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RESEARCH ARTICLE

Diagnosis of *Helicobacter pylori* infection using immunochromatography among patients attending Tamboul Hospital in Gezira State, Sudan: a cross-sectional study

[version 1; peer review: 1 approved, 1 not approved]

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V1 First published: 27 Aug 2020, 9:1054
<https://doi.org/10.12688/f1000research.25237.1>

Latest published: 27 Aug 2020, 9:1054
<https://doi.org/10.12688/f1000research.25237.1>

Abstract

Background: *Helicobacter pylori* causes a major health problem worldwide; more than half of the world's population are infected with this pathogen. The diagnosis of the infection was initially made through invasive methods, but now non-invasive methods have been developed to make diagnosis easier. This study aimed to screen the presence of *H. pylori* antibodies and antigen among symptomatic and asymptomatic patients at Tamboul City in Gezira State.

Methods: A cross-sectional study was conducted in Tamboul city, Gezira State, Sudan between March 2016 and December 2019 to compare between antigen and antibody tests results used for diagnosis of *H. pylori* infection among symptomatic and asymptomatic Sudanese patients. Stool and blood samples were collected and analyzed for presence of antigen and antibodies to *H. pylori* using immunochromatography (ICT) cards.

Results: Serum and stool samples were collected from 100 patients; 50 were symptomatic and 50 were asymptomatic. In symptomatic patients, 18/50 (36%) were men (32; 64%, women) with mean age of 16.7±24.6 years. In this group, 35/50 (70%) showed positive results for stool antigen, while 30/50 (60%) were positive for serum antibodies. In asymptomatic patients, 19/50 (38%) were men (31; 62%, women) with mean age of 16.7±20.4 years. In this group, 18/50 (36%) were positive for stool antigen and 25/50 (50%) for serum antibodies. There was a significant association between antigen results and patient group (P=0.001), but there was an insignificant association between

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version 1 27 Aug 2020	view	view

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antibodies results and patient group ($P=0.317$). Age group, history of infected persons in the family, blood group, and previous treatment were all not associated with *H. pylori* infection ($P\geq 0.05$).

Conclusion: The frequency of *H. pylori* antigen was higher than antibodies in symptomatic patients, while the frequency of *H. pylori* antibodies was higher than antigen in asymptomatic patients.

Keywords

H. pylori, Tamboul, ICT, Gezira state.

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Author roles: **Mohammed Elhassan Ali Noor R:** Formal Analysis, Investigation; **Mohammed Abdalla W:** Data Curation, Supervision; **Abd Alla AB:** Methodology, Writing – Original Draft Preparation; **Ibrahim Hashim A:** Data Curation, Resources, Software

Competing interests: No competing interests were disclosed.

Grant information: The author(s) declared that no grants were involved in supporting this work.

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How to cite this article: Mohammed Elhassan Ali Noor R, Mohammed Abdalla W, Abd Alla AB and Ibrahim Hashim A. **Diagnosis of *Helicobacter pylori* infection using immunochromatography among patients attending Tamboul Hospital in Gezira State, Sudan: a cross-sectional study [version 1; peer review: 1 approved, 1 not approved]** F1000Research 2020, 9:1054 <https://doi.org/10.12688/f1000research.25237.1>

First published: 27 Aug 2020, 9:1054 <https://doi.org/10.12688/f1000research.25237.1>

Introduction

Helicobacter pylori is a Gram-negative, microaerophilic, spiral-shaped bacteria that inhabits the mucous layer of the antral gastric (Basher *et al.*, 2011). Humans are living things infected (Abdallah *et al.*, 2014). *H. pylori* is typically symptomless and has no clinical manifestations. Signs and symptoms associated with the disease are mainly due to gastric or peptic ulcer disease or duodenal inflammation. Other symptoms, such as nausea, vomiting, and stomach pain, can be related to other gastrointestinal diseases (Gold *et al.*, 2014). The prevalence of *H. pylori* is still high in most countries, with approximately one-third of adults infected in northern Europe and North America, while the prevalence in southern and eastern Europe, South America and Asia is higher than 50% (Eusebi *et al.*, 2014). Up to 93.6% of adults in developing countries are infected with *H. pylori* (Olokoba *et al.*, 2013) and the prevalence of infection in Sudan was estimated to be between 65.8% and 80% (Abdallah *et al.*, 2014).

