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Original Article

Diagnostic Accuracy of Rapid 13c Urea Breath Test Compared To HpSA Test to Manage *Helicobacter Pylori* Induced Peptic Ulcer

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ABSTRACT

Background. A definitive diagnosis of H pylori infection will ensure better treatment outcomes in today's world. In this regard, breath tests and stool tests are extensively used. Hardly few studies have been done to establish their better diagnostic accuracy. **Objectives.** Hence, this study was undertaken to compare urea breath and stool antigen tests for their accuracy in identifying H pylori infection. M**ethods.** One hundred thirty-nine abdominal pain patients who were diagnosed with rapid urease test underwent stool antigen testing and urea breath test. **Results.** Based on the rapid urease test, for Urea Breath Test Sensitivity, specificity, positive predictive values, negative predictive values, and Accuracy were76% 34%, 60%, 52%, and 58%, and by the HpSA Test Sensitivity, specificity, positive predictive values, negative predictive values and Accuracy were75%, 33%, 60%, 49%, and 57%. There were no significant differences in the performance of these tests. **Conclusions.** Urea Breath and HpSA Tests have the same diagnostic accuracy in H. Pylori Infection.

KEYWORDS: ***Helicobacter Pylori, Urea Beath test, Stool Antigen Test.***

INTRODUCTION

The spectrum of gastroduodenal diseases is vast, ranging from inflammatory lesions such as gastritis and peptic ulcer disease to frankly malignant ones such as gastric carcinoma and lymphoma. Chronic gastritis, if left untreated, may progress to carcinoma (1). A significant cause of gastric ulcers is the gram-negative bacterium *H. pylori*, which colonizes the gastric mucus and releases cytotoxins that damage the gastric mucosa. *H. pylori* contains **urease,** which converts urea to NH3, thus alkalinizing the local environment and permitting *H. pylori* to survive in the otherwise acidic gastric lumen. *H. pylori* is also a significant cause of duodenal ulcers. *H. pylori* inhibits somatostatin secretion and inhibits intestinal bicarbonate secretion. (4) H. Pylori causes gastritis initially but later causes peptic ulcer (2). If Helicobacter Pylori is present, it can be eradicated with antibiotics (3). Stool antigens with specificity and sensitivity >90 are inexpensive, convenient, and not established for eradication but are promising (5). Although serologic tests are easily obtained and widely available, most clinical guidelines no longer endorse their use for testing for helicobacter pylori infection because they are less accurate than other noninvasive tests that measure active infections (2). Although serologic tests are inexpensive, performance characteristics are poor in low-prevalence populations (6). Dependable noninvasive procedures for finding *H. pylori* infection are needed to examine *H. Pylori* Statistics. Determining H pylori antigen in stool is an alternative non-investigation method. Hence, this comparative study compared the accuracy of

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managing helicobacter pylori-induced peptic ulcers using a urea breath test and an HpSA test.

MATERIALS AND METHODS

Design. A Cross-sectional prospective study was conducted in the physiology and pathology departments of Vydehi Medical College.

Participants/Patients. 139 patients who underwent gastric biopsy were included in our study at our hospital. Informed consent was obtained from each patient.

Test procedures and protocol for Urea Breath Test. The diagnostic test approved our study for *H. pylori*, which involved drinking a solution of 13C-urea, which is converted to 13CO2 by urease and measured in the expired air. Breath samples were obtained from 139 patients reported to the Medical Gastroenterology Department, Vydehi Hospital, by asking the patients to blow before and after receiving 75 mg ^{13}C-labeled Urea mixed with lime juice. All subjects enrolled will be nil per oral one hour before the breath tests are conducted. All breath samples will be transported and processed at CDL, Vydehi Hospital, using Helifan plus analyzer l. The 13C breath test device Helifan plus analyzer l. is a compact 13C infrared analyzer with easy-to-operate software with which we could manage our urea breath samples by connecting it to automatic sample feeder FANas.

