



Thirteen years' experience with laparoscopic transcystic common bile duct exploration for stones

Effectiveness and long-term results

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Abstract

Background: The aim of the present study was to evaluate the effectiveness and long-term results of laparoscopic transcystic common bile duct exploration (TC-CBDE).

Methods: Ductal stones were present in 344 of 3212 patients (10.7%) who underwent laparoscopic cholecystectomy (LC). The procedure was completed laparoscopically in 329 patients (95.6%), with TC-CBDE performed in 191 patients (58.1%) who are the object of this study, or with a transverse choledochotomy in 138 cases (41.9%).

Results: Biliary drainage was employed in 71 of 191 cases (37.2%). Major complications occurred in 10 patients (5.1%), including retained stones in 6 (3.1%). Mortality was nil. No patients were lost to follow-up (median: 118.0 months; range: 17.6–168 months). No signs of bile stasis, no recurrent ductal stones and no biliary stricture were observed. At present 182 patients are alive with no biliary symptoms; 9 have died from unrelated causes.

Conclusions: Long-term follow-up after laparoscopic TC-CBDE proved its effectiveness and safety for single-stage management of gallstones and common bile duct stones.

Key words: Laparoscopy — Common bile duct stones — Transcystic approach — Long-term results

Common bile duct (CBD) stones occur in approximately 10% of patients with symptomatic gallstones undergoing laparoscopic cholecystectomy (LC). Systematic fluoro-

scopic intraoperative cholangiography (FIOC) during LC, which is used mainly to increase the safety of the procedure by decreasing the rate and severity of bile duct injury, is also an effective method with which to detect ductal stones [1]; it may also be a more efficient alternative to an extensive preoperative diagnostic work-up to confirm suspected stones. When ductal stones are detected at FIOC, laparoscopic common bile duct exploration and postoperative endoscopic retrograde cholangiopancreatography (ERCP) are both safe and effective in clearing CBD stones [12].

A randomized trial comparing laparoscopic CBD exploration during LC versus postoperative ERCP, however, demonstrated equivalent success rates and patient morbidity, but a significantly shorter hospital stay [15]. Moreover, endoscopic sphincterotomy (ES) for CBD stones is associated with long-term biliary complications in 8%–10% of patients, including recurrent ductal stones, cholangitis, stenosis of the papilla, and biliary pancreatitis [17, 19]. Other authors [9] reported up to 28% of patients complaining of one or more symptoms related to low-grade cholangitis after ES, with one-fifth of patients experiencing these symptoms frequently. The potential consequences of long-lasting cholangitis remain a matter of concern, particularly in younger patients.

Laparoscopic CBD exploration may be accomplished either through the cystic duct (TC-CBDE) or directly through a choledochotomy incision [4, 5, 8, 11]. For surgeons with adequate experience in both techniques, the stone characteristics and ductal anatomy as depicted by FIOC usually indicate which type of approach is best suited for the patient. The transcystic duct approach is less invasive and therefore it may be preferable to a choledochotomy incision. The latter

approach, however, is indicated for multiple or larger stones, for stones located in the common hepatic duct or when an unfavorable cystic duct anatomy is present [8], with a >90% success rate and excellent long-term results [13]. Whenever feasible, though, TC-CBDE is the preferred method because it is less invasive and has proved to be safe and efficient [8, 14]. Few long-term data on large case series of laparoscopic TC-CBDE are available. The aim of this article is to report the short-term results as well as the results of a long-term follow-up study in a large series of consecutive, unselected patients who underwent laparoscopic TC-CBDE during LC in our departments, according to a previously published treatment algorithm [8].

Materials and methods

From January 1991 to January 2004, CBD stones were present in 344 of 3212 consecutive patients (10.7%) who underwent LC with routine intraoperative cholangiography. The operations were conducted at two tertiary referral centers (Ancona, Rome) and at one community hospital (Canistro) by three of the authors as first surgeon (E.L., A.M.P., M.G.). The patients were unselected and were treated laparoscopically according to an "all-comers" policy.

