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and Other Interventional Techniques

Role of endoscopic retrograde cholangiopancreatography in the management of suspected choledocholithiasis

S. K. Sharma, K. A. Larson, Z. Adler, M. A. Goldfarb

Department of Surgery, Monmouth Medical Center, 300 Second Avenue, Long Branch, NJ 07740, USA

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Abstract

Background: Indications for endoscopic retrograde cholangiopancreatography (ERCP) are not precisely defined. With the increasing availability of magnetic resonance cholangiopancreatography (MRCP) and several prospective studies proving the accuracy of this modality, it is important to select appropriate criteria for invasive testing when common bile duct (CBD) pathology is suspected.

Methods: We reviewed 200 consecutive ERCPs performed for jaundice, pancreatitis, noninvasive visualization of CBD stones, radiologic evidence of CBD dilatation, elevated liver function tests, or biliary colic. Diagnostic and therapeutic yields are determined for each indication and various combinations thereof.

Results: Of the 180 ERCPs performed for suspected choledocholithiasis, 97 (53.8%) were performed for multiple indications, whereas 83 (46.2%) were performed for only one indication. One hundred two patients (56.6%) had CBD pathology, whereas 78 explorations (43.4%) were negative. If multiple indications for ERCP were present, the diagnostic yield was 85.6%. When there was only one indication, the diagnostic yield decreased to 25.3%.

Conclusions: ERCP is an invasive procedure with significant morbidity that should be used selectively. MRCP may be a more appropriate initial evaluation of suspected CBD pathology in many patients.

Key words: Common bile duct — Endoscopic retro grade cholangiopancreatography—Magnetic resonance cholangiopancreatography — Choledocholithiasis

With the evolution of laparoscopic cholecystectomy as a standard treatment for symptomatic gallstone disease, surgeons have come to recognize endoscopic retrograde cholangiopancreaticography (ERCP) as an essential tool for the evaluation of common bile duct (CBD) pathology [1, 2, 4, 11, 17]. The role of ERCP needs to be more precisely defined. The accuracy of predicting choledocholithiasis noninvasively has been variable [10]. It is known that approximately 3–5% of patients suffering from gallstone disease have incidental CBD stones. The clinical picture, biochemical tests, and radiographic evaluation can increase suspicion for the presence of CBD stones; however, none of these tests are definitive.

ERCP is often used as a diagnostic and therapeutic tool in patients suspected of harboring common duct stones. In conjunction with the dramatic increase laparoscopic cholecystectomies performed, there has been an increase in the number of ERCPs performed. This test is performed to evaluate the CBD when any of several clinical conditions, laboratory abnormalities, or radiographic findings are present. Typical clinical indications include jaundice or a history of jaundice, cholangitis, pancreatitis or a history of pancreatitis, and biliary colic. Laboratory abnormalities such as elevations of the serum bilirubin, amylase, lipase, alkaline phosphatase, or transaminase levels have been used as criteria to perform ERCP. Finally, positive findings on transcutaneous ultrasonography (US) of the right upper quadrant or computed tomography (CT) scanning of the abdomen are used to justify invasive evaluation of the CBD. Positive findings include radiographic visualization of CBD stones or radiographic demonstration of CBD dilatation. Indications for performing ERCP in these different situations have not been standardized.

Prior to performing invasive testing, it is important to know as precisely as possible the likelihood that CBD pathology will be present. ERCP is an invasive procedure with a reported complication rate of approximately 13% [3]. Unnecessary invasive procedures delay appropriate treatment, add cost, and subject patients to iatrogenic complications. The use of ERCP should be very selective [12, 13, 17]. If it is known that choledocholithiasis is unlikely, then alternative techniques can be utilized to definitively image the CBD and invasive evaluation may be avoided.

Materials and methods

This study is a retrospective analysis of 200 consecutive ERCPs performed at Monmouth Medical Center, a 527-bed teaching hospital. The procedures were performed by six attending gastroenterologists over a duration of 20 months from May 1999 through December 2000.

Charts were carefully reviewed. Pre-ERCP laboratory test results were tabulated. All patients had had at least one documented amylase, lipase, alkaline phosphatase, total bilirubin, alanine aminotransferase (ALT) level, and aspartate aminotransferase (AST) level measured prior to ERCP. The highest level of each of these tests was entered into the study database. All patients had had either a CT scan of the abdomen or a dedicated right upper quadrant US prior to ERCP. All 200 charts included operative reports dictated by the gastroenterologist who performed the procedure. Each report documented the CBD pathology seen and discussed the nature of any therapeutic interventions performed. Many of the reports discussed procedural indications and a few mentioned procedural complications.

