

# A scoring system for the prediction of choledocholithiasis: a prospective cohort study

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**BACKGROUND:** Techniques for diagnosing choledocholithiasis pose significant morbidity and mortality risks.

**OBJECTIVES:** We aimed to develop and validate a clinical scoring system for predicting choledocholithiasis.

**DESIGN:** Data from a prospectively maintained database of all patients with gallstones.

**SETTING:** Patients were admitted to the general surgery department of a military hospital.

**PATIENTS AND METHODS:** We enrolled consecutive patients with symptomatic gallstones, biliary pancreatitis, obstructive jaundice, or cholangitis, who subsequently underwent biochemical testing and ultrasonography. A predictive model was developed from a scoring system using their imaging and laboratory data. Endoscopic retrograde cholangiopancreatography (ERCP) or intraoperative cholangiography were used for confirmatory diagnoses. The predictive efficacy of the scoring system was validated using a retrospective cohort of 272 patients.

**MAIN OUTCOME MEASURES:** Predictive accuracy of the scoring system.

**RESULTS:** We enrolled 155 patients in the development group. The common bile duct diameter, alkaline phosphatase of  $\geq 200$  IU, elevated bilirubin levels, alanine transaminase of  $\geq 220$  IU, and male age of  $\geq 50$  years were significantly associated with choledocholithiasis and were included in the scoring system. Ninety-six patients (35%) had scores of  $\geq 8$  (high risk), 86 patients (32%) had scores of 4–7 (intermediate risk), and 27 patients (10%) had scores of 1–3 (low risk). In the validation cohort, the positive predictive value for a score of  $\geq 8$  was 91.7%, and the scoring system had an area under the curve of 0.896.

**CONCLUSION:** Scores of  $\geq 8$  were strongly correlated with choledocholithiasis in the developmental and validation groups, which indicates that our scoring system may be useful for predicting the need for therapeutic ERCP. However, prospective validation in a large multicenter cohort is needed to fully understand the benefits of the system.

**LIMITATIONS:** The retrospective validation cohort might have introduced selection and observational biases. The study may have been underpowered because of the sample size of the developmental cohort. The delay between admission and the time of ERCP theoretically may have increased the number of negative ERCP results, but our false negative rate for ERCP was consistent with the previously reported rates.

Gallstone disease is among the most prevalent disorders affecting the biliary system. The overall prevalence of gallstone disease in Saudi Arabia is approximately 12%, although in high-altitude regions of the country, such as Taif, the prevalence is even higher (15–20%).<sup>1-6</sup> The relatively high prevalence of this condition can also lead to a higher

incidence of common bile duct (CBD) stones.<sup>1,2</sup> The symptoms of choledocholithiasis vary greatly. Patients frequently present with conditions that range from obstructive jaundice to life-threatening conditions, such as ascending cholangitis and pancreatitis. Furthermore, 10% of patients with choledocholithiasis also develop pancreaticobiliary malignancies.<sup>7</sup> Therefore, a method

of accurately predicting choledocholithiasis in the pre-operative setting (among patients who are undergoing definitive procedures for gallstone removal) would be useful in preventing the complications that are associated with choledocholithiasis.<sup>8</sup>

Patients with gallstones typically undergo a preoperative evaluation of clinical data and liver function. In addition, imaging techniques (magnetic resonance cholangiopancreatography [MRCP], endoscopic ultrasound [EUS], and endoscopic retrograde cholangiopancreatography [ERCP]) are often used to investigate choledocholithiasis.<sup>9-15</sup> However, these imaging techniques are complicated, are associated with risks of morbidity and mortality, lead to operative delays, are expensive, and have accessibility-related challenges.<sup>11</sup> For example, ERCP is known to increase the patient's risk of morbidity and mortality.<sup>9</sup> The use of MRCP is often limited by its high cost and long waiting lists, and EUS is an invasive technique.<sup>12,16</sup> Intraoperative cholangiography (IOC) is a relatively simple test, although it is also associated with an increased operative time and risk of morbidity.<sup>1,6,11-15</sup> Unfortunately, there are currently no blood tests that can accurately detect choledocholithiasis among patients with gallstones, although a limited number of predictive systems have been proposed in the literature.<sup>4,5,9,15</sup> For example, Jovanovic et al assessed the need for therapeutic ERCP using biochemical and ultrasonography findings,<sup>4</sup> but the predictive accuracy of these models remains far from satisfactory.<sup>13,14</sup> In this study, we aimed to develop a scoring system for the prediction of choledocholithiasis, by using patients' biochemical profiles and ultrasonography findings. We used a second cohort of patients with gallstones to validate the clinical relevance of this scoring system.

