*Original Article*

# Accuracy of 2019 ASGE Guideline and Predictive Parameters for Choledocholithiasis before Endoscopic Retrograde Cholangiopancreatography

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**Background**: In 2019, the American Society for Gastrointestinal Endoscopy (ASGE) revised their guidelines for endoscopic management of common bile duct stones (CBDS).

**Objective**: To evaluate the accuracy of the 2019 ASGE criteria in evaluation of CBDS and to identify additional predictive parameters that might improve the accuracy of those criteria.

**Material and Methods**: The present study design was a retrospective cohort study. Patients suspected of having CBDS and treated with ERCP by the Surgery Department of Thammasat University Hospital between January 2017 and January 2020 were enrolled. Clinical, laboratory, radiological, and endoscopic data were retrospectively collected by medical chart review.

**Results**: Five hundred sixty-five patients were enrolled, with 85.8% in the high-risk group by ASGE criteria. CBDS were found in 75.4% by ERCP. The overall high-risk criteria had sensitivity of 90.6%, and accuracy 75.4%. CBDS on imaging was the most powerful criterion with an odds ratio of 3.36 ($p<0.01$) with the highest sensitivity at 68.1%, specificity at 61.2%, and accuracy at 66.4%. Post-cholecystectomy, age, and elevated alkaline phosphatase (ALP) level were significant factors in finding of CBDS by multivariate analysis. The newly proposed high-risk condition of "TB 1.8 to 4.0 mg/dL, elevated ALP, and CBD dilatation" had improved sensitivity at 92.3%, accuracy at 76.4%, and odds ratio at 4.65 compared to the original high-risk criteria with an odds ratio of 3.90.

**Conclusion**: The high-risk criteria of the ASGE 2019 guideline is an effective evaluation for patients clinically suspected of having CBDS. Adding a new criterion of "TB 1.8 to 4.0 mg/dL and elevated ALP and CBD dilatation" could make the high-risk criteria more sensitive to CBDS and improve accuracy.

**Keywords**: Choledocholithiasis; Common bile duct stone; ASGE guideline; Endoscopic retrograde Cholangiopancreatography; ERCP

Received 27 June 2022 | Revised 4 August 2022 | Accepted 16 August 2022

**J Med Assoc Thai 2022;105(10):1007-14**

**Website:** http://www.jmatonline.com

Common bile duct stone (CBDS) is one of the most common health problems worldwide. Clinical manifestations of CBDS include asymptomatic manifestations, which may be discovered in the evaluation of abnormal liver chemistry or imaging for other reasons, symptomatic manifestations such as abdominal pain or jaundice, and complications such as cholangitis, pancreatitis, or liver abscess. The condition is classified by its origin. Primary CBDS are formed in the extrahepatic bile duct, associated with bile stasis and biliary tract infection[1]. Secondary CBDS are mostly originated within the gallbladder, then migrate into bile duct. CBDS were found in 10% to 20% of patients with symptomatic gallstones[2]. In patients with normal liver chemistry and normal duct size on trans-abdominal ultrasound (TAUS), the prevalence of CBDS at the time of cholecystectomy should less than 5%[2].

Endoscopic retrograde cholangiopancreatography (ERCP) is currently the treatment of choice for CBDS. It is an endoscopic procedure to remove stones from the biliary tract. Ductal cannulation at ERCP is highly successful when performed by experienced endoscopists. Cannulation success rates over 80% have been reported in publications[3]. Cotton et al, for example, declared 96% success for biliary

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**How to cite this article:**

Sriussadaporn E, Tongyoo A, Pipatbouwornkul S, Limpavitayaporn P, Mingmalairak C. Accuracy of 2019 ASGE Guideline and Predictive Parameters for Choledocholithiasis before Endoscopic Retrograde Cholangiopancreatography. J Med Assoc Thai 2022;105:1007-14.