After review of the charts, it was clear that 20 ERCPs were not performed for suspected choledocholithiasis. Indications for these procedures included anatomic evaluation of the pancreatic duct, biopsy of a previously imaged mass, and evaluation of previously placed ampullary stents. None of these procedures are included in the analysis.

The remaining 180 ERCPs were performed for one or several of six specific indications: biliary colic only, CBD dilatation on CT or US, CBD stone visualization on CT or US, elevation of liver function tests (LFTs), jaundice, and pancreatitis. Jaundice is defined as a total serum bilirubin level >1 mg/dl (normal, 0.2–0.9 mg/dl), whether or not clinical jaundice was present. The median serum bilirubin level in the jaundiced group was 2.5 mg/dl. Pancreatitis was defined as hyperamylasemia (>118 U/L) or hyperlipasemia (>62 U/L). Elevation of LFTs was defined as an ALT level higher than 50 U/L, an AST level higher than 48 U/L, an alkaline phosphatase level higher than 128 U/L, or any combination thereof. Seven millimeters was used as an arbitrary cutoff for defining CBD dilatation. Biliary colic only was considered to be the indication for ERCP when all other indications were absent *and* pain or other unpleasant symptoms were referred to in the gastroenterologist's procedural dictation.

Based on earlier research showing jaundice to be highly predictive for choledocholithiasis [2, 11, 17], patients were classified into two groups—those with jaundice and those without jaundice. Patients were further categorized as possessing one or multiple indications for the ERCP. Note that *by definition* the biliary colic only group did not possess multiple indications for ERCP.

The diagnostic and therapeutic yields for ERCP were then calculated for each subgroup. Visualization of either CBD stones or CBD sludge was considered a positive diagnostic study. Visualization of either CBD stones or CBD sludge followed by complete evacuation of all stones and sludge at the time of the initial ERCP was considered a successful therapeutic study. Finally, procedural complications are reported and discussed.

Results

Of the 200 consecutive ERCPs performed over 20 months, 180 (90%) were performed to evaluate for choledocholithiasis. The remaining 20 ERCPs are not analyzed further. Ninety-seven of the 180 patients (53.8%) had more than one indication for performing the procedure. Eighty-three patients (46.2%) had only one indication for ERCP. Seventy-two of 180 patients (40%) had jaundice, whereas 108 patients (60%) had normal bilirubin levels prior to ERCP. Interestingly, the vast majority of jaundiced patients, 68 of 72 (94.4%), had additional indications for ERCP. Seventy-nine patients (73.1%) without jaundice had only one indication for ERCP (Table 1).

Total number of ERCPs performed over 20-month study period	
ERCPs performed to evaluate suspected choledocholithiasis	180
ERCPs performed for another reason (not included in study)	20
Patients with jaundice (serum bilirubin $> 1.0 \text{ mg/dl}$)	72
Patients with jaundice as the only indication for ERCP	4
Patients with jaundice as one of multiple indications for	
ERCP	68
Patients without jaundice (serum bilirubin $\leq 1.0 \text{ mg/dl}$)	108
Patients without jaundice with only one indication for	
ERCP	79
Pancreatitis; no other indication for ERCP	20
CBD stone seen on US or CT; no other indication for	
ERCP	3
Dilated CBD on US or CT; no other indication for	
ERCP	17
Elevated LFTs; no other indication for ERCP	20
Biliary colic; no other indication for ERCP	19
Patients without jaundice with multiple other indications	
for ERCP	29

CBD, common bile duct; CT, computed tomography; ERCP, endoscopic retrograde cholangiopancreatography; LFT, liver function test; US, ultrasonography

Of all ERCPs performed, 102 patients (56.6%) had positive diagnostic studies, and the other 78 patients (43.3%) had a negative exploration. Thus, the overall diagnostic yield for ERCP in this study is 56.6%. Eightyfive of the 102 patients with positive findings had successful clearance of their CBD at the time of the initial ERCP (i.e., when mechanical clearance of the CBD was necessary endoscopic intervention was successful 83.3% of the time). The overall therapeutic yield in this study is 47.2%; 85 of the 180 interventions resulted in mechanical benefit to the patient.

