The Utility of the helicobacter pylori stool antigen test in managing dyspepsia: an experience from a low resource setting

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Abstract

Background: Dyspepsia is defined as a chronic or recurrent pain or discomfort centered in the upper abdomen. Endoscopy is the best strategy for confirming the cause of dyspepsia. Non- invasive strategies would be more appropriate in low resource countries where endoscopy is not readily available. However, there is concern that these strategies may miss serious disease like gastric cancer. One test that needs to be assessed in this regard is the Helicobacter pylori stool antigen test (HPSAT).

Objective: To determine the validity of the stool antigen test in predicting H. pylori associated disease among patients with dyspepsia.

Methods: In this prospective study patients with dyspepsia attending Mulago Hospital were recruited consecutively. Helicobacter pylori was determined using the Rapid Strip HpSA ®, endoscopy and gastric mucosal biopsy were done.

Results: 167 patients with dyspepsia were recruited into the study. There were ninety six (57.5%) females and seventy one (42.5%) males with an average age of 48.1(±18.1) years. Patients presenting with dyspepsia in Mulago hospital were more likely to come from the Central 60 (36%) and western tribes 55 (33%). The commonest endoscopic finding was oesophagitis 25 (15%). Peptic ulcer disease was found in 32 (19.2%) and 54 (32.3%) had normal endoscopy findings. H pylori was found in 33.5% and 32.5% using the HPSAT and histology respectively. The validity of the HPSAT in predicting H.pylori associated diseases was generally low with an overall sensitivity of 55.8%, and specificity of 74.2%. However, the validity was higher in predicting the diagnosis of peptic ulcer disease with a sensitivity 59.4% and specificity 72.6%.

Conclusion and recommendations: The HPSAT may be used in the test and treat strategy for young patients with dyspepsia without alarm signs and symptoms in low resource settings. However, because of its low validity in predicting H.pylori associated disease, it is important to follow up patients so that if symptoms persist or recur endoscopy is performed

Keywords: helicobacter pylori, stool antigen, dyspepsia, low resource setting

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Introduction

Dyspepsia is defined as a chronic or recurrent pain or discomfort centered in the upper abdomen[1]. Helicobacter pylori associated diseases such as peptic ulcer disease, gastritis and gastric cancer commonly present as dyspepsia. In the evaluation of dyspepsia, clinical signs and symptoms have a limited role because they do not reliably predict underlying pathology and endoscopy findings[2]. Symptom assessment by medical workers is therefore not sufficient in the evaluation of the cause of dyspepsia.

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Endoscopy is the best strategy for confirming the cause of dyspepsia. However, it is an expensive procedure and is not readily available in low resource countries. One of the main reasons for performing endoscopy in patients with dyspepsia is to detect underlying H.pylori associated diseases like peptic ulcer.

Non-invasive testing of H. pylori using the urea breath test has been shown to be a useful surrogate marker of peptic ulcer disease in patients with dyspepsia in a study conducted in the United Kingdom[3].

The Helicobacter pylori stool antigen (HPSAT) test has been shown to be another accurate non-invasive test for the initial diagnosis of H.pylori infection[4]. However, there is no data on its utility in managing dyspepsia in low resource countries. It is in light of the above that we conducted this study.

Methods

This was a descriptive cross sectional study conducted among patients with dyspepsia presenting to the gastroenterology division of Mulago hospital between October 2009 to April 2010. All patients with dyspepsia 12 years and above who had provided consent to participate in the study were consecutively enrolled into the study. The patients had to have been off proton pump inhibitor therapy and antibiotics for atleast 2 weeks. We excluded patients with dyspepsia attributable to non- steroidal ant-inflammatory drugs, dysphagia and those with epigastric pain due to pancreatic or hepatic disease.

A physical examination was conducted and a questionnaire was administered to obtain social demographics, severity of dyspepsia symptoms, alarm signs and symptoms. The study participants were asked to provide a stool sample for H.pylori testing on the morning of endoscopy was performed. The stool was tested immediately using the Rapid Strip HpSA ® from Meridian bioscience Europe.

