







ORIGINAL ARTICLE

Multi-institutional expert update on the use of laparoscopic bile duct exploration in the management of choledocholithiasis: Lesson learned from 3950 procedures

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Abstract

Background: Recently there has been a growing interest in the laparoscopic management of common bile duct stones with gallbladder in situ (LBDE), which is favoring the expansion of this technique. Our study identified the

standardization factors of LBDE and its implementation in the single-stage management of choledocholithiasis.

Methods: A retrospective multi-institutional study among 17 centers with proven experience in LBDE was performed. A cross-sectional survey consisting of a semi-structured pretested questionnaire was distributed covering the main aspects on the use of LBDE in the management of choledocholithiasis.

Results: A total of 3950 LBDEs were analyzed. The most frequent indication was jaundice (58.8%). LBDEs were performed after failed ERCP in 15.2%. The most common approach used was the transcystic (63.11%). The overall series failure rate of LBDE was 4% and the median rate for each center was 6% (IQR, 4.5-12.5). Median operative time ranged between 60-120 min (70.6%). Overall morbidity rate was 14.6%, with a postoperative bile leak and complications $\geq 3a$ rate of 4.5% and 2.5%, respectively. The operative time decreased with experience ($P = .03$) and length of hospital stay was longer in the presence of a biliary leak ($P = .04$). Current training of LBDE was defined as poor or very poor by 82.4%.

Conclusion: Based on this multicenter survey, LBDE is a safe and effective approach when performed by experienced teams. The generalization of LBDE will be based on developing training programs.

KEYWORDS

bile duct exploration, biliary tract, cystic duct, laparoscopy, lithiasis

1 | INTRODUCTION

The original treatment for choledocholithiasis was surgical.¹ The expansion of endoscopic retrograde cholangiopancreatography (ERCP) together with the laparoscopic cholecystectomy took over the management of choledocholithiasis with gallbladder in situ, due, to a certain extent, to the lack of technical skills to perform a laparoscopic bile duct exploration (LBDE).^{2,3} In the last decade, helped by the development of laparoscopic surgery together with technological advances, there has been a growing interest in the laparoscopic approach to the bile duct.⁴

Single-stage laparoscopic management of choledocholithiasis appears in most international clinical guidelines as one of the recommended options for the treatment of common bile duct stones with gallbladder in situ, allowing the cholecystectomy and the bile duct clearance to be done in the same sitting, with a low rate of complications.⁵ Despite this evidence, the lack of surgical experience and training in LBDE has maintained ERCP followed by laparoscopic cholecystectomy as the most popular and widespread option.⁶

Numerous studies have been carried out trying to demonstrate the superiority of one of the approaches. However, most of them show that both are valid in terms

of efficacy in removing the lithiasis from the main bile duct, and with a similar rate of complications and a very low mortality.⁷⁻⁹ When local expertise is available, the one-step approach should be the choice because it allows the surgeon to solve the problem in one episode with a low rate of complications, especially when it is performed through the transcystic route, and also avoids extra admissions and aerosol generating procedures (ERCP), which is important nowadays in COVID times.¹⁰

The aim of this study was to analyze the technical details, surgical indications, preoperative planning, surgical outcomes, and training in this procedure in centers with proven experience in LBDE.

2 | METHODS

2.1 | Study design

This is a retrospective multi-institutional study in which 17 centers with proven experience in LBDE from eight countries participated (Belgium, India, Italy, Cuba, Finland, Spain, United Kingdom, and China). A cross-sectional survey consisting of a semi-structured pretested questionnaire was self-administered covering the main aspects on the use of LBDE in the management of

choledocholithiasis as determined by the working group members. The link giving access to the survey, together with a covering letter, was emailed to 58 corresponding authors elected because they had publications indexed related to LBDE and 17 answered. Only those authors who provided us with data on their experience and perioperative outcomes were included in the study. Ethical approval for this study was reviewed from the Clinical Research and Ethics Committee at the Virgen de la Arrixaca Clinic and University Regional Hospital Murcia, Spain (Internal Protocol Code: NE-2021-2-HCUVA).

