Infectious Diseases Diagnosis & Treatment
Agnes TD, et al. Infect Dis Diag Treat 7: 263.
www.doi.org/ 10.29011/2577- 1515.100263
www.gavinpublishers.com

OPEN ACCESS

GAVIN PUBLISHERS

Research Article

Evaluation of the Non-Invasive Diagnostic Method for Helicabacter *pylori* from 50 Patients (Case of CHU-RN)

Tariam Djibangar Agnes, Bessimbaye Nadalaou, Mahamat Nadjib Abderrahim Saleh, Mayana Habkreo, Ache Djimet, Moustapha Ahmat, Bakaranga-Via Issakou, Abdelsalam Tidjani

[1]National Reference University Hospital Laboratory (CHU-RN), CHAD

[2]Faculty of Human Health Sciences of the University of Ndjamena, CHAD

***Corresponding author:** Tariam Djibangar Agnes, National Reference University Hospital Laboratory (CHU-RN), CHAD.

Citation: Agnes TD, Nadalaou B, Nadjib M, Habkreo M, Djimet A, et al., (2024) Evaluation of the Non-Invasive Diagnostic Method for Helicabacter *pylori* from 50 Patients (Case of CHU-RN). Infect Dis Diag Treat 8: 263. DOI: 10.29011/2577-1515.100263

Received Date: 12 June 2024; **Accepted Date:** 19 June 2024; **Published Date:** 24 June 2024

Abstract

Introduction: Helicobacter pylori (H. pylori), as a negative and spiral microorganism Gram, is responsible for the colonization of the gastric micro niche for over 50% of the global population. Recent studies have shown the crucial role of H. pylori in the development of gastro duodenal ulcers, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric cancer. The aim of this work is to determine the sensitivity and specificity of two non-invasive tests used for the diagnosis of H. pylori. **Material and Methods:** This is a prospective analytical study which took place from February 2nd to May 5th, 2022, at the CHU-RN laboratory. 50 patients, including 31 women and 19 men aged from 15 to 75 years old underwent two rapid detection tests for H. pylori in the blood and stools. **Results:** The most representative group was the one of women with a percentage of 62 and the average age of 37 years old. From the 50 samples tested for H. pylori antibodies in the blood and antigens in the stools, the sensitivity was 44.44% and the specificity was 90.91%, with a positive predictive value (PPV) of 66.67% and a negative predictive value (NPV) of 80%. **Conclusion:** H. pylori infection is a significant public health issue, especially in developing countries, mainly in Chad. However, the study showed a lower sensitivity rate in both non-invasive methods. This could be due not only to the small size of our sample but also to the absence of some elements that could contribute to a good sensitivity.

Keywords: Stools; Blood; Sensitivity; Specificity; H. pylori

Introduction

Since the revolutionary discovery of Helicobacter pylori (H. pylori) in 1983, a challenging era in the management of gastro duodenal diseases began [1]. We think that this infection considered generally as being chronic plays an inevitable role in gastro duodenal ulcers and gastric adenocarcinomas. H. pylori, as the most widespread and recognized bacterium, is carried by more than half of the world population [2,3]. Once colonized, H. pylori induce a persistent but superficial inflammation, leading to a duodenal ulcer, a gastric ulcer and a gastric cancer [4,5]. As expected, many recent studies have confirmed the critical role of H. pylori in the development of gastro duodenal ulcers, of lymphoma associated lymphoid tissue to the gastric mucosa (MALT) [6]. Given the causal role of H. pylori in duodenal ulcer and gastric cancer, clinicians and microbiologists are eager to find the best diagnostic approach [7,8]. Currently, various diagnostic methods are used for H. pylori infection in different persons (children and adults), but only those with both high sensitivity and specificity remain useful and recommendable.

During the last decade, the use of non-invasive tests for diagnosing H. pylori infection has raised significant interest. Hence, in this

study, we wanted to aim at testing these two diagnostic methods for H. pylori in the blood for antibody detection by ABON and antigen detection in stools by PRIMA, both of which are immunochromatographic methods. Unfortunately, limited data were found regarding the sensitivity and specificity of these two tests, particularly in Chad. The use of the two non-invasive qualitative diagnostic tests for H. pylori, namely ABON and PRIMA Lab, are immunochromatographic methods for detecting H. pylori antibodies in the blood and antigens in the stools.