As expected, intervention yields increased significantly when multiple indications were present. The diagnostic and therapeutic yields for the 97 patients with more than one indication for ERCP were 85.6 and 70.1%, respectively. The diagnostic and therapeutic yields for the 83 patients with only one indication for ERCP were 25.3 and 20.5%, respectively. Of the six studied indications, only two proved to be independently highly predictive of choledocholithiasis. The diagnostic yield for ERCPs performed with pretest jaundice as the only indication was 50%, and the diagnostic yield for ERCPs performed with pretest noninvasive radiologic visualization of CBD stones as the only indication was 100%. The other four indications did not predict choledocholithiasis accurately when present individually. The diagnostic yields of ERCPs performed for biliary colic, abnormal LFTs, dilated CBD, and pancreatitis were 26.3, 20, 17.6, and 20%, respectively (Table 2). A total of 76 invasive studies were performed in these low-yield clinical situations. The combined diagnostic yield was 21.1% in these situations, and the combined therapeutic yield was 15.8%.

Twenty-two of 180 patients (12.2%) suffered a procedural complication (Table 3). There were 15 cases of post-ERCP pancreatitis, determined by careful chart review. All 15 patients with pancreatitis had documented hyperamylasemia (>118 U/L) within 10 days following the procedure. Three of these patients had

Table 2. Diagnostic and therapeutic yields for 180 patients undergoing ERCP

Indication(s) for ERCP	No. of patients	No. of positive studies	Diagnostic yield (%)	No. of successful studies	Therapeutic yield (%)
Multiple	97	83	85.6	68	70.1
With jaundice	68	59	86.8	51	75
Without jaundice	29	24	82.8	17	58.6
Single	83	21	25.3	17	20.5
Jaundice	4	2	50	2	50
Pancreatitis	20	4	20	3	15
CBD stone seen on US or CT	3	3	100	3	100
Dilated duct on US or CT	17	3	17.6	3	17.6
Elevated LFTs	20	4	20	4	20
Biliary colic	19	5	26.3	2	10.5

CBD, common bile duct; CT, computed tomography; ERCP, endoscopic retrograde cholangiopancreatography; LFT, liver function test; US, ultrasonography

Table 3. Complications of ERCP

Complication	No. of occurrences	%
Pancreatitis	15	8.3
Unintended stent migration	1	0.6
Pulmonary	3	1.7
Cholangitis	1	0.6
Duodenal perforation	2	1.1
Total	22	12.2

outpatient ERCPs, presented later to the office, and were found to have elevated amylase levels by outpatient laboratory serum analysis. These patients did not require hospital admission. Twelve of the 15 post-ERCP pancreatitis patients were kept on bowel rest as inpatients. Four of these patients were already inpatients at the time of ERCP, and the remaining 8 were admitted that evening, the next day, or, in one case, 7 days later for monitoring and bowel rest after initially being scheduled for outpatient ERCPs. Bowel rest consisted of either nothing by mouth or clear liquids only; treatment ranged from 1 to 7 days, except for 1 patient who required 24 days of bowel rest. Three patients required intravenous hyperalimentation.

There was one case of an unintended migration of a previously placed ampullary stent. There were three pulmonary complications requiring inpatient monitoring. One patient desaturated during the procedure, and there were two cases of aspiration pneumonia. One patient developed cholangitis after endoscopy. Finally, two duodenal perforations occurred but neither required operative intervention. One perforation was suspected immediately by the endoscopist performing papillotomy. Plain films followed by a CT scan that evening revealed large amounts of retroperitoneal air. The patient was kept in our intensive care unit for 8 days and supported with intravenous hyperalimentation. She made a full recovery. The other patient was monitored closely for vomiting and abdominal pain after ERCP. Plain films were normal but a CT scan 6 days postprocedure revealed minimal retroperitoneal air. The patient had recovered clinically by this time and was discharged home on postprocedure day 7.

There was no mortality related to ERCP in this study. No gastrointestinal bleeding requiring transfusion could be ascribed to endoscopic intervention in this study.