2.2 | Outcomes

Data was collected and analyzed about: the type of hospital, most common approach to treat choledocholithiasis with gallbladder in situ in each center, years of experience with LBDE, number of total cases performed, demographic data (ASA or BMI), number of patients with previous cholecystectomy, indications for LBDE, preoperative imaging test, percentage of LBDE performed after failed ERCP, rate of transcystic exploration, preferred scope diameter (5 or 3 mm), experience with lithotripsy (laser or electrohydraulic), type of choledochorraphy (T-tube, stented or primary closure), operative time, postoperative complications, postoperative biliary leak, hospital stay, failure rate of LBDE and state of current training of LBDE during the residency.

For the diagnosis of choledocholithiasis, depending on the availability, experience of the center and the clinical situation of the patient, the roles of the liver function test (ALT, AST, serum bilirubin, alkaline phosphatase, and gamma-glutamyl transpeptidase), abdominal ultrasound, computed tomography (CT), magnetic resonance cholangio pancreatogram (MRCP), intraoperative cholangiography (IOC), or intraoperative ultrasound were also analyzed.

2.3 | Definitions

All the patients included in the study had suspected choledocholithiasis requiring single stage laparoscopic cholecystectomy \pm intraoperative imaging \pm LBDE. Abnormal liver function tests were defined as: elevation of direct bilirubin or cholestatic enzymes (alkaline phosphatase and/or gamma-glutamyl transpeptidase) compared to the normal values. Bile duct dilatation was defined as a duct >6 - 7 mm in patients with gallbladder in situ on preoperative imaging. Patients with proven lithiasis in the main bile duct on imaging tests (ultrasound, CT or MRCP) were also subjected to LBDE.

Bile leakage was defined as the presence of bile outflow from the biliary tree through an environmental surgical drain, biochemical demonstration of the fluid, extravasation of bile contents during ERCP or MRCP, or placement of a radiological drain due to the formation of a biliary collection. On the other hand, biliary stenosis was defined as narrowing of the bile duct causing cholestasis with elevated liver enzymes and/or serum bilirubin and bile duct dilation observed by imaging or ERCP. Clavien-Dindo classification was used to assess 90-day morbidity. LBDE failure was defined as the impossibility to retrieve the stones by laparoscopy during the procedure.

2.4 | Statistical analyses

Statistical analyses were carried out using SPSS Statistics 25.0 software (SPSS Inc). Because there were differences in the number of cases contributed by each center, qualitative variables from the total cohorts of patients were expressed as frequencies and percentage and quantitative variables in relation to cases contributed by each center were expressed as median and interquartile range (IQR). The comparison of means between groups was carried out using Student's *t*-test (pooled *t*-test) or with the non-parametric Mann-Whitney test when the data were discrete or lacked a normal distribution. To compare the percentages between the groups, an analysis using contingency tables was used with the χ^2 test or the Fisher exact test when the frequency of cases was low, together with a study of typed residuals to assess the directionality of the associations. The values were considered statistically significant at a *P*-value $<.05$.

3 | RESULTS

3.1 | Baseline demographics, surgical indications, and preoperative imaging

A total of 3950 cases coming from the 17 centers with experience in LBDE that participated in the study were analyzed. Fifteen were tertiary level and two were secondary level hospitals. The most frequently used approach for choledocholithiasis was still the traditional ERCP followed by laparoscopic cholecystectomy (52.9%). Surgeon's experience in LBDE is shown in Table 1 and Figure 1. The percentage of patients with an ASA ≥ 3 was 22.8% and with a BMI ≥ 40 of 7.5%. The rate of patients with a previous cholecystectomy was 1.9%. The most frequent indication for LBDE was jaundice (58.8%) followed by findings in the IOC (23.5%) (Figure 2). Of the 17 centers that participated in the study, most frequent preoperative imaging tests

used was the abdominal ultrasound in 12 centers, MRCP in four, and only in one center the preference was to directly perform an IOC (Figure 3A). The overall percentage of patients with no choledocholithiasis found during LBDE was 3.8%.