**PATIENTS AND METHODS**

We evaluated data from a prospectively maintained database of all patients with gallstones who were admitted to the General Surgery Department at the Al-Hada Armed Forces Hospital. In the first stage of this study, we prospectively collected demographic, liver function,

and ultrasonography data for a cohort of 155 patients (43% men and 57% women, mean age: 49 years) over a 1-year period (October 2012 to September 2013), and used these data to develop a choledocholithiasis prediction model. In the second stage, the predictive scoring from this model was validated in a retrospective cohort of 344 patients who were admitted between October 2010 and September 2012 (44% men and 56% women, mean age: 51 years). Ethical approval for this study was obtained from our institutional ethics committee (PTRC #: 12-08-117 E).

Patients were selected for the developmental and validation cohorts according to strict inclusion and exclusion criteria. The inclusion criteria were: ≥18 years old, an American Society of Anesthesiologist (ASA) score of <4, and the presence of symptomatic gallstones, biliary pancreatitis, obstructive jaundice, or cholangitis. The exclusion criteria were absence of CBD imaging during IOC or ERCP, evidence of malignancy, being unfit for ERCP under general anesthesia, or jaundice that was secondary to non-CBD causes (**Table 1**). According to our hospital's protocol, all patients with uncomplicated symptomatic gallstones (pure biliary colic) were offered laparoscopic cholecystectomy. On-table IOC was performed among select patients who were undergoing definitive procedures (at the attending physician's or consultant's discretion) via the trans-cystic approach. Patients with obstructive jaundice were initially evaluated using ultrasonography, as well as MRCP if the ultrasonography findings were ambiguous. If choledocholithiasis or a dilated CBD (>10 mm, in the absence of stone visualization) was identified, the patient was asked to undergo ERCP before definitive gall bladder surgery was offered.

For the predictive stage of the study, a *P* value of <.05 was considered statistically significant, and an a priori calculation indicated that a sample of 155 patients was required to achieve 80% power. For the validation stage, a sample size of 250 was selected to provide 90% power for detecting a *P* value of <.05. All analyses were performed using SPSS software (version 20; SPSS Inc., Chicago, IL). Categorical variables were analyzed using the chi-square test and continuous variables were analyzed using the paired *t* test. The relationship between the presence of CBD stones and each variable was evaluated using univariate and multivariate analyses. All variables were evaluated in a univariate intent-to-treat analysis. A receiver operator characteristics (ROC) curve was created, and the positive predictive value (PPV) and predictive accuracy were calculated. Predictive accuracy was defined as the percentage of correct predictions: [(Number of patients who were predicted to have cho-

**Table 1.** Patient selection criteria.

Inclusion criteria	Exclusion criteria
Adult patients (>18 years old) ASA score of <4 Admitted patients with symptomatic gall bladder stones	No CBD imaging Evidence of malignancy Patient unfit for ERCP Jaundice secondary to other causes Severe acute pancreatitis Cholangitis

ASA: American Society of Anesthesiologists, CBD: common bile duct, ERCP: endoscopic retrograde cholangiopancreatography

