

Clinical utility of ESGE and ASGE guidelines for prediction of suspected choledocholithiasis in patients undergoing cholecystectomy

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ABSTRACT

Background Recent guidelines from the European Society of Gastrointestinal Endoscopy (ESGE) and American Society for Gastrointestinal Endoscopy (ASGE) recommend risk stratification according to liver function test (LFT) and abdominal ultrasound in patients with suspected choledocholithiasis. We evaluated and validated the clinical utility of these new risk stratification criteria for choledocholithiasis.

Methods We retrospectively analyzed prospectively maintained data of patients with suspected choledocholithiasis between January 2016 and December 2018 in patients undergoing cholecystectomy. Patients with common bile duct stricture, cirrhosis, and portal biliopathy were excluded. After LFT and ultrasound, all patients were stratified according to ESGE and ASGE criteria into high, intermediate, and low likelihood of choledocholithiasis.

Results 1042 patients were analyzed. Using ESGE guidelines, 213 patients (20.4%) met high likelihood criteria, 637 (61.1%) met intermediate, and 192 (18.4%) met low likelihood criteria. Using ASGE guidelines, 230 (22.1%), 678 (65.1%), and 134 (12.9%) met high, intermediate, and low likelihood criteria, respectively. Specificity and positive predictive value (PPV) of ASGE high likelihood criteria were 96.87% (95% confidence interval [CI] 95.37–97.98) and 89.57% (95%CI 85.20–92.75) for choledocholithiasis compared with 98.96% (95%CI 97.95–99.55) and 96.24% (95% CI 92.76–98.09), respectively, for ESGE criteria. ASGE classified 17 (7.4%) additional patients as high likelihood compared with ESGE, only one of whom had choledocholithiasis. ASGE classified 58 (8.6%) additional patients as intermediate, none of whom had choledocholithiasis.

Conclusion This study validates the clinical utility of new ESGE and ASGE criteria for predicting choledocholithiasis. ESGE risk stratification appears more specific than ASGE.

Introduction

Although the majority of gallstones remain asymptomatic [1, 2], 10%–25% of them develop complications, which include biliary pain, cholecystitis, obstructive jaundice, and pancreatitis [3]. These complications develop mostly due to migration of gallstones into the common bile duct (CBD) [4]. Choledocholithiasis is commonly managed by endoscopic retrograde cholangiopancreatography (ERCP) or surgically during cholecystectomy [1]. ERCP has been the standard of care for confirmed choledocholithiasis [1, 4]. However, it carries a significant risk (6%–15%) of major adverse events, which include post-ERCP pancreatitis, bleeding, and perforation [5]. Recently, the Euro-

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► Table 1 Comparison of American Society for Gastrointestinal Endoscopy and European Society of Gastrointestinal Endoscopy stratification for likelihood of choledocholithiasis.

Criteria	ASGE	ESGE
High likelihood	<ul style="list-style-type: none"> Cholangitis CBD stone on ultrasound Combination of total bilirubin >4 mg/dL and CBD dilation on ultrasound 	<ul style="list-style-type: none"> Cholangitis or CBD stone on ultrasound
Intermediate likelihood	<ul style="list-style-type: none"> Abnormal LFTs Age >55 years CBD dilation on ultrasound 	<ul style="list-style-type: none"> Abnormal LFTs and/or CBD dilation on ultrasound
Low likelihood	<ul style="list-style-type: none"> Normal LFTs and ultrasound (no CBD dilation on ultrasound) 	<ul style="list-style-type: none"> Normal LFTs and ultrasound (no CBD dilation on ultrasound)

ASGE, American Society for Gastrointestinal Endoscopy; ESGE, European Society of Gastrointestinal Endoscopy; CBD, common bile duct; LFT, liver function test.

pean Society of Gastrointestinal Endoscopy (ESGE) and American Society for Gastrointestinal Endoscopy (ASGE) published guidelines for the management of choledocholithiasis (► **Table 1**) [1, 4]. Both guidelines updated the diagnostic strategies for patients with suspected choledocholithiasis in order to minimize the use of diagnostic ERCP.

