Comparative Study Between Urea Breath Test and Immunochromat Ographic Antigen Test in Stool for the Diagnosis of *H. pylori* infection in Shendi Locality

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ABSTRACT

Background: *H. pylori* is now accepted to be the infective pathogen that causes most gastric and duodenal ulcers. *H. pylori* infection causes chronic atrophic gastritis during the later stage of the illness. ***Objectives:*** This study aimed to evaluate the efficiency of (*H. pylori*) antigen in stool used in the detection of *H. pylori* infection compared with a urea breath test. ***Methods***: 65 patients undergoing a routine health check-up were prospectively enrolled. A (13) C-urea breath test, and a stool antigen test were performed for the detection of *H. pylori*. ***Results***: Sensitivity, specificity, positive and negative predictive values, and accuracy of the stool antigen test was 96.9%, 50.0%, 82.3%, 76.9%, and 95.6%, respectively. The sensitivity of the (13) C-urea breath test was100%, and their specificity was 100%, found that H. pylori are lower in males than females. ***Conclusions***: stool antigen test was highly sensitive and low specific when compared with the urea breath test in the diagnosis of *H. pylori* infection. In this study, age is one risk factor age group (21– 40) is more affected than another age group.

Keywords: Helicobacter pylori, Immunochromatographic, Shendi, Urea Breath Test, Stool Antigen Test

INTRODUCTION

Helicobacter pylori (*H. pylori*) is a curved rod or spiral-shaped, multi-flagellate gram-negative bacterium measuring 2 to 4 µm in length and 0.5 to 1 µm in width. *H. pylori* is found in the gastric mucous layer or adherent to the epithelial lining of the stomach **[1].**

It has been 3 decades since *H. pylori* were first identified. Barry Marshall and Robin Warren described the successful isolation and culture of a spiral bacterial species. The genus *Helicobacter* belongs to the subdivision of the proteobacteria, order *campylobacterrales* family *Helicobacteraceae* to date the genes helicobacter consist of over 20 recognized species. Gastric *Helicobacter* species are found at the gastric mucosal surface, it is highly motile through flagella, and urease positive allows it to survive for a short term in the highly acidic gastric lumen, whereas motility is thought to allow rapid movement toward the neutral pH of the gastric mucosa. The spiral morphology and flagella motility help in penetration into the viscous mucus layer, where the more pH-neutral condition allows the growth of the gastric Helicobacter species **[2].** Most persons who are infected by *H. pylori* never suffer any manifestations related to the infection. However, *H. pylori* cause chronic gastritis (95%), gastroduodenal ulcers (70-80%), and duodenal structural and functional abnormalities. Infected persons have a 2- to 6-fold increased risk of developing gastric cancer and mucosal-associated- lymphoid-type (MALT) lymphoma **[1].** Gastric MALT lymphomas are a rare type of non-Hodgkin lymphoma that is characterized by the slow multiplication of B lymphocytes, a type of immune cell, in the stomach lining. This cancer represents approximately 12 percent of the extranodal (outside of lymph nodes) non-Hodgkin lymphoma that happens among males and approximately 18 percent of extranodal non-Hodgkin lymphoma among females During the period 1999–to 2003, the annual incidence of gastric MALT lymphoma in the United States was about one case for every 100,000 persons in the population. Normally, the lining of the stomach lacks lymphoid (immune system) tissue, but the development of this tissue is often stimulated in response to colonization of the lining by *H. pylori* exclusively in rare cases, this tissue gives rise to MALT lymphoma. However, almost all patients with gastric MALT lymphoma show symptoms of *H. pylori* infection, and the risk of developing this tumor is more than six times higher in infected people than in uninfected people .*H. pylori* is now accepted to be the infective pathogen that causes most

gastric and duodenal ulcers. Treatment of *H. pylori* infection by specific antibiotics, and thereby the elimination of organisms from the stomach, results in the healing of these ulcers and a marked reduction in the recurrence of ulcers **[3].** *H. pylori* infection causes chronic atrophic gastritis during the later stage of the illness **[3].** The diagnosis of *H. pylori* infection can be made using a variety of invasive and non-invasive techniques, such as endoscopy with biopsy, immunoglobulin titers through serology, stool antigen analysis, and the urea breath test (UBT). Stool antigen tests (SATs) were developed after the urea breath test and are noninvasive diagnostic tools for *H. pylori* infection (UBT). There are two different SATs available for the diagnosis of *H. pylori* infection, one based on immunochromatography and the other on EIA (ICA). Although both types of tests have high sensitivity and specificity, a recent study found that EIA-based tests are more reliable than the ICA-based tests that are currently available **[3].** The non-invasive, user-friendly characteristics of UBT make it possible that this detection method will be preferred in many clinical settings. However, the performance characteristics of UBT have only been partially defined and have received inconsistent descriptions to date **[1,3].** In the diagnostic assessment of dyspeptic patients with comorbidities that increase their risk of upper endoscopy, who are unable to undergo upper endoscopy, or who have known or suspected gastric atrophy, UBT can be helpful. The clinical usefulness of serum antibody tests for determining the presence or absence of current infection is limited because they can vary regionally and may remain positive for a long time after *H. pylori* eradication **[1,3].**

MATERIALS AND METHODS

An analytic cross-sectional laboratory base study was done in, the Shendi locality. Patients were suspected to have peptic ulcers or had signs and symptoms of *H. pylori* infection. Data were collected from November 2019 to February 2020. Two types of specimens were collected; 65 stool specimens and 65 urea breath bags.

