Common bile duct clearance of stones by open surgery, laparoscopic surgery, and endoscopic approaches (comparative study)

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Background and aim of the work
Around 10–18% of patients undergoing cholecystectomy for gallstones have common bile duct (CBD) stones. Treatment can be provided as open cholecystectomy plus open CBD exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC+LCBDE), or precholecystectomy or postcholecystectomy endoscopic retrograde cholangio-pancreatography (ERCP) in two stages for CBD clearance. The aim of this study is to compare the CBD clearance rate by each procedure in a well-equipped tertiary center.
Patients and methods
A total of 250 patients with choledocholithiasis were included from the General Surgery Department, Sohag and Assiut University Hospitals, and managed randomly by either conventional surgery, endoscopic, or laparoscopic procedures.
Results
The ages of our patients ranged from 20 to 60 years (mean=40 years), with a slight female predominance (1.6 : 1); most of them presented with calcular obstruction (54.3%). However, there were also other presentations such as colic, cholangitis, or accidental discovery in 14.3, 10, and 21.5%, respectively. Patients were categorized randomly into three groups: group I included 100 patients (40%) who were treated by open choledocholithotomy and T-tube insertion; the operative time was 90 (60–180) min, with the success rate of the attempted procedures reaching 100%, and CBD clearance of stones was achieved in 95% of cases (five cases of missed stones). Hospital stay was 8 (5–12) days, with no mortality, and morbidity rate reached 15% in the form of wound infection, bile leak, and missed stone. The patient could return to work after 2 weeks (12–20 days). Group II included 100 patients (40%) treated by endoscopic sphincterotomy; basket extraction was performed in 45%, balloon in 25%, the combined maneuver in 15%, and mechanical lithotripsy in 13%, with failure of the technique in two cases (2%); the duration of the procedure was about 30 (20–45) min, with a success rate of attempted procedures of 98%, and CBD clearance of stones was achieved by 100%, with no mortality; the morbidity rate was 9% in the form of cholangitis (3%) and mild pancreatitis with hyperamylasemia (6%). The period of hospital stay was 1 (1–2) days and the patient returned to work after 3 (2–5) days. Group III included 50 patients (20%) treated by laparoscopic approaches: transcystic approaches in five cases and transcholedochotomy approaches in 45 cases. Choledochoscopic exploration was performed in almost all cases (45 cases) to detect, extract the stones, and test CBD clearance, and there was conversion to open techniques in one case. The time needed for this procedure was 123 (70–292) min, with CBD clearance of stones in 96% (two cases of missed stone), with no mortality, and a morbidity rate of about 10% in the form of mild hyperamylasemia, fever, and missed stone. The period of hospital stay was 3.2 (2–4) days, with return to work after 7 (5–10) days.
Conclusion
Both ERCP/LC and LCBDE were highly effective in CBD clearance, and equal in terms of the overall cost and patient acceptance. However, the overall duration of hospitalization was shorter for LCBDE with elimination of the potential risks of ERCP-associated pancreatitis, further procedures, and anesthesia risks. It is feasible, cost-effective, and ultimately should be available for most patients in each specialized center.

Keywords:
choledocholithotomy, ERCP, laparoscopic common bile duct exploration, sphincterotomy

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Introduction and aim of the work

Around 10–18% of patients undergoing cholecystectomy for gallstones have common bile duct (CBD) stones [1]. Symptoms caused by CBD stones consist of colic or may

result from complications such as jaundice, cholangitis, or pancreatitis [2]. In case of symptomatic CBD stones, decompression of the CBD and removal of ductal stones is warranted. Decompression may be achieved using endoscopic methods such as endoscopic sphincterotomy, papillary dilatation, and nasal-biliary drainage [2].

Treatment of the bile duct stones can be performed as open cholecystectomy plus open CBD exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC+LCBDE), or precholecystectomy or postcholecystectomy ERCP in two stages usually combined with either sphincterotomy (commonest) or sphincteroplasty (papillary dilatation) for CBD clearance [1].

LCBDE was postulated through the transcystic approach in small-sized stones or by choledochotomy, which allows a more selective approach for the removal of CBD stones, thus avoiding unnecessary preoperative ERCP. It has the advantage of combining two procedures into a single minimally invasive operation [3].

The majority of secondary biliary stones can be diagnosed at the time of cholecystectomy and cleared transcystically; otherwise, the choledochotomy approach or postoperative ERCP is needed, but choledochotomy should be avoided in ducts less than 7 mm in size at the time of operative cholangiogram, and also in severely inflamed friable tissues with difficult dissection. Choledochotomy is advocated as a good choice for patients after gastrectomy, failed ERCP access, or absence of medical service for ERCP [4]. The intraoperative ERCP approach for CBD stones during LC also benefits the patient by reducing the treatment from a two-step procedure to a single-step procedure under general anesthesia. It minimizes the risk of pancreatitis and avoids exploration of the CBD [3].

Both ERCP/LC and LCBDE were highly effective in detecting and removing CBD stones and were equivalent in overall cost and patient acceptance. However, the overall duration of hospitalization was shorter for LCBDE; moreover, LCBDE eliminates the potential risks of ERCP-associated pancreatitis and the need for another procedure and the associated risks of anesthesia. It is feasible, cost-effective, and ultimately should be available for most patients [5].

As surgical skill with LCBDE increases, the need for routine preoperative ERCP will likely decrease, except in unique high-risk situations. Therefore, a single surgical procedure for CBD stone is needed [5].

All randomized clinical trials that compared the results from open surgery versus endoscopic clearance and laparoscopic surgery versus endoscopic clearance for CBD stones showed no significant difference in the mortality and morbidity between laparoscopic and endoscopic CBD clearance. Also, there was no significant reduction in the number of retained stones and failure rates in the laparoscopy groups compared with the preoperative and intraoperative ERCP groups. Moreover, there was no significant difference in the mortality, morbidity, retained stones, and failure rates between the single-stage laparoscopic bile duct clearance and two-stage endoscopic management [2].

