



**A COMPARATIVE STUDY OF ICT STOOL ANTIGEN, SERUM AND ELISA TECHNIQUES IN DETECTION OF *HELICOBACTER PYLORI* AMONG SUDANESE FOOD HANDLER**

**<sup>1</sup>Mohammed Shams Alfalah, <sup>1</sup>Abdelhafez Awad Elkarim Ahmed,, <sup>2</sup> Yousif Abdelhameed Mohammed, <sup>3</sup>Albadawi Abdelbagi Talha**

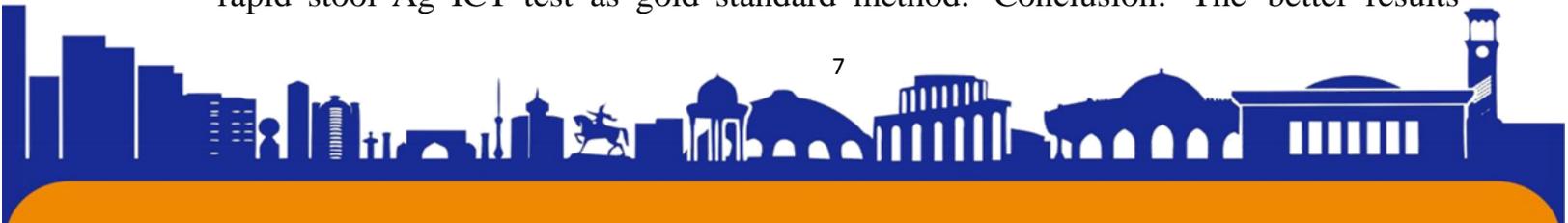
<sup>1</sup>Gezira Fertility Center, Ministry of Health Gezira State, Sudan

<sup>2</sup> Department of Clinical Chemistry, National Cancer Institute, , University of Gezira, Sudan.

<sup>3</sup>Department of Medical Parasitology, Faculty of Medical Laboratory Sciences, University of Gezira, Sudan

Email: [3badawiat@gmail.com](mailto:3badawiat@gmail.com)

**Abstract:** Background: *Helicobacter pylori* (*H. pylori*) remains one of the most common human infections in Sudan recently and is associated with a number of important chronic gastritis, peptic ulcer disease and gastric malignancy. Objectives: The aim of this study was to compare the detection of *H. pylori* IgG in serum using ELISA techniques compared to ICT blood test and stool antigen. Materials and Methods: Stool and blood specimens were collected from 100 patients (mean age  $31.2 \pm 11.7$  years, 56% males). Stool samples were analyzed using rapid stool antigen test for *H. pylori* and Serum samples were analyzed for *H. pylori* IgG by Accurate© (USA) ELISA and ICT blood test. Data analysis was made by the software of the Statistical Package for Social Sciences (SPSS) program (version 22). Results: The incidence of *H. pylori* among male was 12/17 (71%) compare to 5/17 (29%) females. 17 (17%) patients have positive with rapidstoolAg ICT test compare to 20 (20%) patients have positive by *H. pylori* IgG ELISA [the Accurate© (USA)]. The sensitivity, specificity, positive predictive value and negative predictive value for *H. pylori* IgG ELISA were (100%, 96.1%, 93.3% and 100% respectively) compared to ICT. *H. pylori* IgG for blood (41.18%, 71.08%, 43.4% and 69.2% respectively) using rapid stool Ag ICT test as gold standard method. Conclusion: The better results





ISSN (E): 2181-4570 ResearchBib Impact Factor: 6,4 / 2023 SJIF 2024 = 5.073/Volume-2, Issue-5

Sensitivity and Specificity obtained for *H. Pylori* diagnosis was *H. pylori* IgG using ELISA techniques compared to ICT blood test.