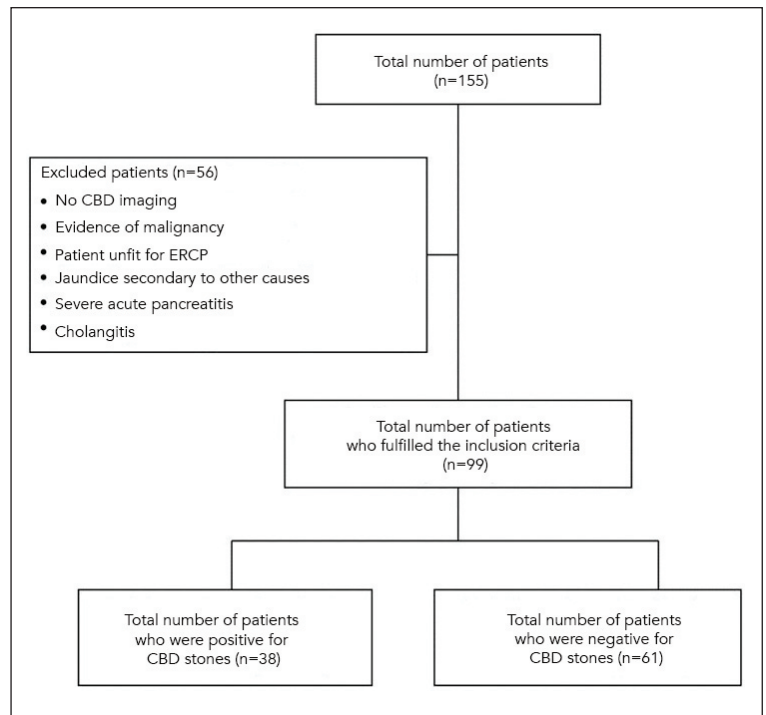
ledocholithiasis by a variable) / (Number of patients with a confirmed diagnosis of choledocholithiasis)] × 100.

## RESULTS

Among the 155 patients selected for the predictive stage of this study, only 99 patients were included in the development stage, based on our inclusion and exclusion criteria (**Figure 1**). Among the 99 included patients, 38.3% (38/99) had choledocholithiasis and 61.6% (61/99) were negative for gallstones.

### Developing the scoring system

The parameters that exhibited significance in the multivariate analysis were subsequently included in the scoring system, and a weighted score was assigned to the different variables based on their prediction accuracy (in this study) and their reported significance in the existing literature.<sup>9-16</sup> The presence of a CBD acoustic shadow during ultrasonography, a CBD diameter of >10 mm, alkaline phosphatase levels of ≥200 IU, alanine transaminase levels of ≥220 IU, elevated serum bilirubin levels, and a male age of ≥50 years were significantly correlated with the presence of choledocholithiasis. Subgroup analyses of each predictive variable revealed a 94.7% PPV for a positive acoustic shadow, an 80% PPV for a CBD diameter of >10 mm, a 75% PPV for alkaline phosphatase levels of ≥200 IU, a 71% PPV for alanine transaminase levels of ≥220 IU, a 69% PPV for elevated serum total bilirubin levels, and a 75% PPV for male age of ≥50 years. Based on the predictive accuracy for each variable (**Table 2**), a single-digit weighted score was assigned to each variable to develop the prediction model (**Table 3**). Based on the prediction model, we chose a patient management algorithm (**Figure 2**), in which the confirmatory diagnosis is made using ERCP or IOC. To sequentially exclude the possibility of CBD stones, all patients underwent IOC, ERCP, or MRCP, and these decisions were made based on the patients' risks of morbidity, and the techniques' sensitivity and specificity. Patients with a low score (1–3) underwent ERCP only if their IOC findings were positive, patients with a score of 4–7 underwent MRCP and only MRCP-positive patients subsequently underwent ERCP. All patients with a score of ≥8 underwent ERCP. Seven patients with a normal CBD via ultrasonography were subsequently found to have CBD stones via MRCP, and 16 patients with a dilated CBD via ultrasonography had normal MRCP findings. Fourteen patients with a normal CBD via ultrasonography were subsequently found to have CBD stones via ERCP/IOC, and 47 patients with a dilated CBD via ultrasonography had normal ERCP/IOC findings.



**Figure 1.** The flow chart for the developmental cohort. Among the 155 patients who were enrolled, 99 were included and 56 were excluded. Among the 99 included patients, 38 were positive for common bile duct (CBD) stones and 61 were negative for CBD stones. ERCP: endoscopic retrograde cholangiopancreatography.

**Table 2.** The predictive accuracy of different variables in the scoring system.

Variable	Predictive accuracy (%) <sup>a</sup>
CBD acoustic shadow during ultrasonography	94.3
CBD diameter of >10 mm	93.3
CBD diameter of 7–10 mm	84
Alkaline phosphate levels of >200 IU	69.7
Alanine transaminase levels of >220 IU	62
Abnormal bilirubin levels	63
Male age of >50 years	58.1

<sup>a</sup>Predictive accuracy = [(Number of patients who are predicted to have choledocholithiasis by a variable) / (Number of patients with a confirmed diagnosis of choledocholithiasis)] × 100.