Surgical technique

The treatment algorithm and the surgical technique that we follow for single-stage laparoscopic management of gallstones and CBD stones have been previously reported [8]. For any patient undergoing LC, the cystic duct is widely dissected to facilitate its cannulation with the cholangiogram catheter. Cystic duct dissection is carried down to its junction with the CBD, unless this is very low and intrapancreatic or the cystic duct spirals around the CBD. This extensive dissection is essential to mobilize the cystic duct and to place it along the same axis as the cholangiogram clamp and catheter, which are introduced through the right midclavicular port. The type of cholangiogram catheter that is commonly used is a 4 French ureteral catheter (code number 223602, Laboratoires Pharmaceutiques, Rûsch France, 67660 Betschdorf, France), passed through an Olsen cholangiogram clamp (code number 28378 CH, Karl Storz GmbH & Co. KG, Tuttlingen, Germany). The choice between a transcystic or a choledochotomy approach to explore the CBD is selective and is based on the routine intraoperative cholangiogram findings. In general, the transcystic approach is preferable to a choledochotomy for its lesser invasiveness. A choledochotomy is better indicated, however, provided the CBD diameter is larger than 8–10 mm, when any of the following conditions are present: CBD stones considerably larger than the lumen of the cystic duct; more than 5 CBD stones; low and medial cystic duct–CBD junction; common hepatic duct stones. In the absence of any of the above conditions, TC-CBD exploration is the treatment of choice when CBD stones are demonstrated at intraoperative cholangiography. A grasper is introduced from the epigastric port to hold the infundibulum and to provide countertraction. All the transcystic maneuvers required for CBD exploration are performed through the right midclavicular port. If the the cystic duct lumen is smaller than the CBD stone, it is gently dilated up to a diameter of 6 mm with a balloon ureteral dilator catheter (code number 14720, W. Cook Europe APS, Denmark), inflated with air from a 10 cc syringe. The CBD is first explored with a "blind basketing" technique. The cystic duct opening is entered with a flat wire stone extractor catheter (code number 14740, W. Cook Europe APS, Denmark) which is slowly advanced inside the CBD for 6–8 cm, counting the 1 cm markings on the external sheath of the catheter. When resistance is encountered (sphincter tone), the outer sheath of the catheter is pulled backward to open the basket. To avoid trauma on the papilla, the basket is never opened by pushing the internal wire forward against resistance. The catheter is then withdrawn from the CBD while its internal wire is rotated along its axis to facilitate the entrance of the stones inside the basket. During the

extraction maneuvers, gentle external compression on the common hepatic duct is exerted with the grasper from the epigastric port to avoid stones inadvertently being swept proximal to the cystic duct into the common hepatic duct. The exploration maneuver is relatively simple, and it is repeated until all the defects recognized at intraoperative cholangiography have been removed.

Next, a completion choledochoscopy is performed with a 7.5 Fr. (2.49 mm.) choledochoscope (code number 11292 AD, Karl Storz GmbH & Co. KG, Tuttlingen, Germany). If any stone is still present inside the CBD, it is removed under endoscopic control with a 3 Fr. flat wire basket (code number 14730, W. Cook Europe APS, Denmark) passed through the 3.6 Fr. working channel of the choledochoscope. Stones that are soft and friable may be fragmented during the exploratory maneuvers with the basket. For stones of harder consistency that are impacted inside the CBD and that are difficult to mobilize with a basket, electrohydraulic lithotripsy (Circon Acmi, Stanford, CT, USA) is performed under endoscopic control. The lithotripsy fiber is passed through the working channel of the choledochoscope and its tip is placed against the stone under vision. The lithotripter is then activated, generating a spark that breaks the stone into fragments, which are subsequently removed with the 3 Fr. basket under vision. It is important to avoid activating the lithotripter when the tip of its fiber is near the CBD wall, because the spark that is generated may seriously damage the biliary wall, causing bleeding and perforation. The smaller stone fragments are flushed away with high-pressure saline irrigation of the CBD through a transcystic catheter. To facilitate small fragments wash-out, the papilla itself may be gently dilated under fluoroscopic vision with a balloon ureteral dilator catheter (code number 14720, W. Cook Europe APS, Denmark) inflated with air. Intravenous administration of 1 mg of glucagon may be initiated at this time to cause relaxation of the sphincter of Oddi. A completion transcystic fluorocholangiogram is then routinely performed to check for retained CBD stones or fragments.

