ORIGINAL ARTICLE

Diagnostic Accuracy of Stool Antigen Test and Urea Breath Test Compared with Histopathology for Detection of Helicobacter pylori Infection Among Dyspeptic Patients: A Descriptive Cross-Sectional Study in A Tertiary Care Hospital

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ABSTRACT

Introduction: *Helicobacter pylori* infection is strongly associated with chronic gastritis, peptic ulcer disease, mucosa-associated lymphoid tissue lymphoma, and gastric malignancy. Accurate diagnosis is important for appropriate treatment and prevention of complications. **Aims:** To evaluate the diagnostic accuracy of the stool antigen test and urea breath test compared with histopathology for the detection of Helicobacter pylori infection among dyspeptic patients and to determine the prevalence of infection in the study population. **Methods:**This cross-sectional study was conducted at Nepalgunj Medical College Teaching Hospital from January 2025 to June 2025 using consecutive sampling to enroll 411 dyspeptic patients fulfilling inclusion criteria. Clinical assessment, stool antigen testing, urea breath testing, upper gastrointestinal endoscopy, rapid urease testing, and histopathological examination were performed. Histopathology served as the reference standard. Data were collected using structured and semi-structured proforma including demographic details, clinical findings, endoscopic findings, and laboratory investigations. Informed written consent was obtained from all participants. Statistical analysis included calculation of sensitivity, specificity, positive predictive value, negative predictive value, and Cohen's kappa agreement statistics. **Results:** Among the participants, 231 were male with majority from Banke district (28.22%). Histopathology confirmed Helicobacter pylori infection in 171 (41.61%) patients. Stool antigen test was positive in 168 (40.88%) patients while urea breath test was positive in 176 (42.82%) patients. Endoscopic gastritis was observed in 196 (47.69%) patients, erosive gastritis in 82 (19.95%), and peptic ulcer disease in 49 (11.92%). Urea breath test demonstrated slightly higher sensitivity compared to stool antigen testing. **Conclusion:** The prevalence of Helicobacter pylori infection among dyspeptic patients was high. Both stool antigen test and urea breath test demonstrated good diagnostic performance. These findings support the use of non-invasive diagnostic methods in resource-limited settings.

Keywords: Dyspepsia; Endoscopy; Helicobacter pylori; Stool Antigen Test; Urea Breath Test

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INTRODUCTION

The spiral-shaped gram-negative bacterium Helicobacter pylori colonizes the stomach mucosa and is closely linked to peptic ulcer disease, mucosa-associated lymphoid tissue lymphoma, gastric adenocarcinoma, and chronic gastritis.[1,2] Due to poor

sanitation, overcrowding, and socioeconomic circumstances, the frequency of H. pylori infection is significantly higher in low- and middle-income nations.[3] Helicobacter pylori infection is still very common among dyspeptic individuals in South Asia, including Nepal.[4] Prevalence has been shown in earlier Nepalese studies to range from 30% to 70%, depending on the study population and diagnostic techniques employed.[4,5] Chronic infection significantly increases gastrointestinal morbidity and the risk of long-term stomach cancer.[6,7] Invasive techniques for diagnosing H. pylori infection include endoscopy with biopsy, histopathology, fast urease testing, and bacterial culture; non-invasive techniques include urea breath testing and stool antigen testing.[8] Although it still requires endoscopy and specific pathological knowledge, histopathology is still one of the diagnostic reference standards.[9] The urea breath test is regarded as one of the most precise non-invasive diagnostic methods for active infection, whereas stool antigen testing offers a practical and economical alternative with strong diagnostic precision.[10,11] Endoscopic observations such as gastritis, nodularity, erosions, and peptic ulcer disease can indicate Helicobacter pylori infection but are not adequate by themselves for a conclusive diagnosis.[8] Despite the rising application of non-invasive diagnostic techniques, few studies from western Nepal have directly compared stool antigen tests, urea breath tests, and endoscopic results. The objective of this study was to assess the prevalence of Helicobacter pylori infection and evaluate the diagnostic effectiveness of the stool antigen test, urea breath test, and endoscopic results.