The purpose of this study is to determine the sensitivity and specificity of these two tests.

Methods

Type and Place of Study

This is a prospective analytical study taking place from February 2nd to May 5th, 2022, at the CHU-RN laboratory.

50 patients, including 31 women and 19 men aged from 15 to 75 years old, underwent two rapid detection tests for H. pylori in the blood and stools.

The patients were referred to the laboratory for an examination to detect H. pylori in the stools and blood.

A questionnaire was completed for each patient, and information was collected on inquiry forms. However, we obtained informed consent from the patients' parents before their recruitment.

Study Population

The study was focused on 50 patients, 31 women and 19 men aged from 15 to 75 years old. The 50 patients underwent two rapid detection tests for H. pylori in the blood for antibody detection by ABON and in the stools for antigen detection by PRIMA Lab.

Blood and Stool Sampling

Blood was drawn by puncturing a peripheral vein into a red tube for antibody detection.

Stools were collected in sterile containers for antigen detection.

Analysis

The brand used for the rapid qualitative detection test for H. pylori antibodies in the blood was ABON REF IHP-402, an immunochromatographic test. The method involves removing the strip from the sealed aluminum packet, then peeling off the adhesive strip from the test card and sticking the test strip in the middle of the card with the arrows pointing upwards. For serum samples, hold the dropper vertically and add 2 drops of serum (approximately 50 ML) to the pad on the strip and start the timer. Then wait for the red line to appear. A positive result shows two red lines, a negative result shows one red line in the control area, and an invalid result shows no line in the control area.

The PRIMA Lab. SA test is an immunochromatographic test that allowed us to detect small amounts of H. pylori antigens in the stools using monoclonal antibodies. The test involves collecting the sample with the collection leaflet, unscrewing the cap of the vial, dipping the collection stick in three different points of the sample, and screwing the cap back on. Break the end of the cap, releasing the dropper part, and add 3 drops of the diluted sample into the well (S) indicated on the cassette, then wait 10 minutes before reading the result.

Statistical Analyzes

Data entry was carried out using Microsoft Excel software. The statistical analysis of these data was carried out using the Epi Info 2008 software (Version 3.5.1) with a significance threshold set at 5%.

Ethical Considerations

The survey was conducted after obtaining informed and written consent from the patients. Anonymity and confidentiality of the information obtained were guaranteed.

Results

We collected a total of 50 patients among whom we have a greater representation of women at 62%, i.e. an average age of 37 and a standard deviation of 13.76 according to Chart 1 showing the distribution of the population according to the gender.

Descriptive Statistics for Each Value of Crosstab Variable						
	Obs	Total	Average	Variance	Standard deviation	
F	3,10,000	1,17,30,000	3,78,387	18,94,731	1,37,649	
M	1,90,000	90,90,000	4,78,421	28,02,515	1,67,407	
	Minimum	25%	Median	75%	Maximum	Mode
F	70,000	2,80,000	3,90,000	4,30,000	7,00,000	4,00,000
M	1,80,000	3,20,000	5,00,000	6,10,000	7,10,000	3,20,000

Chart 1: Distribution of the population according to age AVERAGE Age Gender.

Regarding the sensitivity and specificity of the 2 tests at the level of 50 patients. Chart 2 shows that out of 50 patients tested for Helicobacter pylori antibodies and antigens, 13 are positive for Helicobacter pylori antibodies in the blood, i.e. a percentage of 26, whereas 18 are positive for Helicobacter pylori antigens. In the stools, a percentage of 36.

	HPStools(1=Positive 0=Negative)		
HP BLOOD (1=POSITIVE 0=NEGATIVE)	Negative	Positive	Total
Negative	28	9	37
Row%	75,68%	24,32%	100,00%
Col%	87,50%	50,00%	74,00%
Positive	4	9	13
Row%	30,77%	69,23%	100,00%
Col%	12,50%	50,00%	26,00%
TOTAL	32	18	50
Row%	64,00%	36,00%	100,00%
Col%	100,00%	100,00%	100,00%

Sensitivity (Se) = 50%

Specificity (Sp) = 87%

Positive Predictive Value (PPV) = 69.23%

Negative Predictive Value (NPV) = 75.68%

Chart 2: Sensitivity and Specificity of the 2 tests from 50 patients

CHARTS [Blood HP (1=Positive 0=Negative)] [Stool HP (1=Positive 0=Negative)] (for all people).