The ESGE guideline stratifies patients with suspected choledocholithiasis into a high likelihood group if there are features of cholangitis or CBD stones identified during ultrasound. Patients are stratified as intermediate likelihood if they have abnormal liver function tests (LFTs) and/or CBD dilation on ultrasound, and low likelihood if LFTs and ultrasound are normal. The ASGE high likelihood criteria for choledocholithiasis include cholangitis, CBD stone on imaging, and a combination of total bilirubin >4 mg/dL and CBD dilation on ultrasound. Intermediate likelihood criteria include abnormal LFTs, age >55 years, and CBD dilation [4]. Both guidelines recommend that patients with any high risk criteria should proceed to preoperative ERCP or direct cholecystectomy with CBD exploration depending on available expertise, and those with intermediate risk criteria should undergo either endoscopic ultrasound (EUS), magnetic resonance cholangiopancreatography (MRCP) or intraoperative cholangiogram (IOC). Patients categorized as having a low likelihood of choledocholithiasis should undergo cholecystectomy if indicated for symptomatic cholelithiasis.

In this study, we aimed to evaluate and validate the clinical utility of these new diagnostic strategies for choledocholithiasis.

Methods

Institutional review board approvals were obtained prior to this retrospective study of prospectively maintained data. The study population included patients undergoing cholecystectomy at a

large tertiary care academic hospital from January 2016 to December 2018. We reviewed clinical, endoscopic, and radiological records of all consecutive patients who underwent cholecystectomy for symptomatic gallstones. Based on these records, those patients who had abnormal LFTs, CBD dilation with or without CBD stone or sludge, acute biliary pancreatitis, or cholangitis were identified. These patients subsequently underwent EUS, MRCP, ERCP or IOC for suspected choledocholithiasis. The records of these cases were reviewed according to eligibility criteria. Patients were excluded if there was a history of underlying liver disease, significant alcohol consumption, prior biliary surgery, prior biliary sphincterotomy, pancreaticobiliary neoplasm, biliary strictures, portal biliopathy, recurrent pyogenic cholangitis or primary sclerosing cholangitis.

Using a standardized data collection sheet, the following data were collected: age, sex, pre-intervention LFTs, ultrasound findings (CBD dilation, presence of CBD stone and/or sludge), presence of clinical cholangitis, pancreatitis. Patients with any of the strong predictors of CBD stone (i.e. CBD stone on ultrasound and cholangitis) underwent ERCP or IOC. Those with moderate predictors (i.e. altered LFTs, acute biliary pancreatitis or dilated CBD on ultrasound) underwent EUS or MRCP. Those with no predictors for CBD stones were recommended for cholecystectomy for symptomatic cholelithiasis. Following initial endoscopic and/or radiological interventions such as EUS, ERCP, and MRCP, the presence or absence of CBD stones was noted. In cases of discrepancy, the presence of CBD stones was confirmed if ERCP showed stones during cholangiogram and subsequent retrieval was performed or diagnosed within 6 months of follow-up after cholecystectomy. For those patients who underwent cholecystectomy with CBD exploration, the presence of CBD stones was confirmed with IOC. CBD stones diagnosed during 6 months of follow-up after cholecystectomy were considered as missed CBD stones.

Statistical analysis

After collection of the data, we stratified patients with risk of choledocholithiasis according to ESGE and ASGE guidelines into high, intermediate, and low likelihood. The clinical utility of the two guidelines was evaluated in terms of specificity and positive predictive value (PPV) of high likelihood of choledocholithiasis with the aim of reducing the need for diagnostic ERCP. We also calculated sensitivity, negative predictive value, and diagnostic accuracy of high and intermediate likelihood groups and individual risk factors.

Clopper–Pearson confidence intervals (CIs) were calculated for sensitivity, specificity, and accuracy. The log method was used to calculate the CIs for the likelihood ratio, and standard logit was used for CIs for the predictive values. SPSS version 23 (IBM Corp., Armonk, New York, USA) and MedCalc version 19.1.3 (MedCalc Software bv, Ostend, Belgium) were used for statistical analysis.

► Table 2 Baseline characteristics of study population (n = 1042).

