young population 3.8%.

Table 2:
Medication Regimen Used in the Treatment of *Helicobacter pylori* in MeTRH

	Frequency	Percentage
7 days	61	23.30
10 days	28	10.69
14 days	173	66.03
Total	262	100%
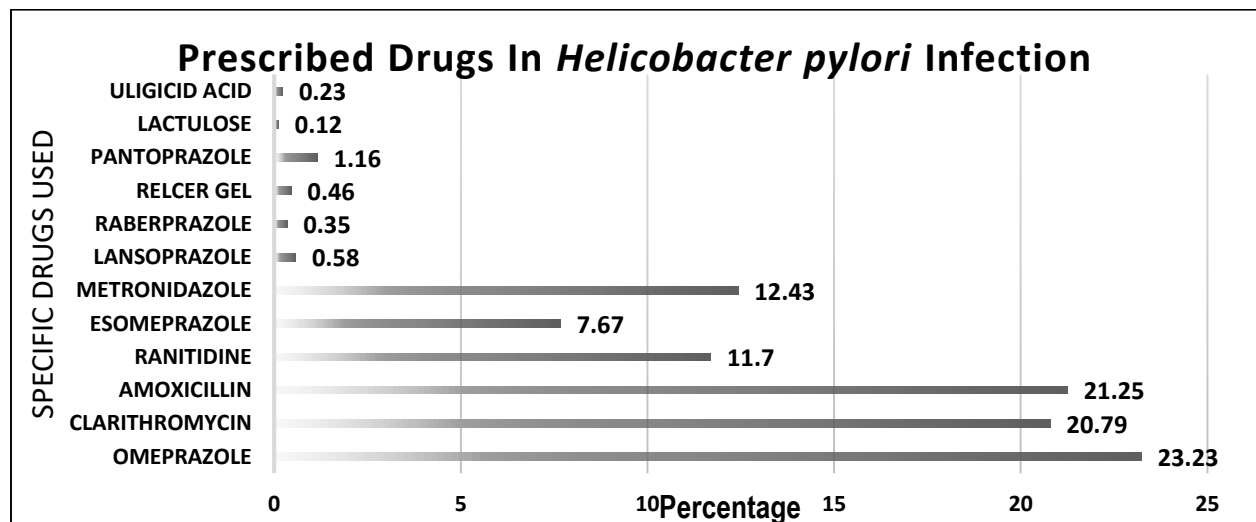
Figure 2:
Specific Drugs Used in the Medication Regimen to Treat *Helicobacter pylori* Infection

Previous studies have shown that *H. pylori* infection increases with age (1). The study identified that males (56.40%) were more highly infected than females (43.60%). Previous studies done in Korea found that adult men were at higher risk of having *Helicobacter pylori* infection (5).

Various factors might play a role in increasing the infectious condition and lifestyle increases the incidence of *H. pylori* infections. The most administered drug class was the proton pump inhibitors (43.30%) followed by antibiotics (40.10%), and lastly, H2 receptor blockers (16.50%). Proton pump inhibitors and H2 antagonists are both acid-lowering agents. H2 receptor antagonist is seldom prescribed in MeTRH. Studies have shown that *Helicobacter pylori* eradication rates for treatment protocols with one or two antibiotics in combination with acid-lowering agents are not different for the proton pump inhibitors or the H2 receptor antagonist (6). Studies have shown that currently, regimens that use proton pump inhibitors in combination with several antibiotics such as clarithromycin, amoxicillin, and metronidazole have been successful in *Helicobacter pylori* eradication (7).

Even though research has shown bismuth salts to be used in the medical field in developed countries compared to developing countries, commonly used agents like colloidal bismuth sub-citrate (CBS), bismuth sub-salicylate and bismuth citrate exert local effects on the gastro-duodenal mucosa. Bismuth monotherapy is effective in vivo in suppressing *Helicobacter pylori* however, cure rates are substantially low (8). The data collected from MeTRH showed that there was no prescription for bismuth citrate.

The clarithromycin triple-based regimen for 14 days was highly prescribed (66.03%), followed by 7 days (23.30%), and the 10-day clarithromycin triple therapy was the least prescribed. According to the Ministry of Health in Kenya, for the last 2 decades, the approved treatment for *Helicobacter pylori* elimination is the standard triple therapy using ranitidine, bismuth, or a proton pump inhibitor, combined with amoxicillin and clarithromycin or metronidazole for 2 weeks. 14 days of clarithromycin triple-based therapy has a significantly higher eradication rate in MeTRH which complies with a previous study conducted (9). In MeTRH, 7 days of therapy was less prescribed, because of its high probability of reoccurrence.

The optimal omeprazole dose for anti-*H pylori* therapy in MeTRH is 10-40mg/day in adults and 10-20mg/day in children for 7, 10, or 14 days in combination with two antibacterial agents. Some studies showed omeprazole was at least as effective as lansoprazole, pantoprazole, bismuth compounds, and ranitidine (10). The antibiotic combinations that were used in MeTRH were clarithromycin and amoxicillin, clarithromycin, and metronidazole for 7, 10, and 14 days. Previous studies have shown that clarithromycin has higher incidences of resistance as compared to other antibiotics therefore a combination of either clarithromycin and amoxicillin or clarithromycin and metronidazole has been used to reduce this incidence of resistance (11).

Conclusion

In conclusion, our study highlights the prescription patterns for *Helicobacter pylori* treatment in MeTRH, offering valuable insights for optimizing patient care and addressing the challenge of antibiotic resistance. The highly prescribed drug classes were antibiotics, proton pump inhibitors, and H2 blockers. Bismuth citrate was not prescribed at MeTRH and this may be due to salicylate toxicity associated with bismuth compounds or cost-effectiveness or its availability. This finding will help to pharmaceutical management department in the hospital to procure the disease-related drugs. The medication regimen was clarithromycin triple-based therapy since it's the first-line treatment therapy for *Helicobacter pylori* infection

according to the Ministry of Health in Kenya. Our research findings suggest that general public awareness of *Helicobacter pylori* infection will significantly reduce the transmission of infection and further gastrointestinal-associated disorders, especially malignant conditions.

Conflict of interests. All the authors of this manuscript have declared that they have no conflict of interest in publishing this work.

Availability of data statement. The research work is original and has been not published in any other journals.

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