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ORIGINAL ARTICLE

Comparison of Molecular vs. Conventional Methods for Detection of Helicobacter Pylori: A Study of 140 Patients

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ABSTRACT

Background: Helicobacter pylori (H. pylori) is a major cause of gastrointestinal diseases, including peptic ulcers and gastric cancer. Accurate detection methods are critical for diagnosis and treatment. This study compares molecular methods (Polymerase Chain Reaction [PCR] and Urea Breath Test [UBT]) and conventional methods (Stool Antigen Test, Serological Test, Endoscopy with Biopsy) in detecting H. pylori in 140 patients.

Methods: 140 patients suspected of H. pylori infection were enrolled and underwent diagnostic testing using PCR, UBT, Stool Antigen Test, Serology, and Endoscopy with Biopsy. Results were compared across methods to assess sensitivity, specificity, and diagnostic accuracy.

Results: PCR and UBT demonstrated high sensitivity (92% and 89%, respectively), with Endoscopy and Biopsy providing the highest specificity (95%). The Stool Antigen Test showed moderate sensitivity (81%) but was cost-effective. Serological tests had the lowest sensitivity but provided a simple and quick method for detecting past infections.

Conclusion: Molecular methods (PCR and UBT) offer high accuracy in detecting H. pylori, especially in patients with active infection, while conventional methods, though less sensitive, remain effective and more accessible for diagnosis and treatment monitoring.

Keywords: Helicobacter pylor, Molecular methods, PCR, Urea Breath Test, Diagnostic Accuracy

INTRODUCTION

Helicobacter pylori is a gram-negative bacterium that colonizes the human stomach, causing gastritis, peptic ulcers, and increasing the risk of gastric cancer[1]. Accurate detection is crucial for proper treatment and to avoid complications associated with untreated infections. Several diagnostic methods for detecting H. pylori have been developed, including both conventional and molecular techniques.

Conventional methods such as the Urea Breath Test (UBT), stool antigen tests, and serological tests have been widely used in clinical practice. These methods are cost-effective and less invasive but may have limitations in terms of sensitivity and specificity[2,3]. UBT is based on the bacterium's urease activity, while stool antigen tests detect antigens shed by the bacteria[4]. Serological tests, detecting antibodies against H. pylori, have been useful in identifying past infections but cannot differentiate between active and past infections[5,6].

On the other hand, molecular methods, particularly Polymerase Chain Reaction (PCR), have gained attention for their ability to detect the genetic material of H. pylori with high sensitivity and specificity[7,8]. PCR can be performed using various biological samples, including stool, blood, or gastric biopsies. Furthermore, PCR is capable of identifying antibiotic resistance genes, aiding in the selection of appropriate treatment regimens[9]. Other molecular methods such as LAMP (Loop-Mediated Isothermal Amplification) are emerging as rapid alternatives to PCR, offering similar sensitivity but at a lower cost and with simpler equipment requirements[10].

This study aims to compare the performance of molecular methods (PCR and UBT) with conventional diagnostic techniques (Stool Antigen Test, Serological Test, Endoscopy with Biopsy) for detecting H. pylori infection in 140 patients. The focus is to evaluate the sensitivity, specificity, and diagnostic utility of each method.

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MATERIALS AND METHODS

Study Design and Participants: This prospective observational study was conducted at Hayatabad Medical Complex between April 2023 and September 2023. A total of 140 patients, aged 18–65 years, presenting with symptoms suggestive of gastrointestinal disorders (e.g., abdominal pain, dyspepsia, nausea) were enrolled.

Inclusion Criteria:

- Adult patients aged 18–65 years
- Patients with symptoms suggestive of H. pylori infection (e.g., abdominal pain, dyspepsia, nausea)
- Patients who consented to participate in the study and undergo the diagnostic tests

Exclusion Criteria:

- Patients with prior treatment for H. pylori infection within the last month
- Known gastrointestinal malignancies (e.g., gastric cancer)
- Chronic gastrointestinal conditions such as inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis)
- Patients on proton pump inhibitors or antibiotics within two weeks of enrollment
- Pregnant or breastfeeding women

Diagnostic Methods

Polymerase Chain Reaction (PCR): PCR was performed using gastric biopsy samples or stool samples. DNA was extracted and amplified using primers specific for the H. pylori 16S rRNA gene. The reaction was conducted using a thermal cycler, and the products were analyzed by gel electrophoresis.

