Comparison of Stool Antigen Test with Histopathology of Endoscopic Gastric Biopsies for Detection for Helicobacter Pylori; A Hospital-Based Study

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ABSTRACT

Objective: To evaluate the diagnostic accuracy of the H. pylori Stool Antigen (HPSA) test keeping histopathology as the gold standard.

Study Design: Retrospective longitudinal study.

Place and Duration of Study: Najran Armed Forces Hospital, Kingdom of Saudi Arabia, from Jan 2015 to Mar 2020.

Methodology: A Total of 151 patients in whom *H. pylori* Stool Antigen test was done were included in the study. They were followed for their results of histopathology on gastric biopsies.

Results: Among 151 patients 85 (56.3%) were females and 66 (43.7%) were males. The mean age was 40 ± 13.7 years. Forty-three (28.5%) patients were positive for both *H. pylori* Stool Antigen test and histology; fifteen (9.9%) patients were positive on the H. pylori Stool Antigen test but negative on histology. Twenty-two (14.6%) patients were negative on *H. pylori* Stool Antigen test but they were positive on histology. Seventy-one (47%) patients were negative for both *H. pylori* Stool Antigen test and histology. The sensitivity and specificity were 66.1% and 82.5%, respectively. Positive predictive value (PPV) was 74.1% and negative predictive value (NPV) was 76.3% for *H. pylori* Stool Antigen test. The diagnostic accuracy for this test was 75.5%.

Conclusion: Keeping in view the low sensitivity and diagnostic accuracy *H. pylori* Stool Antigen test cannot be used as a screening tool in all patients; however it can be used for clinical correlation in setups where other diagnostic tests are not available due to the simplicity of its use, low cost and easy repeatability.

Keywords: Histopathology, Helicobacter pylori, Stool antigen test.

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INTRODUCTION

Helicobacter Pylori is a Gram-negative bacterium, responsible for inflammation in the stomach. It is more prevalent in developing countries with poor socioe-conomic conditions. Approximately 50% of the population worldwide is infected with this bacteria.[1] It is responsible for most of the upper gastrointestinal diseases like chronic gastritis, peptic ulcer disease, gastric adenocarcinoma and gastric mucosa-associated lymphoid tissue (MALT) Lymphoma.[2]

Epidemiological studies show a higher prevalence of *H. pylori* in developing countries as compared to developed countries.[3] Its prevalence was also found to be high in immigrants of developing countries than the local population in developed countries.[4] In a study done at Saudi Arabia, showed an overall prevalence of 28.3%,[5] with increasing trend in older patients. In another study done at three different regions of Saudi Arabia on young students aged 16-18 years the overall prevalence of H. pylori was 47%.[6]

There are various invasive and non-invasive diagnostic methods for the detection of *H. pylori* infection but the method with both high sensitivity and specificity is recommended. Non Invasive tests include detection of *H. Pylori* antigen in stool specimen (HPSA), Urea Breath test (UBT), and Serology, while invasive tests like Polymerase chain reaction (PCR), culture and histological examination are done on bio-psy samples taken via Oesophago-gastroduodenoscopy (OGD).[7] Both invasive and non-invasive methods have their advantages and disadvantages. Choice of diagnostic method largely depends on the age of the patients, signs and symptoms, physical examination, previous history of endoscopic examina-tion, family history of gastric cancer, history of treat-ment for *H. pylori*, the prevalence of *H. pylori* in concerned population, and preference of clinician and patient.[8]

Among these tests histopathological examination has the highest sensitivity and specificity and is considered gold standard for its diagnosis.[9] However, due to the high cost of endoscopy, non-availability of this

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diagnostic facility and poor patient compliance for the procedure, it is not done routinely for detection of *H. Pylori*. Therefore, clinicians prefer an easy to perform, non-invasive test, which is also rapid, cost-effective, and can be easily repeated with no requirement of special expertise. Aforementioned, detection of antigen for *H. pylori* in stool specimens is a very easy yet effective method for detection of the infection. There are some studies which show comparable results of HPSA with histological diagnosis, but no such studies are available in this area. Therefore, we performed this study to correlate the results of HPSA with histopathology in our local population which will be helpful for the patients, clinicians and for making local guidelines.

METHODOLOGY

This study was performed at Najran Armed forces Hospital from January 2015 to March 2020.

Inclusion Criteria: Patients of both genders with age ranged from 16-72 years and presen-ting symptoms of dyspepsia, epigastric pain, weight loss, hematemesis, and melena were inlcuded in the study.

Exclusion Criteria: Patients who already received treatment for *H. pylori* were excluded from the study.

The patients in whom HPSA followed by endoscopic gastric biopsies with results of histology by histopa-thologist were retrieved and included in the study and their results were correlated. The study has been approved by the research and ethics committee of Najran Armed Forces Hospital (Reference number REC-001-2020 dated 14th Mar 2020).

HpSA was tested using the rapid test (SD BioLine *H.pylori* Ag) using Immunochromatographic techique for the qualitative detection of Helicobacter pylori antigen in human fecal specimen. Results of biopsies were interpreted by histopathologist (Figure-1).

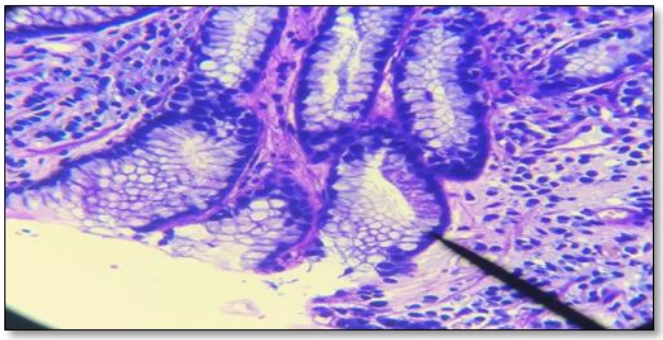

Figure-1: Showing gastric antral biopsy with h.pylori infection on giemsa stain.

