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The Accuracy of Predictive Parameters for The Presence of Common Bile Duct Stones

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Abstract

Backgroud: **Common bile duct stones (CBD stones) are the most common cause of obstructive jaundice and cholangitis. Many technological refinements have been made in radiology, endoscopy and clinical laboratory testing that improve the diagnosis and evaluation of patients with CBD stones. This study was designed to determine the accuracy of the predictive parameters for preoperative diagnosis of CBD stones.**

Methods: **From January 1997 to September 2002, the data of 244 patients who underwent preoperative ERCP with a high index of suspicion for CBD stones based on clinical, biochemical and ultrasonographic criteria were evaluated.**

Results: **A raised serum alkaline phosphatase level was found to be of highest sensitivity (87%) but of low specificity (26%) indicator for CBD stones. Ultrasonography yielded the highest specificity (92%), the positive predictive value was 85 per cent and likelihood ratio positive of 6.48 for CBD stone. The combination of a raised serum alkaline phosphatase and dilated CBD on ultrasonography increased sensitiviity to 91 per cent. The combination of finding CBD stone on ultrasonography and pancreatitis increased the specificity to 99 per cent for predicting presence of CBD stone.**

Conclusions: **A raised serum alkaline phosphatase level, CBD stone finding on ultrasonography, dilated CBD on ultrasonography and pancreatitis could be used as criteria for selective preoperative ERCP or cholangiogram in patient undergoing cholecystectomy.**

Choledocholithiasis or common bile duct (CBD) stones is the most common cause of obstructive jaundice and cholangitis.[1-4] In many patients, the stones may also be associated with pancreatitis.[5,6] Approximately 11-18 per cent of patients with gallstones will have associated CBD stones at the time of operation. In the last decade, many technological refinements have been made in radiology, endoscopy and clinical laboratory testing that improve the diagnosis and evaluation of patients with CBD stones.[7-9]

In most patients with CBD stones, the serum alkaline phosphatase will be elevated along with the serum gamma glutamyl transpeptidase (GGTP). These tests are among the most sensitive laboratory indicators of biliary obstruction and may be elevated even when the total bilirubin remains in the normal range.[7-9] Patients with fully developed obstruction will show elevations of alkaline phosphatase, GGTP, and bilirubin. Often alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels are mildly

elevated in longer standing obstruction and markedly elevated in associated cholangitis. Abdominal ultrasound examination is the preferred first imaging study in most patients in whom biliary tract obstruction is suspected. When biliary tract dilatation has been demonstrated by ultrasound, the clinician must consider the next imaging study, in most cases, a cholangiogram.[10-13] The preferred types of cholangiograms in most medical centers today is the endoscopic retrograde cholangiopancreatogram (ERCP) done by surgical or medical endoscopists. A widely adopted policy is to subject patients considered to be at high risk of CBD stones to preoperative ERCP. The criteria for ERCP were based on recognized clinical, biochemical and ultrasonographic abnormalities.[14-16] Using these criteria, bile duct stones may be positively identified at ERCP in only 10-60 per cent of cases. Consequently, a large number of patients would undergo unnecessary ERCP with an attendant potential for morbidity and poor cost-effectiveness.

The purpose of this study is to evaluate the accuracy of clinical presentation, liver function tests, and abnormal ultrasonographic findings as predictor criteria in CBD stone detection. The sensitivity and specificity of these criteria may thereby be used to rationalize the need for preoperative ERCP in patients undergoing cholecystectomy.

Materials and Methods

This study was carried out in the Division of General Surgery, Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira Hospital. Eligible patients were those with signs and symptoms of biliary obstruction seen between January 1997 and September 2002. Age, sex, detailed history regarding episodes of jaundice, acute pancreatitis or acute cholangitis were recorded. Liver function tests (bilirubin, aspartate aminotransferase, alanine aminotransferase and alkaline phosphatase levels) and ultrasonographic findings were determined. Biochemical investigations at presentation were considered abnormal when the serum bilirubin level was more than 1.0 mg/dl, serum alkaline phosphatase concentration exceeding 279 U/L, serum aspartate aminotransferase level more than 40 U/L, and serum alanine aminotransferase level more than 35 U/L. Ultrasonographic criteria used for suspecting common bile duct stone were the visualization of sonographic features of a CBD stone, presence of bile duct dilatation or CBD size greater than 7 mm.