Age, mean (SD), years	46 (14.9)
Male sex, n (%)	480 (46.1)
Pancreatitis, n (%)	408 (39.2)
Cholangitis, n (%)	71 (6.8)
Cholecystitis, n (%)	266 (25.5)
Bilirubin >4 mg/dL, n (%)	101 (9.7)
Bilirubin >4 mg/dL and dilated CBD on USG, n (%)	57 (5.5)
Ultrasound abdomen, n (%)	
▪ Dilated CBD	434 (41.7)
▪ CBD stone	174 (16.7)
▪ CBD stone/sludge on definitive investigation, n (%)	276 (26.5)
Choledocholithiasis on definitive Investigations, n/N (%)	
▪ EUS	59/568 (10.4)
▪ MRCP	19/233 (8.2)
▪ IOC	35/63 (55.6)
▪ ERCP	247/255 (96.9)

SD, standard deviation; CBD, common bile duct; EUS, endoscopic ultrasound; MRCP, magnetic resonance cholangiopancreatography; IOC, intraoperative cholangiogram; ERCP, endoscopic retrograde cholangiopancreatography.

Results

During the study period, 1042 patients with suspected choledocholithiasis were enrolled for analysis. The mean age of patients was 46 years (standard deviation 14.9), and 480 (46.1%) were male. At presentation, 408 (39.2%) had pancreatitis, 71 (6.8%) had cholangitis, and 266 (25.5%) had cholecystitis. Ultrasound of the abdomen showed a dilated CBD in 434 patients

(41.7%) and CBD stones in 174 (16.7%). Baseline characteristics of the study population are summarized in ► **Table 2**.

From results of clinical, biochemical, and ultrasound tests, 213 patients (20.4%) met high likelihood criteria, 637 (61.1%) met intermediate criteria, and 192 (18.4%) met low likelihood criteria according to the ESGE guideline. According to the ASGE guideline, 230 (22.1%), 678 (65.1%), and 134 (12.9%) patients, respectively, met high, intermediate, and low likelihood criteria.

After confirmatory tests, 276 patients (26.5%) had choledocholithiasis; of these patients, 241 (87.3%) underwent ERCP and CBD stone removal, and the remaining 35 patients (12.7%) underwent surgical CBD exploration and CBD stone removal during cholecystectomy. The majority of patients (>98%) in the high likelihood groups underwent direct ERCP or surgical therapy for CBD stones after biochemical tests and abdominal ultrasound. None of the patients in the low likelihood groups underwent ERCP without CBD stone confirmation by either EUS or MRCP. A total of 28 out of the 637 patients (4.4%) in the ESGE intermediate likelihood group and 42 out of 678 patients (6.2%) in the ASGE intermediate likelihood group underwent ERCP or surgical CBD exploration. The remaining patients underwent EUS or MRCP for confirmation of CBD stone.

Performance of ASGE and ESGE criteria

Of the study population, 230 patients (22.1%) met ASGE high likelihood criteria with specificity of 96.87% (95%CI 95.37–97.98) and PPV of 89.57% (95%CI 85.20–92.75) for detection of choledocholithiasis. A total of 213 patients (20.4%) met ESGE high likelihood criteria with a specificity of 98.96% (95%CI 97.95–99.55) and PPV of 96.24% (95%CI 92.76–98.09) for detection of choledocholithiasis. In low likelihood groups, 5 of 192 patients (2.6%) with ESGE criteria and 5 of 134 patients (3.7%) with ASGE criteria had choledocholithiasis. The diagnostic performance of both guidelines is summarized in ► **Table 3**. In total, 24/230 (10.4%) ASGE high likelihood patients and 8/213 (3.8%) ESGE high likelihood patients were at risk of undergoing diagnostic ERCP.

► Table 3 Performance of American Society for Gastrointestinal Endoscopy and European Society of Gastrointestinal Endoscopy criteria for likelihood of choledocholithiasis.

Criteria	Performance parameters, % (95%CI)						
	Specificity	Sensitivity	PPV	NPV	LR+	LR–	Accuracy
ESGE High	98.96 (97.95–99.55)	74.28 (68.69–79.33)	96.24 (92.76–98.09)	91.44 (89.73–92.88)	71.12 (35.57–142.19)	0.26 (0.21–0.32)	92.42 (90.64–93.95)
ASGE High	96.87 (95.37–97.98)	74.64 (69.08–79.66)	89.57 (85.20–92.75)	91.38 (89.64–92.85)	23.82 (15.97–35.53)	0.26 (0.21–0.32)	90.98 (89.07–92.65)
ESGE Intermediate	25.46 (22.41–28.70)	23.91 (19.00–29.39)	10.36 (8.53–12.53)	48.15 (44.72–51.60)	0.32 (0.26–0.40)	2.99 (2.60–3.43)	25.05 (22.44–27.80)
ASGE intermediate	19.97 (17.20–22.98)	23.64 (18.74–29.11)	9.59 (7.88–11.62)	42.15 (38.39–46.00)	0.30 (0.24–0.37)	3.82 (3.27–4.47)	20.94 (18.51–23.54)

CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; LR+, positive likelihood ratio; LR–, negative likelihood ratio; ESGE, European Society of Gastrointestinal Endoscopy; ASGE, American Society for Gastrointestinal Endoscopy.

► Table 4 Overlap and difference between American Society for Gastrointestinal Endoscopy and European Society of Gastrointestinal Endoscopy criteria for likelihood of choledocholithiasis.

Criteria	Overlap	n	Choledocholithiasis, n
ASGE High (n = 230)	ESGE High likelihood	213	205
	ESGE Intermediate likelihood	17	1
ASGE Intermediate (n = 678)	ESGE Intermediate likelihood	620	65
	ESGE Low likelihood	58	0
ESGE Low (n = 192)	ASGE Intermediate likelihood	58	0
	ASGE Low likelihood	134	5

ASGE, American Society for Gastrointestinal Endoscopy; ESGE, European Society of Gastrointestinal Endoscopy.

The overlap and differences between two guidelines are shown in ► **Table 4**. ASGE criteria stratified 17 additional patients into the high likelihood group compared with the ESGE criteria. Of these 17 patients, only one had choledocholithiasis. ESGE high likelihood criteria compared with ASGE avoided 7.0% (16/230) ERCs in high likelihood patients and 1.5% ERCs in the overall population. For intermediate likelihood groups, using ESGE criteria 637 patients required EUS or MRCP to confirm choledocholithiasis, 66 of whom (10.4%) had CBD stones. Using ASGE criteria, 678 patients required EUS or MRCP, 65 of whom (9.6%) had choledocholithiasis. Of the 678 patients in the ASGE intermediate likelihood group, the ESGE criteria classified 620 as intermediate and 58 as low likelihood. None of these 58 patients had choledocholithiasis. ESGE intermediate likeli-

hood criteria avoided 8.6% (58/678) EUS or MRCPs compared with the ASGE intermediate likelihood criteria. The diagnostic performance of individual criteria is described in ► **Table 5**.

Discussion

Choledocholithiasis is one of the most common indications for ERCP [4]. ERCP is considered a complex endoscopic procedure that is associated with potentially severe adverse events and mortality [5]. Previous ASGE risk stratification criteria were more liberal, with up to 40% of patients categorized as high likelihood of choledocholithiasis and at risk of requiring diagnostic ERCP [6, 7]. EUS and MRCP have emerged as safe and effective diagnostic modalities for choledocholithiasis [8–10]. Given the widespread availability of EUS and MRCP and the risk associated with diagnostic ERCP, there was clear need for improvement in previous risk stratification criteria [6, 11, 12]. ESGE and ASGE have recently updated their guidelines for the management of choledocholithiasis with the aim of improving pretest probabilities to reduce the risk of undergoing diagnostic ERCP [1, 4].

In this study, we investigated the clinical utility of the recent guidelines and showed that ESGE high likelihood criteria have specificity of 98.96% and PPV of 96.24% for choledocholithiasis compared with 96.87% and 89.57%, respectively, with ASGE criteria. ESGE high likelihood criteria compared with ASGE criteria avoided 7.0% (16/230) ERCs in high likelihood patients. In the intermediate likelihood groups, ESGE criteria avoided 8.6% (58/678) EUS or MRCPs compared with ASGE criteria. These findings indicate that ESGE criteria are more specific than ASGE criteria.

The difference between ASGE and ESGE criteria for high likelihood of choledocholithiasis is driven by the inclusion of bilirubin >4 mg/dL and dilated CBD on ultrasound into the high likelihood category of ASGE criteria. In the current study, specificity

► Table 5 Diagnostic performance of individual criteria.