Patients and methods

Study design

This prospective observational study included all consecutive patients who were referred for the management of choledocholithiasis to the Surgery Department, Assiut and Sohag University Hospitals. The study protocol was approved by the local ethical committee of our hospitals. Also, a written informed consent was obtained from all patients' before recruitment into the study.

Patients

From June 2014 to July 2016, patients with symptomatic choledocholithiasis at the General Surgery Department, Assiut and Sohag University Hospitals, were enrolled in this study. The inclusion criteria were patients with a preoperative diagnosis of symptomatic CBD stones aged from 20 to 60 years, American Society of Anesthesiologists (ASA) grade I, II or III, and agreement to complete the study requirement. Exclusion criteria were patients with contraindication to laparoscopy, or endoscopy, suspected Mirizzi syndrome, malignancy, previous upper abdominal surgery, previous mesh repair of an umbilical hernia, long-term anticoagulant treatment, pregnant women, and diagnosis of intrahepatic stones in preoperative ultrasonography. In all, 250 patients who fulfilled all the criteria of the study were enrolled in the study protocols and thoroughly investigated and studied.

Randomization

This was done with the permuted block method using blocks of 10. Envelopes were drawn and opened by an operating room nurse who was not involved in the study. Randomization was performed just before the procedure. Only operating surgeons and operating room staff were aware of the procedure performed. Records of the procedure were kept in a sealed envelope during the patient's hospital stay to keep the patient and ward personnel blinded to the procedure used.

Management protocols

The proposed treatment option was assigned randomly by one of the three procedures of either conventional surgery, endoscopic, or laparoscopic approaches as group I, group II, and group III, respectively.

Operative techniques

All surgeries were performed by the same experienced surgical team, under general anesthesia, with standardized techniques.

The conventional surgical approach includes open cholecystectomy plus choledocholithotomy and a T-tube drain through the choledochotomy incision with a subhepatic drain in all cases (Figs 1 and 2).

Endoscopic treatment was performed by precholecystectomy or postcholecystectomy ERCP, with sphincterotomy or sphincteroplasty to clear CBD from stones by either basket, balloon extraction, basket extraction with balloon sweeping, or mechanical manual internal or external lithotripsy (Figs 3–8).

LCBDE was performed by the transcystic or the transcholedochotomy route. Intraoperative cholangiogram was used in most of the cases, and a choledochoscope was used in choledochotomy patients to detect, extract, and assess CBD clearance. T-tube drain application was performed; however, direct CBD primary closure was also performed in some cases, with a subhepatic drain in all cases (Figs 9–22).

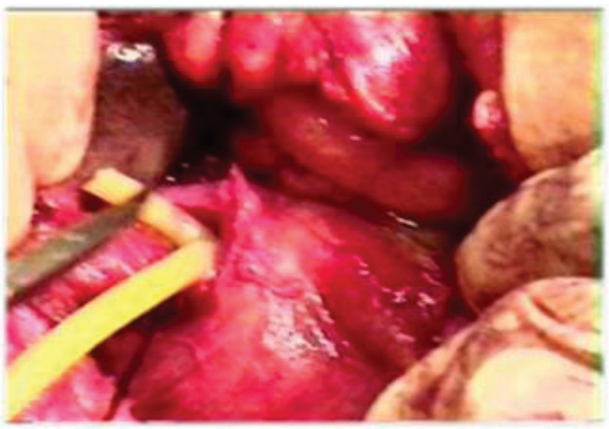
Statistical analysis

Descriptive data were expressed as mean and standard error of the mean, or as median and ranges for continuous variables and proportions for categorical variables. Statistical analysis was carried out using Fisher's and χ^2-tests. A P value less than 0.05 was considered statistically significant.

Figure 1

Open choledocholithotomy.

Figure 2



T-tube application after choledocholithotomy.

Results

The ages of our patients ranged from 20 to 60 years (mean=40 years), with a slight female predominance (female to male=1.6 : 1). The main presentation of our cases was calcular obstructive jaundice in 54.3%, biliary colic in 14.3%, cholangitis in 10%, or accidental discovery in 21.5%. Patients were categorized randomly into three groups according to stone treatment as follows:

Group I

Group I included 100 patients (40%) treated by open choledocholithotomy and T-tube insertion; the operative time was 90 (60–180) min, with a success rate of attempted procedures reaching 100%, and CBD clearance of stones was achieved in 93% of cases (seven cases of missed stones). Hospital stay was 8 (5–12) days, with no mortality, and morbidity rate reached 13% (Table 1). The patient could return to work 2 weeks (12–20 days) postoperatively.

