



Comparison between Immunochromatographic Test and Enzyme Linked Immunosorbent Assay in Diagnosis of *Helicobacter pylori* Infection among Gastritis Patients in Khartoum State-Sudan

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The gold standard for the diagnosis of *Helicobacter pylori* infection requires an endoscopic biopsy of gastric mucosa for histological examination, urease test and culture; however serological tests are useful as a screening test for *Helicobacter pylori* infection.

Objective: To compare between Immunochromatographic Test and Enzyme Linked

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Immunosorbent Assay techniques in detection of *Helicobacter pylori* immunoglobulin gamma antibodies in serum of patients suffer from gastritis.

Materials and Methods: 245 patients were screened for *Helicobacter pylori* infections by rapid urease test. Sera from these patients were tested for anti- *Helicobacter pylori* immunoglobulin gamma antibodies by Enzyme Linked Immunosorbent Assay and Immunochromatographic Test techniques.

Results: Of 245 patients tested, Immunochromatographic Test positive/negative 114 (46.5%)/131 (53.5%), whereas Enzyme Linked Immunosorbent Assay positive/negative were 124 (50.6%)/121 (49.4%). Sensitivity/ specificity was 67.4%/74.5% and 90.2%/89.3% for Immunochromatographic Test/Enzyme Linked Immunosorbent Assay positive/negative, respectively. The diagnostic accuracy was 71%/89.7% for Immunochromatographic Test/Enzyme Linked Immunosorbent Assay, respectively.

Conclusion: The Enzyme Linked Immunosorbent Assay technique was found to be more sensitive, specific and accurate compared to the Immunochromatographic Test while The Immunochromatographic Test is commercially available, inexpensive and easy to perform compared to the Enzyme Linked Immunosorbent Assay.

Keywords: Immunochromatographic test; enzyme linked immunosorbent assay; helicobacter pylori; gastritis; Sudanese.

1. BACKGROUND

The researchers were studied the prevalence of *H. pylori* in the Sudanese subject with gastroduodenal inflammation. *H. pylori* was found in 80% of patient with gastritis, 56% of patients with duodenal ulcer, 60% of patient with duodenitis and 16% of normal control subjects. It was neither detected in patients with gastric ulcer, nor in patients with oesophagitis. Approximately 2/3 of world population is infected with *H. pylori*. Any age can get infection and women are affected just as often as men. *H. pylori* are more prevalent among the elderly and more frequent in males than females [1].

Epidemiology: At least half the world's populations are infected by the bacterium, making it the most widespread infection in the world [2]. Actual infection rates vary from nation to nation; the Third World has much higher infection rates than the West, where rates are estimated to be around 25%. Infections are usually acquired in early childhood in all countries [2].

Prevention: *H. pylori* is a major cause of diseases of the upper gastrointestinal tract. Eradication of the infection in individuals will improve symptoms including dyspepsia, gastritis and peptic ulcers, and may prevent gastric cancer [3].

In a 2009 study has found that green tea can prevent inflammation if ingested prior to exposure to *Helicobacter* infection [4,5].

2. MATERIALS AND METHODS

Serum sample from 245 patients were screened for *H. pylori* infection by rapid urease test, from those patients 123 were infected by *H. pylori* while 122 were non-infected. Venous blood was collected after obtaining an informed consent from each patient. Sera from these patients were tested for anti-*H. pylori* IgG antibodies by ELISA and ICT techniques.

2.1 Study Design

A descriptive comparative study conducted in the digestive system disease clinic (DDC), Khartoum state. The study was conducted during the period from May to August 2017 and a total of 245 patients were included in this study.

2.2 Study Population

The study population included patients suffer from gastritis that undergoing diagnostic endoscopy.

2.3 Data Collection

Data were obtained using an interviewed-administered questionnaire.

Inclusion criteria: Patients admitted to doctor with abdominal problem and diagnosed with Gastritis.

Exclusion criteria: *H. pylori* positive adult Sudanese individual suffering from disease that may affect the result.

2.4 Statistical Analysis

$$\text{Sensitivity} = \frac{TP \times 100}{(TP+FN)}$$

$$\text{Specificity} = \frac{TN \times 100}{(TN+FP)}$$

TP: Patients with a condition who are correctly classified by a test to have the condition.

FN: Patients with the condition who are classified by the test as not having the condition.

TN: Individual not have a condition who are correctly classified by a test as not having the condition.

FP: Individual not have a condition who are correctly classified by a test to have the condition.

2.5 Method

Serum sample from 245 patients were screened for *H. pylori* infection by rapid urease test, from those patients 123 were infected by *H. pylori* while 122 were non-infected.

2.6 Specimen Collection

About 3 ml venous blood will be collected under aseptic conditions by using sterile disposable syringes and placed in sterile plain containers, stand in room temperature for 30 minutes and centrifuged at 3000 rpm, for 5 minutes.

