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UPPER GUT

Efficacy of 'Triple Therapy' in Eradicating Ulcer Related *Helicobacter pylori* Infection at a Tertiary Hospital in Fiji—A Pilot Study

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ABSTRACT

Background: Fiji currently uses a seven-day Clarithromycin based triple therapy regimen for *Heliobacter pylori* (*H. pylori*) eradication, and the local eradication rate is unknown. *H. pylori* testing is performed using a rapid urease test (RUT) during gastroscopy in Fiji.

Methods: A year-long prospective observational study was undertaken at the Colonial War Memorial Hospital in Fiji. Eligible participants included patients who had peptic ulcer disease (PUD) on gastroscopy and a positive RUT. Consenting participants were prescribed Clarithromycin based triple therapy for 7 days, and underwent a second gastroscopy with RUT after 6 to 8 weeks. Participants who tested positive on a repeat RUT received Clarithromycin based triple therapy for 14 days, and underwent a third gastroscopy and RUT. Participants who remained positive for *H. pylori* were prescribed quadruple therapy for 14 days.

Results: Forty-nine patients were enrolled in the study. Thirty-six (73.5%) had a negative RUT after a seven-day Clarithromycin-based regimen. Eleven of the 13 participants who remained positive eradicated *H. pylori* after being given another course of the same regimen for 14 days, resulting in a final eradication rate of 95.9%. The remaining two participants received quadruple therapy for 14 days.

Conclusion: This study demonstrates an eradication rate of 73.5% using a seven-day Clarithromycin-based regimen in Fiji among *H. pylori* positive patients with PUD on gastroscopy. This was significantly improved using a 14-day regimen. *H. pylori* has reduced susceptibility to the current seven-day Clarithromycin based regimen. Future local guidelines should extend to 14 days to achieve a greater eradication rate.

JEL Classification: Upper Gut

1 | Introduction

Helicobacter pylori (*H. pylori*) is a Gram-negative bacterium first identified in 1982 [1]. *H. pylori* has been identified as causing gastritis and peptic ulcer disease (PUD), and is also a known carcinogen for gastric cancer [2, 3].

Clarithromycin-based triple therapy had been the standard therapy for eradicating *H. pylori* worldwide. However, clinical evidence and phenotype testing have confirmed increasing resistance to antibiotics used in the traditional triple therapy regimen, particularly to Clarithromycin, in several regions [4, 5]. As a result, some countries use triple therapy for a longer duration

while other countries use newer regimens such as quadruple therapy as the first-line therapy [5–8].

Local guidelines in Fiji currently recommend Clarithromycin based triple therapy for 7 days [7]. The prevalence of *H. pylori* has been previously shown at 57.6% in patients undergoing gastroscopy in Fiji [9]. There are no local published data available on the resistance rate of *H. pylori* to triple therapy. This study investigates the eradication rate of a seven-day Clarithromycin based triple therapy eradication regimen for PUD related *H. pylori* infection in patients in Fiji.

2 | Methods

This was a single center prospective observational study conducted at the Colonial War Memorial Hospital (CWMH) in Suva, Fiji, from 1st May 2019 to 30th April 2020. CWMH is one of the three tertiary care government facilities in Fiji, and the main center for diagnostic and interventional gastrointestinal endoscopy.

Ethics approval was sought from the Fiji National University (FNU) Centre for Health, Human Research Ethics Committee (CHHREC) and the Fiji Ministry of Health Research and Ethics Committee and permission was obtained from the CWMH before data were collected.

All consenting patients over the age of 14 years, who underwent gastroscopy which showed PUD and were positive for *H. pylori* on a rapid urease test (RUT) [10] in the defined study period were eligible for this study. Performing a RUT during gastroscopy is the only currently available method of testing for *H. pylori* in Fiji. Gastroscopies were performed by surgeons and gastroenterologists at CMWH, and all proceduralists were aware of the study. Performing a RUT during a gastroscopy was at the proceduralist's discretion, and those who were acutely unwell with an upper gastrointestinal bleed or on anti-platelet agents or anticoagulants did not receive a RUT.