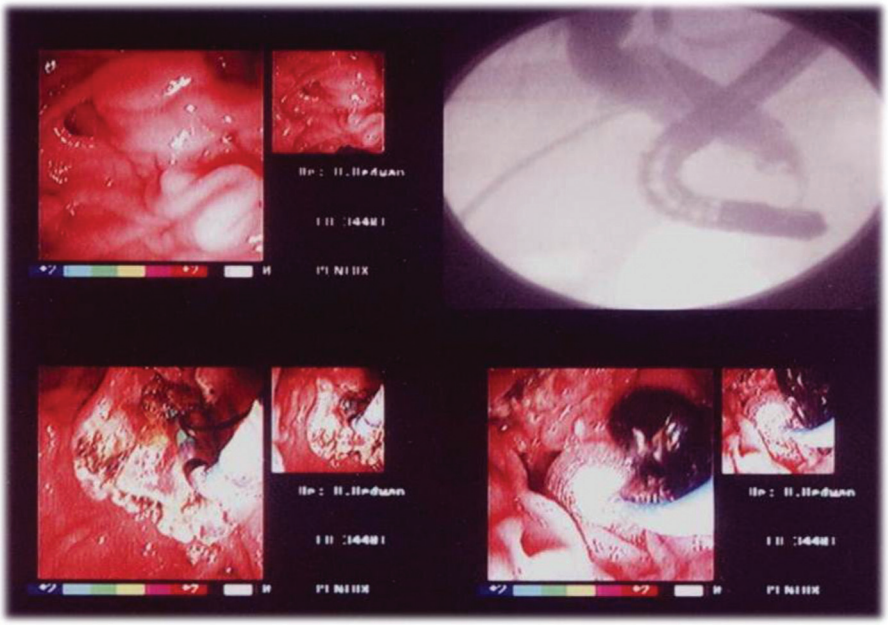
Group II

Group II included 100 cases (40%) treated by endoscopic sphincterotomy and stone(s) extraction using variable techniques (Table 2), with failure of the technique in two cases (2%); the procedure time was about 30 (20–45) min, with a success rate of attempted procedures of 98%, and CBD clearance of stones was achieved by 100%, with no mortality, and a morbidity rate of 7% (Table 3). The period of hospital stay was 1 (1–2) days and the patient returned to work after 3 (2–5) days.

Group III

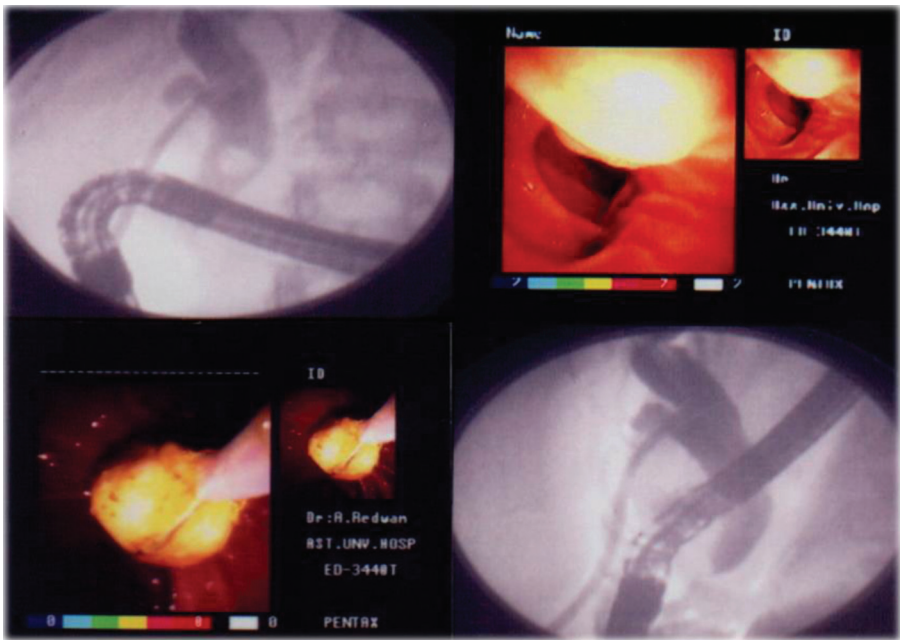
Group III included 50 cases (20%) treated by LCBDE: transcystic in five cases and transcholedochotomy in 45

Figure 3



Sphincterotomy and balloon extraction of common bile duct (CBD) stone.

Figure 4



Basket extraction of common bile duct (CBD) stone.

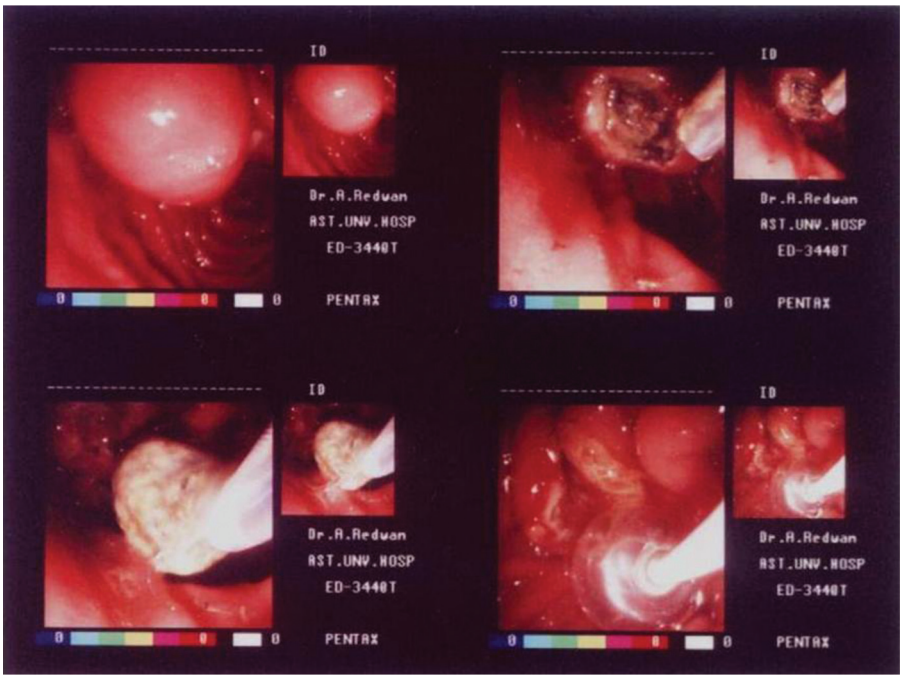
cases (Table 4). Choledochoscopy was performed in almost all cases (45 cases), with conversion to open techniques in one case. The time needed for this procedure was 123 (70–292) min, with CBD clearance of stones in 96% (two case of missed stone), with no mortality, and the morbidity rate was about 20% (Table 5). The period of hospital stay was 3.2 (2–4) days, with return to work after 7 (5–10) days.

Data of all patients were collected and categorized in each group to evaluate and compare these techniques of CBD stone clearance (Table 6).

