

# Reflections on indications for ERCP among patients with suspected choledocholithiasis

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The passage of gall stones to the bile duct, or the development of stones in the bile duct, is called choledocholithiasis. This complication occurs in between 3% and 10% of patients who undergo cholecystectomies (1). Initial diagnostic methods have limitations. Abdominal ultrasound which is commonly used in the USA has a sensitivity of 22% to 55%. Use of the diameter of the common bile duct as an indirect indicator of choledocholithiasis when the gallbladder is in situ has also been used. Diameters of 3 mm to 6 mm are considered to be normal. When the diameter is greater than 8 mm, it indicates biliary obstruction. This indicator's sensitivity is between 77% and 87%. The liver profile (bilirubin, transaminases and alkaline phosphatase) has a positive predictive value of 25% to 50% (2). Other methods which have been developed to improve detection of choledocholithiasis have higher levels of sensitivity. Endoscopic ultrasound's (EUS) sensitivity is between 84% and 100% while magnetic resonance cholangiography's (MRC) sensitivity is 100% for stones larger than 1 cm and 71% for stones less than 5 mm (7). The main limitations of these two methods are cost and lack of availability in outlying regions.

Endoscopic treatment has changed the treatment of choledocholithiasis since the introduction of endoscopic retrograde cholangiography (ERCP) in 1974. Today ERCP is the method of choice which is used most frequently for treatment. 85% of all stones are less than 1 cm in diameter and can be extracted by the standard methods of papillotomies and extraction with either a Dormia basket or a balloon catheter. Due to the size of stones or anatomical abnormalities 10% to 15% of these cases are more complex and require more advanced techniques for stone removal including lithotripsy and surgical removal (1).

ERCP is a procedure with high rates of complications in all series. 9.8% of 2,347 patients who had undergone ERCP and were included in a multicenter prospective study in the United States presented complications. Pancreatitis, which developed in 5.4% of these patients, was the most frequent complication. It was followed by bleeding (2%), cholangitis (1%), cholecystitis (0.5%) and perforations (0.3%) (1). Since ERCP is the endoscopic procedure with the highest rate of complications and mortality in gastroenterology, it is very likely that gastroenterologists who perform this procedure regularly will have to confront these complications at some point. Complications are a major reason why many gastroenterologists have opted to stop performing this procedure.

Complications related to endoscopic procedures including ERCP can result in legal claims against physicians, other medical personnel and against medical institutions. Although these claims are made less frequently than those in other fields of medicine

their numbers are increasing. A publication from Cataluña, Spain shows that total numbers of ERCP related lawsuits follow in number those related to colonoscopies, but if we take into account the total volume of procedures performed, the percentage of ERCPs that result in lawsuits is probably much higher than that for those related to colonoscopies. In the United States in 2006, Dr. Peter Cotton published an analysis of 59 ERCP related lawsuits in which he had been asked to give his expert opinion. His primary conclusions were clear, many procedures were performed without good indications and with poor patient information (3). It is important to note that when these cases occurred, the 2002 National Institutes of Health (NIH) guidelines had already been published (5). In 2010 the same author published a letter to the editor entitled *Twenty more ERCP Lawsuits: Why? Poor Indications and communications* (4). His title emphasizes how inexplicable it was that despite prior notification by easily available, new guides he was called as an expert in 20 cases of complaints in which there were at least 12 cases with the same errors related to lack of instructions tailored to the guides. Despite signed informed consent forms, patients reported that they would not have accepted ERCP as the first choice if they had known there were less risky diagnostic alternatives. For these reasons Dr. Cotton believes that these claims are very difficult to defend (4). I do not know of any relevant publications here in Colombia regarding this difficult to face situation. Usually lawsuits are assumed individually which causes high personal and economic costs. Reducing risks from lawsuits should be one of our key objectives. Scientific societies should lead and promote the best practices based on the evidence to provide greater confidence for both physicians and patients.

Since ERCP is an endoscopic procedure that requires increasing technical expertise, recommendations regarding the training curve have been published. In 1996, guidelines recommended that physicians perform 100 endoscopic procedures before performing ERCP. Moreover, those 100 procedures should have included 25 therapeutic procedures with a success rate of 80%. Subsequently the number of procedures performed prior to performing ERCP was increased to 200 in order for physicians to acquire expertise. The newer recommendation included a proviso that physicians continue to perform between 40 to 50 procedures per year with a success rate greater than 90% to maintain their level of training (7). This is approximately 1 procedure per week. For these reasons the United States has programs for an additional year of training before physicians perform ERCP (10). It is clear that it is very difficult for students in the two year graduate programs in our country to perform this number of procedures. Most of us only reach this number after graduation during our practice. For this reason it is advisable for newly graduated gastroenterologists to have

support from more experienced colleagues during the initial phases of their professional practices.

