World Journal of Gastrointestinal Endoscopy

Online Submissions: http://www.wjgnet.com/1948-5190office
wjge@wjgnet.com
doi:10.4253/wjge.v3.i12.248

World J Gastrointest Endosc 2011 December 16; 3(12): 248-255
ISSN 1948-5190 (online)

EDITORIAL

Intraoperative ERCP: What role does it have in the era of laparoscopic cholecystectomy?

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Author contributions: Rábago LR, Ortega A, Castro JL and Chico I contributed equally to the conception, design, and acquisition of data, analysis and interpretation of data; Collado D, Olivares A, Castro JL and Quintanilla E contributed to the drafting and critical review of the article for important intellectual content.

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Received: April 9, 2011 Revised: August 24, 2011
Accepted: December 1, 2011
Published online: December 16, 2011

Abstract

In the treatment of patients with symptomatic cholelithiasis and choledocholithiasis (CBDS) detected during intraoperative cholangiography (IOC), or when the preoperative study of a patient at intermediate risk for CBDS cannot be completed due to the lack of imaging techniques required for confirmation, or if they are available and yield contradictory radiological and clinical results, patients can be treated using intraoperative endoscopic retrograde cholangiopancreatography (ERCP) during the laparoscopic treatment or postoperative ERCP if the IOC finds CBDS. The choice of treatment depends on the level of experience and availability of each option at each hospital. Intraoperative ERCP has the advantage of being a single-stage treatment and has a significant success rate, an easy learning curve, low morbidity involving a shorter hospital stay and lower costs than the two-stage treatments (postoperative and preoperative ERCP). Intraoperative ERCP is also a good salvage treatment when preoperative ERCP fails or when total laparoscopic management also fails.

Key words: Intraoperative endoscopic retrograde cholangiopancreatography; Laparoendoscopic treatment; Postoperative endoscopic retrograde cholangiopancreatography; Rendezvous technique

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Rábago LR, Ortega A, Chico I, Collado D, Olivares A, Castro JL, Quintanilla E. Intraoperative ERCP: What role does it have in the era of laparoscopic cholecystectomy? *World J Gastrointest Endosc* 2011; 3(12): 248-255 Available from: URL: http://www.wjgnet.com/1948-5190/full/v3/i12/248.htm DOI: http://dx.doi.org/10.4253/wjge.v3.i12.248

INTRODUCTION

The rate of choledocholithiasis (CBDS) in patients with symptomatic cholelithiasis is estimated to be approximately 10%-33%, depending on the patient's age[1]. For many years, open cholecystectomy (OC) with choledochotomy or sphincteroplasty and cleaning of the bile duct were the gold standard to treat both pathologies. Over the past decade, laparoscopic cholecystectomy (LC) has replaced OC in the treatment of biliary lithiasis. The technical difficulties in the laparoscopic treatment of CBDS and the development of endoscopic retrograde cholangiopancreatography (ERCP)[2] have led to considerably broader endoscopic/surgical treatment possibilities for patients with cholelithiasis and suspected CBDS. No consensus currently exists regarding universally accepted therapeutic management.

One of the most important consequences of the

universal use of LC is the promotion and development of various pre-operative screening methods for CBDS, which had already been used during the open surgery era.

Intraoperative cholangiography (IOC) was used selectively in patients with suspected CBDS, since it required longer surgery time. It also had a false positive rate of up to 26%[3] which affected the performance of unnecessary therapeutic surgical procedures, such as choledochotomy or sphincteroplasty, with a higher risk of secondary postoperative complications and morbidity of 17%-21%[4-6].

The universal use of LC rekindled an old debate concerning the need for the routine use of IOC, which ultimately led it to being used selectively on patients with suspected CBDS during preoperative studies[7]. The low rate of CBDS during negative screening tests, from 2%-4%[8], and the low rate of anatomical alterations of the bile duct that could involve a real surgical risk do not justify its systematic use. Consequently, the selective use of IOC helps to reduce surgical morbidity and minimises the use of unnecessary resources[7,9].