Discussion

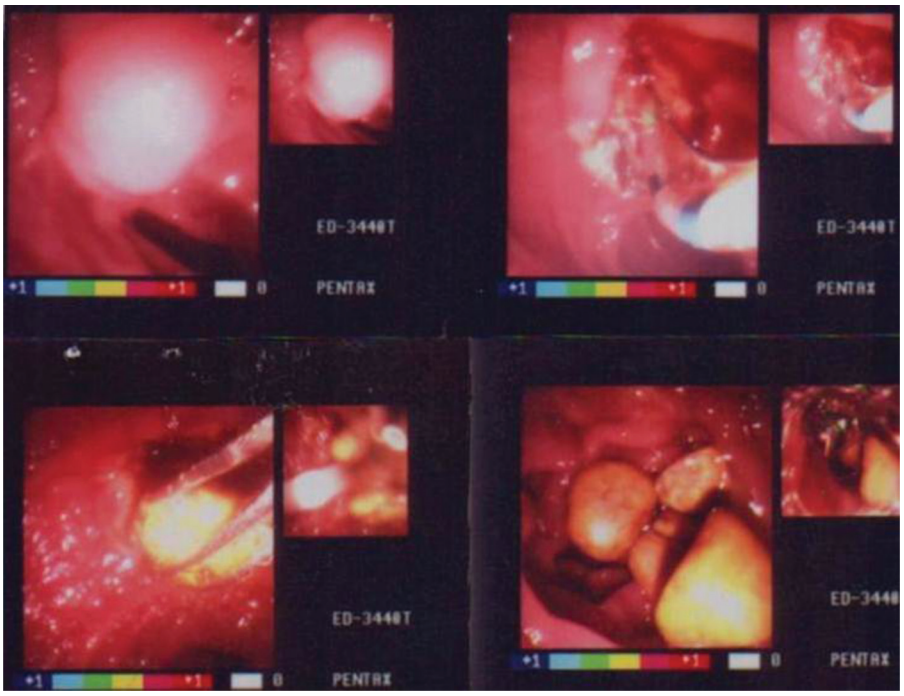
Symptomatic gallstone disease is a very common indication for abdominal surgery [6]. Before the laparoscopic era, cholecystectomy and CBD stones

Figure 5



Basket stone extraction and balloon sweeping of common bile duct (CBD).

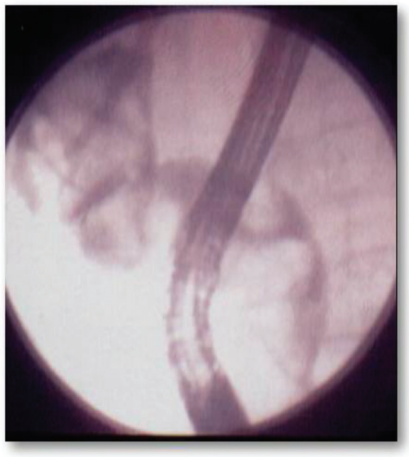
Figure 6



Basket extraction of multiple common bile duct (CBD) stone.

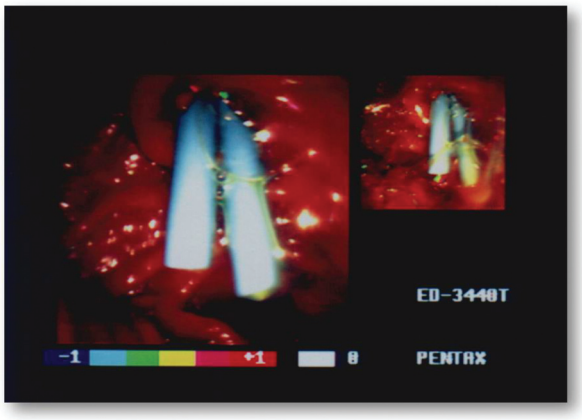
were removed during a single procedure. This approach has been effective, with morbidity below 15% and mortality below 1% in patients up to 65 years of age [7]. In the era of minimally invasive procedures, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries; thus, therapeutic decision-making is based on the local availability of expertise [8], and hence concomitant gallstones and CBD stones were managed by preoperative or postoperative ERCP [9]. Although this approach is effective and safe, it has several drawbacks as it requires two periods of anesthesia and two hospital admissions, which increase expenses. Furthermore, if patients still have CBDS detected intraoperatively, surgeons will face

Figure 7



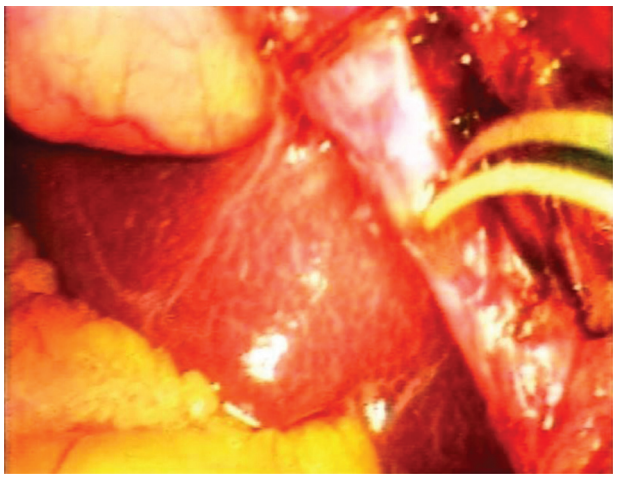
Radiologic view showing multiple common bile duct (CBD) stones casting whole CBD.