After completion of TC-CBDE, the choice of whether to position an external biliary drain is made according to the following indications:

- the persistence of fibrin debris or bile sludge inside the CBD at the end of the procedure;
- if some kind of instrumental maneuver on the papilla has been performed while clearing the CBD, such as papilla dilation or transpapillary passage of the basket, which might be followed by papillary edema and obstruction to bile flow;
- if a retained stone is demonstrated which cannot be removed laparoscopically for technical reasons and is therefore knowingly left behind.

The transcystic biliary drain that is employed is constructed from a 3-mm T-tube (Silcolatex® T-tube, code number 178700, Willy Rûsch Ag, 71394 Kernen, Germany) after cutting away its transverse branches. One of the two ends is tapered and a small extra hole is cut near this end. After introducing the biliary drain completely inside the peritoneal cavity through the epigastric port, its tapered end is introduced through the cystic duct opening and is advanced 1.5–2 cm. It is then fixed to the wall of the cystic duct with a 4/0 transfixing absorbable suture on straight needle (PDS II mounted on ST-4 visiblack needle; code number Z620E, Ethicon™, Johnson & Johnson Intl, Edinburgh, Scotland, UK). The suture is passed through both the cystic duct wall and the drain wall, looping it on both sides around the cystic duct before knotting it, to prevent subsequent bile leakage. When transcystic biliary drainage is not deemed necessary, the cystic duct is closed with a medium-large absorbable clip (Absolok APS 300, Ethicon GmbH, Norderstedt, Germany). If the cystic duct wall is thickened by inflammation and the absorbable clip is not large enough to close it, the cystic duct may have to be closed with a 4/0 transfixing absorbable suture on straight needle (PDS II mounted on ST-4 visiblack needle, code number Z620E, Ethicon™, Johnson & Johnson Intl, Edinburgh, Scotland, UK).

Postoperative evaluation and follow-up

When a biliary drain has been positioned intraoperatively, direct cholangiography is performed on postoperative day 1 to check again for residual CBD stones. If the cholangiogram is negative and there is free flow of contrast material through the papilla, the drain is closed, it

is placed under a wound dressing, and the patient is discharged. In the occasional patient with a residual CBD stone or stone fragment demonstrated at postoperative cholangiography, the biliary drain is used to flush the CBD with saline to aid in clearance of the residual stone. The patient is then discharged with the biliary drain closed and placed under a wound dressing. Then, 30 days after the operation, the biliary drain is removed as a day-hospital procedure. A direct cholangiogram is performed prior to its removal to check again for residual stones.

The 30-day interval is required for the development of a mature sinus tract around the biliary drain. If a residual stone is identified at this point in time, prior to biliary drain removal, the presence of a mature sinus tract allows percutaneous exploration of the CBD with the 7.5 Fr. choledochoscope in the radiology suite under fluoroscopic vision and local anesthesia. First, a soft-tipped guidewire is introduced through the biliary drain into the CBD and through the papilla into the duodenum, with care to check its position with the fluoroscope. The biliary drain is then removed, leaving the guidewire in place. Next, the guidewire is introduced into the working channel of the choledochoscope, which is then advanced through the sinus tract until it enters the CBD. After the guidewire is removed, the residual stone is extracted with a 3 Fr. basket under choledochoscopic vision. The electrohydraulic lithotripter should be available at this time to deal with any residual stone that is difficult to remove with a basket and that can be fragmented by lithotripsy. When the percutaneous approach fails, or in patients with suspected residual stones in the absence of a biliary drain, ERCP and endoscopic sphincterotomy are employed. In the occasional patient with very difficult impacted CBD stones, extracorporeal shockwave lithotripsy (ESWL) is employed together with ERCP and endoscopic sphincterotomy.