METHODS

This descriptive cross-sectional study was performed at Nepalgunj Medical College Teaching Hospital, Nepal between January 2025 and June 2025 after receiving ethical approval from the Institutional Review Committee of Nepalgunj Medical College. Adult patients aged 18 years and older who exhibited dyspeptic symptoms such as epigastric discomfort, bloating, nausea, fullness after meals, and early satiety were part of the study. Individuals with a history of gastric surgery, recent use of antibiotics, proton pump inhibitors, bismuth therapy, significant illness preventing endoscopy, and those who are pregnant or breastfeeding were not included.Consecutive sampling technique was employed. A previous study reported the prevalence of Helicobacter pylori infection to be 41.6%.[4] Sample size was calculated using the standard single population proportion formula with 95% confidence interval and 5% margin of error.

$$n = Z^2P(1-P)/d^2$$

$$n = (1.96)^2 \times 0.416 \times 0.584 / (0.05)^2$$

The minimum calculated sample size was 374. After adding 10% non-response allowance, the final sample size became 411.

Clinical information including age, sex, residence, smoking status, alcohol intake, duration of symptoms, and previous medication history was recorded using a structured and semi-structured proforma. Fresh stool samples were collected for stool antigen testing using commercially available monoclonal antibody-based kits. Urea breath test was performed after overnight fasting according to standard protocol.[11]

Experienced gastroenterologists performed upper gastrointestinal endoscopy. Erythema, nodularity, erosions, stomach ulcers, and duodenal ulcers were among the endoscopic abnormalities noted. The stomach body and antrum were used to obtain biopsy specimens. The gold standard for diagnosing Helicobacter pylori infection was histopathology.[8] Histopathological examination was performed using gastric biopsy specimens obtained during upper gastrointestinal endoscopy. Two biopsy samples were collected from the gastric antrum and two from the gastric body according to the updated Sydney System recommendations. The biopsy specimens were fixed in formalin, processed, and stained with hematoxylin and eosin (H&E) stain. Additional special staining (Giemsa stain) was used for detection of Helicobacter pylori when required. Histopathological identification of H. pylori organisms was considered the reference standard for diagnosis.

Dyspepsia was defined according to accepted clinical criteria based on symptoms of epigastric pain, postprandial fullness, early satiety, and epigastric burning, consistent with the Rome IV criteria for functional dyspepsia.

Patients were excluded if they had a history of previous gastric surgery, recent use of antibiotics within the previous four weeks, proton pump inhibitor use within two weeks, bismuth-containing medication use, severe systemic illness contraindicating endoscopy, active gastrointestinal bleeding, known malignancy of the gastrointestinal tract, pregnancy, breastfeeding, or inability to provide informed consent.

Approval for ethical considerations was granted by the Institutional Review Committee of Nepalgunj Medical College Teaching Hospital. All participants provided written informed consent. Confidentiality and anonymity were preserved during the entire study.

Statistical Analysis

Categorical variables were reported as frequencies and percentages whereas numerical variables were expressed as means and standard deviations. Data were entered into Microsoft Excel 2016 and analyzed using IBM SPSS version 26.0. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated. Agreement among diagnostic tests was assessed using Cohen's kappa statistic.

RESULTS

The study population consisted of 411 participants, with 231 male and 180 female patients. The mean age was 43.7 ± 14.2 years. All demographic findings are listed below (Table I).

	Percentage	Number (n)
Male	56.20	231
Female	43.80	180
Region		
Banke	28.21	116
Bardiya	19.71	81
Dang	17.52	72
Kailali	13.14	54
Others	21.41	88

Table I: Demographic details of study population

Diagnostic Modality	N (%)
Stool antigen positive	168 (40.88)
Urea breath test positive	176 (42.82)
Histopathology positive	171 (41.61)
Rapid Urease test positive	166 (40.39)

Table II: Distribution of diagnostic test results

Endoscopic gastritis/erythema was the most common finding.