Figure 8



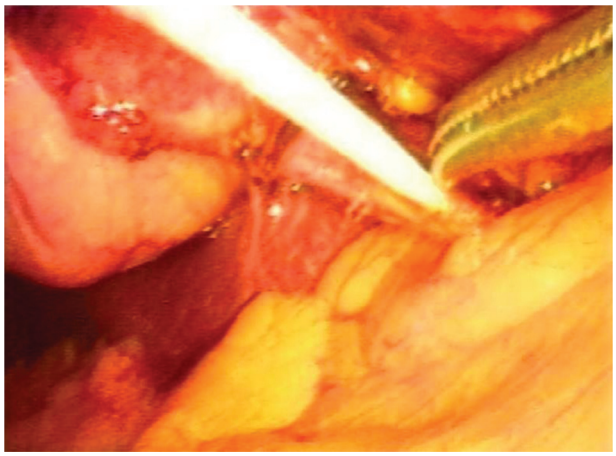
Endoscopic stenting for multiple common bile duct (CBD) stones before surgery.

Figure 9



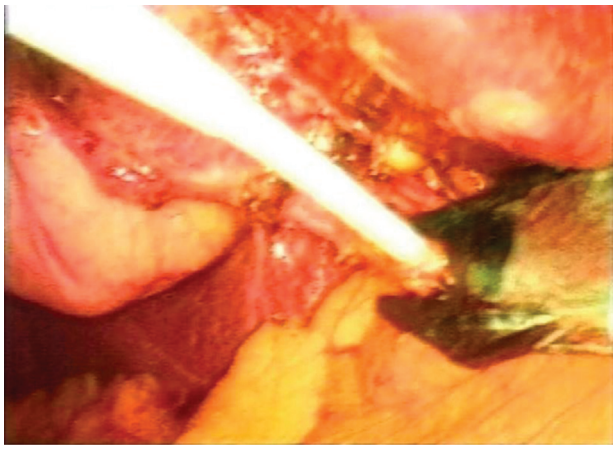
Laparoscopic cut in cystic duct prior intraoperative cholangiogram.

Figure 10



Ureteric catheter in the cystic duct for intraoperative cholangiogram.

Figure 11

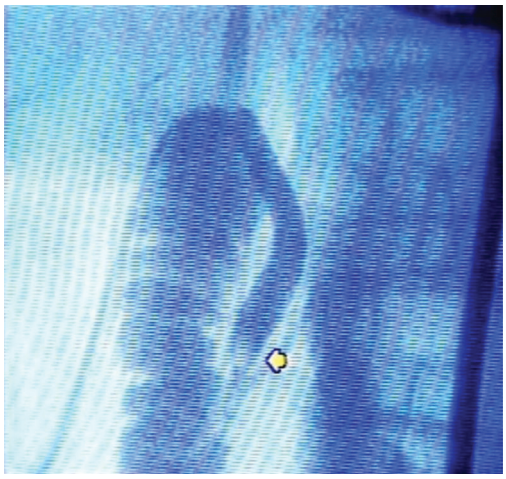


Light clipping of cystic duct over the catheter prior cholangiogram.

the dilemma of depending on LCBDE, postoperative ERCP, or traditional open choledochotomy [10]. Most importantly, even in those patients with clinical, biochemical, and imaging risk factors for CBDS, preoperative ERCP can produce false-negative results, leading to the possibility of increasing the morbidity and mortality [3]. Although with postoperative ERCP the risk of preoperative ERCP in patients without CBDS can indeed be avoided, it necessitates another surgical procedure when it fails to remove the CBDS [11]. Both preoperative and postoperative ERCP are likely to lead to some short-term and long-term complications [10].

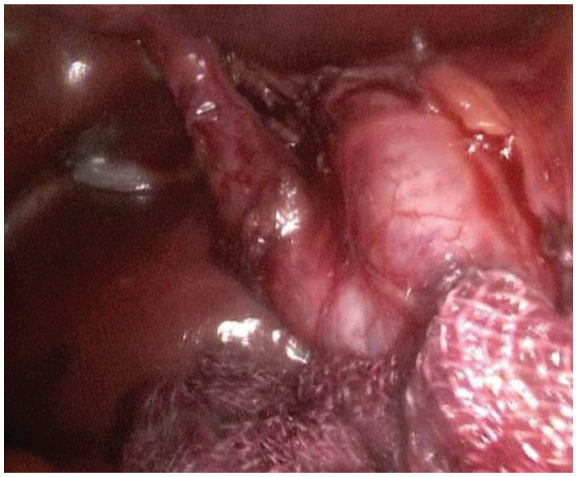
With the improvement in laparoscopic equipment and skills, LCBDE has increasingly been used to remove the CBDS [12–19]. Moreover, the use of single incision laparoscopic surgery in CBDE was introduced by many centers [20–25]. Although LCBDE has a crucial advantage in that it simultaneously treats cholelithiasis and choledocholithiasis, thereby shortening hospital

Figure 12



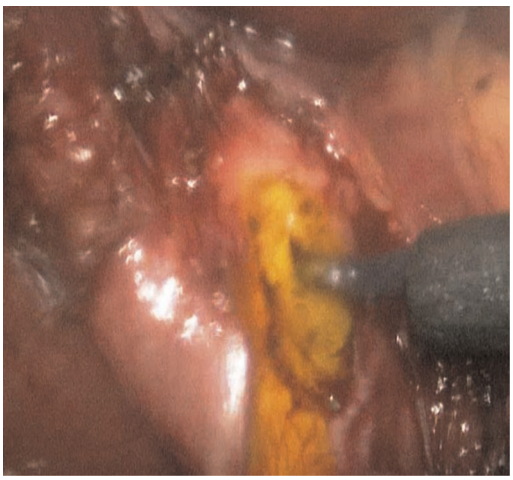
Intraoperative cholangiogram view showing common bile duct (CBD) stone.