**DOI**: 10.35755/jmedassocthai.2022.10.13685

**Table 1.** ASGE 2019 guideline to assign risk of choledocholithiasis based on clinical predictors

| Probability | Predictors of choledocholithiasis | Recommended strategy |
|---|---|---|
| High | Common bile duct stone on US/cross-sectional imaging, or clinical ascending cholangitis, or total bilirubin >4 mg/dL and dilated common bile duct on US/cross-sectional imaging | Proceed to ERCP |
| Intermediate | Abnormal liver biochemical tests, or age >55 years, or dilated common bile duct on US/cross-sectional imaging | EUS, MRCP, laparoscopic IOC, or intraoperative US |
| Low | No predictors present | Cholecystectomy with/without IOC or intraoperative US |

US=ultrasound; ERCP=endoscopic retrograde cholangiopancreatography; EUS=endoscopic ultrasound; MRCP=magnetic resonance cholangiopancreatography; IOC=intraoperative cholangiography

cannulation at an academic center[4]. However, large studies reported complication rates between 4% and 12%, including post-ERCP pancreatitis, bleeding, and perforation[5,6]. For those reasons, appropriate criteria should be established to avoid unnecessary ERCP, thereby decreasing ERCP-related complications.

In patients with clinically suspected CBDS, the initial evaluation should include a liver function test (LFT) and TAUS. In 2010, the American Society for Gastrointestinal Endoscopy (ASGE) provided a guideline for the role of endoscopy in the evaluation and management of CBDS. This guideline categorized patients into low, intermediate, and high risk for CBDS by predictors based on clinical models, LFT, and TAUS[7]. Subsequently, the ASGE criteria were revised in 2019, as shown in Table 1. High-risk criteria were: 1) cholangitis, 2) stone on imaging, and 3) total bilirubin greater than 4 mg/dL with CBD dilation greater than 6 mm or greater than 8 mm if cholecystectomy performed. Patients with any one of these high-risk criteria were considered at high risk for CBDS, and ERCP was recommended. For patients with intermediate-risk criteria, endoscopic ultrasound (EUS), magnetic resonance cholangiopancreatography (MRCP), laparoscopic intraoperative cholangiography (IOC), or laparoscopic intraoperative ultrasound (US) were recommended for further evaluation[8].

The present study aimed to evaluate the accuracy of the 2019 ASGE criteria in evaluation of CBDS, and to identify additional predictive parameters that might improve the accuracy of these criteria.

## Materials and Methods

The present study was approved by The Human Research Ethics Committee of Thammasat University (Medicine) (MTU-EC-SU-1-072/64). The study design was retrospective cohort study. Patients who presented with biliary obstruction clinically suspected to be caused by CBDS and treated with ERCP between January 2017 and January 2020 at the Surgery Department of Thammasat University Hospital were considered for enrollment into the present study. The inclusion criteria were patients clinically suspected of having CBDSs by biliary pain and abnormal LFT, with or without cholangitis, and then underwent ERCP with intention to remove stones. Abnormal LFT was defined by serum levels of bilirubin and liver enzyme exceeding the upper limit of the normal range at the time of tests. Cholangitis was defined as systemic inflammation with fever of more than 38°C or leukocytosis with white blood cell greater than 10,000 cells/mm$^3$, coexisting with obstructive jaundice. Patients with prior sphincterotomy were excluded from the study.

ERCP procedures were performed by four endoscopic surgeons of the Hepato-pancreato-biliary unit with similar procedural steps and techniques. This team of endoscopists had experienced over 3,000 ERCP procedures in five years. After successful biliary cannulation, cholangiography was performed to demonstrate filling defects. Sphincterotomy was performed in every case. CBDS were removed by balloon extraction, then cholangiography was repeated to confirm complete clearance of the bile duct.

