

Predictive Ability of Choledocholithiasis Indicators

A Prospective Evaluation

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To assess the predictive ability of various indicators of common bile duct calculi, 457 patients undergoing cholecystectomy for gallstone disease were prospectively screened for the presence of 11 predefined criteria of possible choledocholithiasis. The predictive ability of the criteria, individually and in combinations, was determined. For all criteria, except a history of pancreatitis, a significantly increased incidence of choledocholithiasis was found. The number of positive criteria correlated positively with the frequency of common bile duct calculi. The negative predictive value and sensitivity of the total set of criteria were 98% and 89.5%, respectively. Following common duct exploration, the number of complications and the duration of postoperative hospitalization were significantly increased as compared with simple cholecystectomy. Peroperative cholangiography with cholecystectomy is recommended in all patients, with one or more criteria of possible choledocholithiasis. Routine peroperative cholangiography in patients with no positive criteria does not seem to be necessary.

THE USE OF PREOPERATIVE endoscopic retrograde cholangiography (ERC) and peroperative cholangiography (PC) has greatly reduced the frequency of retained common bile duct (CBD) calculi and unnecessary choledochotomies.^{1,2} However, these investigations are usually not performed in all cases of simple cholecystectomy.

Although many authors advocate routine PC in connection with cholecystectomy for gallstone disease to detect asymptomatic calculi,^{3,4} others prefer to use PC only in selected cases.⁵⁻⁸

If PC is performed only in patients with suspected common bile duct pathology, the individual patient's probability of having CBD calculi must be assessed in order to determine whether PC is indicated or not. If cholangiograms of sufficient quality are not obtained, the probability of choledocholithiasis must be known to enable the surgeon to decide whether the common duct should be explored.

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This study was performed to estimate the reliability of various criteria in predicting the presence of common bile duct calculi, and to assess the consequences of common duct exploration with regard to postoperative morbidity.

Materials and Methods

During the period July 1982 through January 1984, 457 patients operated with cholecystectomy for gallstone disease were prospectively screened for the presence of 11 predefined criteria of possible choledocholithiasis (Table 1). Two hundred and eighty patients, who had no positive criteria and had not been subjected to preoperative ERC, were randomized to PC (N = 142) or no PC (N = 138).

The material of the present study consists of 319 patients (457 - 138 = 319), in whom one or more of the following procedures were performed to demonstrate or rule out choledocholithiasis:

1. Preoperative endoscopic retrograde cholangiography (N = 108).
2. Peroperative cholangiography (N = 227).
3. Common bile duct exploration (N = 44).

Eleven patients in whom endoscopic sphincterotomy had been performed before cholecystectomy were not included in the study.

The material comprised 217 women (mean age 54.2 years) and 102 men (mean age 60.1 years). The number of preoperative diagnostic imaging examinations performed is shown in Table 2. Ninety-eight patients were subjected to more than one examination. For all patients, the duration of the operation, postoperative complica-

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TABLE 1. *Criteria of Possible Choledocholithiasis*

| | |
|---|--|
| Clinical presentation | |
| 1. Jaundice (present, recent, or recurrent) | |
| 2. Light colored feces/dark urine | |
| 3. Pancreatitis (present or recent) | |
| 4. Septic fever (present or recent) | |
| Preoperative investigations | |
| 5. Common bile duct diameter >10 mm | |
| 6. Common bile duct calculi | |
| 7. Serum alkaline phosphatase >250 U/liter | |
| 8. Serum bilirubin >25 μ mol/liter | |
| Intraoperative findings: | |
| 9. Common bile duct diameter >10–12 mm | |
| 10. Cystic duct diameter >4–5 mm | |
| 11. Palpable common bile duct calculi | |

tions, and duration of postoperative hospitalization were recorded.

Common bile duct exploration was performed in 44 (13.9%) of the 319 patients, and calculi were removed in 35. The reasons for negative CBD explorations were false-positive PC in five cases, and false-positive ERC in two cases; exploration of a dilated common duct was performed in one patient without preexploratory PC, but no calculi were found; in another case, the exploration was false-negative.