Storage: The samples were stored as serum in a deep freezer at a temperature of about (-20°C), until it reach the total number of 245 and then they were tested.

Laboratory Testing: All serum samples were tested for *H. pylori* IgG antibodies using both Enzyme-linked immunosorbant assay (ELISA)

and Immunochromatographic test (ICT) for each sample

Enzyme-linked Immune Sorbent Assay (ELISA): (Anti-*Helicobacter pylori* ELISA IgG), EUROIMMUN AG ·23560 Luebeck Germany).

Immunochromatographic Test (ICT): (*H. pylori* Antibody Rapid Test Cassette (Serum/Plasma) Hangzhou biotest Co, Ltd, China).

3. RESULTS

This study compared between the ICT and ELISA techniques in detection of *H. pylori* infection among patients suffer from gastritis. Sera were collected from 245 patents, 123 were infected by *H. pylori* and 122 were not infected. Screening for *H. pylori* infection was done by the rapid urease test (the gold stander test). The same 245 patients were retested for *H. pylori* antibodies by ELISA and ICT techniques.

Sera were collected from 151 men (61.7%) and 94 women (38.3%) and the mean age was 35.5 years, range from 30-50 years.

Retesting of the 123 urease positive patients by ICT technique, showed 83 (67.4%) true-positives, and 40 (32.6%) false-negatives, at the same time retesting of the 122 urease negative patients by ICT, showed 91 (74.5%) true negatives and 31 (25.4%) false positives (Fig. 1).

Retesting of the 123 urease positive patients by ELISA technique, showed 111 patients (90.2%) true-positives, and 12 (9.8%) false-negatives, At the same time, retesting of the 122 urease negative patients by ELISA, showed 109 (89.3%) true negatives and 13 (10.7%) false positives (Fig. 2).

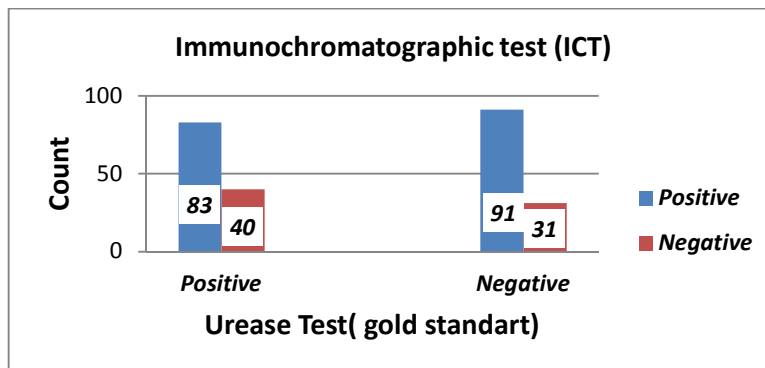


Fig. 1. Distribution of ICT result among urease positive and negative *H. pylori* patients

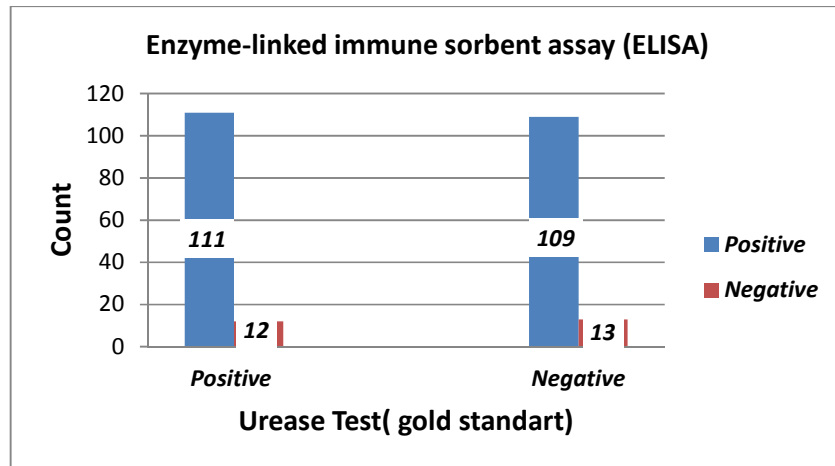


Fig. 2. Distribution of ELISA result among urease positive and negative *H. pylori* patients

Among the 245 patients 114 (46.5%) were positive and 131 patients (53.5%) were negative for anti-*H. pylori* IgG using ICT (Fig. 3).

From the 245 patients 124 (50.6%) were reactive and 121 (49.4%) were non-reactors to anti-*H. pylori* IgG by ELISA (Fig. 4).

The ICT sensitivity was 67.4%, and its specificity was 74.5% on contrast, the ELISA sensitivity was 90.2% and its specificity was 89.3%.

