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A Comparative Study of ICT Stool Antigen, Serum and ELISA Techniques in Detection of *Helicobacter Pylori* among Sudanese Food Handler

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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 ± 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 rapid stool Ag 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 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 ± 11.7 years (range 14 – 60 years). Subjects who had received antimicrobial therapywere 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°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 set up. 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 (%)
Sex	**Male**	56	56
	Female	44	44
	Total	100	100
Age	**14 - 24 Years**	34	34
	25 - 34 Years	32	32
	35 - 44 Years	19	19
	> 44 Years	15	15
	Total	100	100
Symptoms	**No**	74	74
	Yes	26	26
	Total	100	100

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

Stool	***Helicobacter pylori* IgG ELISA***		**ICT*H. pylori* IgG**	
	Positive	**Negative**	**Positive**	**Negative**
Positive N = 17	17	0	7	10
Negative N = 83	3	74	24	59
Total	20	74	31	69

*Only 94samples were tested using ELISA Techniques

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

	***H. pylori* IgG by ELISA**	***H. pylori* IgG by ICT**
Sensitivity (%)	100	41.18
Specificity (%)	96.10	71.08
Area under the ROC curve (AUC)	0.981	0.561
Positive Predictive value (PPV) (%)	93.3	43.4
Negative Predictive value (NPV) (%)	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 *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 %.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

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 8o% 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.

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