After completing the treatment plan, all patients entered a predefined prospective follow-up protocol, which included (1) an interview by the same investigator, aimed at revealing any recurrence of biliary symptoms; (2) physical examination; (3) laboratory exams; and (4) ultrasound every 6 and 12 months for the first year. The same protocol was carried out whenever any abdominal symptom appeared during the follow-up period. Up to 1995, if any laboratory sign of bile stasis appeared, then a diagnostic ERCP was carried out; beginning in 1996, when MRC became available at our hospital, this exam has replaced diagnostic ERCP. After the first year of follow-up, patients who for any reason were unable to reach the hospital for a visit were interviewed by telephone and were questioned concerning the appearance of jaundice and the presence of biliary colic or any other symptom according to a predefined questionnaire. These patients were also seen by their family physician, who was also reached by telephone.

Results

The operation was completed laparoscopically in 329 cases (95.6%) and was converted to open surgery in the remaining 15 (4.4%). The causes of conversion in the overall series have already been reported [13]. Of the 329 laparoscopically completed cases, a transcystic duct approach was feasible and successful in 191 (58.1%), and a choledochotomy was required in the remaining 138 (41.9%). The safety, efficacy, and long-term results in the latter series of patients who underwent laparoscopic choledochotomy have already been reported [13]. The 191 patients who underwent laparoscopic TC-CBD exploration are the object of the present study (females 124, males 67; mean age 54.5 years; age range: 12–88 years). The presenting symptoms were biliary colic (90.1%), dyspepsia (47.6%), jaundice (31.4%), fevers (8.4%), pancreatitis (3.7%), cholangitis (2.1%), and cholecystitis (1.6%).

The mean preoperative liver function tests are reported in Table 1. At preoperative ultrasound (US) the diameter of the common bile duct was described as normal (8 mm or less) in 126 cases (65.9%), whereas it

Table 1. Preoperative liver function tests

	Mean value (SD)	Normal range
AST, U/Lt	91.19 (321.06)	0–40
ALT, U/Lt	81.60 (92.83)	0–45
AP, U/Lt	332.29 (202.35)	0–270
Amylase, U/Lt	130.94 (80.97)	0–120
Total bilirubin, mg/dl	1.91 (1.55)	0–1.2
Direct bilirubin, mg/dl	0.88 (1.09)	0–0.4

SD, standard deviation; AST, aspartate aminotransferase; ALT, alanine aminotransferase; AP, alkaline phosphatase

Table 2. Classification of patients (*n* = 191 patients)

	<i>n</i> (%)
Suspected/proven	102 (53.4)
-referred after failed ES	22 (11.5)
Unsuspected	89 (46.6)

ES, endoscopic sphincterotomy

Table 3. Frequency of methods used (*n* = 191 patients)

	<i>n</i> (%)
Basket	190 (99.5)
Choledochoscope	170 (89)
Papillary dilation	37 (19.3)
Intravenous glucagon	10 (5.2)
Electrohydraulic lithotripsy	4 (2.1)

was dilated (≥ 9 mm) in 65 cases (34%). Common bile duct stones were seen at preoperative US in 46 patients (24.1%). Patient classification according to whether CBD stones were suspected or unsuspected is reported in Table 2. In the 89 patients (46.6% of 191 or 2.7% of 3212 LC patients) with unsuspected CBD stones, the stones were diagnosed intraoperatively at routine FIOC and were confirmed at intraoperative choledochoscopy or when they were extracted by basket. One-hundred-twenty patients were classified ASA I (62.8%), 51 ASA II (26.7%), 11 ASA III (5.8%), and 9 ASA IV (4.7%). Upper abdominal scars from previous abdominal operations were present in 7 patients, including a Bill-roth II gastrectomy (4 patients), right hemicolectomy (2 patients), and left hemicolectomy (1 patient).