Participants received a seven-day eradication regimen of Amoxicillin 1 g twice daily, Clarithromycin 500 mg twice daily, and Omeprazole 20 mg twice daily, and then received a repeat gastroscopy and RUT after 6 to 8 weeks. Consenting patients needed to be agreeable to a follow-up gastroscopy for a repeat RUT to assess for eradication. Although ideally, we would have studied all *H. pylori-positive* patients undergoing a gastroscopy regardless of PUD status, this study focused on PUD-related *H. pylori*. A repeat gastroscopy is only indicated in CMWH to assess for ulcer healing in gastric and suspicious duodenal ulcers. Thus, we restricted our inclusion criteria to those who we could assess for eradication during their repeat gastroscopy, which was already considered clinically appropriate to perform. Patients who had received a prior eradication regimen or an alternative regimen by the primary care team, refused treatment, had a prior history of upper gastrointestinal resection, declined to be part of the study, or were deceased before repeat gastroscopy were excluded. Recruitment of participants was impacted by the COVID-19 pandemic, when regular endoscopy services were suspended.

Participants were recommended to stop Omeprazole at least 2 weeks before repeat gastroscopies. Participants were called by the principal investigator (VS) after completing the Clarithromycin-based triple therapy regimen to verbally confirm access to medications and compliance with the regimen.

As this was an observational study, patient management was undertaken by the primary team. However, if during the data collection a patient was noted to be on inappropriate treatment, then the researchers would inform the primary team as soon as possible to not compromise patient care. All medical management decisions remained with the primary team.

The variables collected included patient demographics, significant past medical history, current and past medication use with a focus on previous eradication regimen or macrolide use, medication allergies, gastroscopy findings, RUT results including initial and follow-up tests, and patients requiring further eradication treatment. Data collected were entered into a Microsoft Excel spreadsheet (v25) and stored as a password-protected file. To ensure confidentiality, patients were de-identified using unique codes. Data were analyzed using SPSS software (v25) to calculate means and standard deviations. Statistical significance was not calculated as this was a single-arm study.

3 | Results

A total of 477 patients underwent a gastroscopy at CMWH during the study period, and PUD was identified in 124 patients (Figure 1). Gastric ulcers were identified in 92 patients, and 67 of those received a RUT. Duodenal ulcers were identified in 32 patients, and 18 of those received a RUT. *H. pylori* was identified in 70.1% of gastric ulcer and 72.2% of duodenal ulcer patients, out of those who underwent a RUT (Figure 1).

Sixty patients had PUD and positive RUT, and were eligible to participate. Eventually, 49 participants were enrolled—four patients declined to participate, and seven patients died before receiving a repeat gastroscopy and RUT (Figure 2).

Most participants were males in the45–65-years age group. There was no prior macrolide use documented, and no participants had been prescribed eradication therapy before. Participant characteristics are shown in Table 1.

All 49 participants were found to be on the appropriate 7-day Clarithromycin-based triple therapy. Daily compliance was 100% for all 49 participants based on self-reporting and follow-up assessment of medication packs. Within the enrolled cohort of participants, 13 (26.5%) remained positive after treatment with the Clarithromycin-based triple therapy for 7 days, while 36 patients (73.5%) had successfully eradicated *H. pylori* on repeat RUT (Figure 2).

Of the 13 participants who had a positive RUT following a seven-day Clarithromycin based triple therapy regimen, 9 had gastric ulcers and 4 had duodenal ulcers. 11 of these participants had successful eradication when given an additional course of triple therapy for 14 days, with an eradication rate of 95.9% (Figure 2). The two patients who had remained positive despite extended