Sample collection

In this study two types of specimens were collected: Faces specimens (about 1-2 ml or 1-2 g) were collected in clean dry waterproof containers with screw-cap lids before endoscopy. Urea breath test bags. The whole cap of the

specimen collection tube was unscrewed then randomly the specimen collection applicator was stabbed into the fecal specimen at least 3 different sites to collect approximately 50 mg of feces. The specimen was shaken and left for 2 minutes. Then the specimen collection tube was held upright. 2full drops of the extracted specimen were transferred to the specimen well (S) of the device. Results were read within 10 min. The subjects should fast for at least 2 hours before the examination, Fill out the required information on the two sample bags with labeled paper, slowly exhale into the first airbag and make it full of gas as much as possible. Immediately fasten the lid of the airbag tightly. This one is the baseline bag (t=0). Dissolve the urea{C13}granules in 80-100 ml cold water, drink it up and sit still for 30 minutes, When time is up, collect the second breath sample(t=30) and slowly exhale into the second airbag and make it full of gas as much as possible. Test the two sample bags with the IR-Force infrared spectrometer.

Data analysis

Data will be analyzed Data collected in this study will be analyzed using SPSS (version 21).

Scientific & Ethical considerations

Ethical approval for this study was obtained from the ministry of health, River Nil state, Sudan. Written consent was obtained from participants before the collection of samples. The specimens and information were collected from participants under privacy and confidentiality and were not used for any purposes rather than this study.

RESULTS

Table-1: Distribution of patients according to gender.

Sex	*Distribution*	*Percent %*
Male	33	49.2
Female	32	50.8
Total	**65**	**100.0**

Table-2: Distribution of patients according to age groups.

Age	*Distribution*	*Percent %*
1-20	9	13.8
21-40	39	60.0
41-60	15	23.1
61-80	2	3.1
Total	**65**	**100.0**

Table-3: Distribution of samples based on the results of UBT and Stool antigen detection test

Type of sample	*Result*	*Frequency*	*Percent %*

Stool sample	***Positive***	65	100.0
	Negative	0	0.0
	Total	**65**	**100.0**
UBT	***Positive***	63	96.9
	Negative	2	3.1
	Total	**65**	**100**

Table-4: The sensitivity, specificity, and accuracy of the urea breath test and stool Ag ICT.

Variables	*Stool Ag ICT*	*UBT*
Sensitivity *(%)*	96.9	100
Specificity *(%)*	50.0	100
Accuracy	95.6	100
P. value	0.000	

DISCUSSION

The prevalence of *H. pylori* infection shows a large geographical distribution, especially in developing countries. This study investigated urea breath test, stool Ag, and risk factors associated with *H. pylori* among people in the Shendi locality. This study was done in, the Shendi locality. Data were collected from November 2019 to February 2020. A total of 65 specimens were collected from a suspected patient with *H. Pylori* infection, and by using stool antigen detection (ICT) and breathing bags for urea breathing tests for detection of *H. pylori.* Findings revealed that *H. pylori* antigen was detected in 65 (100%). Of 65 Urea breathing bags findings revealed the *H Pylori* urea breath test positive in 63 patients (96.6%) and negative in 2 patients (3.4%) Sensitivity, specificity, positive and negative predictive values, and accuracy of the stool antigen test was 96.5%, 50 %, 82.3%, 76.9%, and 80%, respectively. The sensitivity of the 13C-urea breath test is (100%), and their specificity was 100%, the accuracy of the stool antigen test was comparable to that of the urea breath test. In this study, age is one risk factor age group (21– 40) is more affected than another age group. This agrees with (Mohammed Ahmed Ibrahim Ahmed 2020) found that H. *pylori* are lower in male than female. This agrees with Khan and his colleagues, and Jafar and his colleagues **[4,5].** And disagree with the study in Egypt by Manal *et al.,* in 2007 and another study by Huang and his colleagues in Malaysia, kikuchia and Dore in Iran, and Mukherjee in Neither Land **[6].** *H. pylori* stool antigen test reported in the current study had high sensitivity (96.5%) but low specificity (58.5%). This agrees with Yosria Mohammed and his colleagues, Sensitivity, specificity, positive and negative predictive values, and accuracy of the

stool antigen test was 93.1%, 94.6%, 95.1%, 92.3%, and 93.8%, respectively **[7].** The sensitivity of histology, rapid urease test, and the (13) C-urea breath test ranged from 89.1% to 97.6%, and their specificity was > 98%, while serology had high sensitivity, but low specificity. The accuracy of the stool antigen test was comparable to that of other methods (93.6-95.9%), whereas it was higher than that of serology **[8].** *H. pylori* stool antigen test is less expensive than the urea breath test and readily accepted by patients but its diagnostic performance does not recommend its use in the primary diagnosis, when the patient may have an active infection. *H. pylori* in stool has a certain disadvantage: antigen excretion may vary over the period and antigen may degrade while passing through the intestine.

Conclusion

The stool antigen test was highly sensitive and low specific when compared with the urea breath test in the diagnosis of *H. pylori* infection. Found that *H. pylori* are lower in males than females. Age is one risk factor age group (21– 40) is more affected than other age groups.

Acknowledgments:

The authors are thankful to the Department of Microbiology, Faculty of Medical Laboratory Sciences, Shendi University, Shendi, Sudan, for their support during the study period.

Sources of Funding:

There was no specific grant for this research from any funding organization in the public, private, or nonprofit sectors.

Conflict of Interest

The author has affirmed that there are no conflicting interests.

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