Urea Breath Test (UBT): Patients underwent UBT, where they consumed a drink containing a labeled urea compound. The exhaled breath was collected and analyzed for the presence of labeled carbon dioxide, indicative of urease activity by H. pylori.

Stool Antigen Test: The stool antigen test was performed using a commercially available enzyme-linked immunosorbent assay (ELISA) kit. The presence of H. pylori antigens in the stool was detected by colorimetric change.

Serological Test: A serological blood test was used to detect antibodies against H. pylori. The test was performed using a commercially available immunoassay kit.

Endoscopy with Biopsy: Endoscopic procedures were performed on all patients, and gastric biopsy samples were obtained for

histological examination. The biopsy was stained with hematoxylin and eosin (H&E) and evaluated for the presence of H. pylori using microscopy.

Statistical Analysis: Data were analyzed using SPSS version 24.0. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated for each method. Comparisons between methods were made using a chi-square test for categorical data.

RESULTS

Demographic Characteristics of Participants: Of the 140 patients enrolled, 72 (51.4%) were male, and 68 (48.6%) were female, with a mean age of 42.3 ± 12.4 years. The most common presenting symptoms were dyspepsia (58%), abdominal pain (41%), and nausea (27%). (Table No 1)

Table 1: Demographical details of all the included

Characteristic	Value
Total Patients	140
Age (Mean ± SD)	42.3 ± 12.4 years
Gender	
- Male	72 (51.4%)
- Female	68 (48.6%)
Symptoms	
- Dyspepsia	81 (58%)
- Abdominal Pain	57 (41%)
- Nausea	38 (27%)
Comorbidities	
- Diabetes	15 (10.7%)
- Hypertension	23 (16.4%)
- Peptic Ulcer History	12 (8.6%)

Comparison of Diagnostic Methods

Table 2: Summarizes the diagnostic performance of each method

Method	Sensitivity	Specificity	PPV	NPV	Accuracy
PCR	92%	87%	91%	88%	89%
Urea Breath Test	89%	85%	87%	86%	87%
Stool Antigen Test	81%	83%	85%	78%	81%
Serological Test	70%	75%	72%	73%	72%
Endoscopy + Biopsy	95%	94%	94%	95%	94%

Diagnostic Accuracy

- **PCR and UBT** demonstrated high sensitivity (92% and 89%, respectively), making them reliable for detecting active infections.
- **Endoscopy with Biopsy** exhibited the highest specificity (95%), which made it the gold standard for confirming infection.
- **Stool Antigen Test** had moderate sensitivity (81%) but was cost-effective and non-invasive, making it useful for screening.
- **Serological Test** had the lowest sensitivity (70%) and is not reliable for diagnosing current infection but may be useful for identifying past infections.

Statistical Significance: There were statistically significant differences in sensitivity between PCR and serological tests ($p<0.05$). The specificity of Endoscopy with Biopsy was significantly higher than all other methods ($p<0.01$).

DISCUSSION

Our study demonstrates that molecular methods, particularly PCR, offer high sensitivity for detecting H. pylori, making them suitable for confirming active infection, especially in cases with low bacterial load. These findings align with previous studies, where PCR was shown to outperform conventional methods in terms of sensitivity[11,12]. The ability of PCR to detect antibiotic resistance markers is also a crucial advantage, as treatment regimens can be tailored accordingly[13].

The Urea Breath Test, though slightly less sensitive than PCR, is still a reliable method for diagnosing active infection, with similar diagnostic accuracy[14]. The test's non-invasive nature and rapid results make it a preferred choice in many clinical settings[15].

Endoscopy with biopsy remains the gold standard due to its high specificity and ability to detect H. pylori and other gastrointestinal conditions simultaneously[16]. However, its invasiveness, cost, and the need for specialized equipment limit its widespread use as a first-line diagnostic tool[17].

While the stool antigen test showed moderate sensitivity, it remains a useful tool in settings where PCR is not available. It is cost-effective and non-invasive, though it is influenced by recent antibiotic therapy[18,19].

The serological test, although widely available, was the least sensitive in our study, reflecting the limitations of antibody-based methods in diagnosing active infection. As a result, it is better suited for screening and epidemiological studies rather than clinical diagnosis[20].

CONCLUSION

In conclusion, PCR and UBT are the most accurate for diagnosing active H. pylori infection. However, conventional methods such as stool antigen testing and serology still have a role in certain clinical contexts due to their cost-effectiveness and ease of use.

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