

Helicobacter pylori and Symptomatic Cholelithiasis: Correlation Between Rapid Urease Testing and Histopathological Findings

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Abstract

Background: Symptomatic cholelithiasis represents a substantial healthcare burden, with accumulating evidence implicating *Helicobacter pylori* in pathogenesis; however, its preoperative detection merits validation in surgical populations.

Methods: Prospective ambispective observational study conducted at a tertiary care center in South India, enrolled 67 patients aged 12-70 years undergoing elective cholecystectomy for ultrasound-confirmed symptomatic gallstones. Preoperative rapid urease testing assessed *H. pylori* status, with postoperative histopathology serving as reference standard. IBM SPSS Statistics v29.0 analyzed demographics, comorbidities, family history, postoperative outcomes (hospital stay, VAS scores, complications) and diagnostic metrics (sensitivity, specificity, ROC-AUC). Reporting adhered to STROBE guidelines.

Results: Participants were predominantly female (67.2%) and middle-aged (46-60 years: 34.3%). Comorbidities included diabetes mellitus (44.8%), hypothyroidism (34.4%), hypertension (25.4%) and family history of gallstones (43.3%). *H. pylori* prevalence was 52.2% by histopathology (preoperative urease positivity: 55.2%), yielding sensitivity 95%, specificity 83% and AUC 0.95. Mean hospital stay measured 5.76 ± 1.43 days; VAS pain scores declined from 5.78 ± 2.45 postoperatively to 3.27 ± 0.82 at 30 days, accompanied by surgical site infection (32.8%) and peritonitis (44.8%).

Conclusion: Substantial *H. pylori* prevalence underscores the rapid urease test's high diagnostic accuracy for preoperative screening in cholelithiasis, facilitating targeted eradication amid metabolic risk factors; multicentre validation trials are indicated.

Keywords: Cholelithiasis; *H. pylori*; Urease Test; Gallbladder Resection; Biliary calculi; Tissue Diagnosis; Test Performance; Minimally Invasive Surgery; Microbiology

Introduction

Gallstone disease, comprising cholelithiasis and chronic cholecystitis, is among the most common disorders of the biliary system and represents a substantial global health burden [1]. Gallstone disease affects approximately one in five adults in developed nations, with the incidence continuing to rise annually at an estimated rate of 0.60-1.39% [2,3]. Population-based evidence suggests that the pooled global prevalence of gallstones is approximately 6%, increasing progressively with advancing age and demonstrating a pronounced predominance among females [4]. Although many individuals with gallstones remain asymptomatic, approximately 10% progress to symptomatic disease within 5 years of diagnosis, with this figure increasing to 20% over 20 years. Prevalence escalates steadily with age, affecting over 25% of women beyond 60 years. A substantial proportion eventually develop complications including biliary colic, acute cholecystitis, choledocholithiasis and pancreatitis, often

necessitating surgical management [5]. Cholecystectomy is therefore one of the most commonly performed abdominal operations worldwide, contributing considerably to healthcare expenditure and postoperative morbidity [6].

In India, gallstone disease constitutes an important and growing public health concern. Epidemiological studies from different regions of the country report prevalence rates ranging from 3% to 6% in the general population, with substantially higher rates observed among women, older adults and individuals with metabolic risk factors [7]. Regional variation has been documented, with northern and eastern parts of India reporting a higher burden compared to southern regions. Given the large population base, even modest prevalence translates into a substantial absolute number of affected individuals, underscoring the clinical and economic impact of the disease in the Indian setting. The pathogenesis of gallstone disease is complex and multifactorial, involving alterations in bile composition, gallbladder motility and cholesterol metabolism. Established risk factors include obesity, diabetes mellitus, dyslipidaemia, hormonal influences and genetic susceptibility. However, these factors alone do not adequately explain disease occurrence in all patients, prompting investigation into additional contributory mechanisms, including infectious aetiologies [8].