The medical records of enrolled patients were thoroughly reviewed. Demographic data, clinical information, laboratory results, and radiological findings were collected from the electronic medical records. Univariate analysis was performed using chi-square test for categorical data and using student's t-test or Mann-Whitney U test for continuous data to reveal potentially significant variables for ERCP detection of CBDS. Thereafter, the significant factors from univariate analysis were evaluated further by multivariate logistic regression analysis. For the detail of test characteristics of imaging studies and high-risk criteria in detection of CBDS, sensitivity, specificity, positive predictive value, positive likelihood ratio, and accuracy were revealed. All statistical tests were analyzed by IBM SPSS Statistics, version 20.0

(IBM Corp., Armonk, NY, USA). The results were considered statistically significant at p-value less than 0.05.

## Results

According to the inclusion and exclusion criteria, 565 patients were eligible and enrolled into the present study. Their demographic, clinical, laboratory, and radiological data, and their ERCP findings are shown in Table 2. All of continuous data were not normally distributed, therefore, their results were demonstrated in the table using median and interquartile range (IQR). CBDS were found by ERCP in 75.4% of the patients. Complications were reported in 37 cases (6.5%). They were bleeding in 16 cases, post-ERCP pancreatitis in 14 cases, guidewire microperforation in 6 cases, cholangitis in 3 cases, and duodenal perforation in 1 case.

The comparison of continuous data between groups with and without CBDS was performed by Mann-Whitney U test. As shown in Table 3, the univariate analysis revealed three statistically significant factors for finding CBDS by ERCP. They were age, post-cholecystectomy, and alkaline phosphatase (ALP) level. Acute cholangitis and acute cholecystitis, with $p<0.10$, were considered potentially significant variables, and they were also included in the multivariate analysis.

The result of multivariate analysis, shown in Table 4, revealed three variables as significant factors. Post-cholecystectomy patients carried the highest risk of CBDS if clinically suspicious. Increasing age and rising ALP also increased risk of CBDS.

**Table 2.** Demographic, clinical, laboratory, radiological data, and ERCP findings (n=565)

| | |
|---|---|
| Age (years); median (IQR) | 60 (45.5 to 73) |
| Sex (male); n (%) | 274 (48.5) |
| Clinical manifestation; n (%) | |
| Abdominal pain | 501 (88.7) |
| Cholangitis | 303 (53.6) |
| Cholecystitis | 67 (11.9) |
| Post-cholecystectomy; n (%) | 44 (7.8) |
| Laboratory results; median (IQR) | |
| WBC (cells/mm$^3$)* | 9,800 (6,875 to 13,000) |
| TB (mg/dL) | 3.39 (1.41 to 6.09) |
| DB (mg/dL) | 2.37 (0.80 to 4.40) |
| AST (U/L)# | 117 (55 to 253) |
| ALT (U/L)# | 154 (58 to 306) |
| ALP (U/L) | 214 (145 to 322) |
| Imaging; n (%) | |
| Ultrasound | 295 (52.2) |
| CT | 204 (36.1) |
| MRI | 110 (19.5) |
| ASGE; n (%) | |
| High-risk | 485 (85.8) |
| Intermediate risk | 78 (13.8) |
| CBDS by ERCP; n (%) | 426 (75.4) |

TB=total bilirubin; DB=direct bilirubin; ALT=alanine aminotransferase; AST=aspartate aminotransferase; ALP=alkaline phosphatase; WBC=white blood cell; CT=computer tomography; MRI=magnetic resonance imaging; ASGE=American Society for Gastrointestinal Endoscopy; CBDS=common bile duct stone; ERCP=endoscopic retrograde cholangiopancreatography; IQR=interquartile range

Missing data *39 and #10 patients

In Table 5, the test characteristics of each imaging study are displayed. Expectedly, MRCP provided the