Clinical criteria (jaundice, recent history of pancreatitis, cholecystitis), analytical criteria (elevation of total bilirubin, elevation of cytolytic and cholestatic enzymes) and ultrasonographic (EUS) criteria (dilated bile duct or visualisation of repletion defects in the bile duct) have been used and combined as preoperative screening methods for CBDS. A multitude of scores have been published using these criteria, attempting to assess the risk of CBDS, none of which have been implemented in a general manner. In fact, only 27%-54% of patients selected with suspected CBDS ultimately have calculi[7,10].

In 2001, and more recently in 2010[11], the American Society for Gastrointestinal Endoscopy (ASGE) published a review of the pros and cons of each preoperative screening method used to detect CBDS. It proposed a scoring system to categorise CBDS risk into high, intermediate and low and also devised a diagnostic and therapeutic algorithm for its management.

The high risk group would include patients with symptomatic cholelithiasis, total bilirubin > 4 mg/dL, ascending cholangitis, the presence of intracholedochal calculi, or those with a dilated bile duct and total bilirubin of 1.8 mg/dL. For patients > 55 years, alterations in liver biochemistry other than bilirubin or with a recent history of biliary pancreatitis would have intermediate risk. If they do not present with any of these criteria, the patients have low CBDS risk.

The use of magnetic resonance cholangiography (MRC) has facilitated the non-invasive study of the bile duct, with 85%-92% sensitivity and 93%-97% specificity for CBDS[12]. This technique is less sensitive when common bile duct stones measure less than 6 mm and during episodes of acute biliary pancreatitis[13,14].

EUS has also proved very useful in diagnosing CBDS and its morbidity did not at all compare to that of ERCP, with 89%-94% sensitivity and 95% specificity[15,16], although it is probably more operator dependent than MRC and is sensitive in detecting common bile duct stones measuring less than 6 mm[17].

The Spanish National Health Institute[18] and the ASGE[11] recommend patients with intermediate CBDS risk to use non-invasive radiological techniques prior to undergoing preoperative ERCP due to their high diagnostic performance. This would enable candidates undergoing preoperative ERCP before LC to be more appropriately selected. However, the limited availability of resources and the cost of these diagnostic techniques mean that they cannot be used universally as a replacement for the screening methods used to date. They should be used selectively in order to improve the diagnostic yield of patients with intermediate risk.

However, although at least 10% of cases with symptomatic cholelithiasis who undergo surgery could be included in the intermediate risk group for CBDS, the repercussions from implementing the aforementioned diagnostic strategy in clinical practice and its cost have not yet been established. Also, it might be difficult to use under certain circumstances due to its scarcity or lack of availability, intolerance or contraindication[19].

Furthermore, the sensitivity and specificity of these diagnostic techniques vary in relation to the quality of the technology available and the experience of the teams that interpret them at different hospitals. Lastly, there is a small group of intermediate risk patients in which, despite the fact that MRC or EUS fail to confirm the existence of CBDS, diagnostic doubts remain due to conflict between clinical, analytical and ultrasound findings[14].

Therefore, MRC or EUS are not the definitive solution for diagnosing CBDS, and at the moment, its diagnosis during the intraoperative stage still has an important role. We must also remember that there is a group of patients with negative screening tests, in which the surgical findings during surgery recommend that IOC be performed in order to rule out CBDS, with an estimated rate of 2%-4%[3].

There is a general consensus regarding the therapeutic algorithm of high and low CBDS risk patients. The first group would require preoperative ERCP followed by LC, and the second only LC. However, intermediate-risk patients have a great variety of endoscopic/surgical therapeutic options (LC with total laparoscopic cleaning of the bile duct in a single stage, or with the assistance of intraoperative ERCP, or two-stage management with preoperative ERCP followed by LC, or LC and postoperative ERCP). Currently, there is still a lack of consensus and the most appropriate therapeutic management is the subject of debate between the various surgical and endoscopic groups.

AVAILABLE TREATMENTS FOR CHOLELITHIASIS AND CBDS

ERCP was introduced in the 1970s as a treatment for residual or recurrent CBDS, with a success rate of over 85%-90%, immediate severe morbidity of 2.5%-11%, and mortality of 0.5%-3.7%[20].