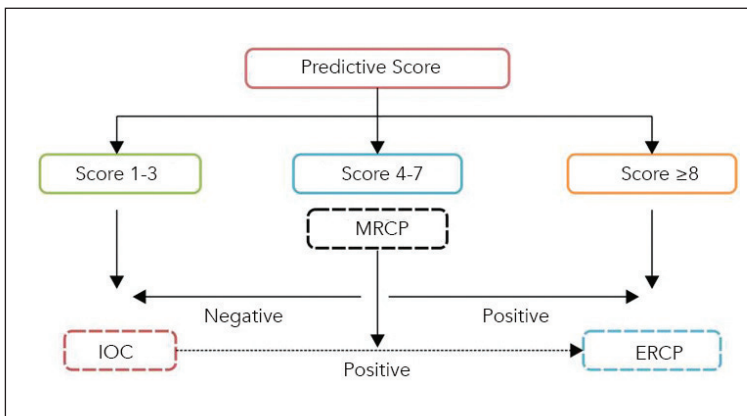
### Validating the scoring system

We validated the predictive model by retrospectively analyzing data from a similar, although unique, cohort of 344 patients. Among these patients, 272 patients fulfilled the inclusion criteria (**Figure 3**). In this cohort, the PPV values for CBD diameters of <7 mm, 7–10 mm, and >10 mm were 28%, 84.3%, and 93%, respectively. The PPV for alkaline phosphatase levels of ≥200 IU

**Table 3.** The predictor variables and their assigned scores.

Predictor variable	Score
CBD stone during ultrasonography	7
CBD severe dilatation (>10 mm)	6
CBD mild dilatation (7–10 mm)	4
Alkaline phosphatase levels of >200 IU	3
Abnormal bilirubin levels	2
Alanine transaminase levels of >220 IU	1
Male age of >50 years	1

A single digit score was assigned to each predictor variable, based on the predictive accuracy of that variable. CBD: common bile duct.



**Figure 2.** The predictive scoring model. The predictive model was developed using ultrasound scanning for common bile duct (CBD) stone grading and liver function parameters. A score of 1–3 is classified as a low probability of CBD stones and intraoperative cholangiography (IOC) is recommended to rule out choledocholithiasis. A score of 4–7 is classified as an intermediate risk of CBD stones and magnetic resonance cholangiopancreatography (MRCP) is recommended for further evaluation. If CBD stones are detected via MRCP, patients should undergo endoscopic retrograde cholangiopancreatography (ERCP) before definitive surgery. If the MRCP findings are negative, IOC is recommended. A score of ≥8 is highly predictive of CBD stones and patients should undergo ERCP before definitive surgery.

was 69.7%, the PPV for alanine transaminase levels of ≥220 IU was 62.2%, the PPV for serum total bilirubin was 63.5%, and the PPV for male age of ≥50 years was 58.1%.

The scoring system was highly accurate for predicting the presence of choledocholithiasis at higher scores, with a predictive accuracy of 91.7% for CBD stones in patients with scores of ≥8 points, a predictive accuracy of 43.5% in patients with scores of 4–7, and a predictive accuracy of 22% for patients with scores of 1–3 (Table 4). Scores of ≥8 provided a specificity of 95.8% (95% confidence interval [CI]: 89.7–97.7%) and a PPV of 91.7% (95% CI: 84.2–99%). The area under

the ROC curve was 0.896 (95% CI: 0.829–0.963,  $P < .05$ ) (Figure 4).

## DISCUSSION

The limited availability of ERCP, EUS, and MRCP in Saudi Arabia, along with the associated costs and risk of morbidity, highlight the importance of developing simple and effective systems for predicting a diagnosis of choledocholithiasis. Several studies have evaluated the predictive power of biochemical and imaging parameters and their combinations,<sup>13–16</sup> although there is still no validated scoring system.<sup>17,18</sup> In the present study, we developed and validated a scoring system that uses simple laboratory and imaging parameters, and recommend a systematic approach that uses ERCP only when it is essential.

