

# Predictive Factors for Choledocholithiasis in Symptomatic Gallstone Patients

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**Background:** Complications of common bile duct stones (choledocholithiasis) can vary from simple biliary colic to life-threatening conditions. Approximately 10-25% of symptomatic gallstone patients may be associated common bile duct stone (CBDS) at the time of diagnosis. Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard for diagnosis and treatment of CBDS but this procedure is invasive and has high morbidity and mortality rate. Moreover, routine preoperative ERCP is not cost-effectiveness.

**Objective:** This study aimed to determine the predictive factors for predicting CBDS in symptomatic gallstone patients.

**Material and Method:** Between March 2008 and February 2011, 149 symptomatic gallstone patients who underwent preoperative ERCP or intraoperative cholangiography (IOC) during laparoscopic cholecystectomy at Her Royal Highness Princess Mahachakri Sirindorn Medical Center (MSMC) were evaluated by clinical presentations, biochemical blood test and transabdominal ultrasonography. The preoperative predictive factors for choledocholithiasis were determined by univariate and multivariate analysis.

**Results:** Age more than 55 years, history of jaundice, history of cholangitis, total bilirubin  $\geq 2.0$  mg/dL, Aspartate aminotransferase  $> 2$  times the normal value, Alanine aminotransferase  $> 3$  times the normal value, Alkaline phosphatase  $> 300$  U/L, Gamma glutamyltranspeptidase  $\geq 90$  U/L, sized of CBD  $\geq 8$  mm and visualized CBD stones by ultrasonography were found to be associated with CBD stones by univariate analysis. For multivariate analysis, history of cholangitis (p-value 0.027), sized of CBD  $\geq 8$  mm (p-value 0.003) and detected CBD stones by ultrasonography (p-value 0.000) were found to be predictive factors for choledocholithiasis.

**Conclusion:** This study presented that the helpful preoperative predictive factors for choledocholithiasis were history of cholangitis, dilatation of CBD  $\geq 8$  mm and visualized CBD stone by ultrasonography.

**Keywords:** Predictive factors, Choledocholithiasis, Gall stone, Common bile duct stone

**J Med Assoc Thai 2016; 99 (Suppl. 8): S112-S117**

**Full text. e-Journal:** <http://www.jmatonline.com>

Symptomatic gallstone is one of the most common diseases in surgical patients. Approximately 10-25% of symptomatic gallstone patients may have stones in common bile duct (choledocholithiasis) at the time of diagnosis<sup>(1,2)</sup>. Common bile duct stones (CBDS) cause of obstructive jaundice and cholangitis. Complications of common bile duct stones can vary from biliary colic to life-threatening conditions such as suppurative cholangitis and septicemia. Accurate preoperative prediction of choledocholithiasis is necessary to decrease operative risk and help surgeons to decide type of surgery. Clinical evaluation, biochemical blood tests and transabdominal

ultrasonography are routinely used as preoperative workup for predicting choledocholithiasis. However, these approaches are not accurate to establish a firm diagnosis. Magnetic resonance cholangiopancreatography (MRCP) is a noninvasive procedure with no associated morbidity and mortality that has become the gold standard in diagnosing CBDS. However, MRCP is an expensive, requires expertise for interpretation and may miss stones less than 5 mm in diameter. Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard for diagnosing and treating CBDS; however, it is invasive procedure with high morbidity and mortality rate such as duodenal perforation, acute cholangitis and acute pancreatitis. Preoperative ERCP may be not recommended routinely due to its high negative finding, expensive and had significant morbidity. The development of predictive factor for CBDS, based on the patient's clinical, biochemical blood test and

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transabdominal ultrasonography could allow a more accuracy of preoperative diagnosed CBDS. Therefore, the aim of this study was to determine the predictive factors for predicting CBDS in symptomatic gallstone patients.

