

# Prediction of Common Bile Duct Stones Prior to Cholecystectomy

## A Prospective Validation of a Discriminant Analysis Function

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**Background:** Selection routines for preoperative endoscopic retrograde cholangiopancreatography (ERCP) in patients with symptomatic gallstone disease should give a low frequency of both false-negative ERCP results and residual common bile duct stones (CBDS).

**Objective:** To validate a discriminant function (DF) based on retrospectively collected data, for characterization of patients with symptomatic gallstone disease as regards presence of CBDS, and to compare clinical, ultrasonographic, and DF characterization.

**Design:** Prospective registration of CBDS criteria in consecutive patients with symptomatic gallstone disease.

**Setting:** A department of surgical gastroenterology in a Norwegian central hospital.

**Patients:** One hundred ninety-two patients with gallbladder stones.

**Intervention:** Laparoscopic cholecystectomy or ERCP with or without endoscopic sphincterotomy.

**Main Outcome Measurements:** Sensitivity and speci-

ficity of the clinical, ultrasonographic, and DF characterizations, and test of the validity of the DF.

**Results:** Thirty-two patients had CBDS. The clinical criteria of CBDS were present in 152 patients (79.2%): 21.1% of these patients had CBDS and there were no false-negative results (sensitivity, 100%; specificity, 25%). The risk of CBDS in patients with normal bile ducts at ultrasonographic examination was 8 of 124, and in patients with dilated ducts or suspected CBDS, 17 of 47 (sensitivity, 68%; specificity, 80%). The DF was positive in 50 patients (26%): 60% of these had CBDS, and there were 2 false-negative results (sensitivity, 94%; specificity, 88%). A discriminant analysis of the prospectively registered data selected the same set of CBDS criteria, and a new DF did not alter the characterization of any patient.

**Conclusions:** Clinical characterization had a higher sensitivity for CBDS detection than ultrasonography alone, but a lower specificity. The DF analysis was both more sensitive and specific than ultrasonography, and seemed efficient in selecting symptomatic gallstone patients for ERCP. It was reproducible and simple to use.

*Arch Surg.* 1998;133:162-166

**A**BOUT 10% to 20% of patients presenting with symptomatic gallstone disease have common bile duct stones (CBDS).<sup>1-5</sup> The symptoms of CBDS may be difficult to distinguish from those of gallbladder stones.<sup>1</sup>

The clinical implications of residual stones are debatable<sup>1,6,7</sup> but may be serious,<sup>6-8</sup> and detection of CBDS is therefore important in cholecystectomy patients. Laparoscopic CBDS removal is not feasible in many centers. Furthermore, 85% of patients, in whom an endoscopic sphincterotomy (EST) has been performed, will not need a cholecystectomy.<sup>9</sup> Thus, preoperative detection of CBDS is justified.

In a previous study,<sup>6</sup> a discriminant function (DF)

$$y = -7.58525 + 0.06617 \times \text{Age} + 0.0260967 \times \text{Bilirubin Level} + 0.00832 \times \text{Alanine Aminotransferase Level} + 0.0088144 \times \gamma\text{-Glutamyltransferase Level}^*$$

to select patients for preoperative ERCP was shown to reduce the rate of unneces-

\*A negative y value indicates a low risk of common bile duct stones. Age was measured in years, bilirubin level in micromoles per liter, and alanine aminotransferase and  $\gamma$ -glutamyltransferase levels in units per liter.

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## PATIENTS AND METHODS

From October 1993 to August 1994, 192 patients with gallbladder stones were included in the study. There were 140 women and 52 men, with a mean age of 52.8 years (range, 9-99 years). Patients who had a previous EST, chronic or acute hepatitis, inflammatory bowel disease, or a history of alcohol abuse were excluded.

The CBDS parameters (liver function test results and previous or current clinical or ultrasonographic signs of biliary obstruction)<sup>6</sup> were recorded for all the patients. Blood samples were obtained no more than 2 weeks before surgery or endoscopy; this was also the maximum interval for ultrasonography. The presence of 1 or more positive clinical criteria was defined as a positive clinical characterization. A diameter larger than 6 mm or suspected CBDS was considered a positive ultrasonographic indication. The DF characterization included the most recent liver function test results. A positive value indicated CBDS.<sup>6</sup> Patients with gallstone pancreatitis underwent ERCP independently of their DF value.