Discussion

Since the introduction of laparoscopic cholecystectomy, there has been interest in the study of ERCP as a minimally invasive tool for the diagnosis and treatment of choledocholithiasis [1, 2, 4, 6, 8, 9, 11–13, 17]. Non-therapeutic preoperative ERCP evaluation of the CBD represents an additional trauma to the patient, with a substantial morbidity [3]. However, patients operated on without preoperative clearance of the CBD often require additional surgical procedures with additional exposure to complications. In planning a safe, cost-effective approach to patients with suspected choledocholithiasis, it is essential to know precisely the preoperative likelihood that CBD stones will be present.

Routine evaluation of these patients includes laboratory tests and radiologic imaging in addition to the physical examination. The laboratory workup should include LFTs, amylase and/or lipase assays, and measurement of the serum bilirubin concentration. Noninvasive imaging typically consists of right upper quadrant transcutaneous US. Abdominal CT scan may substitute for US when there is suspicion of extrabiliary pathology. Earlier studies attempted to quantify the preinterventional likelihood of choledocholithiasis based on the results of routine laboratory tests and radiologic imaging, but in most of these studies relatively few patients received a "gold standard" CBD investigation (open or endoscopic cholangiography) [1, 2, 4–6, 8, 9]. Two larger studies succeeded in assessing the preinterventional likelihood that stones will be present on endoscopic intervention. However, one study included the now rarely used intravenous cholangiography as an essential part of the preinterventional workup [11], and the other provided preinterventional expectations for only some of the several indications for ERCP [17].

Our large review provides the surgeon with preoperative expectations based on readily available noninvasive tests. We agree with Tham et al. [17] that appropriate indications for endoscopic CBD evaluation include noninvasive visualization of CBD stones and the presence of jaundice. We further conclude that the presence of any combination of at least two of three "softer" indications (CBD dilatation on US or CT, pancreatitis, and elevated LFTs) justifies endoscopic CBD evaluation. Most important, based on low diagnostic yields, innate procedural risks, and the existence of alternative imaging modalities, ERCP should not be performed as the initial evaluation in cases of isolated pancreatitis, isolated LFT elevations, isolated CBD dilatation, or isolated biliary colic. These patients should receive an alternative evaluation of the CBD prior to ERCP.

Many studies similar to ours have recommended intraoperative cholangiography as the appropriate alternative evaluation when the likelihood of CBD stones is intermediate or low [2, 4, 6, 8, 11, 17]. Laparoscopic US of the CBD has also been advocated [14]. Unfortunately, when these tests are positive most surgeons rely on postoperative ERCP to clear the duct, a procedure predicted to be successful only 83.3% of the time based on our data. Preoperative endoscopic ultrasonographic evaluation of the CBD has been advocated as well [15]. This technique deserves more study and may prove useful, especially if immediate ERCP can be performed in the same session when indicated; however, endoscopic US remains an invasive technique with concomitant morbidity.

It is increasingly accepted within the endoscopic interventionalist community that MRCP will become the gold standard for diagnostic evaluation of the CBD when the likelihood of pathology is intermediate to low. Multiple recent prospective studies [7, 16, 18] have demonstrated the reliability of this technique. MRCP evaluation of lower probability patients would result in a limited number of preoperative ERCPs for positive cases and allow the surgeon to perform laparoscopic cholecystectomy without the need for intraoperative evaluation of the CBD in negative cases.

Table 2 shows that 76 of the 180 ERCPs in our study were performed for low-yield indications. Had MRCP been part of our algorithm, 60 negative ERCPs could have been avoided. Considering our complication rate of 12.2%, 7 patients would have theoretically been spared procedural morbidity. In fact, 8 patients who had negative ERCPs developed complications in our study. Six patients developed postoperative pancreatitis, one duodenal perforation occurred, and one unintended stent migration occurred.

In situations in which the likelihood of choledocholithiasis is high, it is probably more cost-effective to refer directly for ERCP rather than MRCP; however, if the patient is high risk for any intervention, MRCP may still have a role. It is hoped that future studies will address this issue. We acknowledge that in certain centers laparoscopic CBD exploration (LCBDE) is available as an alternative to MCRP- and ERCP-based algorithms. However, LCBDE is not popular because the technique requires specialized surgical expertise and investment in expensive equipment that will rarely be used in the typical hospital operating room. With the increasing availability of MRCP and in recognition of an ongoing imperative to avoid iatrogenic morbidity, we believe our study supports current trends in the endoscopic interventionalist community toward the increased use of MRCP for diagnostic evaluation of the CBD.

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