Accuracy of ICT was found to be 71% whereas the Accuracy of was ELISA was found to be 89.7%.

4. DISCUSSION

Humans harboring *H. pylori* in their gastric mucosa develop serum antibodies to the organism, these antibodies can be detected using several methods, including ICT and ELISA.

These methods require equipment and skilled personnel to fulfill a reliable, rapid, and an easy technique to detect *H. pylori* antibodies.

In this study the sensitivity, specificity and accuracy of ICT IgG was compared with the ELISA IgG technique. The ELISA sensitivity was 90.2% and it yields an accuracy of 89.7%. These findings were similar to those obtained by Sufi et al. from Bangladesh, who showed sensitivity and accuracy of 96.7% and 82.9% respectively however the two studies were not similar regarding to the specificity of the ELISA [6].

Among 101 sera investigated in a study done by Lutfi Fathi in Khartoum Sudan to compare between the ICT and ELISA techniques in detection of *H. pylori* infection, the ICT sensitivity was 90.2% and specificity was 66%, the ELISA sensitivity was 43.1% and specificity was 98% which are not matching with finding showed by this study [7].

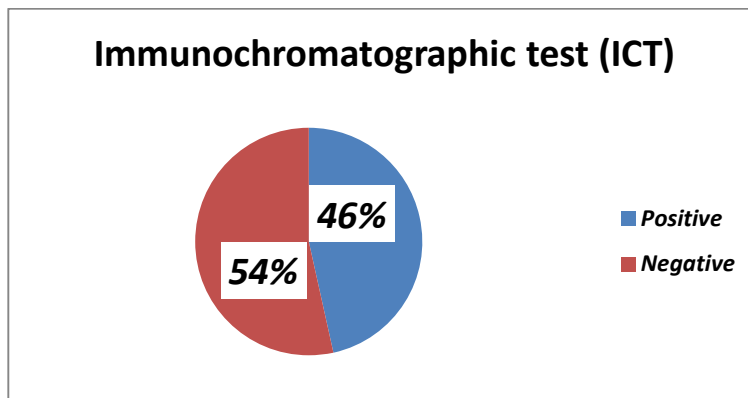


Fig. 3. Positive and negative patients by ICT

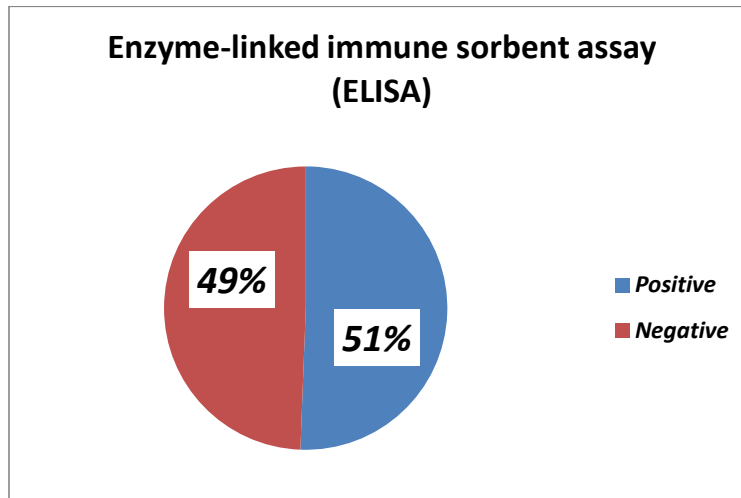


Fig. 4. Positive and negative patients by ELISA

Cognein et al. [8] evaluated the Flex-Sure (a rapid ICT), the ICT yield a specificity of 73.9% and an accuracy of 78.8% which is close to the finding of this study, however the study show a sensitivity of 96.1% which is not agreed with the current study.

Cherian et al. [9], compared the ICT with the monoclonal fecal antigen enzyme immunoassay (MFAT) show a sensitivity of 74.6% and specificity of 63.6% for the ICT which to some extent close to the finding of this study.

The ELISA kit used in this was sensitive and specific. This is similar to the findings of previous workers from the Netherlands, they evaluated eight commercial ELISA tests and found sensitivities ranged from 86 to 98% and specificities ranged from 83 to 98% [10].

5. CONCLUSION

The ELISA technique is found to be more sensitive, specific and accurate compared to the ICT.

The ICT method used is commercially available, inexpensive and easy to perform compared to the ELISA.

ELISA testing is important in detection of *H. pylori* infection because results are given in a quantitative manner on contrast the ICT give only a qualitative result and this is important in population of high prevalence of infection like Sudan.

CONSENT AND ETHICAL APPROVAL

Ethical approval will be obtained from ethical committee of university of medical science technology and Informed consent will be taken from all the participants prior to their inclusion in the study. All the procedures will inform to the patients in their native language and informed written consent will be taken from them.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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