The attachment of *H. pylori* to the gastric mucosa is mediated by the Lewis (Le6) antigen. The availability of these receptors may be reduced in blood groups A and B compared to blood group O. H antigen is also an important gastroduodenal mucosal cell receptor for *H. pylori* attachment (Alcout *et al.*, 2000).

Laboratory testing for *H. pylori* infection is very important part of the diagnosis process for gastric and duodenal inflammatory disease. A number of different diagnostic test methods, both invasive and non-invasive, are available. Invasive methods, such as antibody (Ab) detection is cheap and easy to perform, but may give false positive results (Quartero *et al.*, 2000). The stool antigen (Ag) test has recently become more acceptable as it is non-invasive, convenient for patients and can be performed easily even in small laboratories. Other non-invasive tests may also include detection of *H. pylori* antigens in saliva (Logan & Walker, 2001; Malfetheriner *et al.*, 2007).

This study aimed to screen the presence of *H. pylori* antibodies and antigen among symptomatic and asymptomatic patients at Tamboul City in Gezira State.

Methods

Study design

This descriptive, cross-sectional, hospital-based study was conducted at Tamboul Hospital in Gezira State, Sudan, between March 2016 and December 2019.

Ethical considerations

Ethical approval was obtained from the Scientific Research Committee of the College of Medical Laboratory Sciences, Sudan University of Science and Technology (Ethical No SRC-MLS-01-19). Written informed consent was initially obtained from participants for participation in the study and publication of data; however, the researchers noticed that participants preferred to agree verbally. After requesting permission from the Scientific Research Committee to change the consent process, verbal informed consent was obtained from participants for participation in the study and publication of data.

Patients

Patients were selected by non-probability, convenience sampling and were recruited by physicians.

Patients with and other without symptoms of *H. pylori* infection with different age and gender were included in this research.

Exclusion criteria: symptomatic patients undergoing treatment of *H. pylori* infection and patients with other diseases.

A structured questionnaire containing demographic data and medical history was used to collect information from participants.

Sample size

Sample size was determined according to the formula below.

$$n = t^2 \cdot p(1-p) / \mu^2$$

$$t = 1.96 \quad (t^2 = 3.8416)$$

$$p = \text{prevalence} (0.80) (80\%)$$

$$\mu = 0.05 \quad (\mu^2 = 0.0025).$$

$$30841 \cdot 0.8(0.92) / 0.0025 = 113$$

Due to high cost, the sample size was kept at 100 sera and stool samples; 50 symptomatic patients and 50 asymptomatic patients.

Data collection

Serum sample. Five ml blood sample were collected from each patient in a plain blood container. Serum was then separated by centrifugation (3000 rpm for five minutes). *H. pylori* antibodies (IgG and IgM) were detected in the serum using ALL TEST (Hangzho Biotics, China; REF IHP-302). 2 drops of sample (about 100µl) were added into the sample well (S) of the test device and then 1 drop buffer was added to this. As the test began to work, a purple color moving across the window to the center of the device.

The presence of two-color bands as test band (T) and control band (C) within the results window, no matter which band appeared first, indicated a positive result. It should be noted that some invalid results are because the directions have been followed incorrectly or the test may have deteriorated beyond the expiration date (Ansorg *et al.*, 1991).

Stool sample. Patients were asked to provide a stool sample at the hospital. Fresh stool samples were collected into spoon-cover and outer-labeled stool container for antigen detection. Using a wood stick, a small portion of the stool sample was transferred into buffer, incubated for 2 minutes and then two to three drops of the mixture were poured in the hole of the ICT of *H. pylori* stool antigen detection (ALLTEST; Hangzho Biotics, China; catalog number 30226). The color migrated from the well containing the tested sample in the ICT device (Ansorg *et al.*, 1991). The presence of two bands (test band (T) and control band (C)) within the result window, no matter which band appeared first, indicated a positive result.