Criteria	Specificity	Sensitivity	PPV	NPV	Accuracy
Cholangitis	98.96 (97.95–99.55)	22.83 (18.01–28.24)	88.73 (79.27–94.91)	78.06 (76.94–79.15)	78.18 (76.18–81.24)
Stone on ultrasound	99.61 (98.86–99.92)	61.96 (55.94–67.71)	98.28 (94.83–99.44)	87.90 (86.21–89.42)	89.64 (87.62–91.42)
Bilirubin >4 mg/dL and dilated CBD	96.78 (94.82–98.15)	42.66 (32.66–53.22)	71.93 (60.02–81.39)	89.74 (88.03–91.23)	88.03 (85.14–90.53)
Dilated CBD	68.54 (65.12–71.81)	69.93 (64.14–75.28)	44.47 (41.29–47.70)	86.35 (84.00–88.40)	68.91 (66.00–71.71)
Pancreatitis	55.09 (51.49–58.65)	23.19 (18.34–28.62)	15.69 (12.89–18.95)	66.56 (64.51–68.56)	46.58 (43.58–49.72)
Abnormal LFT	38.51 (35.05–42.06)	90.22 (86.09–93.45)	34.58 (33.06–36.14)	91.61 (88.31–94.05)	52.21 (49.12–55.28)
Age >55 years	69.45% (66.05–72.70)	36.96 (31.25–42.95)	30.36 (26.55–34.46)	75.35 (73.41–77.20)	60.84 (57.81–63.82)

PPV, positive predictive value; NPV, negative predictive value; CBD, common bile duct; LFT, liver function test.

and PPV of these combined criteria was 96.78% (95%CI 94.82–98.15) and 71.93% (95%CI 60.02–81.39), which was lower than data for cholangitis and stone on ultrasound. Another study reported specificity of 96% (95%CI 95–97) and PPV of 78% (95%CI 73–83) [13]; the PPV of these combined criteria can be increased to 85% (95%CI 82–88) if CBD stone on ultrasound is added [13]. The combination of bilirubin >4 mg/dL and dilated CBD on ultrasound was evaluated in two other studies, which showed specificity of 93% and 94% and PPV of 59% and 70%, respectively, which are comparable to the present study [6, 12]. As these criteria have low PPV, it may be included to stratify these patients into intermediated likelihood rather than high likelihood criteria. This would reduce the risk of being subjected to diagnostic ERCP in 17/230 patients (7.4%), but they would need to undergo EUS or MRCP to rule out choledocholithiasis before undergoing cholecystectomy.

The difference in criteria for intermediate likelihood in the two guidelines is driven by the inclusion of age >55 years in the ASGE intermediate criteria. Age >55 years had a specificity and PPV for choledocholithiasis of 69.45% (95%CI 66.05–72.70) and 30.36% (95%CI 26.55–34.46) in the current study, compared with a previous study, which showed specificity of 54% (95%CI 51–56) and PPV of 46% (95%CI 43–48) [13]. Two other studies showed that specificity and PPV of age >55 years was 69% and 63%, and 38% and 72%, respectively [11, 14]. If age >55 years was removed from the ASGE intermediate likelihood criteria, it would reduce the need for confirmatory diagnostic tests such as EUS or MRCP in 58/678 patients (8.6%).

Our study has some limitations. In addition to being a retrospective study, we did not study the effect of serial biochemical testing. However, two studies have shown that persistent elevation of bilirubin >4 mg/dL had 86%–90% specificity to detect choledocholithiasis with very low PPVs (52%–71%) [6, 11]. In addition, another study has shown that serial biochemical testing may not influence clinical decision making in suspected choledocholithiasis [13]. The current study might also include selection bias as it was conducted at a referral center, with choledocholithiasis in 26.5% and biliary pancreatitis in 39.2%. We analyzed patients with preoperative suspicion of choledocholithiasis rather than all patients undergoing cholecystectomy, as our aim was to test the clinical utility of guidelines in preoperative suspected choledocholithiasis. This might have changed diagnostic accuracy only slightly, as two previous studies have shown that CBD stone with normal LFT is rare and accounts for only 1.69%–5.4% of all cases [15, 16].

To conclude, the current study validated recent guidelines to improve specificity for detection of choledocholithiasis and minimize the risk of patients requiring diagnostic ERCP. ESGE guidelines may be more specific than ASGE for suspected choledocholithiasis. Cost-effectiveness of these predictive models, however, needs to be evaluated.

Competing interests

The authors declare that they have no conflict of interest.

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