The measurement of the bile duct diameter was performed during routine ultrasonography and the part of the measured bile duct was not specified. During ERCP the diameters of the hepatic duct, the bile duct at the cysticohepatic confluence, and the CBD were measured, using the diameter of the endoscope as a reference.

The patients who underwent cholecystectomy had primary follow-up by a telephone interview after 1 month, followed by a written questionnaire after 1 year. The slightest symptoms of residual stones were used as indications for examination at the outpatient clinic with liver function tests and ultrasonography. If stones could not be ruled out, ERCP was performed.

The definite CBDS classification of the patients was based on ERCP or a postoperative follow-up period of at least 1 year without indication of residual stones.

Continuously distributed variables and factors were expressed by mean values with SDs and categorized variables in contingency tables. Univariate comparisons between groups were carried out by using 2-tailed tests with a significance level of 5%. A 1-way analysis of variance (ANOVA) model was used for analysis of the assumed continuously distributed variables, and categorical variables were analyzed with the Fisher exact test and paired binomial test.<sup>12</sup> The Pearson correlation coefficient was also used.<sup>12</sup>

To characterize patients with gallstone disease, the Fisher linear discriminant model<sup>13</sup> was used. The discriminant analysis procedure<sup>14</sup> has been described previously.<sup>6</sup>

sary ERCP without an increase in the number of missed CBDS as compared with selection by clinical criteria.<sup>6,10,11</sup> The DF was based on a discriminant analysis of retrospectively collected CBDS criteria.<sup>6</sup> The discriminant analysis selected the combination of the age of the patient and the levels of serum bilirubin, alanine aminotransferase, and  $\gamma$ -glutamyltransferase as the best criteria to predict the risk of CBDS.

The aim of our study was to prospectively compare the sensitivity and specificity of the clinical and ultrasonographic characterizations with the DF characterization for the presence of CBDS in patients with symptomatic gallstone disease. We also wanted to validate the DF.

## RESULTS

Seventy-two patients had ERCP as the primary procedure. Fifty-seven of them had either a positive DF value ( $n=35$ ), a positive DF value and pancreatitis ( $n=16$ ), or a negative DF value and pancreatitis ( $n=6$ ). Forty-four (79%) of these patients were treated with EST, 30 because of CBDS and 14 prophylactically. Fifteen patients had a negative DF value and no pancreatitis; none of them had CBDS.

One hundred thirty-seven patients underwent surgery with laparoscopic cholecystectomy and no preoperative ERCP ( $n=120$ ) or after a negative ERCP ( $n=17$ ). One patient underwent intraoperative cholangiography, and 3 had early postoperative ERCP. One of them, with an unrecognized positive DF value, had a residual stone, as did 1 of 2 others with a negative DF value. One patient died of myocardial infarction postoperatively; autopsy results revealed no CBDS.

There were no dropouts in the follow-up program. At the primary follow-up ( $n=132$ ), 4 to 12 weeks postoperatively, 27 patients were examined in the outpatient department and 7 of them had an ERCP examination; the results were negative for all. At the second follow-up ( $n=125$ ), 11 to 32 months (mean, 17.5 months) postoperatively, 1 patient had had symptoms that suggested the spontaneous passage of a stone 2 months postoperatively. Twenty-five patients were examined at the outpatient department and 7 of them underwent ERCP: 6 had normal results and in 1 patient the ERCP results were uncertain and an EST was done, but no stone was found. Thus, no late residual stones were found.

According to our definitions, 32 of 192 patients had CBDS. The mean age of the patients with CBDS was 61.5 years (range, 22-99 years), while the mean age of the patients without CBDS was 50.8 years (range, 9-87 years) ( $P=.02$ ).

