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Comparison of various *Helicobacter pylori* diagnostic techniques in samples isolated from Iraqi patients

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ABSTRACT

The *Helicobacter pylori* infection is a major global health concern, contributing to various gastrointestinal disorders, including gastritis, peptic ulcers, and gastric cancer. Disease management relies on the availability of both accurate and reliable diagnostic methods. This study evaluates and compares the diagnostic accuracy of three widely used non-invasive tests (the ^{13}C-urea breath test or ^{13}C-UBT, the stool antigen test, and serological testing) against endoscopy (as the gold standard) in Jood Specialist Lab in Hillah (Iraq) between February and December 2024. A total of 100 patients was included in this study, and specimens were inspected using each of the aforementioned tests. Results showed that the ^{13}C-UBT had the highest sensitivity (98.9%) and specificity (76.9%), which makes it the best non-invasive test for the diagnosis of an *H. pylori* infection. Meanwhile, the stool antigen test exhibited a slight lower performance in both sensitivity (94.8%) and specificity (65.2%), while the serological testing exhibited the lowest specificity (24.5%), resulting in a greater frequency of false positives. These findings underscore the limitations of serological testing and reinforce ^{13}C-UBT's position as the method of choice for the non-invasive diagnosis of *H. pylori* infections in Iraqi patients.

1. Introduction

A microaerophilic spiral-shaped gram-negative bacterium, *Helicobacter pylori*, colonises the stomach and causes most duodenal ulcers, gastritis, mucosa-associated lymphoid tissue lymphoma, and

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stomach cancer cases. Poor countries have 70% to 90% *H. pylori* prevalence, while wealthy ones have 25% to 50%. Person-to-person transmission is most likely. The diagnostic methods for *H. pylori* include invasive and non-invasive methods. Histology, the rapid urease test (RUT), microbiological culture, and PCR are endoscopic biopsy tests. On the other hand, the ^{13}C-urea breath test (^{13}C-UBT), the stool antigen test, and serological testing are non-invasive methods for the diagnosis of an *H. pylori* infection. Clinical circumstances, sensitivity, specificity, and cost-effectiveness influence diagnostic approaches[1]. All approaches have downsides. Countries with lots of endoscopes chose histopathology. Histopathology demands skilled pathologists and appropriate samples, as misleading results derive from poor biopsies and depend on observer factors, stomach topography, *H. pylori* density and patchy distribution, and the *H. pylori* stain type. Stomach biopsies cultured for bacteria can reveal an *H. pylori* infection. However, technical approaches can affect the lab culturing process and the test sensitivity[2].

RUT is the dominant approach in clinical practice, but its sensitivity requires at least 105 bacteria in the sample. Since this amount may not be present after 4 weeks of an eradication treatment failure, the test is not recommended for post-eradication follow-up. Serum antibodies are easiest to perform in non-gastroscopist settings in order to diagnose an *H. pylori* infection. Finally, ^{13}C-UBT is more sensitive and specific than other non-invasive tests, but gut urease-producing bacteria limit it[3]. Moreover, it needs expensive and advanced hardware.

The aim of this study was to evaluate and compare the diagnostic accuracy of three widely used non-invasive tests (i.e., the ^{13}C-UBT, the stool antigen test, and serological testing) against endoscopy (as the gold standard) in Iraqi patients.

2. Methodology

This study was undertaken from February 2024 to December 2024 at the Jood Specialist Lab and the Merjan Medical City in Hillah, Iraq. Ethical approval was obtained from the Ethics Committee of the Merjan Medical City Hospital (July 15, 2024). Written informed consent was obtained from all participants before enrolment.

Extensive testing for *H. pylori* was performed on 100 patients, with a mean age of 43 years (range: 17–70 years). Three rigorous non-invasive testing methods were applied in this evaluation: the ^{13}C-UBT, the stool antigen test, and serological testing. Subsequently, the results were correlated to traditional endoscopy results being done at the time. Just as importantly, the consumption history of antibiotics as well as the use of H_2-receptor antagonists, proton pump inhibitors, and nonsteroidal anti-inflammatory drugs during the 30 days prior to the evaluation were among the exclusion criteria for this study.

The SPSS v.25 software was used in order to analyse the data collected during the investigation and to determine sensitivity, specificity, and accuracy. Moreover, the chi-squared and the McNemar's tests were used in order to note the statistical significance of the observed differences in the results.

3. Results and Discussion

The ^{13}C-UBT and the stool antigen test yielded high sensitivity percentages, as both tests demonstrated a sensitivity of 98.9% for the ^{13}C-UBT and 94.8% for the stool antigen test, respectively (Table 1). The serological testing's sensitivity was lower, at 91.5% (Table 1). Our results also showed that the ^{13}C-UBT had the highest specificity (76.9%), which makes it the best non-invasive test for the diagnosis of an *H. pylori* infection (Table 1). Meanwhile, the stool antigen test exhibited a lower performance in terms of specificity (65.2%), while the serological testing exhibited the lowest specificity (24.5%), resulting in a greater frequency of false positives (Table 1).

Patients with peptic ulcers or *H. pylori* infections are often diagnosed using endoscopic procedures. Yet, these procedures are costly, riskier, and more uncomfortable than other non-invasive options. Typically, serological testing, stool antigen tests, and ^{13}C-UBTs are less expensive. The results of the herein assessed *H. pylori* tests have been confirmed by endoscopic examination, which is considered

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Table 1. The results of three non-invasive diagnostic methods for H. pylori infections are compared to the gold standard (standard endoscopy).

Diagnostic methods	Standard endoscopy		Sensitivity	Specificity	Accuracy	McNemar's test *p*-value
	positive	negative				
^{13}C-urea breath test						
positive	86	3	98.9%	76.9%	90.7%	0.625
negative	1	10				
stool antigen test						
positive	73	8	94.8%	65.2%	82.8%	0.388
negative	4	15				
serological testing						
positive	43	40	91.5%	24.5%	56.0%	<0.001
negative	4	13				

the gold standard for the diagnosis of *H. pylori* infections[4–6]. While serological testing is overall less sensitive than other testing platforms for the identification of an *H. pylori* infection[7,8], its relative low cost and ease of use make it ideal for wide availability (e.g. in a general practitioner's office). On the other hand, numerous stool antigen tests have been developed so far, but despite the high sensitivity performance of these tests, their specificity is relatively low, thereby indicating that there is still room for improvement[9]. To an extent, one might consider that in the same way that surgery and medical management can be combined in order to produce the best clinical outcomes for a number of diseases, the same principles could be applied to the diagnosis of *H. pylori*[10].

4. Conclusion

The ^{13}C-UBT surpassed both the stool antigen test and serological testing in terms of sensitivity and accuracy in diagnosing an infection due to *H. pylori*. However, the stool antigen test was the more rapid and cost-effective option for the Iraqi patients.

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Conflicts of interest

None exist.

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