**Table 3.** Univariate analysis comparing important factors between patients with and without CBDS identified by ERCP

| | CBDS by ERCP | | p-value |
|---|---|---|---|
| | Yes (n=426) | No (n=139) | |
| Age (year); median (IQR) | 62 (46 to 75) | 56 (43 to 66) | <0.01 |
| Sex (male) | 47.7% | 51.1% | 0.48 |
| Acute cholangitis | 55.2% | 46.8% | 0.09 |
| Post-cholecystectomy | 9.2% | 3.6% | 0.03 |
| Acute cholecystitis* | 11.4% | 17.2% | 0.08 |
| WBC (cells/mm$^3$); median (IQR) | 9,700 (6,912.5 to 13,300) | 9,800 (6,775 to 12,400) | 0.68 |
| TB (mg/dL); median (IQR) | 3.66 (1.41 to 6.58) | 2.91 (1.41 to 5.30) | 0.13 |
| DB (mg/dL); median (IQR) | 2.49 (0.81 to 4.52) | 2.06 (0.75 to 3.93) | 0.18 |
| AST (U/L); median (IQR) | 114.5 (55 to 251) | 128 (51 to 285.5) | 0.88 |
| ALT (U/L); median (IQR) | 148 (55.8 to 296.3) | 162 (63 to 365) | 0.21 |
| ALP (U/L); median (IQR) | 225 (146.8 to 347) | 191 (139 to 285) | 0.04 |

TB=total bilirubin; DB=direct bilirubin; ALT=alanine aminotransferase; AST=aspartate aminotransferase; ALP=alkaline phosphatase; WBC=white blood cell; CBDS=common bile duct stone; ERCP=endoscopic retrograde cholangiopancreatography; IQR=interquartile range

* Excluding 44 patients with gallbladder removed

**Table 4.** Multivariate analysis of CBDS found by ERCP

| Factors | p-value | Adjusted odds ratio (95% CI) |
|---|---|---|
| Post-cholecystectomy | 0.04 | 2.620 (1.003 to 6.846) |
| Age (years) | 0.01 | 1.014 (1.003 to 1.025) |
| ALP (U/L) | 0.01 | 1.002 (1.000 to 1.003) |

ALP=alkaline phosphatase; CI=confidence interval

highest accuracy among the three types of imaging study. Of the three ASGE criteria for high-risk, CBDS on imaging seemed to be the most reliable condition to predict CBDS at ERCP.

For the next step, the three significant variables from multivariate analysis were considered as new additional criteria. Elevated ALP was the one factor chose to apply in the newly proposed criteria. The new additional criteria for high-risk was "total bilirubin 1.8 to 4.0 and elevated ALP with CBD dilatation". After the four criteria, including the new one, were applied to redefine the high-risk group, the accuracy and odds ratio of new high-risk group were higher, as shown in Table 6.

## Discussion

CBDS is one of the most common abdominal problems worldwide. It presents with various clinical manifestations, from vague abdominal pain to life-threatening conditions, such as toxic cholangitis. The ASGE guideline was established to provide recommendations on the proper use of endoscopic treatment, based on clinical evaluation and investigation of suspected CBDS. The latest update, in 2019, was revised from the previous 2010 edition, to make the criteria less complicated and more practical for clinical use.

Most patients with CBDS also have abnormal LFTs. Meta-analysis from Wang et al reported sensitivity of 85% with a range of 71% to 99%,

**Table 5.** Test characteristics of imaging study and ASGE criteria

| | Suspected CBDS (%) | Sensitivity (%) | Specificity (%) | Positive predictive value (%) | Accuracy (%) | Positive likelihood ratio (%) |
|---|---|---|---|---|---|---|
| Imaging studies | | | | | | |
| US | 41.0 (121/295) | 46.2 | 71.8 | 80.2 | 53.6 | 1.64 |
| CT | 72.5 (148/204) | 80.1 | 52.1 | 84.5 | 73.5 | 1.67 |
| MRCP | 79.1 (87/110) | 88.6 | 59.1 | 89.7 | 82.7 | 2.17 |
| Original high-risk criteria | | | | | | |
| CBDS on imaging | 60.9 (344/565) | 68.1 | 61.2 | 84.3 | 66.4 | 1.76 |
| Clinical cholangitis | 53.1 (300/565) | 55.2 | 53.2 | 78.3 | 54.7 | 1.18 |
| TB >4 and CBD dilatation | 32.7 (185/565) | 37.6 | 82.0 | 86.5 | 48.5 | 2.09 |
| Overall of high-risk group | 85.8 (485/565) | 90.6 | 28.8 | 79.6 | 75.4 | 1.27 |
| Newly proposed high-risk criteria | | | | | | |
| TB 1.8 to 4.0 and elevated ALP and CBD dilatation | 16.8 (95/565) | 17.8 | 86.3 | 80.0 | 34.7 | 1.30 |
| Overall of new high-risk group | 87.3 (493/565) | 92.3 | 28.1 | 79.7 | 76.5 | 1.28 |