**Keywords:** *H. pylori*, Stool antigen test, ELISA, ICT blood test

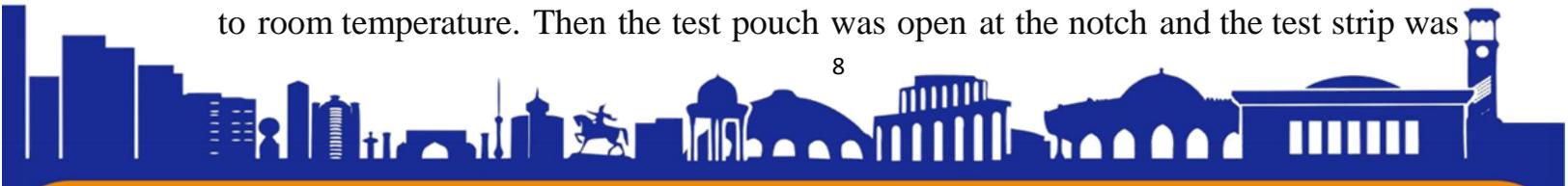
## INTRODUCTION

*Helicobacter pylori* (*H. pylori*) is a spiral shaped Gram- negative microaerophilic bacterium that grows in human gastric epithelial tissues and mucus of the stomach (1,2). *H. pylori* remains one of the most common worldwide human infections and is associated with a number of important chronic gastritis, peptic ulcer disease, and gastric malignancy (3). The prevalence of *H. pylori* is closely associated with socioeconomic conditions and accordingly, this infection is more common in developing countries than in developed countries (4). The prevalence of *H. pylori* infection is 25 - 50% in developed countries and 70 - 90% in developing countries (5,6). Invasive and non-invasive techniques are used to diagnose *H. pylori* infection. Some factors influence the choice of a diagnostic test, such as the sensitivity and specificity of the tests, the clinical circumstances and the cost-effectiveness of the testing strategy (7).

## Materials and Methods:

Totally, 100 food handlers were willing to cooperate in this study were included. A direct interviewing structural questionnaire was designed to collect and maintain all information of patients under the study. Demographical data (name, gender and age) were collected from all subjects investigated. Each subject was questioned about major symptoms suggesting peptic ulcer. Data analysis was made by the software of the Statistical Package for Social Sciences (SPSS) program (version 22). The participants included 56 males and 44 females with a mean age of  $31.2 \pm 11.7$  years (range 14 - 60 years). Subjects who had received antimicrobial therapy were excluded from the study. The ethics committee of the University of Gezira granted approval for the study and all the participants gave their consent to participate. Stool and blood specimens were collected from each subjects, serum was obtained and kept on  $-20^{\circ}\text{C}$  until used.

*H. pylori* fecal antigen rapid ICT was used to detect monoclonal antibodies in all stool samples collected. The fecal specimen and test components were brought to room temperature. Then the test pouch was open at the notch and the test strip was



removed and placed on a clean, flat surface. The sample collection tube was vigorously shaken to ensure an effective liquid suspension. Then the tube was held upright, the tip was twisted off, and two drops were dispensed of the solution into the sample pad (s) of the strip. The timer was setup. Results can be read in 15 minutes after adding the specimen. Positive results can be visible in as short as one minute. Results were not read after 15 minutes. To avoid confusion, the test device was discarded after interpreting the result.

Immuno-chromatographic test (ICT), using *H. pylori* IgG antibodies, was used to investigate all serum samples collected. First the serum sample and the test device were allowed to equilibrate to room temperature for 15 – 30 minutes. Later, the test device was removed from its foil pouch, placed on a clean, leveled surface, and 10 µl serum was transferred to the wells of the test device. Then 75 µl of test running buffer were added in to the sample pad. Positive result was indicated by two red lines after 10 minute reaction.