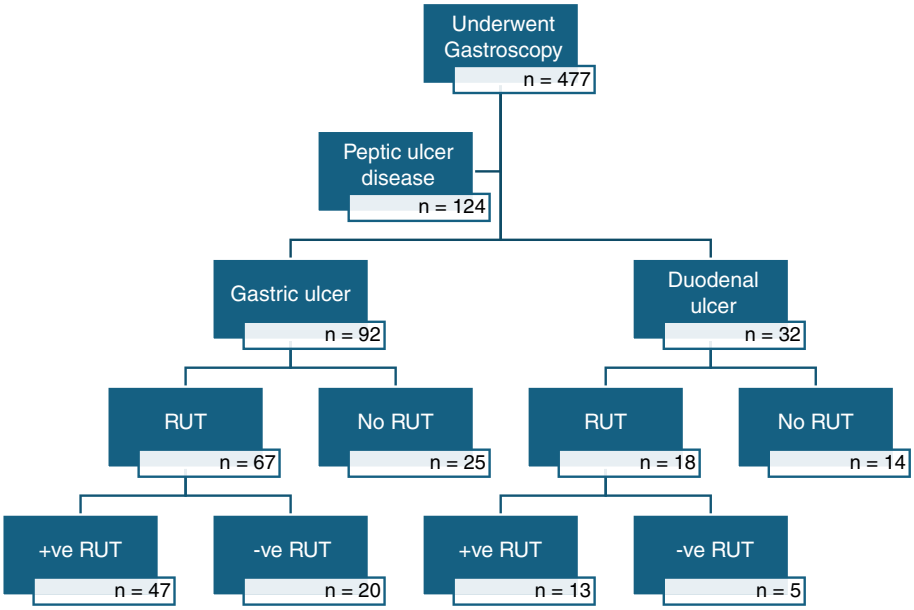

FIGURE 1 | Participant selection flow diagram. Patients who had a gastroscopy, were found to have PUD, and a positive RUT were eligible to participate in the study.

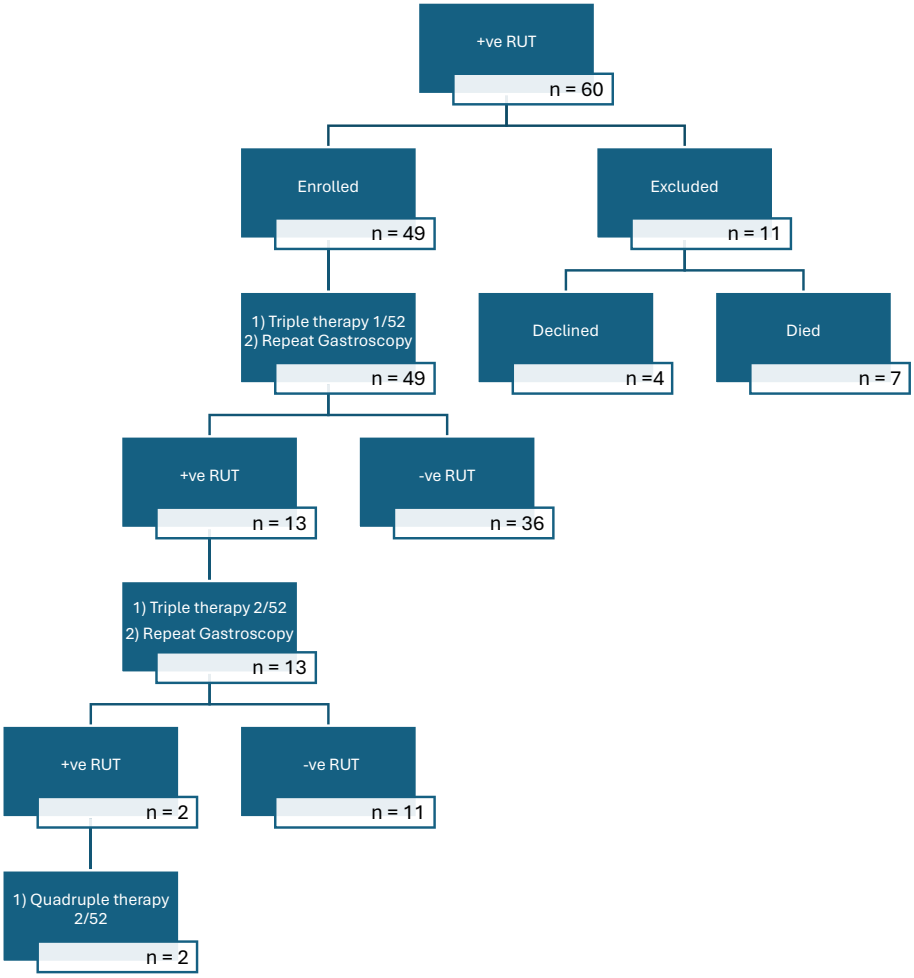

FIGURE 2 | Flow diagram outlining the study process for enrolled participants. They received a seven-day course of Clarithromycin-based triple therapy and a repeat gastroscopy within 6 to 8 weeks of their index procedure. A repeat RUT was performed, and if negative, patients were assumed to have successfully eradicated *H. pylori*. If positive, patients received a 14-day course of Clarithromycin-based triple therapy. A repeat gastroscopy and RUT were performed in those who had remained positive on their repeat RUT, and if this was still positive, they received a 14-day course of quadruple therapy.