TABLE 1 Profile of the experience of the surgical teams participating in the study

Seniority surgeon post qualification, (y), median (IQR)	23 (15.5-29)
Experience with LBDE (y), median (IQR)	13.5 (9.75-22)
Number total cases done by the surgeon, median (IQR)	103 (78.75-306.25)
Number of surgeons who performed LBDE for center, median (IQR)	3 (2-5)
Number of cases per year, median (IQR)	27.5 (19.5-41.25)

3.2 | Preferred approach for the LBDE

Surgical outcomes are presented in Table 2 and Table S1. The number of LBDE performed after a failed ERCP was 15.2% and the median rate for each center was 19% (IQR, 3.5-30). A total of 58.8% of the centers reported experience with lithotripsy (Figure 3B), and laser was the preferred technique over electrohydraulic lithotripsy. The transcystic approach was most commonly used in 63.11% of the cases (Figure 3C). When the transductal route was used, the overall rate of primary closure was 26% but the median rate for each center was 60% (IQR, 10-77). The overall rate of closure over T tube was 10.9% with a similar median rate for each center of 10% (IQR, 3-25). In the LBDE cases due to ERCP failure there was a lower percentage of transcystic approach ($P = .02$). Nine of the 17 centers prefer the use of the 3-mm choledoscope over the 5-mm one.

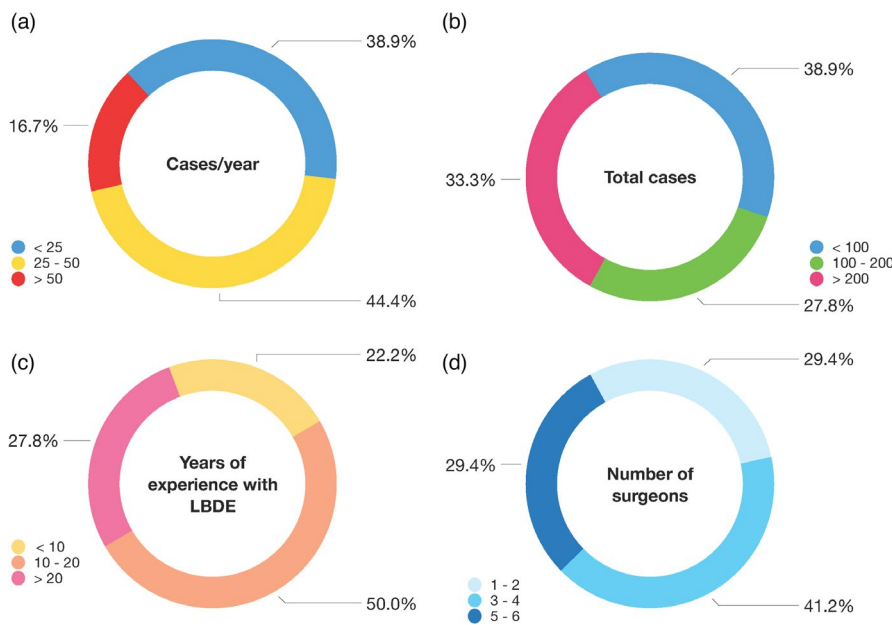


FIGURE 1 Details about surgeons and hospital serie experience with LBDE. LBDE, laparoscopic bile duct exploration

