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When to wait and when to intervene: A retrospective study on predicting spontaneous clearance of common bile duct stones in ERCP candidates

Abstract

Background: While ERCP is a cornerstone in the management of choledocholithiasis, a significant proportion of common bile duct (CBD) stones may clear spontaneously, prompting the need for better risk stratification. To identify independent clinical, biochemical, and radiologic predictors of spontaneous CBD stone clearance in patients referred for ERCP.

Methods: In this retrospective study, 324 patients with suspected choledocholithiasis were evaluated. Demographics, symptoms, laboratory values, imaging findings, and ERCP outcomes were analyzed. Multivariable logistic regression was employed to identify predictors of spontaneous stone passage, defined as the absence of CBD stones during ERCP despite prior radiologic or biochemical suspicion.

Results: Spontaneous clearance occurred in 41.4% of patients. Multivariate analysis revealed that male sex (OR = 2.1; 95% CI: 1.3–3.4), CBD diameter ≥ 7 mm (OR = 2.9; 95% CI: 1.7–5.0), and normalization of liver enzymes prior to ERCP (OR = 1.8; 95% CI: 1.1–3.0) were significant independent predictors. Stone size, number, and comorbidities were not statistically significant in predicting clearance.

Conclusion: A combination of male sex, CBD dilation, and biochemical normalization strongly predicts spontaneous CBD stone clearance. Incorporating these variables into clinical decision-making may help avoid unnecessary ERCPs, reducing patient risk and enhancing procedural efficiency. Prospective validation of these predictors is warranted to develop evidence-based risk models.

Keywords: ERCP, Choledocholithiasis, Common bile duct stones, Spontaneous stone clearance, CBD dilation, Liver enzymes, MRCP, Hepatobiliary imaging.

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Common bile duct (CBD) stones are encountered in approximately 10% to 20% of patients with gallstone disease and are a major indication for endoscopic retrograde cholangiopancreatography (ERCP) (1). While ERCP is a highly effective treatment modality, it is not without risk, carrying complications such as pancreatitis, bleeding, cholangitis, and even perforation (2). However, not all detected CBD stones necessitate immediate intervention, as evidence suggests that a significant proportion can pass spontaneously through the papilla of Vater (3). The decision to intervene or wait presents a clinical conundrum, especially in patients with suspected choledocholithiasis and improving clinical status (4). Unnecessary ERCPs not only increase patient morbidity but also exert a substantial burden on healthcare systems, underscoring the importance of accurate risk stratification (5). Several studies have highlighted factors that may help predict spontaneous passage of CBD stones, including biochemical normalization, stone size, number, and anatomical findings (6).



Determining the factors associated with the development of among these, stone diameter has emerged as a particularly relevant factor, with stones less than 5 mm demonstrating higher rates of spontaneous clearance (7). In addition, rapid improvement in liver function tests particularly decreasing levels of bilirubin and alkaline phosphatase has been associated with spontaneous stone migration (8). Imaging modalities such as ultrasonography and magnetic resonance cholangiopancreatography (MRCP) have been pivotal in detecting the presence and dynamics of CBD stones (9). MRCP, in particular, provides a non-invasive and highly sensitive method for assessing residual stones or clearance after clinical improvement (10).

Despite these advances, predicting stone passage remains a challenge in routine clinical practice (11). Asymptomatic CBD stones further complicate clinical decision-making; in some cases, spontaneous passage occurs silently without overt clinical signs (12). Moreover, in selected patients with clinical improvement and negative imaging, waiting may be a safe and cost-effective alternative (13). However, delaying intervention must be approached cautiously, especially in high-risk patients or those with signs of biliary sepsis, where postponement may result in serious complications (14). Geographic and institutional variability also influence the timing and frequency of ERCP, suggesting a need for standardized decision-making protocols based on validated predictors (11).

Several guidelines exist, but heterogeneity in recommendations reflects the need for more robust, evidence-based risk models (14). Rare reports of spontaneous passage of even large or impacted stones have challenged the conventional notion that all sizable stones require extraction (15). These findings support the concept of a continuum of natural behaviors among CBD stones, further emphasizing the need for personalized care strategies (16). Thus, better understanding and validation of predictive factors could optimize patient outcomes, reduce procedure-related risks, and minimize unnecessary interventions (17).