Preoperative Endoscopic Retrograde Cholangio-Pancreatography (ERCP) was performed in patients with a high index of suspicion for CBD stones based on clinical, biochemical and ultrasonographic criteria. All investigations were performed within 2 weeks prior to ERCP.

The techniques of ERCP is the standard maneuver. The patient initially lays on lateral position and sedated with diazepam 5-10 mgs intravenously. After the side - viewing endoscope has been passed through the pylorus into the duodenal bulb, and corkscrewing the endoscope around the superior duodenal angle, then the patient is turned to prone position. Intermittent intravenous boluses of hyoscine-N-butyl bromide 10 mgs are administered to induce and maintain duodenal paralysis. When the papilla is successfully cannulated, contrast is injected under radiologic control. Attention to radiologic technique is crucial because diagnostic information is only as good as the quality of the images obtained. The patients found to have CBD stones were subject to endoscopic sphincterotomy.

The findings at ERCP and/or stone retrieval were taken as the 'gold standard' for evaluating the predictive value of each parameter.

The results were analysed by calculating the sensitivity, specificity, positive and negative predictive values, prevalence rate and likelihood ratio of each criterion.

Statistical analysis was done using Microsoft Excel 2000 for calculating evaluative indices with 95% confidence interval (CI).

Results

A total of 244 patients, 102 men (42%) and 142 women (58%) were evaluated. The mean age of the patient was 55 years (28-71). The clinical characteristics and results of investigations in patients with and without common bile duct stones are presented in Table 1.

Clinical jaundice was detected in 124 patients of whom 76 were found to have common bile duct stones. Of 73 patients with acute ascending cholangitis, only 28 had common bile duct stones and of 35 patients with acute pancreatitis, only 5 had common

Table 1 Clinical and investigative findings in 244 patients with and without common bile duct stones.

Parameter	No. of patients	Percentage
Age (years)		
< 55	107	43.85
≥ 55	137	56.15
Sex		
Male	102	41.80
Female	142	58.20
Jaundice		
Absent	120	49.18
Present	124	50.82
Ascending cholangitis		
Absent	171	70.08
Present	73	29.92
Pancreatitis		
Absent	209	85.66
Present	35	14.34
Alkaline phosphatase level		
Normal	49	20.08
Greater than normal	195	79.92
Bilirubin level		
Normal	108	44.26
Greater than normal	136	55.74
Aspartate aminotransferase level (AST)		
Normal	104	42.62
Greater than normal	140	57.38
Alanine aminotransferase level (ALT)		
Normal	93	38.11
Greater than normal	151	61.89
Duct diameter on ultrasonography		
Normal	100	40.98
Dilated	144	59.02
CBD stone features on ultrasonography		
Absent	179	73.36
Present	65	26.64

bile duct stones.

A raised serum alkaline phosphatase level above normal was found to be a highest sensitivity indicator (87%) of common bile duct stones although its specificity was low (26%). A raised serum bilirubin level above normal yielded intermediate sensitivity (68%) and specificity (55%).

Serum aspartate aminotransferase level greater than normal was found to have low sensitivity (57%) and low specificity (42%), and similarly the serum alanine aminotransferase level greater than normal had low sensitivity (63%) and low specificity (39%).

A dilated bile duct on ultrasonography was second to a raised serum alkaline phosphatase in predicting the presence of CBD stones, the sensitivity was 80 per cent but specificity was only 59 per cent. Ultrasonography predicted stones in 65 of 244 patients yielding highest specificty (92%) but low sensitivity (49%). The positive predictive value of ultrasonography in detecting common bile duct stone was the highest among parameters (85%) with a likelihood ratio positive of 6.48 (Table 2).

The sensitivities and specificities of any two combined parameters in predicting presence of common bile duct stones are shown in Table 3. Combination of a raised serum alkaline phosphatase and dilated CBD on ultrasonography increased the sensitivity to 91 per cent but with the specificity of only 35 per cent. However, combinations of suspected CBD stone feature on ultrasonography and pancreatitis increased specificity to 99 per cent but having sensitivity of only 12 per cent.