Present CBD calculi were not removed at the primary operation in three patients—one because of a false-negative PC; another because of a false-negative exploration; and in one high operative risk patient, the CBD stone was deliberately left in place, and postoperative endoscopic sphincterotomy was performed.

Thirty eight patients, 19 women and 19 men, had CBD calculi. The mean age of these patients was 64.1 years, compared with 56 years for the patients without choledocholithiasis. The discriminatory ability of the criteria of possible choledocholithiasis (Table 1) was assessed by determining the number of patients with CBD calculi relative to the number of positive criteria.

In order to determine the accuracy of the individual criteria, the following parameters were calculated:

TABLE 2. *Preoperative Diagnostic Imaging Investigations*

| | No. of Patients |
|---------------------------------------|-----------------|
| Endoscopic retrograde cholangiography | 108 |
| Intravenous cholangiography | 67 |
| Peroral cholecystography | 90 |
| Ultrasonography | 162 |
| Cholescintigraphy | 9 |

1. *Sensitivity*. Proportion of the patients with CBD calculi in whom the criterion was present.

2. *Positive predictive value (PPV)*. Proportion of the patients in whom the criterion was present who had CBD calculi.

For subgroups of criteria, and for the entire set of criteria, the following parameters were also determined:

3. *Specificity*. Proportion of the patients without CBD calculi in whom no criteria of the set was present.

4. *Negative predictive value (NPV)*. Proportion of the patients in whom no criteria of the subgroup was present who did not have CBD calculi.

Standard tests for statistical evaluation were employed as appropriate.

Results

The postoperative morbidity and duration of hospitalization are shown in Table 3 for the group of patients with cholecystectomy alone and the group of patients having cholecystectomy and common duct exploration. There was a significant difference in mean age and duration of operation ($p < 0.01$, Student's *t*-test) between the two groups. When CBD exploration was performed, the rate of surgical postoperative complications ($p < 0.05$, Fisher-Irwin test) and duration of postoperative hospitalization ($p < 0.01$, two-sample median test⁹) were also significantly increased.

In 122 patients (38.2%), one or more criteria of possible choledocholithiasis were present, and 34 (34/

TABLE 3. *Postoperative Morbidity*

| | Cholecystectomy | Cholecystectomy + Choledochotomy | <i>p</i> -Value |
|-----------------------------------|-----------------|--|-----------------|
| Number of patients | 275 | 44 | |
| Age (mean) | 55.0 years | 61.5 years | 0.01 |
| Duration of operation (mean) | 74 minutes | 124 minutes | 0.01 |
| Medical complications | 5.5% | 4.5% | N.S.† |
| Surgical complications | 5.8% | 15.9% | 0.05 |
| Postoperative hospitalization* | 5 days | 9 days | 0.01 |
| Residual common bile duct calculi | 0 | 13.6% | — |
| Mortality | 0.7% | 2.3% | N.S. |

* Median.

† N.S. = Not significant.

TABLE 4. Number of Positive Criteria Relative to Choledocholithiasis

| No. of Positive Criteria | No. of Patients | Patients with Choledocholithiasis | |
|--------------------------|-----------------|-----------------------------------|----------|
| | | Number | Per cent |
| 0 | 197 | 4 | 2.0 |
| 1 | 40 | 3 | 7.5 |
| 2 | 26 | 6 | 23.1 |
| 3 | 21 | 4 | 19.0 |
| 4 | 13 | 5 | 38.5 |
| 5 | 8 | 3 | 37.5 |
| 6 | 6 | 5 | 83.3 |
| 7 | 4 | 4 | 100.0 |
| 8 | 0 | — | — |
| 9 | 4 | 4 | 100.0 |
| 10 | 0 | — | — |
| 11 | 0 | — | — |

122 = 27.9%) had CBD calculi. Four patients without any positive criteria (4/197 = 2%) had choledocholithiasis.

