A Comparison of Triple Therapy Drug Regimen Duration for Eradication of *Helicobacter pylori* in Adults Attending a Nairobi Gastroenterology Clinic

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ABSTRACT

Helicobacter pylori (*H. pylori*) infection is a major cause of symptomatic gastritis and peptic ulcers in the Kenyan population. Persistence of *H. pylori* and its medical complications continue to be a major problem. Treatment duration is usually for one or two weeks. Studies in developed countries have shown equal or increased efficacy with two week triple therapy treatment, but no study has been done to establish this in Kenya. The main aim of this study was to compare efficacy of one and two week triple therapy for *H. pylori* eradication in adults at a Nairobi gastroenterology clinic. This was a single-blind randomized clinical trial conducted at the Centre for Clinical Research, Kenya Medical Research Institute, Nairobi - Kenya. Patients aged 18 years and above, referred to the gastroenterology clinic for endoscopy, were interviewed, asked to participate in the study and consent was acquired from them. 479 patients went through rapid urease testing on endoscopy of which 253 patients tested negative and 226 patients tested positive for *H. pylori*. The prevalence rate of *H. pylori* infection was 47%. 150 patients were *H. pylori* positive on rapid urease testing and were randomized to receive either esomeprazole 20 milligrams, amoxicillin 1 gram, and clarithromycin 500 milligrams twice daily followed by one week esomeprazole 20 milligrams plus amoxicillin and clarithromycin placebo twice a day (EAC1, n = 76), or esomeprazole 20 milligrams, amoxicillin 1 gram and clarithromycin 500 milligrams twice daily for two weeks (EAC2, n = 74). A cure check through stool antigen testing (Meridian Bioscience) was performed 4 weeks after conclusion of therapy. Quantitative data was analyzed using SPSS computer program. Bivariate and multivariate analysis was done to measure the strength of association between the exposures and the

outcomes. 40.2% of 112 patients, who completed follow up, were found to have *H. pylori* on stool antigen testing following endoscopy – a cure rate of 59.8%. *H. pylori* was eradicated in 66.1% of EAC1 compared to 53.6% of those in EAC2 of the per protocol analysis. There was no statistical difference noted ($P>0.05$). Both treatments were similarly well tolerated with no unexpected safety concerns. The main side effects were abdominal pain and headache for both treatment groups. There was no significant association between occurrence of a particular side effect and treatment groups ($P>0.05$). There was a significant association between *H. pylori* presence and return of symptoms at the end of the study on bivariate analysis ($P<0.05$). The final logistic regression model incorporated the following significant predictors ($P<0.05$): Age and Return of symptoms in comparison with *H. pylori* presence. For every unit increase in age, an individual was 5% less likely to test positive for *H. pylori*. The older the individual the less likely there were to test positive for *H. pylori*. An individual showing recurring symptoms was 3.31 times more likely to test positive for *H. pylori* compared to one without recurrence of symptoms. In the Kenyan population, the seven day treatment was as effective as the fourteen day treatment for *H. pylori* eradication. However, the seven day treatment was recommended for treatment of *H. pylori* as it has good results and is cost-effective. Both treatments were well tolerated. It may be necessary to check antigen levels of *H. pylori* and drug resistance before treatment or retreatment for *H. pylori*. This will help determine the type of drugs to use and duration of treatment.