Test procedures and protocol for stool sample examination. Stool samples will be collected from each patient. The samples will be stored at -20^{0}c till tested. A one-step *H. pylori* antigen rapicard instates a sandwich immunochromatographic assay and will determine the presence of *H. pylori* in stool samples. An aliquot of diluted stool sample is added to the sample well of the test cassette to perform the test. The sample flowed through a label pad containing H pylori antibody coupled to red-colored colloidal gold particles to form antigen-antibody gold complexes. These complexes moved on the nitrocellulose membrane by capillary action toward the test line region on which *H. pylori*-specific antibodies were immobilized; as the complexes reached the test line, they bound to the antibody in the form of a line.

Statistical Analysis. Using the patients' data, Bland-Altman Plot (BAP)analysis was applied to the agreement between the two tests since it displays the relationship between the urea breath test and stool antigen test in determining the diagnostic accuracy of Helicobacter Pylori Infection. Also, the patients' data was subjected to linear regression analysis as it is helpful as a supplement to BAP in assessing whether the bias between the urea breath test and stool antigen test is constant across the range of measurements.

Ethical Considerations. Informed consent was obtained from each participant included in the study. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in the college's ethics committee VIEC/2022/APP/003.

RESULTS

The mean age of those who volunteered for our study was 34 years. The majority were males. Number of all patients who visited gastroenterology department with abdominal pain is shown in Table 1.

Table 1. Patinents' demographic charachtristic.

Variables	Overall	***Age***			***Gender***	
Level	*All*	*18-35 Years*	*36-54 Years*	*>55 Years*	*Male*	*Female*
N	139	69	40	30	80	59

Of the 80 patients diagnosed positive by the rapid urease test, 60 patients were also positive by the Urea breath test; of the 59 patients diagnosed negative by the rapid urease test, 40 patients were diagnosed as negative by the Urea Breath Test (Table 2). Sensitivity, specificity, positive predictive values, negative predictive values, and Accuracy were 76%,34%,60%,52% and 58%.

H Pylori status by rapid urease test and Urea Breath test. Of the 80 patients diagnosed positive by the rapid urease test, 60 patients were also positive by the HpSA test; of the 59 patients diagnosed negative by the rapid urease test, 40 patients were diagnosed as negative by the HpSA Test. Sensitivity, specificity, positive predictive values, negative predictive values, and accuracy were 75%,33%,60%,49% and 57%, respectively.

H Pylori status by rapid urease test and HpSA test. The outcome of the stool antigen test and urea breath test showed no consistent bias as the points on the Bland Altman Plot (BAP) are scattered above and below the line, as shown in Figure 1. We have done regression analysis to see the linear trend as unstandardized beta is 0.044 and less than 0.05. The model is a good fit as a linear trend and accuracy are good, as shown in BAP (Graph 1).

As the Points in Bland Altman Plot (BAP) are scattered above and below the line, there is no consistent bias of one approach.

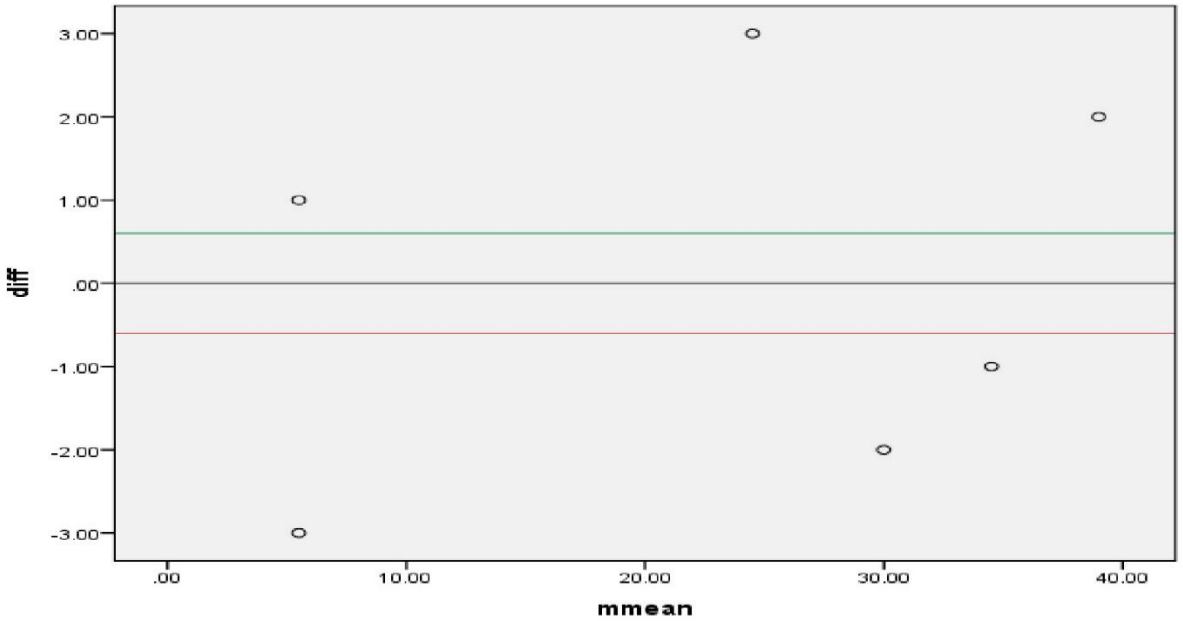
BAP analysis was applied to the agreement between the two tests (Table 4). We have done regression analysis to see the linear trend as unstandardized beta is 0.044 and less than 0.05. The model is a good fit as the linear trend and accuracy are good, as shown in BAP.