Statistical analysis

Statistical Package for Social Science program (SPSS) version 20 was used for analysis. Frequencies were presented as tables and figures. Chi-square test was used to compare between variables and level of significance was set as $P \geq 0.05$.

Results

A total of 100 stool and 100 sera specimens were collected from 50 asymptomatic and 50 symptomatic patients, with different gender, age and blood groups. Age was classified as following: <15 years, 15-50 years, and >50 years old.

In asymptomatic patients, the mean age was 16.7 ± 24.6 years. The majority of the patients in this group were women (32; 64%). In symptomatic patients, the mean age was 16.7 ± 20.4 years, and the majority of patients were women (31; 62%).

For both groups of patients, those who had previous treatment for *H. pylori* had low frequency of infection compared to those with no previous treatment. For both groups, 60% had family members who had also been diagnosed with *H. pylori* infection (Table 1).

There was a higher number of symptomatic patients with a positive antigen result (35/50; 70%) compared with asymptomatic patients (18/50; 36%). There was a significant association between antigen result and patient group ($P=0.001$; Table 2).

Table 1. Demographic variables for patients with *Helicobacter pylori* in patients from Gezira State, Sudan.

Variable	Symptomatic patients, n (%)	Asymptomatic patients, n (%)
Total	50	50
Gender		
Men	18 (34)	19 (38)
Women	32 (64)	31 (62)
Family history		
Yes	30 (60)	30 (60)
No	20 (40)	20 (40)
Previous treatment		
Yes	14 (28)	13 (26)
No	36 (72)	37 (74)
Age group, years		
<15	2 (4)	0 (0)
15-50	40 (80)	45 (90)
>50	8 (16)	5 (10)

Similarly, there was a higher number of symptomatic patients with a positive antibody result (30/50; 60%) compared to asymptomatic patients (25/50; 40%). There was no significant association between antibody results and patient group ($P=0.317$; Table 3).

Symptomatic patients in the 15–50 years age group had the highest number of positive results for antigen and antibodies (antigen, 27 (54%); antibody, 24 (48%)). In asymptomatic patients for this age group, a positive antigen and antibody result was seen in 17 (34%) and 23 (46%) patients, respectively. However, there was no association between age group and positive result for antigen and antibodies to *H. pylori* in either group of patients.

Women showed higher positive results than men for both antigen and antibody in both asymptomatic and symptomatic groups (asymptomatic women, Ag 12 (24%), Ab 14 (28%); asymptomatic men, Ag 9 (18%), Ab 11 (22%); symptomatic women, Ag 21 (42%), Ab 19 (38%); symptomatic men, Ag 9 (18%), Ab 11 (22%)). This association between gender and antigen/antibody presence was not significant in either group of patients.

Patients with O positive blood group showed higher positive results than other blood groups for both antigen and antibody in both asymptomatic and symptomatic groups (asymptomatic O positive, Ab 14 (28%), Ag 17 (34%); symptomatic O positive, Ab 10 (20%), Ag 7 (14%)). The association between

Table 2. Association between *Helicobacter pylori* antigen results and study groups.

Patient group	Antigen results, n (%)		Total	P value
	Positive	Negative		
Asymptomatic	18 (36)	32 (64)	50	0.001
Symptomatic	35 (70)	15 (30)	50	
Total	53	47	100	

Table 3. Association between *Helicobacter pylori* antibody results and study groups. Positive results were those with the presence of both IgM and IgG; presence of either was considered a negative result.

Patient group	Antibody results, n (%)		Total	P value
	Positive	Negative		
Asymptomatic	25 (50)	25 (50)	50	0.317
Symptomatic	30 (60)	20 (40)	50	
Total	55	45	100	

blood group and antigen/antibody presence was not significant in either group of patients.

Patients in both groups with family members who also had *H. pylori* infection showed higher positive antigen results than those without family members who had the infection (symptomatic patients with family infection, 21 (42%), without family infection 14 (48%); asymptomatic patients with family infection, 12 (21%), without family infection 6 (12%). There was no significant association between antigen results and family member infection.