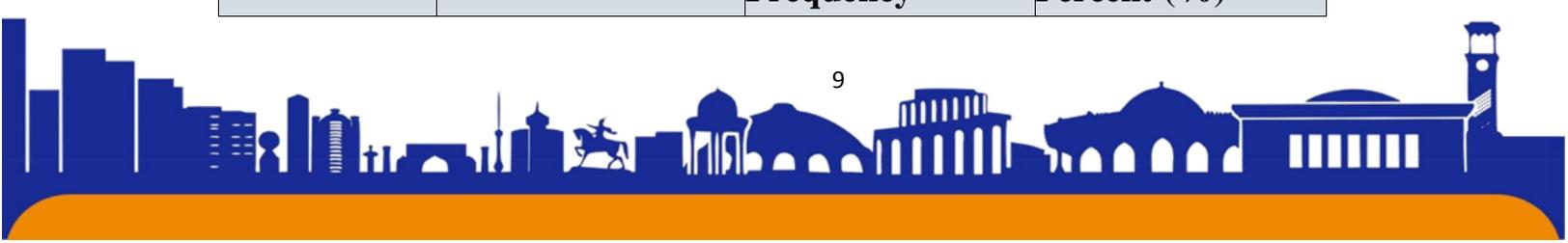
A serological assay for IgG antibodies against *H. pylori* was performed by a commercial *Helicobacter pylori* IgG ELISA kit (the Accurate© (USA)) according to the manufacturer’s instructions. The results were classed as positive if anti-*H pylori* immunoglobulin (Ig) G titers were >12U/ml, negative if they were < 8 U/ml, and equivocal if they were between 8 and 12 U/ml.

**Results:**

The Rapid Stool Ag ICT test only 17 (17%) has positive reactivity, the incidence among male was 12/17 (71%) and 5/17 (29%) among females, the positive reactivity was highest was between age range 25-34 years 6/17 (35%). From the 100 serum specimens of food handler, 20 were found infected by *Helicobacter pylori* IgG ELISA. The ICT sensitivity was 100 %, specificity was 96.1 %, positive predictive value was 93.3 %, and negative predictive value was 100 % and 31 were found infected by *ICT H. pylori* IgG by the Accurate© (USA). The ICT sensitivity was 41.18 %, specificity was 71.08 %, positive predictive value was 43.4 %, and negative predictive value was 69.2 %.

**Table (1).** Demographic Data and Symptoms:

	Frequency	Percent (%)
--	-----------	-------------





<b>Sex</b>	<b>Male</b>	56	56
	<b>Female</b>	44	44
	<b>Total</b>	100	100
<b>Age</b>	<b>14 - 24 Years</b>	34	34
	<b>25 - 34 Years</b>	32	32
	<b>35 - 44 Years</b>	19	19
	<b>&gt; 44 Years</b>	15	15
	<b>Total</b>	100	100
<b>Symptoms</b>	<b>No</b>	74	74
	<b>Yes</b>	26	26
	<b>Total</b>	100	100

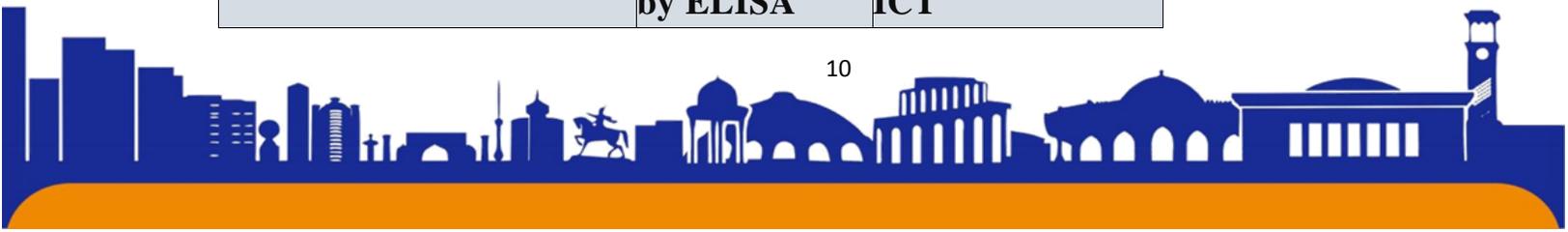
**Table (2).** Distribution of *H. pylori* infection among food handler according to different methods.