Recent studies have also highlighted the predictive value of specific clinical and biochemical markers. A multicenter investigation identified pre-ERCP bilirubin ≤ 2 mg/dL, absence of acute cholangitis, and a largest stone diameter ≤ 5 mm as significant predictors of spontaneous CBD stone clearance, reinforcing the concept that careful patient selection may reduce unnecessary ERCP procedures (18). In this context, our study seeks to bridge the critical gap between clinical observation and procedural intervention by providing robust, evidence-based insights into predictors of

spontaneous CBD stone clearance offering a pathway toward more personalized, judicious, and safer hepatobiliary care.

Methods

Study population and eligibility criteria: This study was designed as a retrospective, cross-sectional observational study conducted at the ERCP unit of Ayatollah Rouhani Hospital, Babol University of Medical Sciences, Iran. The study population included all adult patients (≥ 18 years) referred to the ERCP unit with a clinical or radiologic suspicion of choledocholithiasis during the study period. Patients were identified from the hospital's endoscopy and inpatient databases.

The inclusion criteria were as follows: (1) referral for ERCP with suspected CBD stones based on symptoms, laboratory abnormalities, or imaging findings; and (2) availability of complete clinical and procedural data. Patients were excluded if they met any of the following criteria: (1) previous biliary-enteric anastomosis (e.g., choledochojejunostomy); (2) known hepatobiliary malignancy; (3) history of primary sclerosing cholangitis or cirrhosis; (4) indication for ERCP unrelated to choledocholithiasis (e.g., pancreaticobiliary tumor); or (5) incomplete or missing data in the medical record.

A flow diagram summarizing the patient selection process was created in accordance with the STROBE recommendations. Furthermore, this study was designed and reported in accordance with the strengthening the reporting of observational studies in epidemiology (STROBE) statement to ensure transparent and standardized reporting of observational research (19).

Data collection and variables: Patient data were retrospectively extracted by trained physicians using a predesigned, standardized case report form. The following variables were collected:

Demographic data: Age, sex: Clinical presentation: Presence of right upper quadrant pain, jaundice, fever, nausea, and history of cholecystectomy

Laboratory tests at presentation: Total and direct bilirubin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), alanine aminotransferase (ALT), white blood cell count (WBC)

Imaging findings: CBD diameter, presence of CBD stones on ultrasound, MRCP, or CT scan

Procedural outcomes: Presence or absence of CBD stones during ERCP, based on direct cholangiographic visualization.

Operational definitions: Spontaneous clearance of CBD stones was defined as the absence of stone visualization during ERCP in patients who had prior clinical or radiologic evidence suggestive of choledocholithiasis. Final confirmation was established through endoscopic cholangiography and the judgment of an experienced endoscopist. A CBD diameter ≥ 7 mm was considered dilated. Normalization of liver function tests was defined as total bilirubin <1.2 mg/dL and ALP within normal limits at the time of ERCP.

Statistical analysis: All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize patient characteristics. Continuous

variables were tested for normality using the Kolmogorov–Smirnov test and reported as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR), as appropriate. Categorical variables were expressed as frequencies and percentages.

Univariate analyses were conducted using the independent samples t-test or Mann–Whitney U test for continuous variables and chi-square or Fisher’s exact test for categorical variables. Variables with a p-value <0.20 in univariate analysis were entered into a multivariable logistic regression model using the backward likelihood ratio method. Statistical significance was set at $p < 0.05$, and adjusted odds ratios (OR) with 95% confidence intervals (CI) were reported.

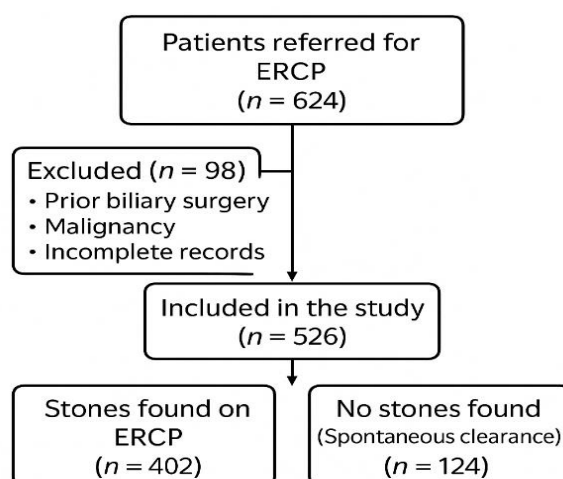


Figure 1. Flowchart illustrating participant selection and classification based on ERCP findings (edit the figure 1)