It has become increasingly indicated including the treatment of possible CBDS before laparoscopic surgery[4,21], because during the OC era, when it was used before surgery it failed to show any advantages over the total surgical management of CBDS[22].

Preoperative ERCP followed by LC has been the most widely used endoscopic/surgical treatment method over the past decade and it is still currently used at many endoscopic units, despite the fact that its routine use to ultimately detect CBDS is unacceptable, due to the high rate of normal explorations and the cost and morbidity inherent to the technique[10,11].

In fact, one of the best preventive measures to reduce ERCP complications is not to perform it if it is unnecessary. This is one of the main reasons why the ASGE[11] has published its guidelines to quantify the risk of CBDS, proposing a therapeutic management algorithm.

When the possibility of CBDS cannot be ruled out for certain using the appropriate preoperative radiological studies - MRC or EUS -, or if they are unavailable, there are long waiting lists causing an unacceptable delay in diagnosis, or if there is an unexplained clinical and radiological discordance, the surgeon must decide between using LC with or without IOC, depending on the reliability of the different radiological studies in his or her environment. IOC has very high specificity (93%-100%), with lower sensitivity (53%-100%)[23].

If IOC shows the presence of CBDS, there are three possible therapeutic options: total laparoscopic management, intraoperative ERCP (single-stage treatment), or immediate postoperative ERCP. However, there are very few surgical groups with sufficient experience and resources to resolve CBDS laparoscopically or many surgeons that agree on leaving stones in the bile duct in order to extract them endoscopically at the postoperative stage, although some studies estimate that approximately 50% of CBDS detected by IOC can resolve spontaneously[3,24].

LAPAROSCOPIC MANAGEMENT OF CBDS (SINGLE-STAGE TREATMENT)

Laparoscopic surgery of CBDS was introduced over 15 years ago[25] and various surgical groups have shown that it has a high success rate[26-30], and is just as efficient and safe as pre- or postoperative ERCP associated with LC, thereby avoiding the need to perform additional procedures[1,27,31]. Nevertheless, its technical difficulties, its long and difficult learning curve and the need for the allocation of technical resources (high-quality fluoroscopy and choledochoscopes), which are not available at many operating theatres[32], has curtailed its expansion.

During the laparoscopic treatment of CBDS, the first surgical step involves the transcystic exploration and extraction of the common bile duct stones[33-35]. Most of the stones (66%-93%) are eliminated in this manner[36,37] using wash-outs, balloons or Dormia baskets in order to extract the small stones through the cystic duct or the papilla. All of these manoeuvres have difficulty in accessing the bile duct through fine or bead-like cystic ducts, sometimes requiring dilations to be performed before the cystic duct. When transcystic extraction is not possible, a choledochotomy must be performed and the bile duct explored[33,36] using balloons or Dormia baskets or through choledochoscopes. All of these techniques are more difficult and dangerous if the bile duct is narrow or if it is affected by inflammatory changes. When exploration of the bile duct is complete, if a primary suture is not performed - which always poses a risk - drains (a Kher tube) are placed which will prolong the patient' s hospital stay. On the whole, the laparoscopic extraction of CBDS has a success rate of 83%-89%, with greater efficiency and lower morbidity for transcystic exploration and extraction of common bile duct stones (68% and 10%, respectively, compared to 31% efficiency with morbidity of 5%-18% for laparoscopic common bile duct exploration)[31,35]. When its efficiency and costs were compared to the two-stage treatment with preoperative ERCP during a multicentric clinical trial, bile duct cleaning and morbidity had similar success rates, but involved a shorter hospital stay[31].

The difficulties regarding the laparoscopic management of CBDS have been shown in certain algorithms proposed, which show intraoperative or postoperative ERCP as a salvage treatment in the event of failure of the transcystic duct or laparoscopic choledochotomy[37-39], encouraging joint endoscopic-laparoscopic treatment of CBDS, with which clinical trials have also been performed comparing their results.

The current use of these therapeutic options depends, to a great extent, on the technical skills and experience of the endoscopic and surgical teams, which must reach a clearly established and accepted consensus[29,38].

The timing of the two-stage treatment with preoperative ERCP and subsequent LC was determined by the ASGE[11] for patients at high risk of CBDS only.