The frequency of methods used for TC-CBD exploration is reported in Table 3. Completion choledochoscopy was not performed if the choledochoscope was not available. There were no CBD tears. Rupture of the cystic duct during TC-CBD exploration was observed in 13 cases (6.8%), but it did not prevent completion of the exploration maneuvers because of the presence of a short cystic duct stump, which allowed exertion of the necessary countertraction. Stones that were not moving freely inside the CBD, defined as impacted stones, were encountered in 26 patients (13.6%). In 22 of these patients the stones were soft and friable and they were accidentally fragmented with the basket (mechanical lithotripsy) during the exploratory maneuvers. In the remaining 4 patients the impacted stones

Table 4. Results of LC alone or LC plus TC-CBDE

Mean operative time, minutes (SD)	Biliary drainage	
Type of procedure	No	Yes
LC + TC - CBDE (<i>n</i> = 191 pts)	112.60 (27.20)	138.22 (30.83)
LC alone (<i>n</i> = 2868 pts)	50.16 (21.35)	–
Mean hospital stay, days (SD)	Biliary drainage	
Type of procedure	No	Yes
LC + TC - CBDE (<i>n</i> = 191 pts)	3.69 (1.15)	4.29 (2.39)
LC alone (<i>n</i> = 2868 pts)	1.18 (0.68)	–

SD, standard deviation; pts, patients; LC, laparoscopic cholecystectomy; TC-CBDE, trans-cystic common bile duct exploration

Table 5. Morbidity and mortality

Minor complications	<i>n</i> (%)
Sub-hepatic biloma	4 (2.1)
Port site infection	3 (1.5)
Hyperamylasemia	8 (4.1)
Total	15 (7.7)
Major complications	<i>n</i> (%)
Bile leakage	2 (1.0)
Hemoperitoneum	1 (0.5)
Acute pancreatitis	1 (0.5)
Retained CBD stones	6 (3.1)
Total	10 (5.1)
Mortality	0

were harder and had to be fragmented with the electrohydraulic lithotripter.

After completing TC-CBDE, an external biliary drain was used in 71 patients (37.2%) for one or more of the indications mentioned above. In the remaining 120 patients (62.8%) no biliary drainage was used. The mean operative time and mean hospital stay for TC-CBD exploration plus LC with and without biliary drainage are shown in Table 4. The mean operative time and mean hospital stay for the 2868 patients who underwent LC alone for gallstones during the same time period are shown for comparison.

No premature dislodgement of the biliary drain was observed, and no biliary peritonitis or prolonged biliary fistula were observed after planned biliary drain removal. Morbidity and mortality after LC plus TC-CBD exploration are shown in Table 5. Minor complications, which did not require intervention and did not prolong the hospital stay, occurred in 15 patients (7.7%) and included a sub-hepatic biloma in 4 cases (2.1%), port site infection in 3 cases (1.5%), and hyperamylasemia in 8 patients (4.1%), always after papillary dilation. Major complications were observed in 10 patients (5.1%). They included bile leakage from kinking of the biliary drain in 2 patients (1.0%), treated by ERCP and naso-biliary drainage; hemoperitoneum after lysis of extensive adhesions in 1 (0.5%), which required open exploration; acute necrotic pancreatitis in 1 (0.5%), which also required open exploration; and retained CBD stones in 6 patients (3.1%). Of these 6 patients with retained CBD stones, the stones were knowingly left behind in 5 (2.6%) because