Results

Study population: Study population out of a total of 437 patients referred to the ERCP unit of Ayatollah Rouhani Hospital (Babol, Iran) between March 2019 and March 2022 for suspected choledocholithiasis, 324 patients met the predefined eligibility criteria and were included in the final analysis. The exclusion of 113 patients was due to factors such as hepatobiliary malignancies, prior biliary-enteric anastomosis, sclerosing cholangitis, liver cirrhosis, or incomplete imaging and procedural data. A detailed flowchart of the patient selection process is provided in Figure 1, following the STROBE guidelines.

Demographic and clinical characteristics: The mean age of included patients was 64.8 ± 11.2 years (range: 32 to 89 years). There was a male predominance (74.6%, $n = 242$), and most patients were symptomatic at presentation. The leading clinical symptoms were biliary colic (88.3%), jaundice (71.6%), and nausea/vomiting (64.1%). Fever was

documented in 31.1%, and 9.4% were diagnosed with acute cholangitis, based on the Tokyo Guidelines 2018 criteria, which include clinical, laboratory, and imaging indicators of infection and biliary obstruction. A history of prior cholecystectomy was found in 22.6% of patients. Among comorbid conditions, 8.3% had hypertension and 6.2% had diabetes mellitus. In terms of lifestyle factors, 48.9% were active or former smokers, 6.2% reported opioid use, and the use of ASA and NSAIDs was recorded in 9.6% and 4.9%, respectively. Baseline demographic and clinical characteristics are summarized in table 1.

Table 1. Baseline characteristics of the study population

Characteristic	Value
Age (years), mean $\pm$ SD	64.8 $\pm$ 11.2
Male sex, n (%)	242 (74.6%)
Biliary colic, n (%)	286 (88.3%)
Jaundice, n (%)	232 (71.6%)

Characteristic	Value
Nausea/Vomiting, n (%)	208 (64.1%)
Fever, n (%)	101 (31.1%)
Acute cholangitis, n (%)	30 (9.4%)
Prior cholecystectomy, n (%)	73 (22.6%)
Hypertension, n (%)	27 (8.3%)
Diabetes mellitus, n (%)	20 (6.2%)
Smoking, n (%)	159 (48.9%)
Opioid use, n (%)	20 (6.2%)
ASA use, n (%)	31 (9.6%)
NSAID use, n (%)	16 (4.9%)
Total bilirubin (mg/dL), mean±SD	5.8±2.1
ALP (IU/L), mean±SD	412±95
AST elevation, n (%)	234 (72.3%)
ALT elevation, n (%)	226 (69.8%)
CBD dilation ≥7 mm, n (%)	216 (66.7%)
Stones on US, n (%)	178 (54.9%)
Stones on MRCP, n (%)	198 (61.1%)
Stones on CT, n (%)	125 (38.7%)
CBD diameter (mm), mean±SD	8.9±1.7
Stone size (mm), mean±SD	6.2±1.3
Number of stones, median (range)	2 (1–4)

Abbreviations: ASA = Acetylsalicylic acid; NSAID = Nonsteroidal anti-inflammatory drug; ALP = Alkaline phosphatase; AST = Aspartate aminotransferase; ALT = Alanine aminotransferase; CBD = Common bile duct; US = Ultrasound; MRCP = Magnetic resonance cholangiopancreatography; CT = Computed tomography; SD = Standard deviation; IU/L = International units per liter.

Laboratory and imaging findings: At presentation, the majority of patients had elevated liver enzymes and cholestatic indices. The mean total bilirubin was 5.8±2.1 mg/dL, and the mean alkaline phosphatase (ALP) level was 412±95 IU/L. AST and ALT levels were elevated in 72.3% and 69.8% of patients, respectively, indicating varying degrees of hepatocellular injury.

Imaging assessments revealed CBD dilation (≥7 mm) in 66.7% of cases. Stones were visualized in 54.9% of patients by ultrasound, 61.1% by MRCP, and 38.7% by CT scan, where applicable. The mean CBD diameter was 8.9±1.7 mm, and the average stone size was 6.2±1.3 mm, with a median number of 2 stones per patient (range: 1–4). MRCP was the most sensitive noninvasive modality for stone detection and played a key role in pre-ERCP risk stratification.