Helicobacter pylori is a gram-negative bacterium classically associated with chronic gastritis, peptic ulcer disease and gastric malignancy [9]. *H. pylori* represent the most prevalent chronic bacterial infection globally, colonizing roughly half of the world's population, with humans serving as the primary reservoir. In developing countries, acquisition typically occurs during early childhood (30-50% prevalence), with infection rates exceeding 90% in adulthoods [10,11]. In India, infection rates are particularly high, often reported in more than two-thirds of adults, reflecting early childhood acquisition and socioeconomic determinants [12]. Beyond its gastric manifestations, increasing evidence suggests that *H. pylori* and related *Helicobacter* species may colonize the biliary tract [13].

The detection of *H. pylori* DNA and organisms in bile and gallbladder tissue has led to the hypothesis that chronic bacterial colonization may contribute to gallstone formation through persistent mucosal inflammation, changes in bile composition and promotion of cholesterol crystallization [14]. However, existing literature demonstrates inconsistent findings, partly due to differences in diagnostic techniques, sample handling and study design. Moreover, data correlating preoperative gastric *H. pylori* infection with direct histopathological evidence of gallbladder involvement remain limited, particularly in the Indian population.

Against this background, the present study aims to evaluate the association between *H. pylori* infection and gallstone disease by integrating preoperative endoscopic detection using rapid urease testing with postoperative histopathological examination of resected gallbladder specimens using Giemsa staining. By correlating microbial findings with histopathological features of cholelithiasis and chronic cholecystitis, this study seeks to clarify the potential role of *H. pylori* in gallstone pathogenesis and contribute evidence relevant to both clinical practice and future preventive strategies.

Materials and Methods

Study Design

This was a prospective ambispective observational study conducted to assess the association between *Helicobacter pylori* infection and gallstone disease, particularly symptomatic cholelithiasis and chronic cholecystitis and the findings are reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Study Setting

The study was carried out at the Institute of General Surgery, Madras Medical College and Rajiv Gandhi Government General Hospital (RGGGH), Chennai, India, a tertiary care referral center.

Study Duration

The study was conducted over a six-month period, from February to August 2025.

Study Participants

The study population comprised patients aged 12-70 years diagnosed with symptomatic gallstone disease and scheduled for elective cholecystectomy. Diagnosis was confirmed by ultrasonography. Only patients who provided written informed consent were included. Patients were excluded if they had received proton pump inhibitors, antibiotics or anti-*Helicobacter pylori* therapy

within two weeks prior to evaluation, had a history of chronic alcoholism, were in an immunocompromised state, had undergone previous hepatobiliary or pancreatic surgery or had a known haemolytic disorder that could independently influence gallstone formation.

Study Procedure

Preoperative Assessment: All participants underwent detailed clinical evaluation, radiological assessment using ultrasonography and preoperative testing for *Helicobacter pylori* infection using standard diagnostic methods (Pre-operative urease test).

Operative and Postoperative Assessment

All patients underwent cholecystectomy following standard surgical protocols. Resected gallbladder specimens were subjected to histopathological examination for confirmation of chronic cholecystitis and detection of *H. pylori*.

Statistical Analysis

The primary exposure variable was the presence of *Helicobacter pylori* infection. The primary outcome variable was gallstone disease, categorized as symptomatic cholelithiasis and/or chronic cholecystitis. Secondary variables included age, sex, clinical presentation, ultrasonographic findings and histopathological features.

Data were entered into a structured proforma and analyzed using IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean \pm standard deviation or median with interquartile range, as appropriate. Associations between *H. pylori* infection and gallstone disease characteristics were evaluated using the Chi-square test or Fisher's exact test for categorical variables and Student's t-test or Mann-Whitney U test for continuous variables. A p-value <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee of Madras Medical College. Written informed consent was obtained from all participants.

Results

A total of 67 patients with symptomatic gallstone disease were included in the final analysis.

Baseline Characteristics

The demographic and anthropometric characteristics of the study population are summarized in Table 1. The highest proportion of patients belonged to the 46-60-year age group (34.3%), followed by those aged 31-45 years (26.9%). Females constituted 67.2% of the cohort. With respect to body mass index, 40.3% of patients had a normal BMI, while 25.4% were overweight and 22.4% were obese.

