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Predicting Factors for Common Bile Duct Stones: How Significance is Significant ?

Soravith Vijitpornkul, MD
Warin Wachirapunyanukul, MD, FRCST
Department of Surgery, Police General Hospital, Bangkok, Thailand

Abstract

Background: **A widely adopted policy is to subject patients with cholelithiasis who is considered to be at risk for CBD stones to endoscopic retrograde cholangiography (ERCP). The criteria for ERCP were based on recognized clinical presentation, liver function test and abnormal sonographic finding. However, following such criteria, CBD stones are present in only 10-60% of patients thus unnecessary ERCP occurs in a significant number of such patients. ERCP is not a totally safe procedure. To avoid complications, patient with low risk may proceed to intraoperative cholangiography (IOC) instead of ERCP.**

Objectives: **To investigate the probable effective factors indicating the presence of CBD stone, thereby decreasing unnecessary ERCP.**

Materials and Methods: **Medical records of 220 patients at Police General Hospital with a diagnosis of acute or chronic cholecystitis or asymptomatic gallstone, between January 1992 and January 2002 were analyzed. Predictors of CBD stones were determined by univariate and multivariable analysis.**

Results: **Age, serum level of bilirubin, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase and the existence of jaundice, dilated bile duct, and pathologic gall bladder were found to be associated with CBD stones. Logistic regression was undertaken. Four factors were found to be significant; age (≥55 years) odds ratio 2.3; SGOT (over two fold normal) odds ratio 1.9; gallstone (multiple) odds ratio 6.8; and size of CBD (>10 mm) odds ratio 3.4.**

Conclusions: **A simple screening of patients at risk for CBDS can be achieved with four predictive criteria adapted for patients.**

Approximately 10-20% of gallstone patients are found to have associated stones in their common bile duct (CBD stones) at the time of diagnosis[1]. Complications of CBD stones (CBDS) can vary from minor signs and symptoms such as abdominal discomfort, jaundice to serious complications such as suppurative cholangitis, which is a life-threatening condition.[2-4]

Therefore, detection and treatment of associated CBD stones is important in order to prevent such serious complications.

Several diagnostic tools have been used to diagnose CBD stones, these include LFT, U/S, MRCP, ERCP and intraoperative cholangiography (IOC).[5-8]

Nowadays, considering information from medical

Correspondence address: *Soravith Vijitpornkul, MD, Department of Surgery, Police General Hospital, Bangkok 10330, Thailand*
E-mail: www.sorawith2929@yahoo.com

records, physical examinations, chemical blood tests, and image finding from ultrasonography, physicians preferably would investigate CBDS by ERCP. With this technique, not only can diagnostic part be performed, but the stones detected can also be removed instantaneously using a special instrument. Nonetheless, even though ERCP has normally been carried out by a specialist, about 5-10% of complications incurred with this method have been stated. These include duodenal perforation, acute pancreatitis and bleeding.[9-15] Furthermore, according to patients' history, symptoms and imaging information, merely 10-60% of ERCP-treated patients have been found to have stones.[16,17] From the aforementioned statements, there have probably been some risks and drawbacks of ERCP in view of inevitable complications and unnecessary high costs beyond the benefits. As a result, this technique should only be utilized based on justified criteria.

The aim of this study was to improve the accuracy of the diagnosis of CBDS by investigating the probable effective factors indicating the presence of CBDS, thereby decreasing unnecessary ERCP. The alternative technique chosen for the study was intraoperative cholangiography (IOC). This technique is considered more familiar for surgeons, more cost-effective and with fewer complications in comparison with ERCP.

Materials and Methods

Retrospective study from medical records of 220 patients diagnosed with acute cholecystitis, chronic cholecystitis, asymptomatic gall stones or symptomatic gallstones from 1992 to 2002, at the Surgical Department, Police General Hospital was conducted. The variables studied were gender, age, signs and symptoms (fever, abdominal pain, and jaundice), morphologic data, and chemical blood tests, i.e., aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, bilirubin, and serum amylase. Criteria used to define abnormal functions included serum AST >37 U/L, ALT >37 U/L, serum alkaline phosphatase >128 U/L, bilirubin >1.0 mg/dL, and serum amylase >90 U/L.

Ultrasonographic criteria mainly focused on sonographic findings and bile duct dilatation (>1 cm) indicated unusual images. The final confirmation techniques to determine the presence of CBDS were ERCP, IOC, and intraoperative palpation. Statistical

Table 1 Frequency of CBDS for quantitative variables

		% CBDS	P	Odd ratio
Age	<55	24.0	<0.001	3.05
	≥55	49.1		
Total bilirubin	≤4 × N	29.7	<0.001	4.73
	>4 × N	66.7		
Direct bilirubin	≤4 × N	29.1	0.001	2.63
	>4 × N	51.9		
SGOT	≤2 × N	22.5	<0.001	5.68
	>2 × N	62.2		
SGPT	≤3 × N	25.5	<0.001	4.38
	>3 × N	60.0		
Alkaline phosphatase	≤2 × N	255	<0.001	4.76
	>2 × N	62.0		
Amylase	≤2 × N	35.5	0.140	(NS)
	>2 × N	55.0		
Stone	single	8.8	<0.001	12.03
	multiple	53.6		
Size of CBD	0-1 cm	11.2	<0.001	27.98
	>1 cm	77.9		

Table 2 Frequency of CBDS for qualitative variables

		% CBDS	P	Odd ratio
Sex	Male	43.2	0.181	(NS)
	Female	33.3		
Hx pancreatitis	No	37.9	0.662	(NS)
	Yes	29.4		
Hx Jaundice	No	27.2	<0.001	3.93
	Yes	59.4		
Hx Cholangitis	No	35.9	0.125	(NS)
	Yes	63.6		

analysis was performed using chi-square test with univariate analysis and multivariable logistic regression analysis.