The interval between blood sampling and surgery or ERCP was 1.7 days (range, 0-14 days, SD, 2.13). Four patients with positive DF values were, for various reasons, observed for 5 to 15 days. Blood sampling and DF analysis immediately before ERCP revealed a negative DF value, and ERCP was negative in all these patients.

Ultrasonographic evaluation of the bile ducts was successful in 171 patients (95.5%); 25 had CBDS. In patients with CBDS, the mean diameter of the duct was 8.4 mm (range, 3-18 mm; SD, 3.72); in patients without CBDS it was 4.8 mm (range, 1-12 mm; SD, 2.02) ( $P<.001$ ). The frequency of CBDS was strongly correlated with the diameter of the duct. In 3 patients, CBDS were correctly diagnosed by ultrasonography, and 2 of the 3 with suspected CBDS proved to have CBDS.

Two patients with CBDS had a negative DF value. In 1 patient with gallstone pancreatitis, the diameter of the bile duct was 4 mm as measured by ultrasonography. In the other patient with an otherwise negative clinical

cal characterization, bile duct diameter by ultrasonography was 9 mm.

At univariate analysis of the clinical variables, only actual jaundice, the findings of dark urine or light stools, and abnormal results of biochemical tests differed significantly ( $P < .01$ ) between patients with and without CBDS.

Clinical characterization was positive in 152 patients (79.2%), but only 32 of them had CBDS (**Table 1**). None were false-negative results (sensitivity, 100%; specificity, 25%).

Ultrasonography was correct in 93.6% of the patients with a bile duct diameter of 6 mm or less, and 35% of the patients with a diameter larger than 6 mm had CBDS. The sensitivity of ultrasonography was 68% and the specificity was 79.5%.

The DF value was positive in 50 patients (26%); 30 (60%) of these had CBDS. Two were false-negative results (sensitivity, 93.8%) and there were 20 false-positive results (specificity, 87.5%).

In 52 patients, both ERCP and ultrasonography had been done within a mean period of 2.7 days (SD, 4.1 days). In many of the patients, the bile duct diameter measured at ultrasonography differed substantially from the diameter measured at ERCP (**Table 2**). The correlation between measurements at ultrasonography and ERCP was significant ( $P < .001$ ), but the correlation coefficient was only 0.52. With ERCP as the standard, the sensitivity of detection of bile duct dilation by ultrasonography was 71% and the specificity was 57%.

The discriminant analysis of the CBDS indicators in the present series selected the same combination as in

the previous series.<sup>6</sup> The previous DF formula based on these prospective data ( $y = -3.40801 + 0.02666 \times \text{age} + 0.02949 \times \text{bilirubin level} + 0.00693 \times \text{alanine aminotransferase level} + 0.00245 \times \gamma\text{-glutamyltransferase level}$ ) did not change the CBDS characterization in any patient in the prospective series. However, applied to the retrospective series<sup>6</sup> it was more sensitive than the retrospectively based formula, detecting 1 more patient with CBDS (10 vs 11 false-negative characterizations; sensitivity, 95.6% vs 95.2%), and also less specific, with 8 more false-positive results (30 vs 22; specificity, 91.9% vs 94.1%). The new formula produced a  $y$  value slightly shifted in the positive direction compared with the retrospectively based formula. The probability of CBDS related to the various  $y$  values was identical in both series.<sup>6</sup>

If strict selection criteria according to the DF had been followed in all the patients, 8 (5.8%) would have had preoperative ERCP results that were negative for CBDS.

#### COMMENT

The frequency of unsuspected CBDS is reported to be 0% to 3.4%,<sup>1,6,10,15</sup> and a routine stone detection procedure does not seem necessary.<sup>4,15,16</sup> On the other hand, only half of the patients with positive clinical criteria<sup>6,15</sup> (in the present study, 1 of 5) have CBDS, and it is important to identify the group of patients in whom the yield of a detection procedure is sufficient to warrant it. Relevant diagnostic criteria are debated in the literature, without general agreement.<sup>2,3,5,17-22</sup>

The DF<sup>6</sup> is an alternate method to ensure a clinically acceptable detection rate and a low rate of unnecessary ERCP. The reduced frequency of ERCP outweighs the risks related to the slight increase in residual stones. The DF program is computerized and is simple to use, as it only requires entering the values of 4 parameters.