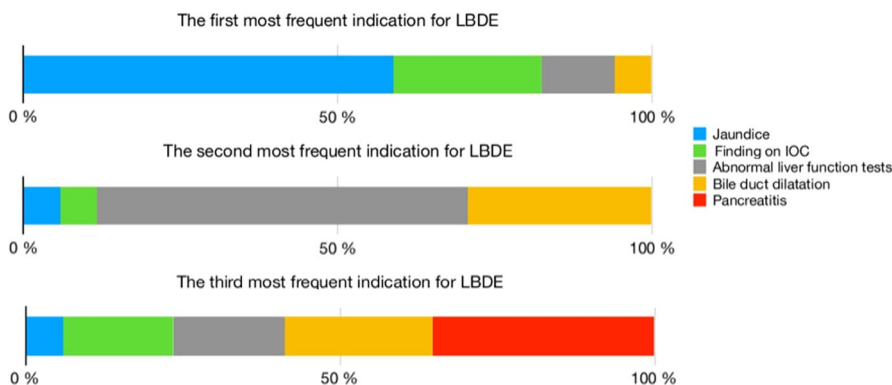


FIGURE 2 Summary of the most frequents indications for LBDE. LBDE, laparoscopic bile duct exploration

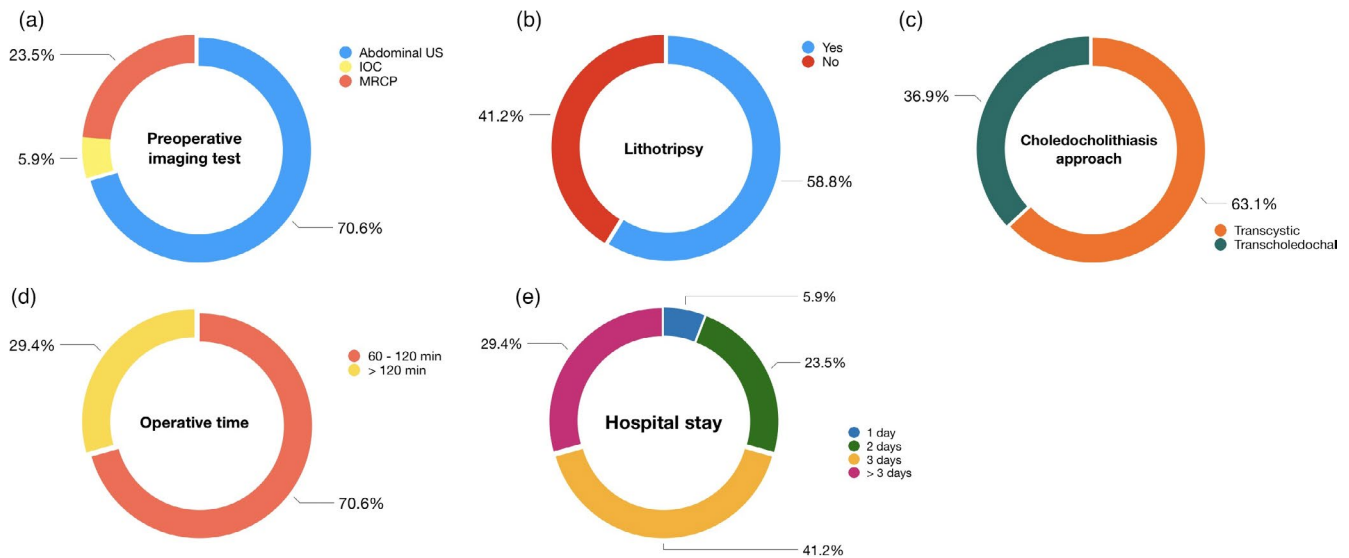


FIGURE 3 Description of perioperative preferences and outcomes of each center related with LBDE. Visual schemes related to preferred preoperative imaging test (A), rate of surgeons with experience in lithotripsy (B), rate of transcystic route (C), median operative time (D), median hospital stay for each center (E). LBDE, laparoscopic bile duct exploration