Figure 13



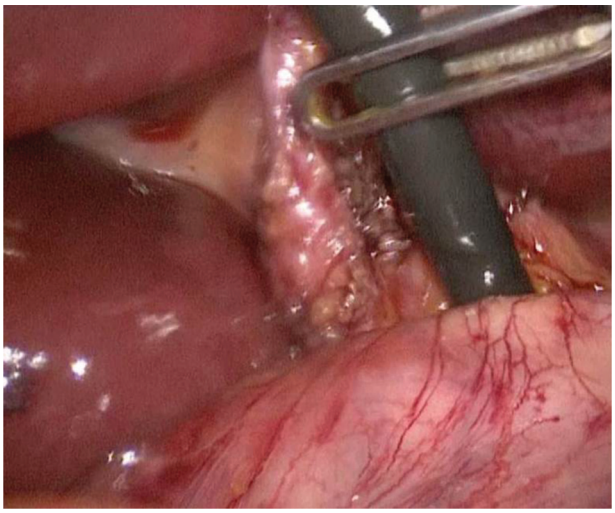
Laparoscopic skeletonization of the anterior surface of common bile duct (CBD) before choledochotomy.

Figure 14



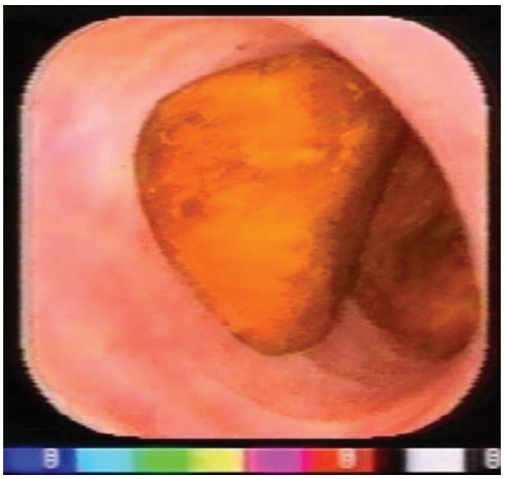
Choledochotomy in the anterolateral aspect of common bile duct (CBD).

Figure 15



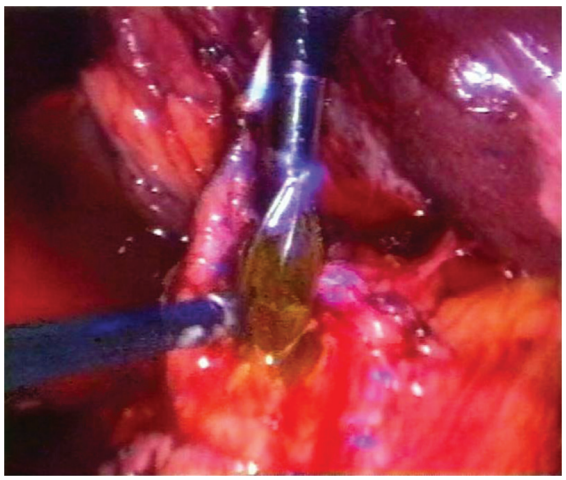
Choledochoscope introduction through choledochotomy.

Figure 16



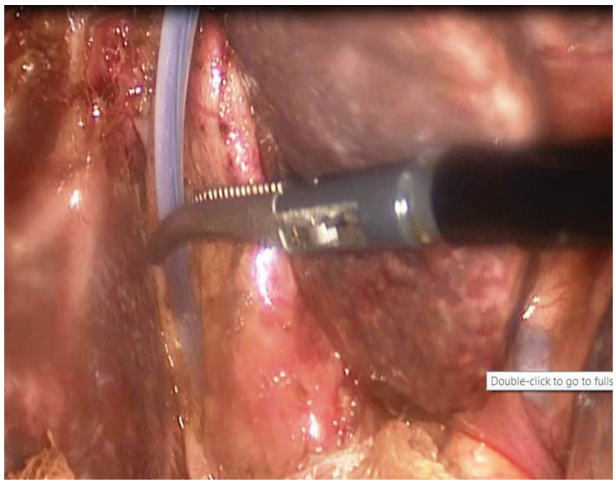
Choledochoscopic view showing common bile duct (CBD) stones.

Figure 17



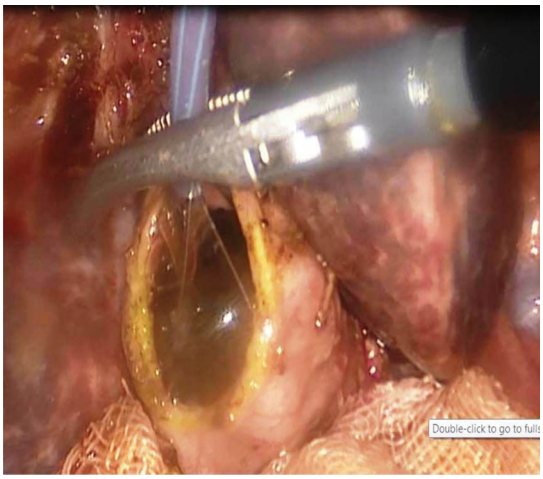
Choledochoscopic extraction of common bile duct (CBD) stones using basket.

Figure 18



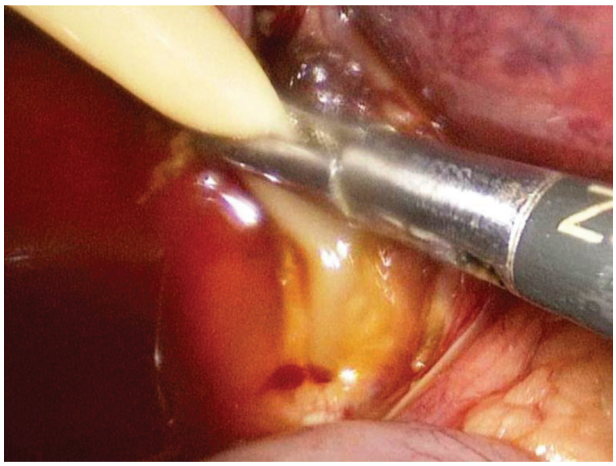
Direct introduction of the ERCP basket through choledochotomy.