The study showed a sensitivity (Se) of 50%, a specificity (Sp) of 87%, a positive predictive value (PPV) of 69.23%, and a negative predictive value (NPV) of 75.68%.

We noticed that Chart 3, showing the sensitivity and specificity of the two tests from women, indicated that 20 patients were negative and 2 patients were positive for H. pylori antibodies in the blood, while for H. pylori antigen detection, 5 patients were negative, and 4 patients were positive. The sensitivity and specificity of these two tests in women were 44.44% and 90.91%, respectively, with a positive predictive value (PPV) of 66.67% and a negative predictive value (NPV) of 80% with a 95% confidence interval.

	HP Stools (1=Positive 0=Negative)		
HP BLOOD (1=POSITIVE 0=NEGATIVE)	**Negative**	**Positive**	**Total**
Negative	20	5	25
Row%	80,00%	20,00%	100,00%
Col%	90,91%	55,56%	80,65%
Positive	2	4	6
Row%	33,33%	66,67%	100,00%
Col%	9,09%	44,44%	19,35%
TOTAL	22	9	31
Row%	70,97%	29,03%	100,00%
Col%	100,00%	100,00%	100,00%
Sensitivity (Se) = 44.44%			
Specificity (Sp) = 90.91%			
Positive Predictive Value (PPV) = 66.67%			
Negative Predictive Value (NPV) = 80%			

Chart 3: Sensitivity and Specificity of the 2 Tests from women

CHARTS [HP Blood (1=Positive 0=Negative)] [HP Stool (1=Positive 0=Negative)] (Women).

	HP Stools (1=Positive 0=Negative)		
HP BLOOD (1=POSITIVE 0=NEGATIVE)	**Negative**	**Positive**	**Total**
Negative	20	5	25
Row%	80,00%	20,00%	100,00%
Col%	90,91%	55,56%	80,65%
Positive	2	4	6
Row%	33,33%	66,67%	100,00%
Col%	9,09%	44,44%	19,35%
TOTAL	22	9	31
Row%	70,97%	29,03%	100,00%
Col%	100,00%	100,00%	100,00%
Sensitivity (Se) = 38.46%			
Specificity (Sp) = 80%			
Positive Predictive Value (PPV) = 71.43%			
Negative Predictive Value (NPV) = 50%			

Chart 4: Sensitivity and specificity of the 2 tests from humans before discussion

CHARTS [HP Blood (1=Positive 0=Negative)] [HP Stool (1=Positive 0=Negative)] (from men).

The sensitivity and specificity of the two tests in men showed that out of 19 patients, 8 patients were negative and 2 patients were positive, making a total of 10 patients for H. pylori antibody detection in the blood. For H. pylori antigen detection in the stools, the study showed 4 patients negative and 5 patients positive, making a total of 9 patients. The sensitivity and specificity of these two tests were 38.46% and 80%, respectively, with a positive predictive value (PPV) of 71.43% and a negative predictive value (NPV) of 50%.

Discussion

The study showed a greater representation of women, which could be explained by the number of women visiting this service. Chart 2, on the sensitivity and specificity of the two tests from 50 patients, showed a sensitivity of 44.44% and a specificity of 90.91% for the two non-invasive methods. According to the literature, the sensitivity and specificity of the serological method exceed 90%. The serological method does not allow for the control of eradication since seropositivity can persist for months or even years after the eradication of the bacterium. However, it finds its place in epidemiological studies. Our results can be explained by the fact that patients are on antibiotics before the examination.

The sensitivity for detecting antigens in the stools varies from 86% to 91.6% and the specificity varies from 92% to 98.4% according to the literature [11,12]. Our results are inconsistent with the literature, which states that this test is performed on fresh stool samples or those stored cool for a maximum of 24 hours and collected in a sterile jar otherwise frozen at -20°C or -80°C.

The sensitivity of this test is reduced in cases of low density of H. pylori in the stomach and a low load in the stools

Failure to comply with sampling and storage conditions may influence the sensitivity of this test [13]. Charts 3 and 4 showed that the detection of H. pylori-specific IgG antibodies in serum has a very low sensitivity in women as well as in men. This could be explained by the use of antibiotics before the examination. Our results are in discordance with those of the literature which have demonstrated that the search for H. pylori antibodies in the serum does not make it possible to control eradication since seropositivity can be maintained for years after the disappearance of the bacteria [14].