We have implemented various techniques to reduce the post-ERCP pancreatitis rate including the use of hydrophilic guide wire during cannulation, administration of NSAIDs and, in special cases, pancreatic stenting. According to the European consensus on post-ERCP pancreatitis, its incidence is similar in centers with both high and low volumes of procedures. The important difference is that centers performing low volumes of ERCP have lower resolution rates (8). The clear conclusion is that wise use of ERCP is the best way to avoid complications.

The importance of this issue led to the publication of the National Institutes of Health (NIH) guidelines in 2002 (5), the American Society for Gastrointestinal Endoscopy (ASGE) guidelines in 2005 (6), the British guidelines in 2008 (7) and revised ASGE guidelines in 2010 (2).

In the ASGE's 2010 guidelines, clinical predictors are used to assign cases of choledocholithiasis to one of three risk groups. In the lowest risk group there is a 10% probability of choledocholithiasis, the intermediate risk group has a 10% to 50% chance of experiencing choledocholithiasis, and the high-risk group has a 50% or higher probability of choledocholithiasis. Table 1, which is adapted from this guide, summarizes these criteria (2).

**Table 1.** Strategy for using clinical predictors to assign risk of choledocholithiasis among patients with symptomatic cholelithiasis (adapted from the 2010ASGE guidelines).

Choledocholithiasis predictors	
<b>Very strong</b>	
<ul style="list-style-type: none"> <li>• Common bile duct stones detected by ultrasound</li> <li>• Clinically increasing cholangitis</li> <li>• Bilirubin higher than 4 mg/dl</li> </ul>	
<b>Strong</b>	
<ul style="list-style-type: none"> <li>• Common bile duct dilatation greater than 6 mm with the gallbladder in situ</li> <li>• Bilirubin level between 1.8mg/dl and 4 mg/dl</li> </ul>	
<b>Moderate</b>	
<ul style="list-style-type: none"> <li>• Biochemical alterations other than bilirubin in abnormal hepatic exams</li> <li>• Clinical biliary pancreatitis</li> <li>• Allocation of risk of choledocholithiasis based on clinical predictors</li> </ul>	
• Presence of a very strong predictor	High
• Presence of both strong predictors	High
• Absence of predictors	Low
• All other patients	Intermediate

Direct indications for ERCP in high-risk patients are considered to be:

1. Choledocholithiasis documented by ultrasonography,

2. Cholangitis,
3. Bilirubin greater than 4 mg/dl, and
4. Bilirubin between 2.8mg/dl and 4 mg/dl with dilated biliary duct diagnosed by ultrasound.

Direct indications for ERCP in intermediate patients are considered to be:

1. Presence of either bilirubin from 2.8 mg/dl to 4 mg/dl or a dilated bile duct diagnosed by ultrasound,
2. Elevated levels of transaminases,
3. Age over 55 years, and
4. Clinical biliary pancreatitis not in the high risk category.

A diagnosis of choledocholithiasis should be confirmed by more sensitive methods such as endoscopic ultrasound or magnetic resonance cholangiography prior to a decision to perform ERCP.

If all parameters are normal, the patient is considered to be at low risk for choledocholithiasis, and a cholecystectomy can be performed without additional study.

This edition of the magazine includes an article by Dr. Gomez, Dr. Pion and Dr. Otero entitled *Predictors of Choledocholithiasis among Patients Undergoing Endoscopic Retrograde Cholangiography at Hospital El Tunal in Bogotá*. The article is the result of a cross-sectional observational study that sought to establish the degree of association between various predictors of choledocholithiasis. For the article's authors two of the main motivations for this study were the high costs of procedures such as endoscopic ultrasound and magnetic resonance cholangiography and the poor availability of these tools in some of this country's regions. Their work determined that high direct bilirubin (30%) and ages higher than 55 years were the strongest predictors for choledocholithiasis. They concluded that, if both of these variables are present, a patient may be referred directly for ERCP. In my opinion it is important to mention that the use of the 30% level of direct bilirubin as an indicator had not been published previously, although these levels are expected in patients suspected of obstructive jaundice. It would have been interesting to know how well bilirubin levels in ranges between 2.8mg/dl and 4 mg/dl and at levels greater than 4 mg/dl predicted choledocholithiasis since according to the ASGE guidelines the first is a strong predictor and the second is a very strong predictor. Using patient age of 55 years or more as a predictor is consistent with previous publications which have considered it to be a moderate risk factor. It would have been important if this article had included the minimum bile duct diameter which the authors considered to be dilated, and it would also have been useful if they had included whether or not bile duct diameters had been measured with ultrasound by radiologists. Although the diameter of the bile duct is usually very important for