Table 4 shows the number of patients with common bile duct calculi relative to the number of positive criteria. The correlation was highly significant (Kendall's $T = 0.81$, $p < 0.01$). The percentage of patients with choledocholithiasis increased from 7.5% with one criterion to 100% with seven and nine criteria.

Three patients with common bile duct calculi had only one positive criterion: a history of light feces/dark urine, a dilated bile duct at operation, and a wide cystic duct at operation, respectively.

Table 5 shows, for each criterion, its prevalence among the 319 patients, the number of patients with choledocholithiasis, and the positive predictive value and sensitivity. For all criteria, except for a history of pancreatitis, there was a highly significant correlation to the presence of CBD calculi ($p < 0.01$, chi square test, Yates correction).

Demonstration of CBD calculi by palpation of the common duct at operation or by preoperative cholan-

giography (endoscopic, retrograde, or intravenous) had the highest PPV, 94.1% and 85.0%, respectively. The sensitivity was 42.1% and 77.3%, respectively. The finding of a dilated common duct had a PPV of 34.3% when demonstrated radiologically compared to 54.8% when found at operation. The PPV of a wide cystic duct (52.0%) was almost the same as for a dilated CBD; however, the sensitivity was lower (34.2% vs. 60.5%).

A history of light feces/dark urine had higher values of both PPV and sensitivity than a history of jaundice or septic fever. Elevation of serum alkaline phosphatase of serum bilirubin had PPVs of 37.3% and 41.5%, respectively.

Table 6 shows the PPV, NPV, sensitivity, and specificity of the criteria when divided in the following groups (Table 1): Clinical presentation, results of preoperative investigations, and operative findings.

The group of operative criteria had the highest values for all the parameters of discriminatory ability: sensitivity 76.3%, specificity 91.5%, PPV 54.7%, and NPV 96.6%. The NPV of the whole set of criteria was 98.0%, whereas the sensitivity was 89.5%.

Discussion

Prior to the introduction of PC, the decision to explore the CBD for calculi had to be based mainly on various criteria of possible choledocholithiasis.

Although PC is now uniformly accepted as a valuable and highly accurate diagnostic tool in biliary surgery, many authors⁵⁻⁸ maintain that PC should be performed only when CBD pathology is suspected. In some cases conventional PC represents a potential hazard (e.g., in patients with infected bile¹⁰ and in high operative risk patients who will tolerate a prolonged operative time poorly). Endoscopic sphincterotomy is now generally recognized as a reliable and safe treatment of choledocholithiasis.^{11,12} Therefore, especially in high operative

TABLE 5. Values of Predictive Ability

| | No. of Patients | Patients with CBD* Calculi | PPV† (%) | Sensitivity (%) |
|--------------------------------------|-----------------|----------------------------|----------|-----------------|
| Jaundice | 35 | 10 | 28.6 | 26.3 |
| Light feces/dark urine | 39 | 17 | 43.6 | 44.7 |
| Pancreatitis | 24 | 2 | 8.3 | 5.3 |
| Septic fever | 22 | 8 | 36.4 | 21.1 |
| CBD diameter >10 mm (radiologically) | 35 | 12 | 34.3 | 62.5 |
| CBD calculi (radiologically) | 20 | 17 | 85.0 | 77.3 |
| Alkaline phosphatase >250 U/liter | 59 | 22 | 37.3 | 57.9 |
| Bilirubin >25 μ mol/liter | 41 | 17 | 41.5 | 44.7 |
| CBD diameter >10-12 mm (operation) | 42 | 23 | 54.8 | 60.5 |
| CD‡ diameter >4-5 mm (operation) | 25 | 13 | 52.0 | 34.2 |
| Palpable CBD calculi | 17 | 16 | 94.1 | 42.1 |

* CBD = Common bile duct.

† CD = Cystic duct.

‡ PPV = Positive predictive value.