Among patients with symptomatic gallstones, approximately 10–15% of patients also present with choledocholithiasis.<sup>19</sup> The majority of patients who have CBD stones with a diameter of <5 mm remain asymptomatic, although larger or multiple CBD stones can present with symptoms of painful obstructive jaundice, acute cholangitis, and/or acute pancreatitis.<sup>7</sup> Therefore, it is essential to detect synchronous choledocholithiasis in patients with symptomatic gallstones, in order to avoid these complications.<sup>20</sup> Interestingly, choledocholithiasis is often suspected in patients who present with high levels of serum bilirubin and alkaline phosphatase,<sup>21–23</sup> and visual confirmation is typically obtained using first-line ultrasonography. Unfortunately, although ultrasonography is highly sensitive for choledocholithiasis, it also has a low specificity.<sup>21</sup> In contrast, ERCP is considered highly sensitive and specific, while EUS and MRCP are used on a case-by-case basis, depending on the clinician's judgment.<sup>11,16,24–27</sup> MRCP is generally considered the first choice, because it is less invasive than EUS; however, ERCP is highly recommended if the risk of choledocholithiasis is high.<sup>14,19,20</sup>

Interestingly, the sensitivity of ultrasonography increases when liver function tests indicate an obstructive pattern.<sup>9,29</sup> Similarly, levels of alanine transaminase also have a strong predictive value, although their significance has only been evaluated in a few studies.<sup>8</sup> In contrast, elevated serum bilirubin has been strongly linked to the presence of choledocholithiasis.<sup>3</sup> Furthermore, the standards of the Practice Committee of the American Society of Gastroenterology recommend that ERCP should be considered in patients with serum bilirubin levels of >4 mg/dL.<sup>24</sup> However, our results indicate that an isolated increase in serum bilirubin is a poor predictor of choledocholithiasis (Table 3), as this discrepancy may be related to local environmental

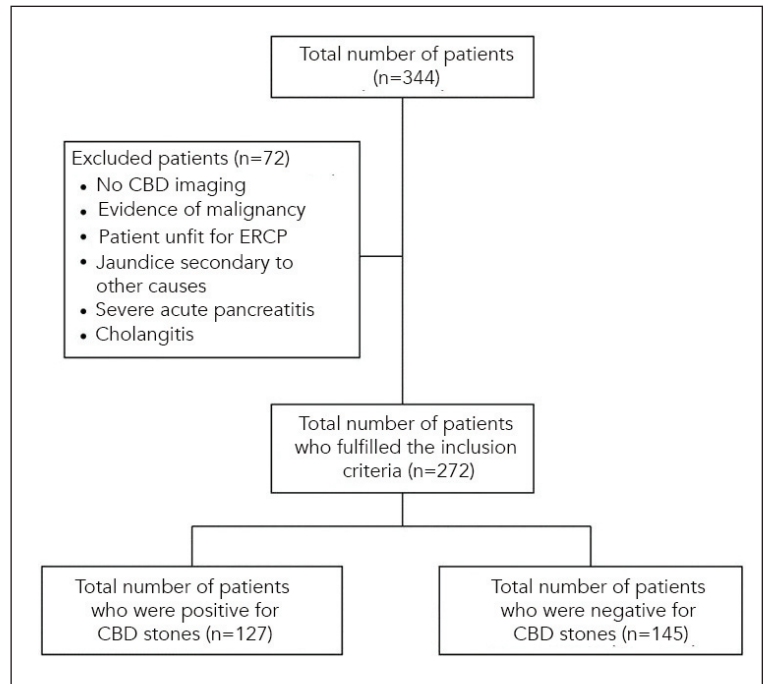
factors or local cultural idiosyncrasies.<sup>7,9,30</sup> Interestingly, our results indicate that CBD size was highly predictive of choledocholithiasis, with the predictive accuracy decreasing with decreasing CBD diameters. It should also be noted that CBD grading according to ultrasonography findings has not been explored as a predictor of choledocholithiasis in prospective studies. Although previous studies have proposed various predictive models (using parameters such as liver function or CBD diameter), none of these models have been validated.<sup>5,19,31-33</sup> Therefore, we developed a novel predictive model (using ultrasonography results, CBD diameter, liver function, sex, and age), and performed a retrospective validation of the model to assess its clinical relevance. Our results indicate that the model has a high predictive accuracy, with a low false negative rate. As this scoring system has a high negative predictive accuracy, it may help physicians avoid unnecessarily referring patients for MRCP/EUS/ERCP, and may help alleviate the related burden on the Saudi healthcare system. In addition, subgroup analyses indicated that 61.7% of the patients with abnormal liver function had symptomatic gallstones, which is much higher than the previously reported incidence of 15%.<sup>34</sup> However, these findings may be highly population-specific, and we believe that the patient population constitutes an integral part of our predictive model. Furthermore, this model is not perfect, as choledocholithiasis was incidentally detected in 1.6% of patients with a score of zero in the model.