ERCP findings and rate of spontaneous clearance: At the time of ERCP, CBD stones were extracted or visualized in 190 patients (58.6%), confirming choledocholithiasis. In contrast, 134 patients (41.4%) had no detectable stones, despite prior imaging or biochemical evidence, consistent with spontaneous stone clearance. These patients did not require any further therapeutic intervention and were observed post-procedure without complications. Detailed endoscopic findings are presented in table 2. The distribution of predictive factors associated with spontaneous clearance is illustrated in figure 1.

Table 2. Endoscopic findings during ERCP

ERCP Finding	Frequency (n)	Percentage (%)
Ampullary diverticula	43	13.3%
Ampullary prominence	9	2.8%
CBD stone visualized	190	58.6%
CBD dilation	224	69.1%
CBD stricture	7	2.2%
Passed stones (no stones seen)	134	41.4%

Abbreviations: ERCP = Endoscopic retrograde cholangiopancreatography; CBD = Common bile duct.

Associations with spontaneous stone clearance: Univariate analyses demonstrated that male sex ($p = 0.003$), CBD dilation ≥7 mm ($p < 0.001$), and normalization of liver function tests (defined as total bilirubin <1.2 mg/dL and normal ALP) prior to ERCP ($p = 0.01$) were significantly associated with spontaneous clearance. No significant associations were observed with age, stone size, and number of stones, comorbidities, or cholecystectomy status. Detailed Univariate analysis results are shown in table 3.

Multivariable analysis: A backward stepwise multivariable logistic regression was performed including variables with $p < 0.20$ from Univariate analysis. The final model identified the following as independent predictors of spontaneous CBD stone clearance. Male gender: adjusted OR = 2.1 (95% CI: 1.3–3.4; $P = 0.002$). CBD diameter ≥7 mm: adjusted OR = 2.9 (95% CI: 1.7–5.0; $p < 0.001$). Normalization of bilirubin and ALP: adjusted OR = 1.8 (95% CI: 1.1–3.0; $P = 0.025$). Multivariable logistic regression results are presented in table 4. These findings underscore the potential of combining biochemical and radiologic indicators to anticipate spontaneous stone migration, thus avoiding unnecessary invasive procedures.

Table 3. Univariate analysis of predictors of spontaneous CBD stone clearance

Variable	Spontaneous Clearance (n=134)	Stones Found (n=190)	P-value
Male sex	112 (83.6%)	130 (68.4%)	0.003
Age (years)	63.1±10.4	65.9±11.7	0.07
CBD dilation ≥7 mm	110 (82.1%)	106 (55.8%)	<0.001
Stone size <5 mm	78 (58.2%)	75 (39.5%)	0.008
Normalization of liver function tests	94 (70.1%)	72 (37.9%)	0.01
Prior cholecystectomy	29 (21.6%)	44 (23.2%)	0.74
Number of stones ≤2	101 (75.4%)	128 (67.4%)	0.12

Abbreviations: CBD = Common bile duct.

Table 4. Multivariable logistic regression for predictors of spontaneous CBD stone clearance

Variable	Adjusted OR (95% CI)	P-value
Male gender	2.1 (1.3–3.4)	0.002
CBD dilation ≥7 mm	2.9 (1.7–5.0)	<0.001
Normalization of bilirubin and ALP	1.8 (1.1–3.0)	0.025

Abbreviations: CBD = Common bile duct; OR = Odds ratio; CI = Confidence interval; ALP = Alkaline phosphatase.

Discussion

In this study, we investigated predictive factors for the spontaneous passage of common bile duct (CBD) stones in patients undergoing ERCP for suspected choledocholithiasis. Spontaneous clearance was observed in 41.4% of cases, and multivariable logistic regression identified male gender, CBD diameter ≥7 mm, and normalization of liver function tests as independent predictors. These findings have significant implications for clinical practice, particularly in avoiding unnecessary invasive procedures in selected patients.