POSTOPERATIVE ERCP AS A TWO-STAGE TREATMENT FOR CBDS

Postoperative ERCP is an important cost-efficient therapeutic alternative[19], which would be indicated to treat CBDS diagnosed intraoperatively, irrespective of the reason for performing IOC[11] and provided that laparoscopic treatment is unavailable or has failed[27,35-38]. One of the pros of postoperative ERCP is that it is available at all equipped hospital centres using the findings from IOC (with high specificity) to establish its indication. However, it also has disadvantages. It requires highly experienced endoscopic support groups with a low ERCP failure rate and the hospital stays are longer than for single-stage treatments[1,27,40]. The possibility that postoperative endoscopic failure could require further surgery should always be taken into account. Accordingly, the specific circumstances of each hospital centre determine whether or not there is a reluctance to implement the aforementioned

technique in clinical practice, although certain studies are available that propose a hopeful wait and see attitude, especially with common bile duct stones measuring less than 5-6 mm[3,10,24].

It was also indicated that the possible failure of postoperative ERCP could be avoided by leaving a transcystic catheter in place or by placing removable biliary prostheses, however, removing them could lead to an increase in the rate of biliary fistula or biliperitoneum[6].

INTRAOPERATIVE ERCP AS A SINGLE-STAGE TREATMENT FOR CBDS

A short and successful series of intraoperative ERCP during LC was published in 1993, describing the insertion of a Fogarty balloon catheter into the transcystic duct in order to direct and correctly perform endoscopic papillotomy[41] and a further series of intraoperative ERCP during OC[42]. In 1994 a new series of intraoperative ERCP was published in which a sphincterotomy was performed using a laparoscopic procedure by inserting the sphincterotome into the transcystic duct using the duodenoscope to ensure its correct position in the papilla[43]. A series of reports was subsequently published, which could be included under the Perioperative ERCP heading, attempting to resolve CBDS in a single stage during LC. They include intraoperative ERCP using the rendezvous technique. Using this technique, a transcystic guide wire is inserted laparoscopically and recovered in the duodenum using the endoscope, facilitating selective access to the bile duct and the subsequent sphincterotomy[44-48]. Initially, perioperative ERCP also included ERCPs performed in theatres using the standard ERCP technique, prior to, during or immediately after surgery[49-52]. The main difference we are aware of regarding postoperative ERCP, is that it is performed in the theatre immediately after surgery while the patient is still under anaesthesia in order to try to shorten hospital stay, thereby allowing the endoscopic/surgical treatment to be performed in a single stage. However, they do not have the benefits offered by the rendezvous technique. Three different types of catheters or Fogarty balloons[41] or even Dormia basket catheters were initially used which were inserted into the transcystic duct to facilitate insertion of the papillotome in the papilla[53]. However, most endoscopic groups have used and still use a transcystic guidewire.

The use of intraoperative ERCP has slowly increased among various endoscopic groups, combining its ease of use with a short learning curve, without the high technical requirements needed by laparoscopic management of the bile duct[54-58].

Very few comparative studies have been made between laparoscopic management[31] with or without intraoperative ERCP[55,59,60] single-stage treatments, and the two-stage treatment with preoperative ERCP that has similar or higher success rates, but has lower morbidity, shorter hospital stay[60] and lower cost. Randomised studies have also been performed comparing the two most important options of the single-stage treatment, such as total laparoscopic CBDS management compared to intraoperative ERCP[32], where no differences in success rate, complications, hospital stay or cost were found.

La Greca *et al*[58] reviewed all the published studies on intraoperative ERCP and found 27 original papers that included between 8 and 96 patients each, thus analysing a total of 795 patients. The success rate ranged between 69.2%[61] and 100%[45,48,57], with an average of 92.3%. The average duration of intraoperative endoscopy was 35 min and the average duration of surgery was 104 min. The average conversion rate to open surgery was 4.7% and morbidity was 5.1% (0%-19%). Mortality is extremely rare, and of the 27 publications reviewed, only three patient deaths were reported, giving rise to a total mortality of 0.37%.