3.3 | Intraoperative and postoperative outcomes

Median operative time by center ranged from 60-120 min in 70.6% of the total number of cases of each series and the median operative time was >120 minutes in the remaining 29.4% (Figure 3D). In all the cohort of patients, global complications, complications $\geq 3a$ on the Clavien-Dindo classification, and postoperative bile leak were 14.6%, 2.5%, and 4.5%, respectively. Mortality rate was 0.2%. In the separate analysis by each center, the median of global complications was 12% (IQR, 6.5-20) with a median rate of complications $\geq 3a$ and postoperative bile leak of 5% (IQR, 3-10) and 3% (IQR, 2-7), respectively. The mean hospital stay in most centers was 3 days (Figure 3E). The overall series failure rate of LBDE was 4% and the median rate for each center was 6% (IQR, 4.5-12.5). The percentage of patients with recurrent choledocholithiasis was 2.6%. The operative time decreased as the number of cases performed per year increased ($P = .03$). The performance of a median of 32.5 cases per year (range: 15-85) was associated with an operative time between 60-120 minutes, while a median of 20 cases per year (range 15-25) was associated with an operative time >120 minutes ($P = .03$) (Figure 4A). Length of hospital stay was longer in the presence of a biliary leak ($P = .03$). The percentage of bile leakage was lower in patients with a hospital stay <2 days ($3.4 \pm 1.5\%$) than in patients with a hospital stay of more than 3 days ($6.6 \pm 4.1\%$) ($P = .04$) (Figure 4B). Current training of LBDE during the

surgical residency was defined by 82.4% of respondents as poor or very poor (Figure 5).

4 | DISCUSSION

The results of this worldwide multi-institutional expert center LBDE survey suggest that in experienced hands, single-stage laparoscopic cholecystectomy +LBDE is safe and effective and allows the resolution of cholelithiasis and choledocholithiasis in a single sitting.

Among the obstacles to the widespread use of the laparoscopic management of choledocholithiasis is the low percentage of surgeons who perform this technique together with the presence of an experienced ERCP service in most hospitals.¹¹ To master the technique, it is necessary to overcome the learning curve, sometimes at the expenses of increased surgical times at the beginning, but this improves with experience.¹²

MRCP is currently the most accurate non-invasive diagnostic test for the diagnosis of bile duct stones and represents the gold standard. However, the sensitivity of this test is lower for small stones (<6 mm) and biliary sludge.¹³ The best approach to the bile duct during LCBE will be determined by the characteristics of the patient, the equipment available and obviously the experience of the surgeon. The two main approaches to the common bile duct are the transcystic and the choledochotomy.¹⁴⁻¹⁶ Classically, the transcystic route was more limited, allowing only the recovery of small stones and providing poor access to the proximal ducts. In recent years, the use of leveraging access technology and

TABLE 2 Details about demographic, intraoperative, and postoperative outcomes of LBDE

	(n = 3950)
BMI \geq 40, (kg/m ²), n (%)	295 (7.5)
ASA \geq 3, n (%)	902 (22.8)
Patients with a previous cholecystectomy, n (%)	74 (1.9)
LBDE performed after failed ERCP, n (%)	600 (15.2)
Number of duct stones, n, median (range)	2 (1-30)
Size of duct stones, mm, median (range)	9 (2-40)
Presence of acute cholangitis, n (%)	279 (7.1)
Choledochotomy, n (%)	
T-tube	429 (10.9)
Primary closure	1028 (26)
Stented choledochorraphy	263 (8.6)
Transcystic approach, n (%)	2493 (63.1)
Global Morbidity, n (%)	575 (14.6)
Postoperative bile leak	179 (4.5)
Postoperative infections	65 (1.6)
Pancreatitis	55 (1.4)
Pulmonary complications	48 (1.2)
Bleeding	15 (0.4)
Cardiovascular complications	12 (0.3)
Cerebrovascular complications	4 (0.1)
Others	159 (4)
NA	38 (1)
Clavien-Dindo \geq IIIa, n (%)	98 (2.5)
Mortality, n (%)	8 (0.2)
Operative time, minutes, median (range)	110 (30-270)
Failure rate of LBDE, n (%)	159 (4)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; ERCP, endoscopic retrograde cholangiopancreatography; LBDE, laparoscopic bile duct exploration; NA, not available.

enhanced surgical techniques (LATEST)¹⁷ have allowed increased rates of transcystic approach in up to 90% of cases. In the present study, the most experienced centers not surprisingly favored the transcystic approach, using advanced methods to improve transcystic exploration such as ultrathin scopes, the use of lithotripsy, and enhanced surgical techniques including the Wiper Blade Manoeuvre for transcystic proximal choledochoscopic access,¹⁸ although a majority of centers preferred the transcholedochal approach.