The variables we selected for the DF function do not differ much from other studies,<sup>18,20,23,24</sup> although alkaline phosphatase levels were not included.<sup>5,17</sup> The use of a combination of CBDS indicators is well recognized. The discriminant analysis by Taylor et al<sup>19</sup> selected the combination of intraoperatively measured bile duct diameter and number of gallbladder stones greater than 10, with an accuracy of 92.5% and false-negative results in fewer than 1% of patients. Onken et al<sup>25</sup> selected the patient age, alkaline phosphatase level, bilirubin level, aspartate aminotransferase level, and CBD diameter by a logistic regression technique and made a diagram from which the probability of CBDS could be read directly. The logistic regression analysis of Houdart et al<sup>4</sup> selected no

**Table 1. Comparison Between Clinical, Ultrasonographic, and Discriminant Function Characterization in Patients With Gallstone Disease Related to Verified Presence of CBDS and Those Without CBDS\***

Type of Characterization	No. of Patients	CBDS	No CBDS
Clinical			
Positive	152	32	120
Negative	40	0	40
Discriminant function			
Positive	50	30	20
Negative	142	2	140
Ultrasonographic			
Positive	46	16	30
Negative	125	9	116

\*See equation for discriminant function formula. CBDS indicates common bile duct stones.

**Table 2. Discrepancy of Diameter of the Bile Ducts as Measured by ERCP and USG\***

Difference	ERCP > USG, No. of Patients	ERCP < USG, No. of Patients	Difference, mm			Difference, %		
			Mean	Range	SD	Mean	Range	SD
Least	36	16	2.1	0-9	2.0	36.9	0-175	41.6
Largest	39	13	4.7	0-11	2.4	77.3	8-212	52.0
Mean	39	13	3.1	0-10	2.2	53.4	0-187	47.9

\*ERCP indicates endoscopic retrograde cholangiopancreatography; USG, ultrasonography.

jaundice, normal transaminase levels, CBD diameter less than 8 mm, and no intrahepatic bile duct enlargement at ultrasonography as the best parameters to predict low risk of CBDS. Two thirds of his patients were at low risk, and CBDS occurred unexpectedly in 1% of them. Barkun et al<sup>22</sup> selected age older than 55 years, bilirubin level greater than 30  $\mu\text{mol/L}$  (1.8 mg/dL), and CBD diameter greater than 6 mm assessed by ultrasonography as the best model for CBDS prediction. The probability of CBDS in that study was 19% when no predictor was present and 72% with 3 predictors present. Suspected or detected CBDS at ultrasonography increased the probability to up to 94%. Robertson et al<sup>17</sup> selected age, jaundice, alkaline phosphatase level, albumin level, and ultrasonography criteria, producing a sensitivity of 89% and a specificity of 75% for the presence of CBDS.

Ultrasonographic bile duct diameter is considered valuable in CBDS prediction.<sup>1,3,15-17,19,25</sup> Our use of 6 mm as the upper normal limit is in accordance with others,<sup>20,22,26,27</sup> but 4 mm,<sup>28,29</sup> 5 mm,<sup>15,30</sup> 7 mm<sup>5,17</sup> and 8 mm<sup>31</sup> are also used. Sensitivity and specificity of bile duct diameter as a CBDS indicator are 94% and 99% and 79% and 85% for 4 mm,<sup>28,29</sup> 76% and 49% for 5 mm,<sup>30</sup> 53% and 73% for 6 mm,<sup>22</sup> and 80% and 70% for 7 mm,<sup>17</sup> respectively; the last 2 sets of value concur with our results.