INTRAOPERATIVE ERCP TECHNIQUE

In the rendezvous technique, firstly, a transcystic guidewire (0.025-inch Jagwire; Boston Scientific Inc., Watertown, Massachusetts, United States) is inserted through the cholangiography catheter. Once it emerges from the papilla, it should be grasped with a standard snare. It is then withdrawn through the endoscope placed opposite the papilla. A double-lumen sphincterotome is then advanced over the guidewire to facilitate bile duct cannulation and to perform the sphincterotomy, followed by bile duct clearance using a Fogarty balloon or a Dormia basket catheter. Finally, the cystic duct is closed and the surgeon proceeds with LC. If the guidewire does not come out through the papilla, the surgeon should try to advance a stiffer Fogarty catheter through the papilla and then a pre-cut sphincterotomy can be performed. If all of these steps fail, intraoperative ERCP must be considered to have failed and postoperative ERCP could be performed using the best technical support available in the Radiology Department or a decision might be made to proceed with OC.

PROS AND CONS OF INTRAOPERATIVE ERCP

Pros

The main advantage of intraoperative ERCP using the rendezvous technique is the selective cannulation of the bile duct, preventing Wirsung opacification using contrast agents, damage and manipulation of the papilla and the use of risky techniques to access the papilla, such as precut sphincterotomies[57]. This technique results in a lower rate of pancreatitis compared to preoperative ERCP[55,59], and of post ERCP acute cholecystitis if the cholecystectomy is delayed[55]. The hospital stay and costs of the process were lower compared to the most used two-stage sequential treatment (preoperative ERCP and laparoscopic surgery)[55,59,60].

Intraoperative ERCP can be an alternative to the laparoscopic management of CBDS[38,46,53] as a salvage treat-

ment during surgery when the bile duct is not adequately cleaned or as an alternative to endoscopic-laparoscopic management in two stages, both with preoperative or postoperative ERCP[37,52,54]. Its main advantage is that it is a single-stage treatment and there is no risk of reintervention in the event of intraoperative ERCP failure. It also offers the possibility of salvage for failed preoperative ERCP[62], attempting to avoid open surgery.

Intraoperative ERCP is not a particularly difficult challenge for an endoscopist with expertise in biliary endoscopic treatment. Performing intraoperative ERCP in theatre with the patient under anaesthesia and in the supine position is infrequent in normal practice, but there is always a patient on whom it is necessary to perform intubated ERCP in order to maintain adequate ventilation, irrespective of the cause. The supine position facilitates and guarantees management of the airways, thereby avoiding the greater risk of adverse cardiorespiratory events that arise when ERCP is performed in the supine patient. No differences were identified in the success, complication and morbidity rates between both forms of ERCP if the endoscopist has sufficient experience[63].

From a technical viewpoint, rotating the patient 180 degrees requires a 90-degree rotation of the endoscope and endoscopist to the right, in order to be positioned opposite the papilla. In practice, this gesture is performed intuitively by the endoscopist and in most reports, there was not much emphasis placed on technical difficulties, and when this was specifically assessed, only 3.7% of the procedures were considered to be technically difficult[57].

Cons

The main problem is the need to coordinate and synchronise the surgical and endoscopic teams, which must work together. This has caused the most difficulty in generalising its use and this opinion is shared by various authors[58].

The endoscopic team must be familiar beforehand with the patient's surgery programme and be ready to go into theatre once CBDS has been confirmed by IOC. While the endoscopic team is getting ready for theatre, the surgeon passes the guidewire into the duodenum through the IOC catheter. Afterwards, the duodenoscope is introduced in order to grasp the wire. It is important to reduce waiting time as much as possible.

The endoscopist will have to work in an environment he/she is not used to. He/she should be positioned between the patient's left arm, usually extended during the surgery, and the patient's head, which causes a certain degree of discomfort. The ERCP should be performed with the patient in the supine position and the radiological quality offered by traditional X–ray rooms that he/she might require will not be available. However, once IOC has been performed, the X-ray arch can be removed, since the rendezvous technique permits selective cannulation of the bile duct without the need for radiological support. After performing the papillotomy, the guidewire is usually removed and reinserted into the bile duct to prevent the Fogarty catheter from ending up in the cystic duct, or the guidewire is removed completely through the duodenoscope to insert the Fogarty catheter or Dormia basket without the guidewire and the bile duct is cleaned. The insistence of, or the need for, the use of radiology in surgery will depend mainly on the number and size of the common bile duct stones. However, the endoscopist should be aware of the risk of producing Glisson's capsule hematomas if the guidewire is introduced deep into the bile duct without radiological control.