Most of the authors of the present study believe that the transcystic approach should be limited by the number of stones (less than 3-6), stone size (less than 6-9 mm), CBD size (under 8-10 mm), dilated cystic duct (diameter >4mm), cystic duct length (>4mm), straight and lateral cystic duct entry into CBD, and the absence of proximal

or intrahepatic stones. Only two authors stated that the transcystic approach should always be the first choice unless there was no cystic due to a previous cholecystectomy.

Jorba et al.¹⁹ recently reported a survey on the contemporary management of concomitant gallstones and common bile duct stones in Spain. The study found that the use of LBDE is limited, despite many surgeons indicating that they would be keen on having it implemented, thus showing the lack of training. Unlike our study, where centers with experience were targeted, the Jorba et al survey¹⁹ included many centers with little experience in LBDE (89% of the centers that responded performed less than 10 cases per year).

The controversial views on the subject are demonstrated by the fact that out of the currently available meta-analyses, three were published in the last 2 years and despite reviewing practically the same studies they reached different conclusions.²⁰⁻²² Some recommend ERCP as the first step and only advice performing LBDE in the event of its failure, whilst others advocate LBDE as the first choice.²³ In this multi-institutional experience, 15.2% of LBDEs were performed following a failed ERCP; whilst on the other hand, the LBDE failure rate was just 4%. In addition, with some exceptions (such as lithiasis larger than 1.5 cm that may require several ERCP sessions), it is widely accepted that both approaches must coexist, and the patients should be treated by a multidisciplinary group, which decides the optimal management for this pathology based on the local expertise and patient characteristics.

In relation to morbidity, ERCP is mostly associated with acute pancreatitis^{24,25} and LBDE with bile leak. As expected, the main complication of LBDE reported in the current study was bile leak (mainly associated with a transductal approach). In the literature, there is a relatively high rate of self-limiting bile leaks reported,²⁶ although according to our survey this should be around 4%. In order to avoid biliary leaks, drains and endo-biliary stents were recommended in some studies²⁷ to decompress the bile duct. However, it has been observed that this does not provide any added value.²⁸ Although our survey reported a 10% use of T-tube, most of the groups do not recommend its routine use. This rate is probably due to the fact that the series includes patients from groups with more than 20 years of experience where, at the beginning, the use of the T tube was a common feature.

Noble et al.⁷ suggested that the single-stage approach will significantly reduce hospital stay regardless of the technique used. The present study showed that most of the centers have an average stay of 2-3 days and, even, only one day in one centre. The reduction in LBDE hospital stay is probably not only explained by the technique itself, but also by the fact that it is a single-stage procedure

FIGURE 4 Relationship between case of LBDE and operative time (A) and rate of biliary leak and hospital stay (B). LBDE, laparoscopic bile duct exploration