US=ultrasound; CT=computer tomography; MRCP=magnetic resonance cholangiopancreatography; TB=total bilirubin; CBD=common bile duct; CBDS=common bile duct stone

**Table 6.** Odds ratios of criteria and high-risk group

| | Crude odds ratio (95% CI) | p-value |
|---|---|---|
| Original criteria | | |
| CBDS on imaging | 3.36 (2.26 to 4.99) | <0.01 |
| TB >4 and CBD dilatation | 2.74 (1.71 to 4.41) | <0.01 |
| Clinical cholangitis | 1.40 (0.95 to 2.06) | 0.09 |
| New criteria | | |
| TB 1.8 to 4.0 and elevated ALP with CBD dilatation | 1.37 (0.80 to 2.36) | 0.25 |
| Overall | | |
| High-risk of original 3 criteria | 3.90 (2.39 to 6.37) | <0.01 |
| High-risk of newly proposed 4 criteria | 4.65 (2.78 to 7.76) | <0.01 |

TB=total bilirubin; CBD=common bile duct; CBDS=common bile duct stone; ALP=alkaline phosphatase; CI=confidence interval

specificity of 25% with a range of 1% to 59%, and positive predictive value (PPV) of 58% with a range of 35% to 82% of abnormal LFT to detect CBDS[9]. The present study results, which are not shown in the tables, demonstrated sensitivity of 92.3%, specificity of 5.8%, PPV of 75.0%, and accuracy of 71.0%. The present study results revealed significantly higher total bilirubin and ALP levels in the CBDS group. Furthermore, multivariate analysis revealed elevated ALP level as one of the significant independent factors. This condition is a potential predictor for the detection of CBDS. Another study by Yang et al reported a similar observation[10].

Radiologic finding is a crucial criterion for identifying high risk of CBDS. Finding stones within the CBD by any type of imaging classifies a patient as high-risk for CBDS and indicates ERCP for stone removal. TAUS is performed as the initial imaging study when CBDS is suspected. US can detect abnormal dilatation of the bile duct, and sometimes bile duct stones, which present as high echogenic lesions with posterior acoustic shadow. Ultrasonography provides high specificity at 87% to 90%, but poor sensitivity at 22% to 55%, and high degree of operator dependency. Stones typically lodge distally in the intrapancreatic part of CBD. Therefore, they may be obscured by duodenal gas[11,12]. In the present study, the data showed sensitivity of 46.2%, specificity of 71.8%, and accuracy of 53.6% in detection of CBDS by TAUS when ERCP was used as standard reference.

Computer tomography (CT) is widely used to investigate patients presenting with abdominal pain. CT has higher sensitivity than US in diagnosis of CBDS. It is also useful for distinguishing malignant biliary obstructions. Attenuation values in CT scans are affected by chemical components in stones. Mixed cholesterol stones or pigment stones are usually hyperattenuated, depending on the components of calcium phosphate or calcium carbonate within the stones. Pure cholesterol stones are iso- or slightly hypoattenuated relative to bile, making them difficult to diagnose[13,14]. Sensitivity of CBDS detection by CT ranges from 71% to 93%[14], and it was 80.1% from the present study, with accuracy of 73.5%.