Discussion

This study highlights the difficulty of attempting to accurately identify CBD stones before operation. The commonly used predictors of common bile duct stones are jaundice, ascending cholangitis or acute pancreatitis, abnormal liver biochemistry and ultrasonographic suspicion of choledocholithiasis.[7,17,18] The criteria for selection of patients for ERCP or cholangiography have to be stringent. The parameters must be sensitive enough to prevent missing patients with common bile duct stones, and must also have a high positive predictive value so that many unnecessary ERCP or cholangiograms are not performed.[8,10-12,14-16]

Several studies tried to improve the accuracy of diagnosis of CBD stones by assessment of clinical, biochemical and ultrasonographic criteria, with variable results. Barkun et al[18] generated a predictive model for selecting patients for preoperative ERCP. Using logistic regression, the best model for predicting common bile duct stones at ERCP included the following independent predictors : age over 55 years, raised bilirubin concentration, CBD dilatation and a CBD stone finding on ultrasonography. The probability of finding ductal stones at ERCP ranged from 8 per cent when none of these predictors was present to 94 per cent when all four were present.

Abboud et al[9] examined numerous indicators for their ability to predict the presence of CBD stones in patients with symptomatic gallstones. Their findings

Table 2 Results of different parameters in predicting the presence of common bile duct stones

Parameter	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	PV (95% CI)	LR
Jaundice	0.61 (0.52 - 0.70)	0.58 (0.49 - 0.66)	0.55 (0.46 - 0.64)	0.63 (0.57 - 0.69)	0.46 (0.40 - 0.52)	+1.43
Ascending cholangitis	0.38 (0.29 - 0.47)	0.77 (0.70 - 0.84)	0.59 (0.48 - 0.70)	0.60 (0.53 - 0.66)	0.46 (0.40 - 0.52)	+1.69
Pancreatitis	0.12 (0.06 - 0.18)	0.83 (0.77 - 0.90)	0.37 (0.21 - 0.53)	0.53 (0.46 - 0.59)	0.46 (0.40 - 0.52)	+0.70
Alkaline phosphatase level greater than normal	0.87 (0.80 - 0.93)	0.26 (0.18 - 0.33)	0.50 (0.43 - 0.57)	0.69 (0.64 - 0.75)	0.46 (0.40 - 0.52)	+1.17
Bilirubin level greater than normal	0.68 (0.59 - 0.77)	0.55 (0.46 - 0.63)	0.56 (0.48 - 0.64)	0.67 (0.61 - 0.73)	0.46 (0.40 - 0.52)	+1.49
Aspartate aminotransferase (AST) level greater than normal	0.57 (0.48 - 0.66)	0.42 (0.34 - 0.51)	0.46 (0.37 - 0.54)	0.54 (0.48 - 0.60)	0.46 (0.40 - 0.52)	+0.99
Alanine aminotransferase (ALT) level greater than normal	0.63 (0.54 - 0.72)	0.39 (0.31 - 0.48)	0.47 (0.39 - 0.55)	0.56 (0.50 - 0.62)	0.46 (0.40 - 0.52)	+1.05
Dilated CBD on ultrasonography > 7 mm	0.80 (0.73 - 0.88)	0.59 (0.51 - 0.67)	0.63 (0.55 - 0.70)	0.78 (0.73 - 0.83)	0.46 (0.40 - 0.52)	+1.96
CBD stone features on ultrasonography	0.49 (0.40 - 0.58)	0.92 (0.88 - 0.97)	0.85 (0.76 - 0.93)	0.68 (0.62 - 0.74)	0.46 (0.40 - 0.52)	+6.48

CI = confidence interval ; PPV = positive predictive value ; NPV = negative predictive value ; PV = prevalence ; LR = likelihood ratio.

Table 3 Sensitivity (upper, right) and specificity (in italics, lower, left) of a single positive result in any combination of two parameters in detection of common bile duct stones (Estimate and 95% Confidence Intervals)