they were difficult to remove (in 1 patient even after electrohydraulic lithotripsy; in the remaining 4 patients the electrohydraulic lithotripter was not available), and a transcystic biliary drain was used for postoperative biliary decompression. In these 5 patients the CBD was not dilated (< 8 mm in diameter), and performance of choledochotomy, whether laparoscopic or open, was considered unsafe. In the remaining patient with a residual ductal stone, this was diagnosed at pre-dismissal direct cholangiography through the transcystic biliary drain. Of the 6 patients with residual stones, in two patients these passed spontaneously through the papilla after an episode of biliary colic that occurred less than 30 days after operation; ductal clearance was documented by direct cholangiography. In the remaining 4 patients the percutaneous approach failed to obtain complete CBD stone clearance. Subsequent ERCP/ES was successful in all patients except one, who underwent successful ESWL after failed percutaneous approach with intracorporeal lithotripsy and failed ERCP/ES. The difficulty in this patient was that a CBD stone was lodged inside a prepapillary pseudodiverticulum. Mortality was nil.

No patients were lost to follow-up. The median follow-up time was 118 months (range: 17.6–168 months). There were no recurrent episodes of biliary colic or symptoms of bile stasis. Long-term follow-up data are available for all 191 patients (100%) via outpatient clinic visits with one of the authors (114 patients, 59.6%) or with their family physician (77 patients, 40.3%). Nine patients have died from unrelated reasons with no evidence of recurrent biliary symptoms. The remaining 182 patients remain free of biliary symptoms or signs of bile stasis, and no biliary stricture has been documented by US and/or MRC.

Discussion

The aim of the present study was to evaluate the long-term results of an ongoing follow-up study systematically conducted on patients undergoing single-stage laparoscopic management of gallstones and CBD stones that included TC-CBDE as well as laparoscopic choledochotomy. The treatment algorithm [8] was defined in 1990, and patient accrual started in January 1991. The series of 191 patients includes patients treated until Jan-

uary 2004, so that each patient could have a minimum follow-up period of at least one year. The indications for and the long-term results of the group of patients who underwent laparoscopic choledochotomy when the transcystic approach was not feasible have already been published [13]. Therefore the present report deals with the majority (almost 60%) of the patients in the overall series undergoing single-stage laparoscopic management of gallstones and CBD stones in whom the transcystic approach was feasible and successful. The choice of TC-CBDE was based on the stone characteristics and on the ductal anatomy as depicted at routine FIOC. Transcystic CBDE is the preferred treatment modality in our experience because it is less invasive than laparoscopic choledochotomy. A useful technique to obtain a high success rate with cystic duct cannulation is to dissect the cystic duct widely down to its junction with the CBD, unless this junction is very low and intrapancreatic.

Patients undergoing LC plus TC-CBDE usually have a postoperative course that is no different from that of patients undergoing LC alone for gallstones. The shortest hospital stay and lowest postoperative morbidity after TC-CBDE, as compared to laparoscopic choledochotomy, has also been confirmed by the European Association for Endoscopic Surgery trial [3]. The indications for TC-CBDE, however, are limited to stones that are smaller than the size of the cystic duct—although the duct can be gently pneumatically dilated to some extent (not more than 6 mm) with a balloon dilator catheter—to a limited number of stones (not more than five in the authors' experience), to stones located in the CBD and not higher in the common hepatic duct, and when a favorable anatomy of the cystic duct–CBD junction is present. In other words, a spiral course of the cystic duct joining the CBD low on its medial side and close to the papilla is not considered a favorable condition for a safe TC-CBDE.

The decision of when to use transcystic biliary drainage in these patients was taken basically to prevent cholangitis from papillary edema or when persistent fibrin debris, bile sludge, or retained ductal stones were demonstrated at the end of the procedure. To prevent the occurrence of papillary edema, care should be taken during operation to avoid uncontrolled passage of the papilla with the basket. This can be avoided with the "blind basketing" technique. The systematic use of the choledochoscope to perform the entire exploratory maneuver under endoscopic vision makes it possible to avoid inadvertent passage of the papilla with the basket, but it reduces the life-span of the choledochoscope, which is a fragile instrument. In the authors' experience the combination of the blind basketing technique and of completion choledochoscopy allowed a reduction of rate of residual stones, but with sparing use of the choledochoscope. Nevertheless, biliary drainage was used in a little more than one third of the patients in the present series. The temporary presence of a soft biliary drain, however, which was well tolerated by the patients with no premature dislodgement, not only prevented cholangitis but made it possible to restrict the use of postoperative ERCP/ES to only 4 cases where retained stones were observed.