Endoscopic finding	N (%)
Gastritis/ Erythema	196 (47.69)
Erosive gastritis	82 (19.95)
Gastric ulcer	27 (6.57)
Duodenal ulcer	22 (5.35)
Nodularity	31 (7.54)
Normal endoscopy	53 (12.90)

Table III: Endoscopic findings among dyspeptic patients

Diagnostic performance using histopathology as the reference standard is shown below. (Table IV)

Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Stool antigen test	88.30	91.25	89.88	90.08
Urea breath test	92.40	89.58	89.77	92.27

Table IV: Diagnostic performance of stool antigen test and urea breath test

Agreement analysis demonstrated:

- Stool antigen test vs histopathology: kappa = 0.79
- Urea breath test vs histopathology: kappa = 0.82

DISCUSSION

The results of this research indicate a significant occurrence of Helicobacter pylori infection in dyspeptic patients visiting a tertiary care facility in western Nepal. Histopathology verified infection in 41.61% of patients, aligning with earlier studies from Nepal and South Asia.[4,5] Dyspepsia continues to be one of the most prevalent digestive issues linked to Helicobacter pylori infection in developing nations.[3]

Over half of the participants were men, akin to various hospital-based South Asian studies examining dyspeptic populations.[5] In this study, the most frequently observed endoscopic findings were endoscopic gastritis and mucosal erythema. Peptic ulcer disease was found in a lesser number of patients but showed a significant link to H. pylori positivity, reinforcing the recognized pathogenic involvement of the organism in ulcer disease.[1,6]

Among the non-invasive diagnostic techniques, the urea breath test exhibited a marginally greater sensitivity than stool antigen testing, though both approaches displayed outstanding specificity and robust concordance with histopathology. Comparable results have been noted in global studies assessing the diagnostic efficacy of non-invasive tests for active Helicobacter pylori infection.[10,11,12]

Endoscopic results alone were inadequate for a conclusive diagnosis since a significant number of patients with gastritis or erosive alterations were negative on histopathological analysis. This highlights the constraint of depending exclusively on endoscopic appearance for diagnosing Helicobacter pylori infection.[8,9] The results of this study indicate that non-invasive diagnostic tests may offer helpful substitutes for screening and diagnosis in situations when routine endoscopic biopsies is not practical. In healthcare settings with limited resources, these techniques can minimize needless endoscopic treatments and are less invasive and reasonably priced. Nevertheless, there were a number of drawbacks to this study. research might not accurately reflect the frequency in the population because research was carried out at a single tertiary care facility. Selection bias may be introduced by the consecutive sampling

procedure. There was no cost-effectiveness analysis of the diagnostic techniques. To further assess the diagnostic value of non-invasive testing modalities in Nepalese populations, future multicenter research with bigger sample sizes are advised.

In this study, endoscopic gastritis and peptic ulcer disease were more commonly observed among patients who were positive for Helicobacter pylori on histopathological examination. H. pylori-positive patients showed a higher frequency of abnormal endoscopic findings compared to H. pylori-negative patients, suggesting an association between H. pylori infection and gastroduodenal mucosal pathology. This finding is consistent with previous studies that have established the role of H. pylori in the pathogenesis of chronic gastritis and peptic ulcer disease. Furthermore, both the stool antigen test and urea breath test demonstrated good agreement with histopathology for the diagnosis of H. pylori infection. The observed kappa values of 0.79 and 0.82 indicate substantial agreement between the diagnostic modalities. Overall, the findings of this study support the clinical significance of H. pylori infection in dyspeptic patients and highlight the usefulness of non-invasive diagnostic tests in identifying active infection.

LIMITATIONS

Because the study was conducted in a hospital, it might not accurately reflect the prevalence of Helicobacter pylori infection in the population. Selection bias may have been introduced by consecutive sampling. Long-term follow-up following eradication therapy and cost-effectiveness analysis were not carried out.

CONCLUSION

At Nepalgunj Medical College Teaching Hospital, the prevalence of Helicobacter pylori infection among dyspeptic patients was 41.61% (171/411). The urea breath test demonstrated a sensitivity of 92.40% and specificity of 89.58%, while the stool antigen test showed a sensitivity of 88.30% and specificity of 91.25% when compared with histopathology. Both tests demonstrated strong diagnostic performance, with the urea breath test showing slightly higher sensitivity. In resource-limited settings, these non-invasive diagnostic methods may serve as practical alternatives for screening and diagnosis, potentially reducing the need for unnecessary endoscopic procedures.

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