This study has several limitations. First, the use of a retrospective validation cohort might have introduced selection and observational biases, although the effects of any design biases may be limited, as all patients who presented within the study period were included. Furthermore, there was only one year between the evaluation periods for the validation and development cohorts, which should minimize the possibility of any

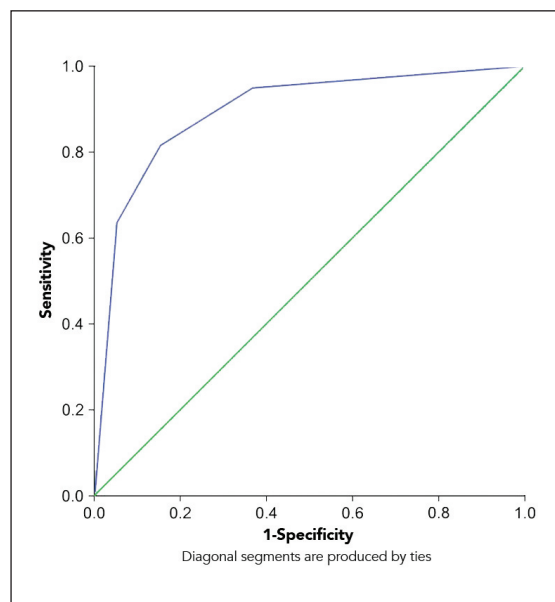
**Table 4.** The correlation between the predictive score and the presence of choledocholithiasis.

Score	Positive CBD stone* n (%)	Negative CBD stone** n (%)
>8	88 (91.7%)	8 (8.3%)
4-7	27 (43.5%)	35 (56.5%)
1-3	11 (22%)	39 (78%)
0	1 (1.6%)	63 (98.4%)

\*Positive CBD stone (n) represents number of confirmed positive diagnosis of CBD stone\*\* Negative CBD stone (n) represents number of confirmed negative diagnosis of CBD stone.



**Figure 3.** The flow chart for the validation group. Among the 344 patients who were enrolled, 272 were included and 72 were excluded. Among the 272 included patients, 127 were positive for common bile duct (CBD) stones and 145 were negative for CBD stones. ERCP: endoscopic retrograde cholangiopancreatography.



**Figure 4.** Receiver operating characteristics curve for the scoring system's accuracy in predicting the presence of choledocholithiasis in the validation cohort.

demographic and technological variations. Second, although 155 patients were indicated by the power calculation for the development cohort, our analysis only included 99 patients, and the development cohort's results are not indicative of 80% power. However, we increased the power to 90% for the retrospective validation, and observed similar results. Third, we observed a delay in the time between the patient's admission and the time of ERCP, and these delays may theoretically increase the possibility that CBD stones were passed before ERCP, and thereby increase the number of negative ERCP results. However, our false negative rate for ERCP (8%) was consistent with the previously reported rates.<sup>35</sup> Therefore, we believe that the delay did not significantly affect our results. Nevertheless, further large-scale prospective multicenter studies are needed to fully validate this scoring system.

In conclusion, our study developed a novel scoring

system to predict the presence of choledocholithiasis using non-invasive tools. The scoring system was validated in a retrospective cohort, and we confirmed that this system was highly accurate in predicting the presence of choledocholithiasis among patients with symptomatic gallstones. Therefore, we believe that this tool may be useful to guide the appropriate management of these patients, and decrease the need for more invasive imaging procedures, such as MRCP and ERCP. However, further large-scale prospective multicenter studies are needed to fully validate the usefulness of this scoring system.

### **Conflict of interest**

*None.*

### **Funding**

*None.*



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