### Material and Method

A prospective analysis study of 149 symptomatic gallstone patients who underwent preoperative ERCP before laparoscopic cholecystectomy or intraoperative cholangiography (IOC) during laparoscopic cholecystectomy from March 2008 to February 2011 at Her Royal Highness Princess Mahachakri Sirindorn Medical Center (MSMC) was evaluated. The preoperative predictive factors which were age, sex, clinical presentations (history of cholangitis, history of jaundice, history of pancreatitis), liver biochemical test [serum bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), gamma glutamyltranspeptidase (GGT)] and transabdominal ultrasonography (number of gallstone, sized of CBD, CBD stones) were recorded. Symptomatic gallstone patients with associated liver cirrhosis, liver abscess, alcoholic liver disease, hepatic malignancy (primary or secondary) and periampullary carcinoma were excluded. The diagnosis of cholangitis was established by the presence of Charcot's triad (fever, abdominal pain and jaundice). The diagnosis of pancreatitis was established by the presence of severe upper abdominal pain radiating to back. Criteria used to define abnormal biochemical blood tests includes total bilirubin >1.0 mg/dL, serum AST >37 U/L, serum ALT >37 U/L, serum ALP >128 U/L and GGT >31 U/L. The transabdominal ultrasonography was performed by three radiologists.

Statistical analysis was performed using Chi-square test with Yates' continuity correction for univariate analysis between the presence of CBDS and the predictive factors. Multiple logistic regression test was used to identify predictive factors CBDS for multivariate analysis. The *p*-value <0.05 was considered statistically significant.

### Results

A total of 149 symptomatic gallstones patients who underwent preoperative ERCP before laparoscopic cholecystectomy or intraoperative cholangiography (IOC) during laparoscopic cholecystectomy between March 2008 and February 2011 were evaluated. Preoperative ERCP was 98 patients (65.78%) and intraoperative cholangiography (IOC) was 51 patients

(34.22%). CBD stones were found in 48 out of 149 patients (32.21%). There were 58 males (38.9%) and 91 female (61.1%). The mean age was 57.25±14.53 (20-90) years old. History of jaundice and cholangitis were more commonly presented in CBDS patients than in without CBDS patients. In contrast, the history of pancreatitis was rarely found in both groups.

For the biochemical blood test, the CBDS patients with total bilirubin  $\geq 2.0$  mg/dL were 37.5% whereas the without CBDS patients were 4.95%. For liver enzyme, the AST >2 times the normal value and ALT >3 times the normal value in CBDS patients were 45.83% and 37.5% whereas those in without CBDS patients were 5.94% and 8.91%, respectively. Alkaline phosphatase (ALP) and Gamma glutamyltranspeptidase (GGT) are the key parameters in CBDS. The data showed that the CBDS patients with ALP >300 U/L and GGT  $\geq 90$  U/L were 35.41% and 79.16% while the without CBDS patients were in only 2.97% and 23.76%, respectively.

For ultrasonographic finding, multiple gallstones were found 75% in CBDS patients and 69.30% in without CBDS patients. CBD dilatation  $\geq 8$  mm which is a meaningful parameter to define CBD obstruction was found 85.41% in CBDS patients while was found only 12.87% in without CBDS patients. CBD stones detected by ultrasonography, were found 77.08% in CBDS patients and 3.96% in without CBDS patients.

For univariate analysis, three predictive factors of clinical history, five predictive factors of biochemical blood test and two predictive factors of ultrasonographic finding demonstrated to be statistically significant. They were age >55 years, history of jaundice, history of cholangitis, total bilirubin  $\geq 2.0$  mg/dL, AST >2 times the normal value, ALT >3 times the normal value, ALP >300 U/L, Gamma GT  $\geq 90$  U/L, sized of CBD  $\geq 8$  mm and ultrasonographic features of CBD stones. The individual significant factors in CBDS diagnosis revealed in univariate analysis were analyzed with multivariable analysis. They showed that three factors were significant for predicting CBDS as follows: history of cholangitis (*p*-value 0.027), sized of CBD  $\geq 8$  mm (*p*-value 0.003) and detected CBD stones by ultrasonography (*p*-value 0.000).

According to the multivariable analysis, diagnostic test of the individual predictive factors for CBDS was shown in Table 3. The history of cholangitis was the highest in specificity (97.02%) whereas sized of CBD  $\geq 8$  mm was the highest in sensitivity (85.41%) and in NPV (92.63%). And the detected CBD stones by