	Sensitivity								
	JD	**Cho**	**Pan**	**ALP**	**Bili**	**AST**	**ALT**	**D.CBD**	**S.CBD**
JD		0.49 (0.38-0.61)	0.14 (0.04-0.24)	0.84 (0.75-0.92)	0.70 (0.60-0.79)	0.64 (0.53-0.74)	0.68 (0.57-0.79)	0.82 (0.73-0.91)	0.58 (0.46-0.70)
Cho	*0.75 (0.66-0.84)*		0.09 (0.02-0.16)	0.76 (0.65-0.87)	0.56 (0.43-0.68)	0.44 (0.32-0.56)	0.62 (0.49-0.75)	0.69 (0.57-0.81)	0.43 (0.30-0.56)
Pan	*0.86 (0.79-0.94)*	*0.93 (0.88-0.99)*		0.21 (0.11-0.32)	0.20 (0.09-0.32)	0.19 (0.08-0.30)	0.26 (0.13-0.39)	0.46 (0.27-0.65)	0.12 (0.04-0.20)
ALP	*0.36 (0.25-0.47)*	*0.53 (0.41-0.66)*	*0.72 (0.62-0.83)*		0.84 (0.77-0.92)	0.85 (0.76-0.93)	0.86 (0.78-0.94)	0.91 (0.85-0.97)	0.84 (0.75-0.94)
Bili	*0.58 (0.48-0.67)*	*0.73 (0.64-0.82)*	*0.83 (0.73-0.92)*	*0.33 (0.23-0.44)*		0.68 (0.57-0.78)	0.72 (0.62-0.82)	0.86 (0.78-0.93)	0.67 (0.54-0.79)
AST	*0.50 (0.40-0.60)*	*0.81 (0.74-0.88)*	*0.74 (0.63-0.85)*	*0.28 (0.19-0.37)*	*0.48 (0.38-0.58)*		0.63 (0.53-0.73)	0.81 (0.72-0.90)	0.57 (0.43-0.72)
ALT	*0.48 (0.37-0.58)*	*0.75 (0.66-0.84)*	*0.75 (0.63-0.86)*	*0.25 (0.16-0.34)*	*0.46 (0.35-0.56)*	*0.39 (0.31-0.48)*		0.87 (0.78-0.95)	0.63 (0.50-0.77)
D.CBD	*0.65 (0.54-0.76)*	*0.79 (0.70-0.88)*	*0.74 (0.61-0.87)*	*0.35 (0.23-0.46)*	*0.63 (0.51-0.74)*	*0.51 (0.40-0.63)*	*0.49 (0.37-0.60)*		0.73 (0.63-0.84)
S.CBD	*0.96 (0.91-1.00)*	*0.94 (0.88-1.00)*	*0.99 (0.97-1.01)*	*0.85 (0.73-0.97)*	*0.94 (0.89-1.00)*	*0.93 (0.86-1.00)*	*0.88 (0.79-0.96)*	*0.90 (0.84-0.97)*	
	Specificity								

CI = confidence interval ; JD = jaundice ; Cho = cholangitis ; Pan = pancreatitis ; ALP = alkaline phosphatase ; Bili = bilirubin ; AST = aspartate aminotransferase ; ALT = alanine aminotransferase ; D.CBD = dilated CBD on ultrasonography ; S. CBD = CBD stone features on ultrasonography.

indicated that several indicators were highly specific. Among these indicators features of CBD stones finding on ultrasonography had the highest specificity (100%), followed by ascending cholangitis, jaundice, dilated CBD on ultrasonography and pancreatitis (specificities of 99, 97, 96 and 95 % respectively). Only elevated bilirubin and alkaline phosphatase yield sensitivities greater than 50 per cent. The sensitivity of elevated bilirubin is 69 per cent and elevated alkaline phosphatase is 57 per cent. In the final analysis, no perfect preoperative predictor of CBD stone has been identified, but the presence of ascending cholangitis, CBD stone finding on ultrasonography or jaundice, are the indicators associated with the greatest discriminatory power (likelihood ratios 18.3, 13.6 and 10.1 respectively).

In this study the indicator that is the most sensitive is elevated serum alkaline phosphatase (sensitivity 87%) but least specific (specificity 26%). The specificty, positive predictive value and likelihood ratios of CBD stone finding on ultrasonography is the highest of all the predictive parameters (specificity 92%, positive predictive value 85% and likelihood ratio positive 6.48). For combination of two predictive parameters, elevated serum alkaline phosphatase and dilated CBD on ultrasonography, yielded the highest sensitivity (91%). The combination of pancreatitis and features of CBD stone on ultrasonography gave the highest specificity (99%). Thus, the statistical data of this study may be used as criteria for selective preoperative ERCP or cholangiogram in patients undergoing cholecystectomy.

Conclusion

Several studies have tried to improve the accuracy of diagnosis of CBD stones by assessment of chemical, biochemical and ultrasonographic criteria with variable results. It is difficult to enable one to identify the presence of CBD stones accurately before operation. To reduce the number of patients undergoing unnecessary ERCP with an attendant potential of morbidity and poor cost-effectiveness, the serum alkaline phosphatase level, CBD stone features on ultrasonography, dilated CBD on ultrasonography and pancreatitis may be used as a guide for selective preoperative ERCP or cholangiogram in patients undergoing cholecystectomy.

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