Figure 19



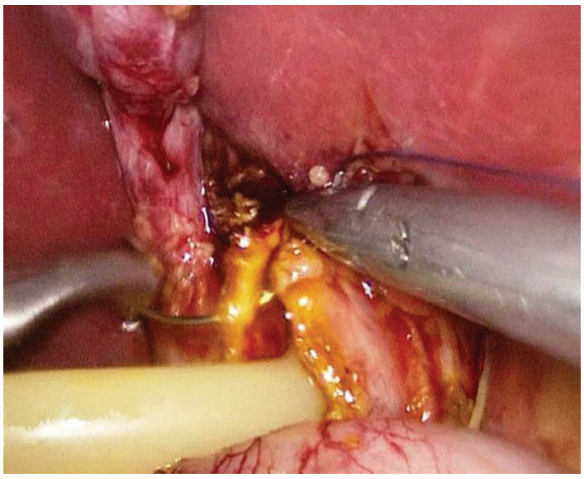
Direct extraction of the stone by ERCP basket through choledochotomy.

Figure 20



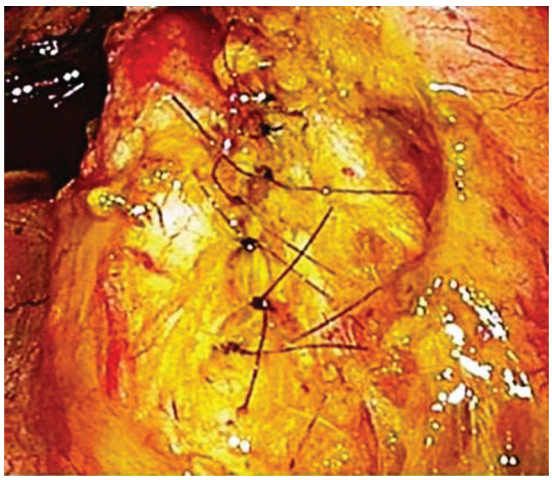
T-tube drain through choledochotomy incision to drain common bile duct (CBD).

Figure 21



Laparoscopic stitching of common bile duct (CBD) over the T-tube drain.

Figure 22



Laparoscopic primary closure of common bile duct (CBD) after choledocholithotomy.

Table 1 Complications of surgical common bile duct clearance

Complications	*n* (%)
Wound infection	3 (3)
Bile leakage	4 (4)
Missed stone(s)	7 (7)
Jaundice (CBD stricture)	1 (1)
Total	15 (15)

CBD, common bile duct.

stays and reducing hospital costs, only surgeons with advanced laparoscopic skills can perform LCBDE because the procedure requires very specialized laparoscopic techniques and equipment [26,27]. Moreover, it is difficult to use laparoscopic techniques (especially during primary closure of the CBD) in conventional LCBDE for patients whose CBD is less

than 1 cm because of the difficulty of laparoscopic manipulation and concerns of postoperative ductal stricture after suturing [27,28].

Table 2 Endoscopic procedure to clear common bile duct

Procedures	*n* (%)
Basket extraction	45 (45)
Balloon extraction	25 (25)
Combined basket and balloon sweeping	15 (15)
Mechanical manual lithotripsy	13 (13)
Stenting of CBD with failure of the attempt	2 (2)
Total	100 (100)

CBD, common bile duct.

Table 3 Complications of endoscopic common bile duct clearance

Complications	*n* (%)
Cholangitis	3 (3)
Mild pancreatitis with hyperamylasemia	6 (6)
Total	9 (9)

Table 4 Methods of laparoscopic common bile duct clearance

Items	*n* (%)
Transcystic approach	5 (10)
Transcholedochotomy approach	45 (90)
Choledochoscopic technique	45 (90)
Converted to open technique (failed attempt)	1 (2)
Total cases	50 (100)

Table 5 Complications of laparoscopic common bile duct clearance

Complications	*n* (%)
Postoperative hypothermia	2 (4)
Postoperative fever and hyperamylasemia	1 (2)
Missed stone	2 (4)
Total	5 (10)

LCBDE is a safe, efficient, and cost-effective treatment, and associated with a high stone clearance rate ranging from 84 to 97%, a postoperative morbidity rate of 4–16%, and a mortality rate of ~0–0.8% [29]. However, to decompress the bile duct and decrease biliary complications, T-tube drainage is routinely used after choledochotomy, which is inevitable with complications including bile leakage, bile infection, and wound infection. Furthermore, it lasted several weeks before removal, causing great discomfort and delaying return to work [30,31].

In our study, the T-tube drain was used in most of the laparoscopically treated patients by LCBDE (30 patients about 60%); however, primary CBD closure was also performed in 20 patients (40% of cases) after retrieval of the stones and choledochorrhaphy was performed by either interrupted or continuous sutures as many reports supported its use, with favorable long-term outcomes [26,32,33]. Although continuous suturing may initially result in increased operative time, with practice, it may actually decrease the total operative time.

CBD repair is one of the most challenging steps during LCBDE and has been performed with various techniques [34,35]. The degree of difficulty is particularly increased when the T-tube is inserted into the CBD; however, meta-analysis data have provided evidence that primary closure instead of T-tube drainage is superior in terms of operative time, overall postoperative complications, and postoperative hospital stay [36,37]. No statistically evident complications occurred in patients treated with primary CBD closure, probably explained by the use of choledochoscopy only without probing for the lower end of the CBD. These measures reduced the risk of

Table 6 Comparison between methods of common bile duct clearance

Items	Group I (surgery)	Group II (endoscopy)	Group III (laparoscopy)	*P* value
Invasiveness	Invasive	Minimally invasive	Minimally invasive	
Operative time (min)	60–180	20–45	70–292	0.000
Mean±SD	90.81±21.45	30.24±8.72	123.72±41.5	Highly significant
Success rate of the attempted procedures	100%	98%	70%	0.245
Failed cases	–	2	1	Not significant
CBD clearance	93%	100%	98%	–
Missed stone(s)	7	–	2	
Procedural mortality	–	–	–	–
Postprocedural morbidity	15%	9%	10%	0.425Not significant
Hospital stay (days)	5–12	1–2	2–4	0.002
Mean±SD	8.3±3.84	1.21±0.27	3.2±1.18	Significant
Return to work (days)	12–20	2–5	5–10	0.030
Mean±SD	14.3±3.71	3.2±1.86	12.61±3.9	Significant
Difficulty	Easy	Difficult	Difficult	–
Feasibility	Feasible	Not feasible	Not feasible	–

CBD, common bile duct.

postoperative biliary leakage, with a significant decrease in postoperative hospital admission and the total cost of treatment; moreover, the primary closure group were not burdened by a T-tube with the additional cost of postoperative cholangiography [7,30].