<b>Stool</b>	<b><i>Helicobacter pylori</i> IgG ELISA*</b>		<b><i>ICTH. pylori</i> IgG</b>	
	<b>Positive</b>	<b>Negative</b>	<b>Positi ve</b>	<b>Negati ve</b>
<b>Positive N = 17</b>	17	0	7	10
<b>Negative N = 83</b>	3	74	24	59
<b>Total</b>	20	74	31	69

\*Only 94samples were tested using ELISA Techniques

**Table (3).** Comparison of three different methods for diagnosis of *H. pylori* infections standardby stool Ag as gold method.

	<b><i>H. pylori</i> IgG by ELISA</b>	<b><i>H.pylori</i> IgG by ICT</b>
--	--------------------------------------	-----------------------------------



<b>Sensitivity (%)</b>	100	41.18
<b>Specificity (%)</b>	96.10	71.08
<b>Area under the ROC curve (AUC)</b>	0.981	0.561
<b>Positive Predictive value (PPV) (%)</b>	93.3	43.4
<b>Negative Predictive value (NPV) (%)</b>	100	69.2

### DISCUSSION

According to age group, the highest infection rate was between (25 and 44) years old without significant correlation. This result agreed with study done by Hamid and Eldaif (2014) (8) in Sudan which showed high prevalence rate of infection among age group (30-50) years old. In this study showed that prevalence rate of *H. pylori* infection was higher in male (71%) than in female (29%). This result nearly study conducted in Yemen by Bin Mohanna *et al* (2014) (9) who found the prevalence in female was (67%) and in males was (33%). According to residence there were highest infection rate of *H. pylori* among rural area, this result indicated that infection was affected by residence which was reflected in the degree of personal hygiene.

Regarding the serum rapid stool Ag ICT test which used as gold stander method for detecting *Helicobacter pylori*, we compared stool result with other method and we find 20 were found infected by *Helicobacter pylori* IgG ELISA. The ICT sensitivity was 100 %, specificity was 96.1 %, positive predictive value was 93.3 %, and negative predictive value was 100 % and 31 were found infected by *ICTH. pylori* IgG by the Accurate© (USA). The ICT sensitivity was 41.18 %, specificity was 71.08 %, positive predictive value was 43.4 %, and negative predictive value was 69.2 %. The sensitivity finding so, it in agree with study done in Tehran (10) and disagree with the findings of other studies (10,11) whom find the sensitivity 96.7%, 70% and 90.2% respectively. In specificity it was not in agreement with other studies (7,10,11) In the present study, the accuracy of the serum *Helicobacter pylori* IgG ELISA test was compared with the rapid fecal test. The *Helicobacter pylori* IgG ELISA method



ISSN (E): 2181-4570 ResearchBib Impact Factor: 6,4 / 2023 SJIF 2024 = 5.073/Volume-2, Issue-5

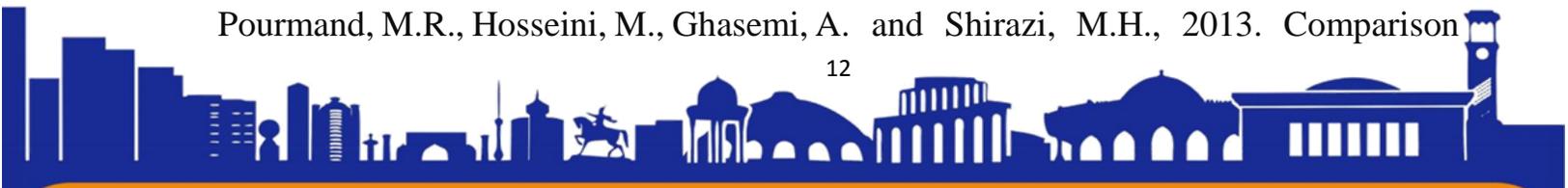
was found to have a sensitivity of 100 % and a specificity of 96,1 %. This finding was similar to that obtained by Kesli, R., *et al* 2010 (13) who reported a sensitivity and specificity of 90% and 80% respectively, however this result was not in agreement with the findings of some workers. Suhaila., *et al* 2010(14)

### CONCLUSION:

Immunochromatography based on the detection of antigen from stool sample is a simple, easy test, with highly sensitivity and specificity, hence the diagnosis of *H. pylori* infection must be based on the detection of *H. pylori* antigen in stool samples.