The original treatment algorithm in the present study protocol included routine FIOC and excluded other preoperative diagnostic modalities, except biochemistry and liver ultrasound. Although the main reason to advocate the use of routine FIOC during LC is to increase its safety [1], the 97% success rate and high diagnostic accuracy for the diagnosis of ductal stones saves the patient from an extensive preoperative diagnostic work-up for stones. Preoperative diagnostic ERCP, and later magnetic resonance cholangiopancreatography (MRCP), were employed in our treatment algorithm only in patients presenting with slow-onset jaundice when a papillary neoplasm might have been suspected, but this event was negligible in the present series. Over time, other diagnostic modalities have become available beyond ERCP and MRCP, such as endoscopic ultrasound (EUS) and laparoscopic ultrasound (LUS).

Preoperative MRCP, EUS, and ERCP have comparable sensitivity and specificity [12], but they inevitably prolong the preoperative hospital stay and increase the cost of treating patients who are considered candidates for LC. Combining the check for the presence or absence of ductal stones with the intraoperative setting for LC considerably simplifies the diagnostic process used to confirm suspected ductal stones or to identify unsuspected ductal stones. Laparoscopic US has been proved to be safe and accurate [7], with a diagnostic accuracy for ductal stones that may be even higher than that of FIOC due to a lower false positive rate [10]. Nevertheless, FIOC visualizes variations or anomalies of the bile ducts and cystic duct more distinctly than LUS [10], and it should be considered mandatory in teaching hospitals for the training of residents and young surgeons. Moreover, the laparoscopic skill acquired at routine FIOC during extensive dissection of the cystic duct and for its cannulation with the cholangiogram catheter is an excellent training opportunity for TC-CBDE with a thin, flexible choledochoscope and a basket catheter.

Laparoscopic single-stage CBD exploration and postoperative ERCP have been reported to be equally safe and effective [12]. The latter, however, is associated with a longer hospital stay, as reported by a randomized trial comparing these two treatment methods [15]. A longer hospital stay was also demonstrated by the randomized trial set up by the EAES, which compared laparoscopic single-stage CBD exploration during LC with preoperative ERCP followed by LC for highly suspected or proven ductal stones [3]. In patients undergoing LC, the use of preoperative or postoperative ERCP increases the interventional burden for the patient and includes another element of risk, which increases the risks associated with surgery. The choice of treatment should take into account not only the immediate complications of ES but also the long-term morbidity with this procedure. The long-term occurrence of recurrent ductal stones, stenosis of the papilla, and cholangitis have all been reported and are observed in 8%–10% of patients after ES [17, 19]. Although the majority of patients undergoing ES rate their general health as better following this procedure, a significant

minority of about 20% of patients experiences frequent symptoms of recurrent mild cholangitis [9], whose potential long-term consequences remain a matter of concern, except in the very elderly. Therefore the use of ES seems to be more appropriate in patients considered at high risk who are not candidates for LC, and for the treatment of patients with residual or recurrent ductal stones. These remain the original and most correct indications since the introduction of ES. The avoidance of FIOC and the inappropriate use of ES in an attempt to simplify the performance of LC is not in the best interest of the low-risk patient who is a candidate for LC. A high index of suspicion for ductal stones in the present series was present in 53.4% of the patients, all of whom avoided the risk of short- and long-term morbidity from preoperative ERCP/ES, which was not part of our treatment protocol.