Magnetic resonance imaging (MRI) is the non-invasive investigation of choice for CBDSs. MRCP is rendered by using a heavily T2-weighted image technique that displays fluid, such as bile, in high signal intensity. Stones have low signal intensity on a T2-weighed image and variable intensity on a T1-weighed image[15]. A Cochrane review by Giljaca et al summarized from seven previous studies, reported high sensitivity at 77% to 100% and high specificity at 73% to 99% of MRCP[16]. The present study found sensitivity of 88.6%, specificity of 59.1%, PPV of 89.7%, negative predictive value (NPV) of 56.5%, and accuracy of 82.7%, using ERCP as reference. Nine patients with CBDS were found by MRI/MRCP but the stones were missing at the time of ERCP, which may be because stones spontaneously passed through ampulla prior to ERCP. The authors had about 10 cases of false negative, found only bile sludge in 3 patients and tiny stones of size 2 to 5 mm in 7 patients.

Among these three criteria for a high-risk group, finding of CBDS on any imaging studies was the most powerful criterion with the highest sensitivity of 68.1%, specificity of 61.2%, and accuracy of 66.4%. In addition, the odds ratio of CBDS found by ERCP was the highest by this criterion. Similarly, a meta-analysis by Wang et al reported "US with stone" had the highest predictive value for choledocholithiasis[9]. The same literature also revealed that the condition of "acute cholangitis" had sensitivity of 23% with a range of 18% to 32%, specificity of 89% with a range of 70% to 100%, PPV of 71% with a range of 9% to 100%, and NPV of 56% with a range of 22% to 88%. In the present study, the authors found sensitivity of 55%, specificity of 53.2%, PPV of 78.3%, and NPV of 27.9% for this clinical predictor. About the condition "total bilirubin greater than 4 mg/dL and CBD dilatation", He et al reported sensitivity of 19%, specificity of 96%, PPV of 78%, and NPV of 58%[17]. Their study was conducted in 267 patients using EUS, MRCP, IOC, PTC, and ERCP as reference modalities. In comparison, the ERCP results of the present study were sensitivity of 37.6%, specificity of 82%, PPV of 86.5%, and NPV of 30%.

Table 7 compares the present study with previous studies[18-23]. The authors enrolled patients who were highly suspected of having CBDS and for whom ERCP was highly indicated. That made a small group of either "non-high risk according to the ASGE 2019 guideline" or "no CBDS". Most previous studies included "symptomatic GS" patients, so they had smaller "high risk" groups and larger "no CBDS" groups. In the present study, false positive cases could reduce the specificity in the smaller group of patients without CBDS.

To find an additional factor to make the high-risk criteria more powerful, the authors considered the three significant variables from the multivariate analysis, which were post-cholecystectomy, age, and elevated

**Table 7.** Comparison of test characteristics from previously published literature and the present study study

| Study | Total | Prevalence of high-risk (%) | Prevalence of CBDS (%) | Sensitivity (%) | Specificity (%) | Positive predictive value (%) | Accuracy (%) | Positive likelihood ratio (%) |
|---|---|---|---|---|---|---|---|---|
| The present study | 565 | 85.8 | 75.4 | 90.6 | 28.8 | 79.6 | 75.4 | 1.27 |
| Hasak, 2022[18] | 1,098 | 50.5 | 66.3 | 65.8 | 79.5 | 86.3 | 70.4 | 3.12 |
| Tunruttanakul, 2022[19] | 521 | 69.7 | 61.0 | 84.0 | 52.7 | 73.6 | 68.7 | 1.78 |
| Jakob, 2021[20] | 267 | 32.2 | 71.9 | 37.0 | 80.0 | 83.0 | 49.1 | 1.85 |
| Lei, 2021[21] | 879 | 53.7 | 70.8 | 59.5 | 60.3 | 78.4 | 59.7 | 1.50 |
| Chandra, 2020[22] | 843 | 37.7 | 31.0 | 42.4 | 75.0 | 82.1 | 51.2 | 1.70 |
| Jagtap, 2020[23] | 1,042 | 22.1 | 26.5 | 74.6 | 96.9 | 89.6 | 91.0 | 23.82 |