### REFERENCES

- 1- Chey, W.D. and Wong, B.C., (2007). American College of Gastroenterology guideline on the management of *Helicobacter pylori* infection. *The American journal of gastroenterology*, 102(8), p.1808.
- 2- Brooks, H.J.L., Ahmed, D., McConnell, M.A. and Barbezat, G.O., (2004). Diagnosis of *Helicobacter pylori* infection by polymerase chain reaction: is it worth it?. *Diagnostic microbiology and infectious disease*, 50(1), pp.1-5.
- 3- Shamsuddeen, U., Yusha'u, M. and Adamu, I.A., (2009). *Helicobacter pylori*: the causative agent of peptic ulcer. *Bayero Journal of Pure and Applied Sciences*, 2(2), pp.79-83.
- 4- Everhart, J.E., Kruszon-Moran, D., Perez-Perez, G.I., Tralka, T.S. and McQuillan, G., (2000). Seroprevalence and ethnic differences in *Helicobacter pylori* infection among adults in the United States. *The Journal of infectious diseases*, 181(4), pp.1359- 1363.
- 5- Kabir, S., (2001). Detection of *Helicobacter pylori* in faeces by culture, PCR and enzyme immunoassay. *Journal of medical microbiology*, 50(12), pp.1021- 1029.
- 6- Dunn, B. E., Cohen, H., & Blaser, M. J. (1997). *Helicobacter pylori*. *Clinical microbiology reviews*, 10(4), 720–741.
- 7- Khalifehgholi, M., Shamsipour, F., Ajhdarkosh, H., Daryani, N.E., Pourmand, M.R., Hosseini, M., Ghasemi, A. and Shirazi, M.H., 2013. Comparison





ISSN (E): 2181-4570 ResearchBib Impact Factor: 6,4 / 2023 SJIF 2024 = 5.073/Volume-2, Issue-5

of five diagnostic methods for *Helicobacter pylori*. *Iranian journal of microbiology*, 5(4),p.396.

8- Hamid, O.S. and Eldaif, W.A., (2014). Association of *Helicobacter pylori* infection with life style chronic diseases and body-index. *Journal of Science*, 4(4), pp.255-258.

9- Mohanna, M.A.B., Al-Zubairi, L.M. and Sallam, A.K., (2014). Prevalence of *Helicobacter pylori* and parasites in symptomatic children examined for *Helicobacter pylori* antibodies, antigens, and parasites in Yemen. *Saudi medical journal*, 35(11),p.1408.

10- Stoicov, C., Saffari, R. and Houghton, J., (2009). Green tea inhibits *Helicobacter* growth in vivo and in vitro. *International journal of antimicrobial agents*, 33(5), pp.473-478.

11- Suganuma, M., Yamaguchi, K., Ono, Y., Matsumoto, H., Hayashi, T., Ogawa, T., Imai, K., Kuzuhara, T., Nishizono, A. and Fujiki, H.,( 2008). TNF- $\alpha$ -inducing protein, a carcinogenic factor secreted from *H. pylori*, enters gastric cancer cells. *International journal of cancer*, 123(1),pp.117-122.

12- Mohammed, L.F.,(2016) A comparative Study of ICT and ELISA Techniques in Detection of *Helicobacter pylori* among Sudanese Duodenal Ulcer Patients.

13- Kesli, R., Gokturk, H.S., Erbayrak, M., Karabagli, P. and Terzi, Y., (2010). Comparison of the diagnostic values of the 3 different stool antigen tests for the noninvasive diagnosis of *Helicobacter pylori* infection. *Journal of investigative medicine*, 58(8), pp.982-986.

14- Suhaila, N., Hussin, S. and Rahman, M.M., (2010). Comparative efficacy sensitivity and specificity of the tests used for the Diagnosis of *Helicobacter pylori*. *Pakistan Journal of Biological Sciences*, 13(21), p.1057.