Table 2. Urea Breath Test

	Rapid Urease Test		
Urea breath test	*Positive*	*Negative*	*Total*
Positive	60	19	79
Negative	20	40	60
Total	80	59	139

Table 3. H Pylori status by rapid urease test and Urea Breath test

	Rapid Urease Test		
HpSA test	Positive	Negative	Total
Positive	60	40	100
Negative	20	19	39
Total	80	59	139



Graph 1. A scatter diagram of the differences plotted against the averages of the two measurements. Horizontal lines are drawn at the mean difference and the limits of measurement.

Table 4. Regression Analysis Coefficients.

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
(Constant)	-1.013	2.097		-.483	.654
mmean	.044	.079	.268	.556	.02

DISCUSSION

Our study showed that urea breath and stool antigen tests are suitable for diagnosing *H. Pylori* infection. The findings of our study showed lower values when compared with a similar study in which only accuracy was low (6). In a study involving Japanese children (7), the diagnostic accuracy was 96.2% for the urea breath test and 100% with the HpSA test, whereas in our study, the accuracy was 57% and 58%, respectively. In our study, we went ahead with Bland Altman plot analysis to rule out incorrect and debatable results, which showed no consistent bias. Also, since the accuracy is good, urea breath tests can diagnose H. pylori infections in adults. Stool antigen tests can be reserved for patients with facial congenital disabilities. One of the Ethiopian studies (8) in children concluded that machine learning approaches predicted infection with 75% accuracy compared to logistic regression, unlike our study, where accuracy was 57%. Similar to our study, a North Korean study (9) showed that the sweeping method had high diagnostic accuracy and sensitivity compared to the conventional biopsy sample.

CONCLUSION

Urea Breath and HpSA Tests have the same diagnostic accuracy in *H. Pylori* Infection.

Since the Urea Breath test is practically more reliable and economically cheaper, we suggest a 13C urea breath test for diagnosing *H. Pylori* infection, and we can reserve a stool antigen test if the subject has any facial congenital disabilities.

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FINANCIAL DISCLOSURE

I have no financial interests related to this research, affiliations, or conflicts of interest.

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ROLE OF THE SPONSOR

We conducted this study independently and received no financial support or sponsorship from commercial entities or external organizations.

AUTHORS' CONTRIBUTION

the author was involved in the study's conception and design, data collection, analysis, and interpretation. I also participated in drafting and revising the manuscript. Furthermore, I revised and approved the final version of the manuscript.

ARTIFICIAL INTELLIGENCE (AI) USE

AI-assisted in interpreting results from urea breath tests and stool antigen tests; by processing large datasets, AI helped distinguish between positive and negative results more accurately.

CONFLICT OF INTEREST

The author declares no conflict of interest concerning this article's publication.

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