Predicting the likelihood of a persistent bile duct stone in patients with suspected choledocholithiasis: accuracy of existing guidelines and the impact of laboratory trends CME

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Background: Existing guidelines aim to stratify the likelihood of choledocholithiasis to guide the use of ERCP versus a lower-risk diagnostic study such as EUS, MRCP, or intraoperative cholangiography.

Objective: To assess the performance of existing guidelines in predicting choledocholithiasis and to determine whether trends in laboratory parameters improve diagnostic accuracy.

Design: Retrospective cohort study.

Setting: Tertiary-care hospital.

Patients: Hospitalized patients presenting with suspected choledocholithiasis over a 6-year period.

Interventions: Assessment of the American Society for Gastrointestinal Endoscopy (ASGE) guidelines, its component variables, and laboratory trends in predicting choledocholithiasis.

Main Outcome Measurements: The presence of choledocholithiasis confirmed by EUS, MRCP, or ERCP.

Results: A total of 179 (35.9%) of the 498 eligible patients met ASGE high-probability criteria for choledocholithiasis on initial presentation. Of those, 99 patients (56.3%) had a stone/sludge on subsequent confirmatory test. Of patients not meeting high-probability criteria on presentation, 111 (34.8%) had a stone/sludge. The overall accuracy of the guidelines in detecting choledocholithiasis was 62.1% (47.4% sensitivity, 73% specificity) based on data available at presentation. The accuracy was unchanged when incorporating the second set of liver chemistries obtained after admission (63.2%), suggesting that laboratory trends do not improve performance.

Limitations: Retrospective study, inconsistent timing of the second set of biochemical markers.

Conclusion: In our cohort of patients, existing choledocholithiasis guidelines lacked diagnostic accuracy, likely resulting in overuse of ERCP. Incorporation of laboratory trends did not improve performance. Additional research focused on risk stratification is necessary to meet the goal of eliminating unnecessary diagnostic ERCP. (Gastrointest Endosc 2015;82:88-93.)

(footnotes appear on last page of article)

Bile duct stones are a common clinical problem.[1-3] ERCP is highly effective in relieving biliary obstruction, but carries up to a 15% risk of post-ERCP pancreatitis,[4] a 1% to 2% risk of post–endoscopic sphincterotomy bleeding, as well as risks of perforation, infection, and anesthesia-related adverse events.[5] Although the risk-benefit profile of ERCP is favorable in the setting of established choledocholithiasis, when the diagnosis is in question, EUS and MRCP represent highly accurate, lower-risk alternatives for initial evaluation.[6,7]

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To restrict ERCP to patients with the highest probability of choledocholithiasis in whom the risk-benefit ratio is most favorable, accurate and reproducible risk stratification strategies are necessary. In 2010, the American Society for Gastrointestinal Endoscopy (ASGE) published

guidelines defining "very strong," "strong," and "moderate" clinical predictors of choledocholithiasis.[8] According to these guidelines, the presence of any "very strong" predictor (common bile duct [CBD] stone on transabdominal US, clinical ascending cholangitis, serum bilirubin level >4 mg/dL) or both "strong" predictors (a dilated CBD >6 mm on US with an intact gallbladder and a serum bilirubin level of 1.8-4.0 mg/dL) indicate a high probability of choledocholithiasis (defined as >50% likelihood), and ERCP is recommended. Patients classified as intermediate probability are best suited for a less-invasive initial test, such as EUS, MRCP, and intraoperative cholangiography (IOC).

Although these existing guidelines provide a straightforward algorithm for this common problem, their accuracy in predicting choledocholithiasis has not been widely validated, and the impact of the evolution of laboratory values is not addressed. Indeed, some clinicians believe that a comparison of liver function test results over time is highly informative, with decreasing values suggesting spontaneous stone passage and prompting a less-invasive initial intervention.

Based on clinical experience, we hypothesized that current guidelines are not sufficiently accurate to minimize unnecessary ERCP and that inclusion of laboratory trends would significantly improve accuracy. To test these hypotheses, we performed a retrospective cohort analysis in which we correlated patients' ASGE risk classification with the presence of choledocholithiasis and assessed whether trends in liver chemistries improved the performance characteristics of the guidelines. By using this same cohort, we also evaluated the strength of association between common clinical and laboratory predictors and documented choledocholithiasis.

METHODS

The University of Michigan Medical Center Institutional Review Board approved this study. The study sample consisted of patients admitted to a large tertiary care academic medical center with suspected choledocholithiasis over a 6-year period, from January 1, 2007 through December 31, 2012. To identify study subjects, we reviewed all EUS and ERCP cases in our institution's endoscopic reporting database (Provation M; Provation Medical, Minneapolis, Minn), which contains reports of all procedures performed at the University of Michigan, and used an institutionally developed search engine of all radiology reports generated by our radiology department (RadQuery; University of Michigan Department of Radiology, Ann Arbor, Mich), which allows keyword searching of all institutional MRCP reports. One investigator (M.A.) manually reviewed the indications for all EUS studies, ERCPs, and MRCPs performed over the study period to generate a list of cases of suspected choledocholithiasis. Because the language denoting procedural indication was not standardized in Provation M records, we initially cast a wide net and selected all patients with the procedural indications of pancreatitis, choledocholithiasis, biliary dilation, abdominal pain, abnormal liver function test results, or other symptoms that could suggest suspected choledocholithiasis. The RadQuery search was run by using the following specific key words: stone, stones, calculus, calculi, or choledocholithiasis, in combination with the terms biliary, bile duct, obstructing, or CBD. The records of potential cases were then reviewed in detail to evaluate for the presence of prespecified eligibility criteria. Subjects were excluded if there was suspicion of ascending cholangitis based on the concurrent presence of fever or leukocytosis (excluded because it is generally accepted that these patients require urgent ERCP for biliary decompression without antecedent bile duct evaluation), a history of liver transplantation or known liver disease, a history of biliary surgery, a history of primary sclerosing cholangitis, suspicion of pancreaticobiliary malignancy, a previously placed endobiliary stent or sphincterotomy, a history of biliary stricture, or a history of cholecystectomy (excluded because the postcholecystectomy state can influence the CBD diameter and because the guidelines apply specifically to patients with "symptomatic cholelithiasis"). These exclusion criteria were applied because they confound the interpretation of liver biochemical markers and may therefore affect the performance of the guidelines.

The following data were abstracted for each eligible subject in independent and duplicate fashion (M.A., A.H.) by using a standardized data collection spreadsheet: age at time of procedure, sex, whether total bilirubin was more than 4 mg/dL or 4 mg/dL or less on the initial or second set of laboratory test results, US findings (presence of visible stone, CBD >6 mm), presence of biliary pancreatitis, initial and second set of preintervention biochemical markers (aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, total bilirubin), initial intervention chosen (EUS, MRCP, ERCP), presence of a stone on CT scan (if available), whether stone/sludge was found on initial EUS, MRCP, or ERCP, and the occurrence of post-ERCP adverse events (if performed). Discrepancies were resolved by consensus.

From this information, we classified subjects' risk of choledocholithiasis according to ASGE guidelines based on initial laboratory values, and then again at the time of their subsequent laboratory evaluation (in the event liver chemistries were analyzed again before EUS, MRCP, or ERCP). For patients who initially presented to an outside hospital and were subsequently transferred to our institution, the outside facility blood draw was considered the initial laboratory evaluation. For cases in which the ERCP report documented stone(s) or sludge, 2 investigators (E.W., B.J.E.) independently verified the presence of clinically significant choledocholithiasis based on the presence of 1 or more of the following: (1) clear filling defect on

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