TABLE 6. Values of Predictive Ability

| Group of Criteria | No. of Patients | Patients with CBD* Calculi | Sensitivity (%) | Specificity (%) | PPV† (%) | NPV‡ (%) |
|-----------------------------|-----------------|----------------------------|-----------------|-----------------|----------|----------|
| Clinical presentation | 82 | 23 | 60.5 | 79.0 | 28.0 | 93.7 |
| Preoperative investigations | 81 | 28 | 73.7 | 81.1 | 34.6 | 95.8 |
| Operative findings | 53 | 29 | 76.3 | 91.5 | 54.7 | 96.6 |
| Total set of criteria | 122 | 34 | 89.5 | 68.7 | 27.9 | 98.0 |

* CBD = Common bile duct.

† PPV = Positive predictive value.

‡ NPV = Negative predictive value.

risk patients, preoperative diagnosis and treatment of CBD calculi is preferable in order to avoid choledochotomy. Thus, whether PC is performed routinely or not, it is important to assess the individual patient's probability of having choledocholithiasis.

Several criteria other than those used in the present study have been said to correlate with choledocholithiasis. Glenn¹³ reported a positive correlation between the duration of gallstone disease and the incidence of CBD calculi. However, other studies did not support this.^{14,15} A history of biliary colics has also been used as criterion of possible choledocholithiasis,⁵ but was found to have no diagnostic significance in a study by Rubin and Beal.¹⁶

In a prospective evaluation of 304 cholecystectomies, Saltzstein, Peacock, and Thomas¹⁷ found no correlation of serum or urine amylase elevation to common bile duct calculi. The predictive value of increased serum transaminase levels also appears to be quite low.^{15,18} However, in a recent study by VanGossum et al.,¹⁹ the serum ALAT level had higher diagnostic ability than other liver function tests in discriminating between biliary and nonbiliary pancreatitis. The presence of small stones in the gallbladder is widely employed as a predictor of CBD stones.^{3,4,14,20} However, there is much evidence to support the preference of an increased cystic duct diameter instead.^{7,21,22}

In the present study, a history of pancreatitis did not correlate significantly with the finding of CBD calculi. This is in accordance with the results of Taylor et al.²² and Hashmonai et al.¹⁴ A possible explanation is that gallstone pancreatitis usually is associated with passage of calculi through the papilla of Vater²³ and, consequently, the CBD does not necessarily harbor stones. It has been estimated that 90% of common bile duct calculi may pass spontaneously.²⁰

The rather low PPV for a history of jaundice or septic fever found in the present study is possibly due to our practice of referring most older patients with marked obstructive jaundice or cholangitis to endoscopic sphincterotomy.

For the serum bilirubin, serum alkaline phosphatase levels, and the width of the common bile duct, there is

a definite association between the degree of abnormality and the probability of choledocholithiasis.^{15,24} The criteria in this study were only classified as either absent or present because, even when slightly abnormal, the incidence of CBD calculi is probably increased.^{15,21}

When the criteria were divided in subgroups, the group of operative criteria had the highest values both for positive and negative predictive ability. This is in accordance with the results of Taylor et al.²² It has been claimed that, if palpation of the CBD is done thoroughly (if necessary, by performing a Kocher maneuver), the absence or presence of calculi may be determined with an accuracy approaching that of PC.²⁵

Summary

For the whole set of criteria, the PPV and NPV were 27.9% and 98.0%, respectively, and for all individual criteria, with the exception of a history of pancreatitis, there was a highly significant correlation to the presence of CBD calculi. Therefore, our results indicate that PC should be performed in all patients with one or more positive criteria if the CBD has not been adequately visualized before surgery by ERC. PC should be performed in patients with pancreatitis if the history or laboratory tests suggest biliary etiology.

Because of the high negative predictive value of the criteria, there is little evidence in favor of routine PC in connection with cholecystectomy. The increased morbidity associated with CBD exploration and the relative safety of endoscopic sphincterotomy^{11,12} also support a policy of performing PC only when CBD pathology is suspected, or in order to clarify the anatomy.

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