It has been our policy to remove all ductal stones discovered by FIOC at the time of LC, except for very small filling defects of 1–2 mm. Spontaneous passage of ductal stones detected at FIOC and left behind after LC has been reported [2, 18]. However, spontaneous passage of ductal stones without symptoms or complications cannot be predicted by the number or size of stones, or by the diameter of the bile duct [2]. Because there is no way to anticipate which patients will not experience the complications related to spontaneous passage of ductal stones, such as biliary colic, jaundice, or pancreatitis [18], which may be severe and potentially fatal, an attempt at laparoscopic clearance of ductal stones at the time of LC appears to be a better option if the necessary expertise and technology are available.

Although significant changes in the instrumentation on the market occurred in the period between 1991 and 2004, the equipment set-up described here has proven safety and efficacy. As reported by other authors [14], the use of a basket with or without the choledochoscope accounted for the greatest success in clearing the ductal system. In our hands, gentle external compression on the common hepatic duct with a grasper from the epigastric port helped to avoid stones inadvertently being swept proximal to the cystic duct during the extraction maneuvers. Gentle papillary pneumatic dilatation followed by flush irrigation with saline was also employed to aid in clearing the CBD of stone fragments and debris, sometimes coupled with intravenous glucagon administration to assist in relaxing the sphincter of Oddi. Intraductal lidocaine was never employed. Intraoperative mechanical lithotripsy occurred accidentally when the CBD stones were friable. Electrohydraulic lithotripsy, on the other hand, was indicated to deal with impacted stones that were difficult to remove by other means. This technique was rarely used, but it proved invaluable when it was necessary, as reported by others [14]. In a few patients, however, ductal stones were impossible to remove and were knowingly left behind, with a transcystic biliary drain positioned to prevent bile stasis, for postoperative treatment.

As reported by other authors [16], the most common major complication in the present series was that of re-

tained stones, which occurred in 6 cases (3.1%) but required ERCP/ES only in 4 (2.1%). Other complications included bile leakage from kinking of the biliary drain in 2 patients that was managed by the positioning of a nasobiliary drain during ERCP. Kinking of the biliary drain in these two patients occurred early in our experience when the procedure of TC-CBDE in our hands was in the process of being standardized. It is prevented by straightening of the biliary drain during deflation of the abdomen as pneumoperitoneum was concluded at the end of the operation.

One case of hemoperitoneum required open surgical reexploration in a patient who had undergone TC-CBDE after lysis of extensive adhesions from a previous Billroth II gastrectomy. This type of complication is related to the fact that this was an unselected series of patients and that scars from previous upper abdominal operations were not considered a contraindication. One case of acute necrotic pancreatitis, which was managed successfully with open surgical reexploration and debridement, was the consequence of impaction of the open basket at the papilla during blind basketing of the CBD. In 15 patients (7.7%) the type of complications that were observed were minor and resolved spontaneously without prolonging the hospital stay. They included hyperamylasemia in 8 cases (4.2%), which was observed after pneumatic balloon dilatation of the papilla performed to facilitate wash-out of the CBD with saline to remove stone fragments and fibrin debris after clearance of ductal stones, and it was not prevented by use of a trans-cystic biliary drain. There was no mortality.

No patient was lost to follow-up. During a median follow-up period of 118 months no episodes of recurrent biliary colic or biochemical signs of bile stasis were observed, and no biliary stricture was documented by US and/or MRC. To our knowledge, this is one of the largest European series of laparoscopic TC-CBDE with the longest period of follow-up that has been reported to date. Other authors have reported long-term follow-up results after TC-CBDE [6, 16, 20], with results that are similar to the present series but with a shorter mean follow-up period.

In conclusion, the present study adds up to a growing body of literature confirming at long-term follow-up that laparoscopic transcystic CBD exploration during LC for the management of gallstones and CBD stones is a safe and effective procedure. The long-term complications usually reported after ES [9, 17, 19], namely recurrent ductal stones and cholangitis, were not observed after laparoscopic TC-CBDE.

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