Asymptomatic patients who had no previous treatment for *H. pylori* showed higher antigen positivity (12/50; 24%) than those with previous treatment. This was similar in symptomatic patients (no previous treatment Ag, 25/50; 50%). There was no significant association between previous treatment and antigen result in asymptomatic and symptomatic patients.

Discussion

H. pylori infection is a co-factor in the development of three important upper gastrointestinal diseases: duodenal or gastric ulcers, gastric cancer and gastric mucosa-associated lymphoid tissue lymphoma (McColl, 2010).

In the present study, *H. pylori* antibodies were present in 25/50 (50%) asymptomatic patients and 30/50 (60%) symptomatic patients. These results were similar to a study carried by Naji *et al.* (2014) in Yemen, which found antibodies in 72%. In contrast, our results are higher than those found by Douraghi *et al.* (2013) in Iran, who found antibodies in 4.6% of patients, and lower than those found by Alfadil (2016) in Sudan who found antibodies in 48% of patients.

In our asymptomatic patients, *H. pylori* antigen was detected in 18/50 (36%) patients, and 35/50 (70%) symptomatic patients. These results are similar to a study carried out in Nigeria by Omosor *et al.* (2018), where stool antigen was found in 56% of patients. Our results for antigen were higher than those reported by Douraghi *et al.* (2013) in Iran (12.4%) and lower than Naji *et al.* (2014) in Yemen (49%). The variation may be due to difference in socioeconomic status of the patients.

Our study results did not find a significant association between age groups and *H. pylori* infection (as diagnosed with antigen/antibody testing). This is similar to study done in Iran by Alvali *et al.* (2010), but it differed from Kabir (2007) in Sweden who reported that the percentage of infection increases with age. In our study, the age group 15–50 years showed the highest rate of infection in both symptomatic and asymptomatic patients for antigen and antibodies. That may be because the vast majority of individuals acquire *H. pylori* infection during childhood, and the infection associated with poor hygiene and overcrowding.

We also found that women were more affected than men both in the symptomatic group (62% vs 38%) and asymptomatic group (64% vs 36%). This was a similar result to that found

in Turkey by Kanbay *et al.* (2005) (60.6% vs 42.9%), but a dissimilar results to those found in Iran by Metanant *et al.* (2010) (32.8% vs 36.4%). The differences between studies could be due to random selection of patients regardless of their gender in our study.

In the current study, patients with blood group O positive had the highest frequency of positive *H. pylori* infection, both for symptomatic (48%) and asymptomatic (38%) patients. These results were the same as another study done in Gezira State, Sudan by Mohammed *et al.* (2015), who found that 58.1% of blood group O positive patients were positive for *H. pylori* infection. This is in contrast to a study done in Turkey by Kanbay *et al.* (2005) who was reported that patients with blood group A positive had a higher frequency of *H. pylori* infection than other blood groups at 38.2%. This dissimilarity may be due differences in ethnic background, and the fact that blood group O positive is the most frequent blood group in Sudan (Hassan, 2010).

In this study, 12/50 (24%) of asymptomatic patients who had family members with *H. pylori* infection were positive for antigen and/or antibody. These results are similar to Gravina *et al.* (2016) in Italy, who found *H. pylori* infection in 28.4% household contacts. However, this study was higher than Mabeku *et al.* (2018) in Cameroon (80.39%). In symptomatic patients, the frequency of antigen and antibodies with family member infection were 21(42%) and 20(40%) correspondingly, that were similar to result of Gravina *et al.* (2016) in Italy who found *H. pylori* infection in 43.2% household contacts. This finding was higher than Manfredi *et al.* (2016) in Italy (81.7%), and variation may be due to personal hygiene.

In the current study, the frequency of antigen in asymptomatic patients who had previous treatment for *H. pylori* were 12% (6/50) while in symptomatic patients this was 20% (10/50). This agreed with a study carried out by Gisbert *et al.* (2005), but was higher than the results reported by Nanivadekar *et al.* (1990) in India (2.4%), and lower than the results found by Bapat *et al.* (2000) in India (60%). This discrepancy may be due to resistance of standard triple therapy. In this study, the association between previous treatment and *H. pylori* reinfection was not statistically significant.