**Table 1.** Baseline characteristics of patient (n = 149)

Predictive factors	GS without CBD stone (n = 101)	GS with CBD stone (n = 48)	p-value
Sex (M/F)	34/67	24/24	0.056
Age $\geq$ 55	45 (44.55%)	36 (75%)	0.001*
History of jaundice	8 (7.92%)	16 (33.33%)	<0.001*
History of cholangitis	3 (2.97%)	20 (41.67%)	<0.001*
History of pancreatitis	4 (3.96%)	2 (4.16%)	0.952
Total bilirubin $\geq$ 2.0 mg/dL	5 (4.95%)	18 (37.5%)	<0.001*
Aspartate aminotransferase $\geq$ 2x normal	6 (5.94%)	22 (45.83%)	<0.001*
Alanine aminotransferase $\geq$ 3x normal	9 (8.91%)	18 (37.5%)	<0.001*
Alkaline phosphatase $\geq$ 300 U/L	3 (2.97%)	17 (35.41%)	<0.001*
Gamma GT $\geq$ 90 U/L	24 (23.76%)	38 (79.16%)	<0.001*
Multiple gall stones	70 (69.30%)	36 (75%)	0.474
Sized of CBD $\geq$ 8 mm	13 (12.87%)	41 (85.41%)	<0.001*
CBD stone by U/S	4 (3.96%)	37 (77.08%)	<0.001*

\* = statistically significant ( $p$ -value <0.05)

**Table 2.** Predictive factors for CBD stones

Predictive factors	Adjusted odds ratio (95% CI)	p-value
Age $\geq$ 55	3.14 (0.46-21.08)	0.238
History of jaundice	0.23 (0.01-4.7)	0.344
History of cholangitis	15.27 (1.36-170.32)	0.027*
Total bilirubin $\geq$ 2.0 mg/dL	8.61 (0.35-209)	0.186
Aspartate aminotransferase $\geq$ 2x normal	0.69 (0.03-5.68)	0.806
Alanine aminotransferase $\geq$ 3x normal	1.73 (0.1-28.93)	0.702
Alkaline phosphatase $\geq$ 300 U/L	0.45 (0.03-5.68)	0.539
Gamma GT $\geq$ 90 U/L	8.66 (0.91-82.31)	0.060
Sized of CBD $\geq$ 8 mm	17.50 (2.70-113.24)	0.003*
CBD stone by U/S	69.61 (10.49-461.94)	<0.001*

\* = statistically significant ( $p$ -value <0.05)

**Table 3.** Diagnostic test of predictive factors for CBD stones

Predictive factor	Sensitivity	Specificity	PPV	NPV	Accuracy
History of cholangitis	41.67%	97.02%	86.95%	77.77%	79.19%
Sized of CBD $\geq$ 8 mm	85.41%	87.13%	75.92%	92.63%	86.57%
CBD stone by U/S	77.08%	96.04%	90.24%	89.81%	96.64%

PPV = positive predictive value; NPV = negative predictive value

ultrasonography were the highest in PPV (90.24%) and accuracy (96.64%).

### Discussion

Gallstones are the common disease.

Laparoscopic cholecystectomy (LC) has become a standard treatment for symptomatic gallstone patients. Approximately 10-25% of symptomatic gallstone patients have CBDS<sup>(1,2)</sup>. CBDS may be associated with severe complication such as acute cholangitis and

pancreatitis. ERCP is invasive procedure and high morbidity and mortality rate. MRCP is an expensive and requires expertise for interpretation. Therefore preoperative ERCP and MRCP routinely use is not cost-effectiveness. There have been several studies which defined the preoperative predictive factor for CBDS by assessing clinical presentation, biochemical blood test and transabdominal ultrasonography. However, the results of these studies were inconclusive.

In clinical presentation parameters, Barkun et al<sup>(3)</sup>, Charatcharoenwittaya et al<sup>(4)</sup> and Vijitpornkul et al<sup>(5)</sup> reported that age >55 years was a predictive factor for CBDS. In our study, age >55 years was helpful predictor for CBDS in the univariate analysis. However, it wasn't statistically significant in the multivariate analysis. In addition, history of jaundice and history of cholangitis were significant for CBDS in the univariate analysis but only history of cholangitis was found to be significant in the multivariate analysis. These might be cause of different clinical presentation of cholangitis, while almost half cases may not have jaundice. History of pancreatitis was found to be insignificant in neither the univariate nor the multivariate analysis. This is in accordance with other clinical series, which explained that almost patients with gallstone pancreatitis are likely to have spontaneously passed the stone across the sphincter of Oddi prior to the time of evaluation<sup>(6,7)</sup>.