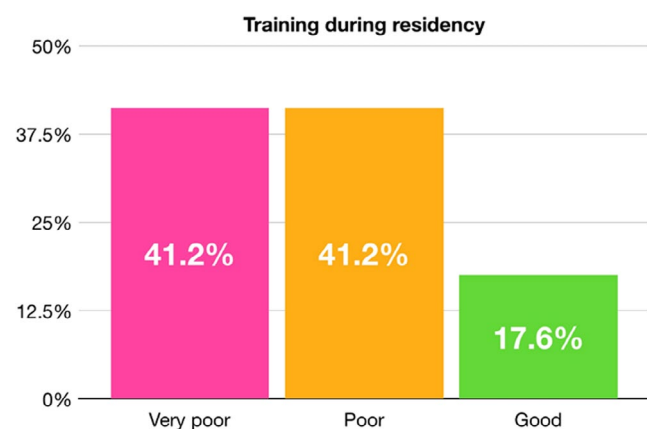
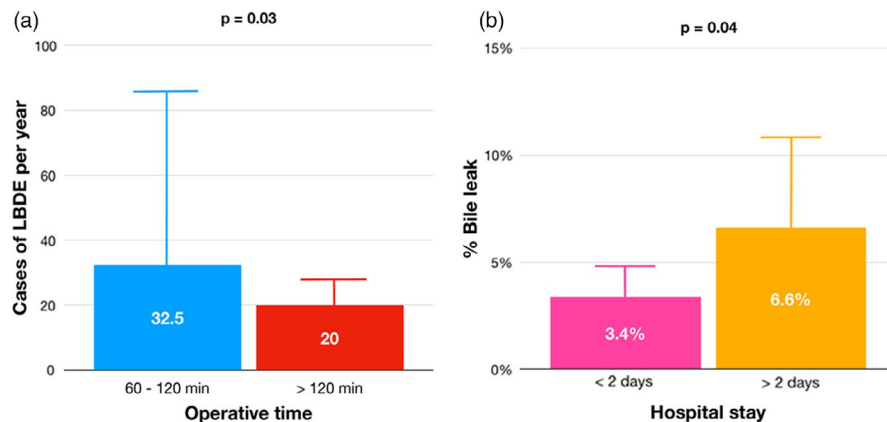


FIGURE 5 Current situation of training of LBDE during the residency. LBDE, laparoscopic bile duct exploration

that avoids repeat hospital admission (ERCP and laparoscopic cholecystectomy are often performed on different admissions).

It is interesting that 82.4% of the participants in this study consider LBDE training to be "poor" or "very poor." During their training, surgeons should learn to perform this procedure, but the fact that it is not performed in many centers, makes it difficult to achieve this target. In a study between 1999-2018 amongst surgical residents, Warner et al²⁹ reported that despite an increase in the number of procedures performed, with 39% more of laparoscopic cholecystectomies, there was a 74% drop in the number of bile duct explorations (open and laparoscopic).

A series of recommendations are proposed by our working group. The trainee/mentee entering LBDE training must be a surgeon competent to safely perform general laparoscopic procedures requiring an advanced skillset and experience in laparoscopic cholecystectomy. LBDE training should start with a theoretical part covering patient selection, indications in different scenarios, as well as knowledge of the technique and the instruments used in LBDE. Lab-based hands-on training on well-designed models, should be done with training boxes such as the

FLS[®] (fundamentals of laparoscopic surgery VTI Medical) or pelvitainers. Many models are available¹⁸ including the PARA model (Porcine Aorto-Renal Artery that allows a realistic choledochotomy and training in the transcystic access including lithotripsy).³⁰ Some follow-up mentoring with an expert center is necessary and can even be delivered remotely using smart surgery glasses and digital remote assistance platforms. In order to structure the training, the procedure will be broken into different steps of different complexity (Table S2).

The current study presents some limitations. It involves multiple surgeons developing different levels of experience over different periods of time. The study does not include the results in patients who have undergone two-stage ERCP-LC, so we cannot directly compare both techniques. However, this has been done in multiple meta-analyses and was not the aim of the study. Finally, this is a retrospective study, and to have a more accurate view it is necessary to carry out prospective multicentric registries.

In summary, based on this multicenter expert center that included a large number of procedures, it is suggested that LBDE, when performed by an experienced team, is a safe and effective approach. This conclusion is currently supported by most clinical guidelines. The next challenge is to address the lack of training as a necessary step before the full adoption of LBDE as a widespread alternative in the treatment of CBD stones with gallbladder in situ.

CONFLICT OF INTEREST

Alberto Isla is a faculty for Johnson & Johnson and consultant for Boston Scientific. The rest of the authors have no relevant financial or non-financial interests to disclose.

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SUPPORTING INFORMATION

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