Family History and Comorbidities

As shown in Table 2, a family history of gallstone disease was present in 43.3% of patients. Diabetes mellitus was the most frequently observed comorbidity (44.8%), followed by hypothyroidism (34.4%) and hypertension (25.4%). Dyslipidaemia was noted in 13.4% of cases.

Helicobacter pylori Status

Preoperative rapid urease testing for *Helicobacter pylori* was positive in 37 patients (55.2%), while 30 patients (44.8%) tested negative. Postoperative histopathological examination of the resected gallbladder specimens demonstrated the presence of *H. pylori* in 35 patients (52.2%) (Table 3).

Postoperative Outcomes

Postoperative clinical outcomes are presented in Table 4. The mean duration of hospital stay was 5.76 ± 1.43 days. The mean immediate postoperative VAS pain score was 5.78 ± 2.45 , which reduced to 3.27 ± 0.82 at 30 days postoperatively. Surgical site infection occurred in 32.8% of patients and 44.8% developed peritonitis.

Diagnostic Accuracy of the Rapid Urease Test

The diagnostic performance of the preoperative rapid urease test, using postoperative histopathology as the reference standard, is shown in Table 5. The test demonstrated a sensitivity of 95% and a specificity of 83%. Receiver operating characteristic curve analysis yielded an area under the curve of 0.95, indicating excellent diagnostic accuracy.

Variable	Category	Number (%)
Age (years)	<30	12 (17.9)
	31-45	18 (26.9)
	46-60	23 (34.3)
	>60	14 (20.9)
Sex	Male	22 (32.8)
	Female	45 (67.2)
BMI	Underweight	8 (11.9)
	Normal	27 (40.3)
	Overweight	17 (25.4)
	Obese	15 (22.4)

Table 1: Demographic and anthropometric characteristics of the study population (n = 67).

Variable	Number (%)
Family history of gallstone disease	
Present	29 (43.3)
Absent	38 (56.7)
Comorbidities*	
Diabetes mellitus	30 (44.8)
Hypothyroidism	23 (34.4)
Hypertension	17 (25.4)
dyslipidaemia	9 (13.4)

table 2: family history and comorbidities (n = 67).

Test	Result	Number (%)
Preoperative Rapid Urease Test	Positive	37 (55.2)
	Negative	30 (44.8)
Postoperative Histopathology	Positive	35 (52.2)
	Negative	32 (47.8)

Table 3: *Helicobacter pylori* detection pre- and post-operatively (n = 67).

Outcome	Measure	Value
Duration of hospital stay (days)	Mean \pm SD	5.76 \pm 1.43
VAS score (immediate post-op)	Mean \pm SD	5.78 \pm 2.45
VAS score (30 days post-op)	Mean \pm SD	3.27 \pm 0.82
Surgical site infection	Yes	22 (32.8%)
	No	45 (67.2%)
Peritonitis	Present	30 (44.8%)
	Absent	37 (55.2%)

Table 4: Postoperative clinical outcomes (n = 67).

Parameter	Value
True Positives (TP)	35
False Positives (FP)	5
True Negatives (TN)	25
False Negatives (FN)	2
Sensitivity	95%
Specificity	83%
Area Under Curve (AUC)	0.95

Table 5: Diagnostic performance of preoperative rapid urease test.

Discussion

The present study evaluated the association between *Helicobacter pylori* infection and gallstone disease in patients undergoing cholecystectomy, with particular emphasis on symptomatic cholelithiasis and chronic cholecystitis. In addition, the diagnostic performance of the preoperative rapid urease test was assessed using postoperative histopathology as the reference standard. The findings of this study suggest a high prevalence of *H. pylori* infection among patients with gallstone disease and demonstrate good diagnostic accuracy of the rapid urease test in this clinical setting.

Gallstone disease in the present cohort predominantly affected middle-aged individuals, with the highest frequency observed in the 46-60-year age group. This was corroborated by the study conducted by Jagadeesh, et al., who found that Gallbladder disorders peaked in the 40-49 age group, with gallstones accounting for 69 cases (92%) [15]. This age distribution is consistent with existing literature, which reports an increasing prevalence of gallstones with advancing age. The marked female predominance observed in this study aligns with well-established epidemiological patterns and is likely attributable to hormonal factors such as oestrogen-induced cholesterol supersaturation of bile [16].