It is recommended in situations where other tests may be lacking: hemorrhagic ulcer, glandular atropia, MALT lymphoma, recent use of antibiotics. It diagnoses H. hylori infection with a sensitivity of 85 to 95% [14].

However, testing for H. pylori antigen in stools in both sexes showed lower sensitivity than literature data. This could be explained by the sample size of 50.

The heterogeneity of the H. Pylori antigen in stools would also be an explanation for this low sensitivity. That is why you must always homogenize before taking samples.

The literature reports that intestinal transit time influences the search for H. pylori antigen in stools. A short intestinal transit time would promote the elimination of unaltered H. pylori antigen while constipation would promote the degradation of this antigen [15].

Conclusion

We evaluated the non-invasive method of H pylori in blood for the detection of antibodies and in stools for the detection of antigens. Our results reveal a low rate of sensitivity in women and men.

This could be explained not only by the small size of our sample but also by some factors which can influence blood and stool examinations, notably the use of antibiotics. Stool collection, storage, etc.

Interest Conflicts: The authors declare no interest conflicts.

References

1. Kusters JG, van Vliet AHM, Kuipers EJ (2006) Pathogenesis of Helicobacter pylori infection. Clin Microbiol Rev 19: 449-490.
2. Hu Y, Wan JH, Li XY, Zhu Y, Graham DY, et al., (2017) Systematic review with meta-analysis: the overall recurrence rate of Helicobacter pylori. Aliment Pharmacol Ther 46:773-779.
3. Elhariri M, Elhelw R, Hamza D, El-Mahallawy HS (2017) Serological evidence and risk factors for Helicobacter pylori infection in animals and humans. J Infect Dev Ctries 11:414-419.
4. Abadi ATB, Ierardi E, Lee YY (2015) Why do we still have Helicobacter pylori in our stomachs. Malays J Med Sci 22:70-75.
5. Smolka AJ, Schubert ML (2017) Helicobacter pylori-induced changes in gastric acid secretion and upper gastrointestinal diseases. Curr Top Microbiol Immunol 400:227-252.
6. Camilo V, Sugiyama T, Touati E (2017) Pathogenesis of Helicobacter pylori infection. Helicobacter Suppl 1. doi: 10.1111/hel.12405.
7. Blaser MJ, Kobayashi K, Cover TL, Cao P, Feurer ID, et al., (1993) Helicobacter pylori infection in Japanese patients with gastric adenocarcinoma. Int J Cancer 55:799-802.
8. Testerman TL, Morris J (2014) Beyond the stomach: an updated view of the pathogenesis, diagnosis and treatment of Helicobacter pylori. World J Gastroenterol 20:12781-12808.
9. Blecker U, Vandenplas Y (1993) Helicobacter pylori serology. J Clin Microbiol 31:173.
10. Malfertheiner P, Mégraud F, O'Morain CA, Atherton J, Axon ATR, et al., (2012) Management of Helicobacter pylori infection – the Maastricht IV/Florence Consensus Report. Gut 61:646-664.
11. Best LM, Takwoingi Y, Siddique S, Selladurai A, Gandhi A, et al., (2018) Non-invasive diagnostic tests for Helicobacter pylori infection. Cochrane Database Syst Rev 3: CD012080.
12. Attumi TA, Graham DY (2011) Follow-Up testing after treatment of Helicobacter pylori infections: Cautions, caveats, and recommendations. Clin Gastroenterol Hepatol 9:373-375.

13. Attumi TA, Graham DY (2014) High-Dose extended-release lansoprazole (dexlansoprazole) and amoxicillin dual therapy for Helicobacter pylori infections. Helicobacter 19:319-322.

14. Shimoyama T (2013) Stool antigen tests for the management of Helicobacter pylori infection. World J Gastroenterol 19:8188-8191.

15. Ricci C, Holton J, Vaira D (2007) Diagnosis of Helicobacter pylori: Invasive and non-invasive tests. Best Pract Res Clin Gastroenterol 21:299-313.

16. Megraud F, Lehours P (2007) Helicobacter pylori Detection and Antimicrobial Susceptibility Testing. Clin Microbiol Rev 20:280-322.