Results

Of 220 patients during 1992 to 2002, at the Department of Surgery, Police General Hospital, there were 88 males (40%) and 132 females (60%) with the average age of 55 years (16-89 years old). (Table 1-3)

For quantitative analysis, the investigation showed that in patients over 55 years old CBDS were found in 49.1% whereas in younger patients less than 55 years, CBDS were found in only 24% (p-value <0.001; odd ratio 3.05). With over fourfold normal total bilirubin level, CBDS could be found in up to 66.7% while those with lower total bilirubin level, CBDS could be detected in only 29.7% (p-value <0.001; odd ratio 4.73). Direct bilirubin also showed similar results. With fourfold normal bilirubin level, CBDS were found in 51.9% in comparison with 29.7% in the lower level group (p-value <0.001; odd ratio 2.63). SGOT and SGPT values became significant in the diagnosis of CBDS when they were over 2 and 3 times normal respectively, with the incidence of CBDS in 62.2% (p-value < 0.001; odd ratio 5.68) and 60% (p-value <0.001; odd ratio 4.38), respectively.

Alkaline phosphatase is also one of key parameters in CBDS investigation when merely double the normal value is found. With this parameter, CBDS could be identified in up to 62% whereas CBDS could be found in only 25.5% in patients with lower level (p-value <0.001; odd ratio 4.76). Serum amylase had no significant difference in CBDS incidence between various values of function (p = 0.14).

Table 3 Multivariate Analysis

	Odds ratio	O.R. 95% CI	P
Age	2.3	1.5 - 8.1	0.012
SGOT	1.9	1.2-7.2	0.006
Multiple (gallstone)	6.8	2.5-18.7	0.001
Size CBD	3.4	1.7-10.6	0.001

When considering gall stone(s), CBDS were found in 53.6% of patients with multiple gall stones compared to in 8.8% of patients with single gall stone (p-value <0.001; odd ratio 12.03). CBD dilatation over 1 cm is also a meaningful parameter to define CBDS with an incidence of 77.9% while in the smaller size only 11.2% were found to have CBDS (p-value <0.001; odd ratio 27.98).

For qualitative analysis of data, only jaundice was significant in the diagnosis of CBDS up to 59.4% (p-value <0.001; odd ratio 3.93). Other variables, which were gender, pancreatitis, and cholangitis, had no significant difference observed in CBDS investigation (p-value 0.18, 0.662, and 0.125, respectively).

Nevertheless, when all individual significant variables in CBDS diagnosis, revealed in univariate analysis, were introduced for multivariable analysis, it was demonstrated that only 4 key parameters were significant in CBDS investigation as follows: age >55 years (p-value 0.012; odd ratio 2.3) (O.R.95% C.I. 1.5-1.8), SGOT >4 folds of normal level (p-value 0.006; odd ratio 1.9) (O.R.95% C.I. 1.2-7.2), multiple gall stones (p-value 0.001; odd ratio 6.8) (O.R.95% C.I. 2.5-18.7), and CBD size over 1 cm (p-value 0.001; odd ratio 3.4) (O.R.95% C.I. 1.7-10.6).

Discussion

This study investigated informative factors from standard physical examinations of patients found to have gall stone(s) and would be subjected to cholecystectomy, as well as patients who had abnormal liver functions, jaundice, cholangitis, and abnormal ultrasonographic data, to justify the appropriate CBDS management, since there has long been no well-defined evidence for proper judgement in such cases. There have been only few studies guiding for treatment, for example, Onken Je et al.[18] which showed that key parameters for CBDS treatment were bilirubin function, common bile duct diameter, AST, and alkaline phosphatase. Reiss R et al.[19] investigated 1,000 retrospective data of patients subjected to cholecystectomy. It was demonstrated that these patients also tend to be found to have CBDS, particularly in cases that unusual common bile duct size and abnormal bilirubin function could be detected prior to operation. In this study, univariate analysis and multiple variable logistic regression analysis of retrospective data have shown that parameters which included age >55 years, SGOT > four fold of normal level, CBD dilated >1 cm, and multiple gall stones, were significant variables for CBDS diagnosis precisely. In addition, the more the number of factors observed, the more the accuracy of CBDS diagnosis obtained. These observations are similar to most other evidence elsewhere despite some different factors, not key parameters. This is due to the fact that different populations and methods of data analysis were used in individual study.

Conclusion

As already stated, the accuracy of CBDS diagnosis come from a combination of factors including image findings, blood chemistry, etc. The well-justified criteria for ERCP would be very helpful either for low risk patients or for cost-effectiveness in terms of complications and unreasonable high-cost treatment. In cases not justified for ERCP, intraoperative cholangiography (IOC) would be considered as the alternative tool for CBDS investigation, especially in patients who would be subjected to cholecystectomy either by laparoscopic technique or by open means.

In conclusion, with respect to the justified criteria stated above, most benefits would be accomplished in CBDS investigation when preoperative ERCP has set up in patient who has gall stone(s) concurrent with age >55 years, SGOT > fourfold normal level, CBD dilated >1 cm, or multiple gall stones found. With higher categorized factors, patients are at higher risk for CBD stones. On the other hand, patients who have not demonstrated any risk factor for elective cholecystectomy, these people would be considered as low risk for CBDS. The latter group, if necessary, should be confirmed for CBDS by intraoperative cholangiography (IOC) instead of ERCP.

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