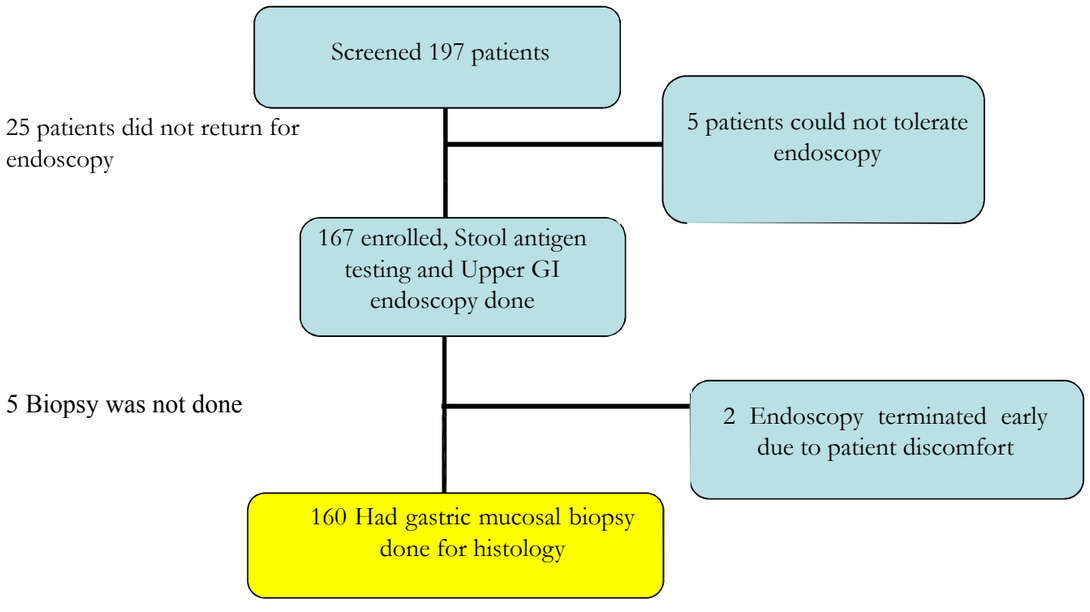
On the day endoscopy was scheduled, the procedure was done according to the standard protocol. At endoscopy a description of the findings was done and three gastric mucosal biopsies for histology were taken off.

All the data was coded and entered using EpiData computer software version 3.1, before being transferred to stata version 10 for analysis. Approval for the study was granted by the School of Medicine Research and Ethics committee of Makerere University College of Health sciences

Results

One hundred and ninety seven (197) patients who attended the Gastroenterology division of Mulago hospital were screened for eligibility. One hundred and sixty seven (167) patients with dyspepsia were recruited into the study (Figure 1). One hundred and sixty patients had gastric mucosal biopsy done.

Figure 1: Patient flow chart



There were ninety six (57.5%) females and seventy one (42.5%) males. The average age of the participants was 48.1(±18.1) years with a range of 13 to 84 years (Table1).

Table 1: socio-demographic characteristics

Variable	Number (n=167) Percentage
Age (years)	
> 45	89 46.7
< 45	78 53.3
Sex	
Female	96 57.5
Male	71 42.5
Region	
Central	60 36
Western	55 33
Northern	25 15
Eastern	14 8
Non-Ugandans	13 8

The commonest H.pylori associated endoscopic diagnoses in order of frequency were gastric ulcer 18 (10.8%), duodenal ulcer 17 (10.2%), cancer of the stomach 12 (7.2%), and duodenitis 9 (5.4%). Oesophagitis was the commonest non-H.pylori associated endoscopic diagnosis, found in 25 (15%). Normal endoscopy was found in a significant proportion of patients 54 (32.3%) (Table 2).

Table 2: Endoscopic and histologic diagnoses among patients with dyspepsia

Endoscopic/histologic diagnosis	Number(N=167)	Percentage
Normal	54	32.3
Gastric ulcer	18	10.8
Duodenal ulcer	17	10.2
Cancer of the stomach	12	7.2
Oesophagitis	25	15
Candidiasis	15	9
Oesophageal varices	6	3.6
Others	19	11.4
Histologic gastritis	119	71.3

The majority of the patients with cancer of the stomach 9 (75%) were above 45 years and had alarm features (Table 3).

The prevalence of Helicobacter pylori was 33.5% and 32.5 % as determined by the HPSAT and histology respectively. Among patients with H.pylori associated diseases, the highest prevalence of H.pylori was found among patients with duodenal ulcer using the HPSAT. It was found in 10 (58.8%) of these patients duodenal ulcers. It was followed by gastric ulcer 55.6% and gastric cancer 50%. Among the patients with a normal endoscopic diagnosis, the prevalence of H.pylori using the HPSAT was low at 24.1% (table 4).

Table 3: Characteristics of patients with Cancer of the Stomach

Variable	Number (n=12)	Percentage
Age		
Below 45 years	3	25
Above 45 years	9	75
Alarm features		

The overall sensitivity of the stool antigen test in predicting H.pylori associated disease among patients with dyspepsia is 55.8%, specificity is 74.2% while the positive and negative predictive values are 42.9% and 82.9% respectively. It was higher in predicting duodenal ulcer with a sensitivity and specificity of 58.8% and 69.3% respectively followed by gastric ulcer with sensitivity of 55.6% and sensitivity of 69.1% (table 4). The test overall showed a high negative predictive value for all the H.pylori associated diseases.