Once the papillotomy has been performed and if the bile duct has not been cleaned completely, a second postoperative ERCP, in the usual radiological environment, is technically easy without the risks associated with the first ERCP.

It is important for the surgical and endoscopic team to agree on the therapeutic options to follow if the rendezvous technique fails. If the guidewire does not emerge through the papilla, an attempt should be made to insert a Fogarty balloon into the transcystic duct, which must always be stiffer than the guidewire, which can prevent it from moving in a retrograde fashion towards the intrahepatic biliary tree. Once the Fogarty balloon emerges from the papilla, a pre-cut papillotomy can be performed using a needle-knife sphincterotome, controlled with the help of the Fogarty balloon catheter. If both manoeuvres fail, the therapeutic options available would be as follows: perform ERCP using a standard technique in surgery immediately after the cholecystectomy has been completed[29,49,50,52], postpone the ERCP to the postoperative stage depending on the patient's evolution or convert the LC to open surgery. The option to take will vary depending on the anatomical characteristics (intradiverticular papilla) and the difficulties envisaged in the standard ERCP of that patient, the quality of the surgical equipment available in theatre and the size of the CBDS.

Special mention should be made of intraoperative ERCP treatment for patients with common bile duct stones measuring more than 15-20 mm detected intraoperatively, or when multiple stones are found. In these cases, although intraoperative ERCP may not be as definitive and conclusive as when it is performed in our usual radiological environment, at the same time, it can prolong the length of surgery unnecessarily. However, it allows and guarantees that intraoperative papillotomy can be performed with lower morbidity than conventional ERCP, helping in particular if the bile duct has not been fully cleaned, during a second stage with postoperative ERCP, with or without dilation of the papilla or with the use of mechanical lithotripsy systems.

Lastly, we would like to refer to the subsequent difficulties of LC in relation to the air insufflated during ERCP on which certain groups have manifested their concern. However, this should not be the case. The surgical teams normally perform LC from the fundus of the gallbladder to the neck with dissection of Calot's triangle, suture of the cystic artery and dissection and section of the cystic duct in order to perform the IOC, so that when

the endoscopist is getting ready to perform ERCP, the LC is virtually finished. When endoscopy is over, usually within an average of 35 min[58], the air introduced is aspirated efficiently in order to restore the visibility of the surgical field and the surgeons have no difficulty in completing the final surgical manoeuvres.

CURRENT ROLE OF INTEROPERATIVE ERCP

During the preoperative study of cholelithiasis pending surgery, it is clear that the risk of associated CBDS must be assessed. Using its algorithm, the ASGE suggests that the preoperative study should be completed using MRC or EUS in patients with intermediate risk or in an intraoperative manner using intraoperative ultrasound or IOC[11]. However, we will still find patients in whom clinical-analytical-radiological discordance makes it advisable to perform a new radiological study, such as IOC, to establish the most appropriate surgical treatment, or patients in which CBDS appears as a casual finding in IOC. The three possible therapeutic options for these intermediate risk patients are the single-stage treatment, total laparoscopic treatment with intraoperative ERCP or the two-stage treatment with postoperative ERCP. At present, there is no scientific evidence to justify the choice of one option or another. The three types of treatment are correct and their choice will depend on the particular circumstances and on the experience of the different endoscopic and surgical teams at each centre.

Intraoperative ERCP could also be a perfect salvage treatment for failed preoperative ERCP[62] in order to avoid open surgery, maintaining a foreseeably high success rate with very low morbidity and mortality.

Therefore, in coming years, we may witness an increase in the use of intraoperative ERCP, not to compete with the indications of preoperative ERCP in general, but rather to prevent the improper use of preoperative ERCP in patients at intermediate risk for CBDS, and to provide a diagnostic and therapeutic alternative to sophisticated techniques that are not always available in all societies and countries throughout the world.

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