decision making, according to this proposal a dilated bile duct would not be a factor in making the decision to perform ERCP when a patient has two of the above mentioned conditions. I think it would be very important to submit this idea and its implications to a broader discussion. Personally, and in accordance with ASGE guidelines (2), when I find a bilirubin level between 2.8 mg/dl and 4 mg/dl, whether or not I move directly to ERCP depends on a determination of duct dilatation by ultrasonography.

It is also important to highlight the authors' emphasis on patient assessment as close in time to the performance of ERCP as possible. In many instances we are confronted with patients who are referred for ERCP because in their early histories they had signs of high probability of choledocholithiasis, but days after, at the moment of the procedure, they have become asymptomatic. This occurs for various administrative logistical or clinical reasons. In these cases, in which acute biliary pancreatitis has evolved satisfactorily, doctors should reallocate the patient to intermediate probability. In addition it is desirable that the presence of choledocholithiasis be confirmed by endoscopic ultrasound or magnetic resonance cholangiography. If the presence of choledocholithiasis is confirmed, an ERCP should be performed as soon as possible. Some institutions have the resources to perform both procedures on the same day.

Many times we are faced with pressures to perform ERCP on patients with intermediate probabilities of choledocholithiasis. These pressures arise because of delays in authorization or absence of diagnostic studies such as endoscopic ultrasound or magnetic resonance cholangiography. In these cases, one option is to perform intraoperative cholangiography. Cannulation of the cystic duct through open cholecystectomy or laparoscopy can be performed in up to 80% of cases. These procedures have sensitivities between 80% and 92% and specificities from 76.2% to 97% (7). If confirmed, choledocholithiasis can be addressed by intraoperative laparoscopic biliary exploration, intraoperative ERCP, or by draining the bile duct and performing postoperative ERCP.

The following reflections sum up my conclusions.

1. Since legal responsibility is individual, doctors who perform ERCP should establish the probability of choledocholithiasis and define its prognosis according to the guide lines for the benefit of both patient and physician.
2. It would be desirable for groups that handle these types of procedures to share experiences. Guidelines guides should be well publicized and physicians should be trained in their use, especially groups of surgeons who initially focus on these patients. It is important to clearly understand when confirmation of a diagnosis of choledocholithiasis by other methods is safer than proceeding directly to ERCP, especially when there is a low probability of choledocholithiasis.

3. Since ERCP continues to be the procedure of choice for the management of choledocholithiasis, it is important that physicians who work in institutions which perform ERCP continuously perform a large number of procedures to maintain their technical abilities at a high level. The most experienced gastroenterologists who work in the institutions with the highest volumes of these procedures are especially useful for difficult cases, but all the gastroenterologists who work in these institutions should be able to perform this procedure.
4. It is important that we have special referral centers with expert practitioners for highly complex procedures. Clearly, the fragmentation in the care of patients in our health care system makes creation and access to these centers difficult. Nevertheless, it is certain that there are people in our country with skills and expertise equal to those of international experts. These physicians can serve as models, mentors and points of reference for advice about, and management of, difficult cases.
5. When there are diagnostic alternatives such as endoscopic ultrasound and magnetic resonance cholangiography they should be used when indicated because the patient's well-being must be prioritized over any other consideration. When endoscopic ultrasound and magnetic resonance cholangiography are not available (and they are not available in every region of this country) intraoperative cholangiography is an alternative for patients with intermediate probability of choledocholithiasis.
6. The article by Dr. Gomez, Dr. Pion and Dr. Otero in this issue raises an interesting proposal related to a rational approach to choledocholithiasis. It proposes that a new criterion be used in deciding when to proceed directly to ERCP without further testing: high probability of

choledocholithiasis. In my opinion, and in accordance with the above considerations, this proposal merits further analysis.

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