Frequency and percentages were calculated for qualitative variables like gender, HpSA and histopathology. A 2x2 table was used to calculate sensitivity and specificity, positive and negative predictive values.

RESULTS

The study comprised a total of 151 patients; among these, 85(56.3%) were females, and 66 (43.7%) were males. Most of the patients were in their fourth and fifth decades, as shown in the Figure-2. The mean age was 40 ± 13.7 years.

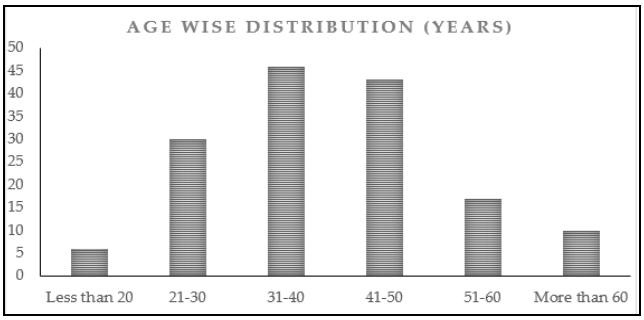

Figure-2: Age wise distribution of patients (n=151).

A total of 43 (28.5%) patients were positive for both HpSA and histology. Fifteen (9.9%) patients were positive on the HPSA test but negative on histology. Twenty-two (14.6%) patients were negative on HPSA, but they were positive on histology. Seventy-one (47%) patients were negative both on HpSA and histology as shown in Table. The sensitivity and specificity were 66.1% and 82.5%, respectively.

Table: Diagnostic accuracy table

	Histology for H. Pylori (n=151)	
	Positive	**Negative**
HpSA Positive	43 (a)	15 (b)
HpSA Negative	22 (c)	71 (d)

Positive predictive value (PPV) was 74.1% and negative predictive value (NPV) was 76.3% for HpSA. Overall diagnostic accuracy for this test was 75.5% for the diagnosis of the infection.

DISCUSSION

Since the detection of *H. pylori* and its association with gastric pathologies, a lot of research has been done to establish its role in gastric cancer.[10] Nobel Prize was awarded to the researchers in 2005 who isolated this bacterium and confirmed its association with gastric disorders.[11] This infection usually occurs in childhood and the risk of complications increase with the duration of infection.[12]

A timely and accurate diagnosis can significantly reduce the morbidity and mortality associated with

this infection and improves the quality of life of the people. Several diagnostic methods are in practice for its detection depending on the symptoms of patients, side effects, cost, test duration, the requirement of special equipment and work force.

Although the gold standard test for diagnosis of *H. pylori* infection is the histopathological examination of gastric biopsy, yet it is performed in special situations like severe vomiting, epigastric pain, unexplained weight loss and anemia, inability to eradicate *H.pylori* infection despite treatment, patients above 45 years and in patients with a family history of gastric cancer.[11] Non-invasive tests like HPSA test and Urea breath test (UBT) are commonly used for detection and treatment purposes, patients with mild dyspeptic symptoms or any risk factors and patients with age less than 45 years. Several studies have been performed previously correlating results of HPSA with histological diagnosis which showed comparable results.[13-16]

In our study, the HPSA was compared with the histological diagnosis keeping the histopathology as the gold standard. The results showed that the sensitivity (66.1%) was low while specificity (82.5%) was good for HPSA test when compared to histopathology. Overall diagnostic accuracy for this test was 75.5% for diagnosis of the infection. Similar findings were noted in studies done by Baqai *et al,*[17] with sensitivity and specificity of 65% and 76% respectively. Sensitivity and specificity were low in a study done by Siddiqui *et al,* 2010,[18] as well. However other studies showed quite high sensitivity and specificity, 87.8% and 75% by Pourakbari *et al,* 2013,[19] 96% and 91% by Qadir *et al*, 2016,[20] respectively, and they suggested it to be the best non-invasive test for *H.pylori* detection.

The accuracy of the HPSA test is affected by many factors like prior treatment with antibiotics, bowel movements, gastroin testinal bleeding, proton pump inhibitors intake,[21] and inappropriate storage of stool sample, etc. Despite the possible limitations, the simplicity of the test and other advantages of the HPSA test recommend its use for diagnosis in patients with mild gastric symptoms, in children, in patients unwilling for the invasive procedure, and monitoring of eradication treatment. It can also be used in any small setup without any need for sophisticated equipment and trained personnel. Its results can be confirmed, whenever indicated, with gastric endoscopic biopsies followed by histopathological or culture examination.

CONCLUSION

We need more non-invasive, cost-effective, and easy methods for the initial diagnosis and confirmation of post-treatment eradication of *H. pylori*. Keeping in view the low sensitivity HPSA test cannot be used as a screening tool in all patients. However due to the simplicity, low cost, and easy repeatability of this test, it can be used with clinical correlation in setups where other diagnostic tests are not available.

Conflict of Interest: None.

Authors' Contribution

MZ: Conceived idea, data collection, designed research methadology, MAN:, NKA: Data collection, literature review, BB: Literature review, data interpretation, MH: Data analysis, critical review, TMM: Critical review, HSG: Data collection and analysis.

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