Table4: Endo scopic diagnoses and prevalence *Helicobacter pylori*

	Helicobacter pylori HPSAT	
	Positive	***Negative***
Overall H.pylori prevalence	56 (33.5%)	*111 (66.5%)*
Endoscopic diagnosis		
Gastric ulcer	10 (55.6%)	*8 (44.4%)*
Gastric cancer	6 (50%)	*6 (50%)*
Duodenal ulcer	10 (58.8%)	*3 (33.3%)*
Duodenitis	7 (41.2%)	*6(66.7%)*

Other endoscopic findings include: Gastric Polyps 1(0.6%), gastric Kaposis sarcoma 1(0.6%), gastric outlet obstruction 5 (3%), portal hypertensive gastropathy1 (0.6%), duodenal mass 2 (1.2%), extrinsic duodenal Mass 1 (0.6%), Barrett's oesophagus 1 (0.6%), dilated oesophagus 2 (1.2%), oesophageal ulcers 3 (1.8%), Ca oesophagus 1 (0.6%), hiatus hernia 3(1.8%). Table 5

Table 5: Utility of the HPSAT in predicting Helicobacter pylori associated diseases among patients with dyspepsia

Validity	Gastric ulcer	Duodenal ulcer	Gastric	*H.pylori*
Sensitivity (%)	55.6	55.8	50	55.8
Specificity (%)	69.1	69.3	67.7	74.2
Positive predictive value (%)	17.9	18	10.7	42.9
Negative predictive value (%)	92.8	93.7	94.6	82.9

Discussion

In this study, oesophagitis 25 (15%) was the commonest endoscopic diagnosis. Gastric ulcer was found in18 (10.8%) and duodenal ulcer in 17 (10.2%). These findings are similar to earlier studies in Mulago hospital[5]. Other studies from Africa have reported higher rates of duodenal ulcer[6]. In both these studies the prevalence of H. pylori was above 70%. It is possible that the high prevalence of H.pylori was responsible for the observed differences in the frequency of peptic ulcer disease. Gastric cancer was found in 12(7.2%) which is similar to findings from other African studies [5 7 8]. A large proportion of the patients with gastric cancer were from the western tribes 6 (50%). In addition the majority of these patients with cancer of the stomach were over 45 years of age and had alarm features (Table 3). Ibingira had similar results in 2001 where he found 49% of the patients were from south western Uganda. The mean age of his patients was 53.8 years for females and 56.1 for males[9].

The overall prevalence of Helicobacter pylori among patients with dyspepsia at Mulago hospital was 33.5% as determined by the H.pylori stool antigen test while it was 32.5% as determined by histology. It is possible therefore that the prevalence of active H.pylori infection is much lower than the sero-prevalence. In our study patients were required to have been off proton pump inhibitor and antibiotics for atleast two weeks. However, most of our patients 146 (73%) reported symptoms lasting over 4 weeks and during that period 63 (38.9%) had been prescribed atleast one of the antibiotics used for H.pylori treatment. It is possible that some of these patients could have eradicated the organism before testing had been done, leading to a lower prevalence rate. In Ghana and Nigeria prevalence rates of 75.4%, 73% and 81%, have been reported using histology and CLO urease tests [7 10 11]. It is possible that the prevalence of active infection has declined in Uganda while that in Ghana and Nigeria has remained constant. Other studies may therefore be needed to determine the prevalence of active H.pylori infection in Uganda and if there have been any changes in the pattern over the years. In developed countries the prevalence of H.pylori has been noticed to be decreasing [12].

The HPSAT had a higher validity in predicting diagnosis of peptic ulcer disease with a sensitivity of 59.4% and specificity of 72.6% and in predicting the diagnosis of cancer of the stomach with a sensitivity of 50% and specificity of 67.7%. With this overall low sensitivity the HPSAT may still be used in the test and treat strategy especially in low resource settings, among young patients less than 45 years of age with no alarm symptoms. In this age group even if the test missed to predict some cases of H.pylori associated diseases, these are relatively few and most of them are benign. In any case, using this strategy, the H.pylori negative patients would be treated with a PPI(proton pump inhibitor) which may result in improvement in the benign

H.pylori associated diseases. However, it is important to follow up patients when this strategy is used, so that if symptoms persist, endoscopy is done to confirm the diagnosis of any H.pylori associated disease that may have been missed by a negative HPSAT.

Conclusions

The helicobacter pylori stool antigen test may have a role in the non-invasive management of dyspepsia in low resource setting. In our study most of the patients with cancer of the stomach were above 45 years and all had alarm features.

We recommend the use of the HPSAT in the non-invasive management of dyspepsia in low resource settings only for young people less than 45 years old without alarm signs and symptoms. However, because of its low validity in predicting H.pylori associated disease, it is important to follow up patients so that if symptoms persist or recur endoscopy is performed.

Abbreviations

HPSAT, Helicobacter pylori stool antigen test; H.pylori, Helicobacter Pylori; PPI, Proton pump inhibitor; CLO test, Campylobacter-like organism test

Competing Interests

The authors declare that they have no competing interest

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