Conclusions

The frequency of *H. pylori* antigen was higher than antibodies in symptomatic patients, while the frequency of *H. pylori* antibodies was higher than antigen in asymptomatic patients.

Data availability

Underlying data

Fighshare: Diagnosis of *H. pylori* in Tamboul Hospital in Gezira State, <https://doi.org/10.6084/m9.figshare.12488432.v2> (Abd Alla & Alhassan, 2020).

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

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Current Peer Review Status:

Version 1

Reviewer Report 23 November 2021

<https://doi.org/10.5256/f1000research.27851.r97083>

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The authors have demonstrated the use of immunochromatography in this cross-sectional, hospital-based study conducted at Tamboul Hospital in Gezira State, Sudan, between March 2016 and December 2019. In the introduction the authors could have mentioned some studies which used immunochromatography for the diagnosis of *H. pylori*. This is an upcoming non-invasive method used for the diagnosis of *H. pylori* infection.

The test was carried out for both antigen and antibody. Sera and stool samples were used. The *H. pylori* status was compared with different parameters in this study. However, it would have been desirable to compare the test results with a gold standard which was not carried out in this study. The gold standard could have been to stool antigen test against which the serology could have been compared, as done in a study by Obaid *et al.* (2021)¹. The statistical analysis could have determined the sensitivity and specificity of this test with the gold standard. That would have given the efficacy of this new test with the existing standards. The authors could have given the details of the data tables which would clarify the results better. This helps the readers to interpret the results better.

However, this study shows that non-invasive methods can be used to test *H. pylori* for antigen as well as antibodies. That's a message taken from this study. The authors concluded that the frequency of *H. pylori* antigen was higher in symptomatic patients, while the frequency of *H. pylori* antibodies was higher in asymptomatic patients when compared to the antibodies. This indicates that in symptomatic patients it may be more prudent to use antigen related tests for the diagnosis of *H. pylori* and for screening antibody test can be recommended using immunochromatography.

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Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

Partly

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Gastroenterology

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 14 December 2020

<https://doi.org/10.5256/f1000research.27851.r75335>

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Milagrosa Montes

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The authors describe two ICT methods to diagnose *Helicobacter* infection in two population groups: symptomatic and asymptomatic.

I see two major errors. The first one, to use the detection of antibodies (Ab) to diagnose *Helicobacter* infection. Serology should only be used for epidemiological studies as it does not differentiate between current and past infections. The second failure that I observe is that

speaking of non-invasive diagnostic methods to detect *Helicobacter* infection, they do not name the urea breath test (UBT), which, to date, is the non-invasive test with the highest sensitivity and specificity, and the one recommended by all *Helicobacter* infection diagnostic guidelines.

My suggestion to the authors would be that they write another paper with the stool antigen data, saying that it is a good technique to detect *Helicobacter* infection when UBT is not available, it is logical that positivity is higher in symptomatic subjects (70 % vs 36%), and to use the serology data to give the seroprevalence in Gezira State; 55 patients have Ab (30 in the symptomatic group and 25 in the asymptomatic group) a figure lower than the 65-80% reported for Sudan by Abdallah *et al.*

They should further describe in detail the test used to detect *Helicobacter* Ag in feces, whether it uses monoclonal or polyclonal Ab.

It would be good to give the data of each test in previously treated patients, it would give an idea of the treatment failures.

The heading of Table 1, "Demographic variables for patients with *Helicobacter pylori* in patients from Gezira State, Sudan" is not correct, since the 100 patients of the study are included, those with and those without infection, it should say "Demographic variables of the 100 patients from Gezira State (Sudan) included in the study".

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Graduated in Pharmacy (1988) and Doctor in Pharmacy from the Universidad de Navarra (1996). Specialist in Microbiology and Clinical Parasitology (1991). I currently work in the Microbiology Service of University Hospital Donostia. I have participated in more than 15 scientific projects, and in more than 95 scientific publications related to the molecular mechanisms of resistance to antimicrobials, diagnosis and epidemiology of Communicable Infections, especially those that are preventable by vaccination, in infection by *Streptococcus pyogenes* and *Helicobacter pylori*.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

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