Our findings are consistent with previous studies emphasizing that a considerable proportion of CBD stones may pass spontaneously, especially in patients without persistent cholestasis. Lefemine and Morgan (2011) observed that over 55% of patients with jaundice experienced spontaneous stone passage, negating the need for CBD exploration (16). This finding is echoed by Frossard et al. (2000), who reported similar rates of natural stone passage and highlighted the diagnostic importance of liver enzyme trends (3). Among radiologic predictors, CBD dilation has repeatedly shown strong association with stone migration. Correia et al. (2025) reported that a CBD diameter ≥7 mm was significantly associated with spontaneous clearance (5). Khoury et al. (2019) proposed a diameter-based scoring system that helped predict

likelihood of clearance in clinical settings (9). These findings are biologically plausible, given that dilated ducts may accommodate stone transit more easily.

Biochemical normalization particularly of bilirubin, ALP, and transaminases serves as a reliable indicator of resolved obstruction. Sakai et al. (2008) demonstrated that normalized liver enzymes predicted negative ERCP findings with high specificity (10). Ding et al. (2021) similarly concluded that biochemical normalization could guide clinical decisions and potentially eliminate unnecessary interventions (8). Stone size remains a debated factor. Our study did not identify it as an independent predictor in multivariable analysis, but other investigations have emphasized its role. Sanguanlohit et al. (2020) and Inoue et al. (2005) both observed that stones smaller than 5 mm had significantly higher rates of spontaneous passage (7, 1). These findings suggest that stone size, although less robust in multivariable models, may still be valuable in low-risk stratification. The utility of MRCP in noninvasive diagnosis is well documented. Elsayed and Talkhan (2024) emphasized its high sensitivity and specificity, especially when combined with biochemical markers (4). In a systematic review, Yamashita et al. (2023) also validated MRCP as a key tool in determining the necessity of ERCP, especially in asymptomatic patients or those with improving laboratory results (11). Reducing unnecessary ERCPs is not

merely a matter of cost, but a patient safety imperative. Complications such as post-ERCP pancreatitis and cholangitis are well-documented, with rates reaching up to 10% in some series. Cianci and Restini (2021) argued for individualized decision-making and selective use of endoscopy in the modern era (2). Integrating validated prediction models, such as that by İnan et al. (2024), into everyday clinical workflows may reduce iatrogenic harm and optimize outcomes (6).

Nonetheless, limitations of our study must be acknowledged. Being retrospective, it is susceptible to selection and information biases. Imaging follow-up was not uniformly available for all patients, which limits confirmation of spontaneous clearance in the absence of stone retrieval. Despite these limitations, our integration of clinical, laboratory, and imaging parameters reflects a pragmatic, real-world approach to predicting CBD stone behavior (20). Taken together, these insights affirm the growing shift toward precision-guided hepatobiliary care. By synthesizing anatomical, biochemical, and radiologic parameters, clinicians can adopt more selective, patient-centered strategies that balance diagnostic accuracy with procedural safety care in patients with suspected choledocholithiasis.

Male sex, CBD dilation ≥ 7 mm, and normalization of liver enzymes emerged as robust, independent predictors of spontaneous CBD stone clearance. These variables, reflective of both anatomic and functional resolution of biliary obstruction, offer a clinically actionable framework for noninvasive risk stratification. Their integration into decision-making algorithms could reduce the burden of unnecessary ERCPs thereby minimizing patient morbidity, optimizing procedural utilization, and enhancing the overall quality of care. Given the widespread use of ERCP and the growing emphasis on precision medicine, developing and externally validating predictive models based on these factors is a critical next step. Future multicenter, prospective trials with standardized biochemical and imaging follow-up will be essential to confirm these findings and guide the adoption of evidence-based protocols in the management of suspected choledocholithiasis.

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Conflict of interests: The authors declare that they have no conflicts of interest.

Ethics approval: The study protocol was reviewed and approved by the Ethics Committee of Babol University of Medical Sciences (approval code: IR.MUBABOL.REC.1401.095). All procedures were conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments. Patient anonymity and data confidentiality were strictly maintained throughout the study, and the requirement for informed consent was waived due to the retrospective design of the research.

Authors' contribution: M.T.H.: Data creation, Supervision, Writing-review & editing. J. Sh.: Conceptualization, Data creation, Supervision, Writing-original draft. M.R.: Data collection, Investigation, Writing-original draft. A. B.: data analysis and interpretation. S.H.A.V.: Data creation, Supervision, Writing-review & editing. All authors have read and approved the final manuscript.

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