With respect to anthropometric parameters, the majority of patients had a normal or increased BMI, supporting previous evidence that overweight and obesity are important risk factors for gallstone formation. Zhen, et al., highlighted that gallstones occurred more frequently among obese individuals (OR = 2.29, 95% CI 1.98-2.65) [17]. Metabolic comorbidities, particularly diabetes mellitus and hypothyroidism, were common in the study population. Diabetes Mellitus (DM) and Hypertension (HTN) emerged as the leading comorbidities among gallstone patients, affecting 15.8% and 14% respectively [18]. These conditions have been implicated in altered lipid metabolism, gallbladder dysmotility and bile composition, thereby contributing to gallstone formation. More than half of the patients in this study tested positive for *H. pylori* infection, both on preoperative rapid urease testing and postoperative histopathological examination. This finding supports the hypothesis that *H. pylori* may play a role in the pathogenesis of gallstone disease. Several mechanisms have been proposed, including bacterial colonization of the biliary tract, induction of chronic inflammation and enzymatic activity (such as urease production) leading to changes in bile composition and stone nucleation [19]. The presence of *H. pylori* in resected gallbladder specimens further strengthens the possibility of a localized pathogenic role rather than mere coincidental gastric colonization [20]. The preoperative rapid urease test demonstrated high sensitivity (95%) and good specificity (83%) when compared with postoperative histopathology. Hibaoui, et al., found that the rapid urease test demonstrated 88.5% sensitivity, 94% negative predictive value, 84.2% specificity and 72% positive predictive value [21]. The high area under the ROC curve (AUC = 0.95) indicates excellent diagnostic performance. These findings suggest that the rapid urease test is a reliable, simple and cost-effective tool for detecting *H. pylori* infection in patients with gallstone disease and may be useful in preoperative evaluation, especially in resource-limited settings. The postoperative outcomes observed in this study were comparable to those reported in similar surgical series. The mean duration of hospital stay was approximately six days and postoperative pain scores showed a significant reduction by 30 days following surgery. Although surgical site infection and peritonitis were noted in a subset of patients, these complications fall within the expected range for cholecystectomy in patients with chronic inflammatory gallbladder disease.

The strengths of this study include its prospective ambispective design, use of both preoperative and postoperative diagnostic modalities for *H. pylori* and comprehensive clinical characterization of the study population. However, certain limitations must be acknowledged. The study was conducted at a single center with a relatively small sample size, which may limit generalizability. Additionally, the absence of a control group without gallstone disease restricts the ability to establish a causal relationship between *H. pylori* infection and gallstone formation.

The observed association between *H. pylori* infection and gallstone disease highlights the potential importance of identifying and managing *H. pylori* infection in patients with symptomatic cholelithiasis. Future multi-center studies with larger sample sizes and inclusion of appropriate control groups are warranted to further elucidate the causal relationship and to determine whether *H. pylori* eradication may influence gallstone formation or recurrence.

Conclusion

This prospective analysis of 67 patients with symptomatic cholelithiasis identifies middle-aged women with metabolic conditions such as diabetes (44.8%) and hypothyroidism (34.4%) as the primary affected group, coupled with notable familial predisposition (43.3%) and *H. pylori* involvement (52.2% via histopathology). Preoperative rapid urease testing delivered robust performance (95% sensitivity, 83% specificity, AUC 0.95) relative to tissue confirmation, advocating its adoption in gallbladder procedures to guide eradication therapy. While pain improved markedly (VAS 3.27 by 30 days post-op), elevated complication rates like peritonitis (44.8%) necessitate refined surgical care; larger trials evaluating *H. pylori* clearance for preventing relapse remain essential in endemic areas.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Data Availability Statement

Not applicable.

Ethical Statement

Ethical approval was obtained from the Institutional Ethics Committee of Madras Medical College. Written informed consent was obtained from all participants.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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