Several studies demonstrated that the biochemical blood test was helpful for predicting CBDS. However these results were highly different. Sgourakis et al<sup>(8)</sup> reported that direct bilirubin >2 times the normal value, AST >2 times the normal value, ALP >2 times the normal value and CBD dilated >1 cm were predictive factor for CBDS. Peng et al<sup>(9)</sup> showed that GGT >90 U/L was highest specificity, PPV and NPV for the predictor CBDS than other liver function test. Santucci et al<sup>(10)</sup> demonstrated that ALP  $\geq$ 300 IU/L, ALT >40 IU/L and CBD dilated >8 mm were variables for CBDS diagnosis. Lakatos et al<sup>(11)</sup> reported that hyperbilirubinemia >2 times the normal value, elevated AST/ALT >50%, elevated GGT/ALP >50%, acute pancreatitis, jaundice, CBD stones and CBD dilated >8 mm were predictive factor for CBDS. Prat et al<sup>(12)</sup> demonstrated that GGT >7 times the normal value, CBD dilated >8 mm and CBD stones were variables for CBDS diagnosis. In this study, total bilirubin  $\geq$ 2.0 mg/dL represented jaundice, AST  $\geq$ 2 times the normal value, ALT  $\geq$ 3 times the normal value represented liver injury and ALP  $\geq$ 300 U/L, GGT  $\geq$ 90 U/L represented bile duct obstruction, were statistically significant as

helpful predictors for CBDS in the univariate analysis. However no any biochemical test was found to be significant in the multivariate analysis.

For ultrasonographic finding, the review literatures showed that CBD dilatation and detected CBD stone by ultrasonography were statistically significant as helpful predictive factors for CBDS both the univariate and the multivariate analysis. This study also demonstrated similar results. Criteria of CBD dilatation was different each study. Most studies used CBD dilated >8 mm which was radiologic criteria for CBD obstruction. Some studies such as Vijitpornkul et al<sup>(5)</sup> and Sgourakis et al<sup>(8)</sup> used CBD dilated >1 cm. On the contrary, Barkun et al<sup>(3)</sup>, Alponat et al<sup>(13)</sup> and Notash et al<sup>(14)</sup> used CBD dilated >6 mm for predicting CBDS. Vijitpornkul et al<sup>(5)</sup> reported that multiple gallstones were predictive factors for CBDS but other studies include this study conversely resulted.

In this study, diagnostic test of sized of CBD  $\geq$ 8 mm for predicting CBDS is the highest in sensitivity and NPV therefore it should be appropriately for screening CBDS. CBD dilatation implies CBD obstruction which may be indirect sign for CBDS. Diagnostic test of the detected CBD stone by ultrasonography is high in specificity, PPV and accuracy because it is direct CBD stone visualization. However it isn't the highest in sensitivity due to operator dependence. Diagnostic test of history of cholangitis for predicting CBDS is low in sensitivity but high in specificity. It is because the most of symptomatic patients with CBDS will present with history of cholangitis.

The limitations of this study, history of cholangitis vary in diagnosis by the physician's finding and the results of ultrasonography are different due to operator dependence. These factors are effect to predict choledocholithiasis in symptomatic gallstone patients. We recommend study in large population for decreasing variation result.

In conclusion, this study present that the helpful preoperative predictive factors for choledocholithiasis are history of cholangitis, dilatation of CBD  $\geq$ 8 mm and visualized CBD stone by ultrasonography. Sized of CBD  $\geq$ 8 mm is the highest in sensitivity, history of cholangitis is the highest in specificity and visualized CBD stone by ultrasonography is the highest in accuracy.

#### **What is already known on this topic?**

There have been several studies which defined the preoperative predictive factor for CBDS by

assessing clinical presentation, biochemical blood test and transabdominal ultrasonography with highly different results.

#### **What this study adds?**

The preoperative clinical prediction for choledocholithiasis is in symptomatic gallstone patients are history of cholangitis, dilatation of CBD  $\geq 8$  mm and visualized CBD stone by ultrasonography. Therefore, preoperative ERCP recommend setting up in gallstone patients who have these predictive factors.

#### **Acknowledgements**

This work was supported by a research grant from Faculty of Medicine, Srinakharinwirot University. Special thanks to Dr. Dolrudee Songtish for assistance in statistical analysis.

#### **Potential conflicts of interest**

None.