TABLE 1 | Participant baseline characteristics.

Characteristics	$N=49$	Percentage
Gender		
Male	36	73.5%
Female	13	26.5%
Age range		
25–35	2	4.1%
35–45	7	14.3%
45–55	13	26.5%
55–65	15	30.6%
>65	12	24.5%
Co-morbidities		
Yes	24	48.9%
No	25	51.1%
Use of NSAIDs		
Yes	13	26.5%
No	36	73.5%
Presenting symptoms		
Melaena	33	67.3%
Nausea/vomiting	29	59.2%
Decreased appetite	23	46.9%
Haematemesis	21	40.8%
Weight loss	15	30.6%

therapy, successfully eradicated organism after a second line quadruple therapy based on locally available and accessible medications, including Omeprazole, Amoxicillin, Ciprofloxacin and Tetracycline.

4 | Discussion

This study investigated the *H. pylori* eradication rate using Fiji's national guidelines of a seven-day Clarithromycin-based triple therapy regimen, amongst consenting patients who underwent gastroscopy and were found to have PUD, as well as a positive RUT. *H. pylori* was identified in 70.1% of gastric ulcer and 72.2% of duodenal ulcer patients, out of those who had a RUT. The seven-day Clarithromycin-based triple therapy in this study had an eradication rate of only 73.5%. The eradication rates improved to 95.9% when the failed group was given an extended duration of treatment for 14 days with the same triple therapy regimen. Two patients failed to eradicate with the extended regimen and were provided with an improvised quadruple therapy of Omeprazole, Amoxicillin, Tetracycline, and Ciprofloxacin.

In the early 1990s, the eradication rate using triple therapies consisting of Omeprazole, Clarithromycin, and Amoxycillin was greater than 80% [11]. Over time, these rates have declined due to increasing antibiotic resistance, particularly to Clarithromycin. Several other factors have been associated with failed eradication therapy, which include inadequate regimens, poor patient adherence, massive gastric bacterial loads, internalizing bacteria, high gastric acidity, gene polymorphisms, antimicrobial washout and dilution, and biofilm formation [11].

Inadequate duration of treatment has been identified as one of the major factors leading to eradication failure. A Cochrane review found that with a Clarithromycin-based triple therapy, significantly higher eradication rates were reported with 14 days versus 7 days of treatment [8]. The American College of Gastroenterology recommends Clarithromycin-based triple therapy as the first line of treatment for 14 days in patients with no history of antibiotic treatment for the infection [5]. Australian guidelines, however, still recommend a Clarithromycin-based regimen for 7 days due to low reported resistance rates to Clarithromycin [12].

This study had some limitations. The COVID-19 pandemic greatly impacted the enrollment of participants into the study, with procedure numbers declining during the period of data collection owing to a focus on emergencies. The unavailability of non-invasive means of detecting active *H. pylori* infection also restricted the profile of patients that could be enrolled, as participants had to be subjected to a repeat gastroscopy. Furthermore, 27.2% of patients with gastric ulcers did not receive a RUT, and 43.8% of patients with suspicious duodenal ulcers did not receive a RUT. This limited our sample size and may have biased our results. Future research should expand from our pilot study assessing PUD-related *H. pylori* positive infections on gastroscopy *to H. pylori* positive infections identified on gastroscopy for any indication, as this would provide a more accurate prevalence of the general population in Fiji. Again, this would require non-invasive testing to be available in order to not overwhelm Fiji's gastroscopy capacity with repeat gastroscopies.

In conclusion, despite being limited by the small sample size, this pilot study presents initial findings of inadequate susceptibility to the local, first line seven-day Clarithromycin-based eradication regimen in Fiji. This prompts the need to further evaluate resistance patterns, especially to Clarithromycin. Local guidelines should consider extending the duration of treatment regimen to 14 days to reduce treatment failure, based on the local eradication rate of 95.9% observed in this study.

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Disclosure

The authors have nothing to report.

Conflicts of Interest

Andrew Hill is an Editorial Board member of the ANZ Journal of Surgery and a co-author of this article. To minimize bias, they were excluded from all editorial decision-making related to the acceptance of this article for publication.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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