

Abstract

EVALUATION OF COMMONLY USED TESTS FOR DETECTING *Helicobacter pylori* IN A SAMPLE OF SYMPTOMATIC PATIENTS FROM THE CENTRAL PROVINCE, SRI LANKA.

Introduction: *H. pylori* gastritis (type II gastritis) is known to have a strong aetiological relationship with benign chronic gastric and duodenal ulcers, gastric atrophy, carcinoma and lymphoma. There are many invasive and non-invasive test methods employed to detect the presence of *H. pylori* in gastric biopsies, i.e., histology, immunohistochemistry, rapid urease tests, culture, urea breath test, stool antigen test, polymerase chain reaction (PCR) and serology. In Sri Lanka, variable prevalence rates of *H. pylori* infection have been reported in different studies ranging from 2.9 to 70.1% using any of the above test methods. Demonstration of *H. pylori* using the histology is the most commonly used method to diagnose *H. pylori* infection in Sri Lanka.

Objectives: The objective of this MPhil project was to evaluate the diagnostic efficacy of commonly used *H. pylori* detection methods in symptomatic patients in Sri Lanka and assess the feasibility of these tests to be adopted in Sri Lankan laboratories.

Methodology: This is a cross sectional study conducted including 205 patients who had dyspeptic symptoms and endoscopically visible mucosal erythema with or without erosions/ulcers at Teaching Hospital, Peradeniya from 2012 to 2013. All patients underwent endoscopic gastric biopsy according to a protocol which included four biopsies from the antrum and one each from incisura angularis and the body of the stomach. The modified one minute rapid urease test was performed on an antral biopsy. The other biopsies were processed for routine histology, toluidine blue staining and immunohistochemistry. On histological examination chronic inflammation, acute inflammation, atrophy, intestinal metaplasia, dysplasia and the presence of *H. pylori* were assessed. PCR was performed on an antral biopsy using primers for the detection of *H. pylori* DNA 16SrRNA. Anti-*H.pylori* antibodies were tested on venous blood using ELISA for anti-IgG antibody (MP Biomedicals, USA) and immunochromatography assay (SD BIOLINE *H. pylori* test, Taiwan). Prevalence of *H. pylori* with each of the detection method was assessed using the test indices such as sensitivity, specificity and positive and negative predictive values.

Results: The sensitivity and specificity of each detection methods were as follows: histology= 54% and 100%, respectively; immunohistochemistry (IHC)= 27% and 100%, respectively; modified one minute rapid urease test (RUT)=100% and 98.4%, respectively; immunochromatography (ICT)=100% and 96% PCR= 100% and 98.4%, respectively. The overall *H. pylori* prevalence using all detection methods were consistently low, indicating a low prevalence of *H. pylori* in the study population (2.9% using histology; 1.4% using IHC; 5.3% using PCR; 3.4% using ELISA; 6.8% using ICT and 6.8% using RUT).

Conclusion: Overall prevalence of *H. pylori* infection in the study sample was low. Moreover, the low prevalence of serum anti-*H pylori* IgG levels suggested low exposure rate to *H. pylori* in the study sample. Modified one minute RUT has shown to be an inexpensive test with good diagnostic efficacy. Since PCR is a highly sensitive method and using PCR as a gold standard comparator to evaluate other methods could underestimate the method under evaluation. Histology appeared to identify the cases with clinically significant gastric disease. ICT shown to have good diagnostic efficacy and it is a low cost serological test when compared to ELISA.