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## ปัจจัยที่มีผลต่อการพยากรณ์นิ้วในท่อน้ำดีในผู้ป่วยที่มีอาการของนิ้วในถุงน้ำดี

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**ภูมิหลัง:** ภาวะแทรกซ้อนของนิ้วในท่อน้ำดีสามารถแสดงอาการได้หลายอย่างตั้งแต่ปวดท้องเล็กน้อยจนถึงมีอาการรุนแรงถึงแก่ชีวิตได้ พบว่ามีประมาณ 10-25% ของผู้ป่วยที่วินิจฉัยว่ามีนิ้วในถุงน้ำดีจะมีนิ้วในท่อน้ำดีร่วมด้วย ซึ่งการส่องกล้องท่อทางเดินน้ำดีจะเป็นวิธีการตรวจที่เป็นมาตรฐานที่สุดในการวินิจฉัยและรักษานิ้วในท่อน้ำดี อย่างไรก็ตามการส่องกล้องท่อทางเดินน้ำดีเป็นหัตถการที่มีความยุ่งยาก และมีภาวะแทรกซ้อนและการตายที่สูงจึงไม่เหมาะสมในการทำการส่องกล้องท่อทางเดินน้ำดีทุกรายในผู้ป่วยที่มีนิ้วในถุงน้ำดี

**วัตถุประสงค์:** เพื่อศึกษาหาปัจจัยทางคลินิก การตรวจทางห้องปฏิบัติการ และการตรวจคลื่นเสียงความถี่สูงทางช่องท้อง เพื่อใช้ในการพยากรณ์นิ้วในท่อน้ำดีในผู้ป่วยที่มีนิ้วในถุงน้ำดี

**วัสดุและวิธีการ:** ทำการศึกษาผู้ป่วยที่มีนิ้วในถุงน้ำดี 149 ราย ที่ได้รับการส่องกล้องท่อทางเดินน้ำดีก่อนการผ่าตัด หรือได้รับการฉีดสีดูท่อทางเดินน้ำดีระหว่างการผ่าตัดเอาถุงน้ำดีออกที่โรงพยาบาลศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี ตั้งแต่ปี พ.ศ. 2551-2554 ข้อมูลปัจจัยต่างๆ ก่อนการผ่าตัดเพื่อใช้ในการพยากรณ์นิ้วในท่อน้ำดีจะได้รับวิเคราะห์ทางสถิติทั้ง univariate และ multivariate

**ผลการศึกษา:** พบว่าอายุมากกว่า 55 ปี ประวัติตาเหลืองตัวเหลือง ประวัติคิดเชื้อในท่อน้ำดี ค่าบิลิรูบินมากกว่า 2 เท่าของค่าปกติ ค่าเอนไซม์ของตับเอเอสที มากกว่า 2 เท่าของค่าปกติ ค่าแอลที มากกว่า 3 เท่าของค่าปกติ ค่าแอลพี มากกว่า 300 หน่วยต่อลิตร ค่าจีที มากกว่า 90 หน่วยต่อลิตร ขนาดของท่อน้ำดีมากกว่า 8 มิลลิเมตรและการพบนิ้วในท่อน้ำดีจากการตรวจคลื่นเสียงความถี่สูงทางช่องท้อง จะสัมพันธ์กับการมีนิ้วในท่อน้ำดีจากการวิเคราะห์แบบ univariate สำหรับการวิเคราะห์ทางสถิติแบบ multivariate จะพบเพียงประวัติคิดเชื้อในท่อน้ำดี (p-value 0.027) ขนาดของท่อน้ำดีมากกว่า 8 มิลลิเมตร (p-value 0.003) และพบนิ้วในท่อน้ำดีจากการตรวจคลื่นเสียงความถี่สูงทางช่องท้อง (p-value 0.000) ที่เป็นปัจจัยในการพยากรณ์นิ้วในท่อน้ำดี

**สรุป:** ปัจจัยทางคลินิกก่อนการผ่าตัดที่ใช้ในการพยากรณ์นิ้วในท่อน้ำดีมีประวัติการคิดเชื้อในท่อน้ำดี การที่มีท่อน้ำดีโตมากกว่า 8 มิลลิเมตร และพบนิ้วในท่อน้ำดีจากการตรวจคลื่นเสียงความถี่สูงทางช่องท้อง ดังนั้นการส่องกล้องท่อทางเดินน้ำดีก่อนการผ่าตัดเอาถุงน้ำดีออกแนะนำว่าควรจะทำในรายผู้ป่วยที่มีปัจจัยเหล่านี้

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