ALP. Patients underwent cholecystectomy might have higher risk of CBDS due to dilated extrahepatic bile duct and bile stasis after their gallbladder was removed. However, "post-cholecystectomy" should not be a high-risk criterion because it does not seem clinically reasonable. ERCP is not appropriate management in patients suspected of having CBDS with only the criterion "post-cholecystectomy", without any imaging studies or clinical cholangitis or elevated bilirubin. The condition "age older than 55 years" is already one of the intermediate-risk criteria in the ASGE 2019 guideline, so it should not be included as a high-risk criterion. "Elevated ALP" was statistically associated with higher risk of CBDS, but elevated ALP is already a component of "abnormal liver biochemical tests" within the intermediate-risk criteria. Nevertheless, the authors thought adding ALP to high-risk criteria would be helpful. In the authors' experience, ALP is a sensitive biomarker for pathology of the biliary system, including obstruction by stones. Rising ALP with mild hyperbilirubinemia could be caused by partial obstruction or early obstruction, especially when associated with bile duct dilatation revealed by imaging studies. The ASGE 2010 guideline referred to mild hyperbilirubinemia, defined as bilirubin 1.8 to 4.0 mg/dL, as a strong predictor.

The authors propose "total bilirubin 1.8 to 4.0 and elevated ALP and CBD dilatation" to be a new criterion for the high-risk group, to include patients with CBDS with early or partial bile duct obstruction. This group of patients does not yet present with obvious jaundice and cholangitis, so they might not otherwise receive adequate treatment. In the present study, only 95 patients had all three of these conditions concomitantly. The new proposed criterion changed their status from intermediate risk to high risk. Statistical analysis revealed that "total bilirubin 1.8 to 4.0 and elevated ALP and CBD dilatation" provided low sensitivity and non-significant odds ratio. The explanation of this finding could be that too few patients were categorized by this highly selective new high-risk criterion. However, the advantage of this criterion is higher specificity than the three original criteria, with similar positive predictive value at 80%. Moreover, the new proposed model of four high-risk criteria has better test characteristics and a higher odds ratio in comparison with the original three criteria.

A limitation of the present research was the study design, which was retrospective study. Data was missing from the electronic medical records, mostly about patients referred from other hospitals. A larger group of patients characterized by the new criteria "total bilirubin 1.8 to 4.0 and elevated ALP and CBD dilatation" might be needed to confirm its effectiveness in predicting the existence of CBDS.

## Conclusion

The high-risk criteria of ASGE 2019 Guideline are an effective evaluation for patients with clinically suspected CBDS. The present study showed positive predictive value of almost 80% and accuracy about 75%. Adding the new criterion "total bilirubin 1.8 to 4.0 and elevated ALP and CBD dilatation" could make the high-risk criteria more sensitive to CBDS with early or partial biliary obstruction and provide higher accuracy.

## What is already known on this topic?

The ASGE guidelines on the role of endoscopy in the evaluation and management of choledocholithiasis were revised in 2019. High-risk criteria were defined as 1) cholangitis, 2) stone on imaging, and 3) total bilirubin of more than 4 mg/dL with CBD dilation greater than 6 mm or greater than 8 mm if cholecystectomy was performed. Patients with any one of these high-risk criteria were determined to carry high-risk for CBDS and ERCP was recommended.

## What this study adds?

The high-risk criteria of ASGE 2019 Guideline are an effective evaluation for patients with clinically suspected CBDS. This study showed positive predictive value of almost 80% and accuracy of about 75%. Adding the new criterion "total bilirubin 1.8 to 4.0 and elevated ALP and CBD dilatation" could make the high-risk criteria more sensitive to CBDS with early or partial biliary obstruction and provide higher accuracy.


## Acknowledgement

The present study was financially supported by The Research Group in Surgery, Faculty of Medicine, Thammasat University. Additionally, the authors would like to express their gratitude to their colleagues, including interns, residents, and nurses, working at Department of Surgery, Thammasat University Hospital, for assistance in clinical processes and endoscopic procedures.


## Conflicts of interest

The authors declare no conflict of interest.

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