Ultrasonography has been reported by some authors<sup>26,30</sup> to be less precise than ERCP in bile duct diameter measurement. However, good to excellent correlation ( $r=0.73-0.94$ ) between ultrasonography and radiographic methods has been described by others.<sup>27,29,31-33</sup> The results of ultrasonography may be improved by special techniques<sup>29,31,33</sup> or especially dedicated examiners.<sup>34</sup>

In our series, 60% of the patients with positive DF values and 1.4% with negative values had CBDS, indicating a acceptable yield for patients selected for ERCP with a low risk of residual stones and comparing well with other methods.<sup>4,19</sup>

Many CBDS pass spontaneously over the sphincter of Oddi.<sup>22,28,35,36</sup> Repeated biochemical tests and a recharacterization of the patient may therefore be worthwhile if some days pass before the ERCP procedure.

The DF characterization we used was dependent on only a few variables that can be precisely determined, and not on clinical signs and technical procedures that may be difficult to interpret. The results of the DF characterization were reproducible. The new formula was slightly more sensitive and less specific, but both formulas have proved efficient in clinical practice. Which one of them should be preferred should be an objective for future studies on large patient series.

In our study, 36.4% of the patients with pancreatitis had CBDS at ERCP; 7 of 16 patients with positive DF values and 1 of 6 with negative values. We think that the dramatic improvement often observed after EST in these patients<sup>37</sup> justifies the low detection rates. We have adopted a liberal practice of prophylactic EST in patients with gallstone pancreatitis, with a recurrence rate of 0%.<sup>38</sup> Only a few patients have later required a cholecystectomy for gallbladder stone disease.<sup>38</sup>

In conclusion, the clinical characterization of patients with symptomatic gallstones with regard to the pres-

ence of CBDS was highly sensitive, but the specificity was too low for practical application. The sensitivity of ultrasonography was too low in our study to concur with that of other selection procedures. The DF was both more sensitive and specific than ultrasonography, and ensured a clinically acceptable detection rate and a low rate of unnecessary ERCP. The DF program was simple to use and dependent on only a few precisely determined variables. The DF formula as well as the DF characterization were reproducible in 2 independent patient series.

Presented as a scientific exhibit at the Fifth Annual United European Gastroenterology Week, Paris, France, November 5, 1996.

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## IN OTHER AMA JOURNALS

### ARCHIVES OF INTERNAL MEDICINE

#### A Comparison of Compression Ultrasound With Color Doppler Ultrasound for the Diagnosis of Symptomless Postoperative Deep Vein Thrombosis

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**Background:** Despite advances in primary prophylaxis, venous thromboembolism still occurs in a considerable number of high-risk surgical patients. Screening with conventional ultrasound imaging to detect asymptomatic deep vein thrombosis (DVT) has been suggested as a strategy to improve management of such patients, but it is insufficiently sensitive. We evaluated the ability of color Doppler ultrasound to improve the sensitivity of compression ultrasound in the detection of asymptomatic DVT in high-risk orthopedic patients.

**Methods:** We prospectively evaluated bilateral compression and color Doppler ultrasound measurements of the entire leg in 204 consecutive patients who underwent elective hip or knee replacement surgery, using contrast venography as the reference test. The sensitivity, specificity, and positive predictive value of the ultrasonography tests were determined.

**Results:** The sensitivity, specificity, and positive predictive value (with 95% confidence intervals [CIs]) of compression ultrasound for the detection of proximal DVT were 60% (39%-81%), 96% (92%-99%), and 71% (48%-89%), respectively. The sensitivity, specificity, and positive predictive value (with 95% CIs) of compression ultrasound for the detection of calf vein thrombosis were 33% (18%-52%), 91% (83%-96%), and 58% (34%-80%), respectively. Color Doppler ultrasonography did not identify any additional proximal or calf vein thrombi to those detected by compression ultrasound alone. The sensitivity for all thrombi was 47% (95% CI, 34%-61%) with a positive predictive value of 65% (95% CI, 48%-79%).

**Conclusions:** Color Doppler ultrasonography has a moderate to low accuracy for the detection of DVT in patients who have had hip and knee replacement surgery. Color Doppler ultrasonography does not increase the detection rate for asymptomatic DVT over compression ultrasound and thus cannot be recommended as a screening test in this setting. *Arch Intern Med*. 1997;157:765-768

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