Comparison between the three groups in this study showed that the operative time was considerably reduced in the endoscopic group (20–45 min), and the open surgery group (60–180 min) versus the laparoscopic group (70–292 min); this was highly significant. These results were supported by previous data.

In terms of CBD clearance from stones in our study, it was 93% in the surgery group, with seven cases of missed stones postoperatively, and 100% in the endoscopic group, versus 98% in the laparoscopic group, with two cases of missed stones postoperatively. Several studies have been reported on the safety and efficiency of CBD clearance of stones whether by ERCP and/or by LCBDE. ERCP with sphincterotomy has been available in most major medical centers worldwide for nearly 30 years, and is currently routinely used in conjunction with LC, rather than open surgery, to treat choledocholithiasis. The overall success rate of ERCP in experienced hands is well established at about 95%. However, the minimum number of ERCP procedures necessary for competency has been suggested to be between 102 and 185 procedures to achieve a success rate of 85–90%. LCBDE has been developed over the past two decades as a means of dealing with CBD stones discovered incidentally during the course of LC with an overall success rate of LCBDE of 94.6% [9].

Some studies showed that LCBDE is equal in terms of efficacy and safety to preoperative ERCP+LC for patients with 'likely' CBD stones. However, stones were more frequently reported during ERCP+LC than during LCBDE; this is likely because ERCP by technique allows fluoroscopic and endoscopic identification of small stones and sludge that would otherwise be immediately pushed clear when contrast is first injected during the antegrade cholangiography phase of LCBDE [9]. Furthermore, ERCP with retrograde passage of occlusion balloons enables better detection and removal of proximal ductal stones. Meta-analysis also showed that single-stage (LC+LCBDE) management was as effective as two-stage (LC+ERCP) management, but one trial [38] was more strongly in favor of the single-stage (LC+ LCBDE) management than any other included studies. One possible reason could be that they abandoned ERCP at an earlier stage when they detected multiple and large stones in the CBD, and they favored a transductal approach if the bile duct diameter was large or if the stones were large and multiple. Another reason might be the use of an intention-to-treat analysis [10].

The difference in our results between laparoscopic and endoscopic clearance rate, which was comparable in many studies, may be explained by the use of choledochoscope techniques alone for detection, extraction of CBD stones and assessment of CBD clearance during laparoscopy versus cholangiogram that is used during ERCP. Therefore, intraoperative cholangiogram is very crucial in LCBDE and must be available for the detection of CBD stones and assurance of CBD clearance during the procedure to guard against these pitfalls.

Hospital stay in days was significantly reduced in endoscopic and laparoscopic-treated cases versus surgery-treated cases (1–2 days for endoscopy, and 2–4 days for laparoscopy versus 5–12 days for surgery), with a P value of 0.002. Consequently, return to work was also significantly reduced in endoscopic and laparoscopic-treated cases versus surgery-treated cases (2–5 days for endoscopy and 5–10 days for laparoscopy versus 12–20 days for surgery), with a P value of 0.030. However, meta-analysis showed that the difference in the length of hospital stay between the two groups was not statistically significant, but two of the included trials reported that the length of hospital stay was shorter for the single-stage (LC+LCBDE) approach with a statistically significant difference compared with the two-stage (LC+ERCP) management [9]. Other data also suggested that single-stage management had the potential advantage of a shorter hospital stay [39]. One probable reason was that the definitions of hospital stay varied, which had an impact on the validity of the data. Some trials defined it as the duration from the last finished procedure to discharge, whereas other trials defined it as the entire duration from hospital admission to discharge [9,10].

The postoperative morbidity and mortality in our study were comparable and not statistically significant; however, the operative time was statistically highly significant between groups (20–45 min for endoscopy, 60–180 min for open surgery vs. 70–292 min for LCBDE), with P value of 0.000, in contrast to previous data showing that total operation durations were similar between two-stage (LC+ERCP) and single-stage (LC+LCBDE) management, with no

statistically significant difference in this meta-analysis. When considering preoperative ERCP+LC versus LC+ LCBDE and postoperative ERCP+LC versus LC+ LCBDE separately in the subgroup analysis, the outcomes, as stated, remained consistent [10,40].

Conclusion

It is important to realize that open CBDE has enjoyed a long and successful history as the benchmark against which all other treatment modalities for choledocholithiasis are compared; furthermore, open surgery enables direct manual palpation and instrumentation of bile ducts using a variety of instruments. However, it has its drawbacks such as long maneuver time, invasiveness, increased mortality and morbidity, long hospital stay, and delayed return to work.

In contrast, endoscopic management of choledocholithiasis has the advantage of minimally invasive maneuvers, that fact that it can be performed in the outpatient clinic, lower duration of procedure, less hospital stay, very low if no mortality and morbidity, and rapid return of the patients to work, but the cost effectiveness and feasibility are still a problem. Moreover, LCBDE is a feasible minimally invasive procedure, with low morbidity and mortality, but it requires excellent laparoscopic surgical skills, a long learning curve, and up-to-date complete equipment including intraoperative cholangiogram facilities, and a good selection of patients.

The minimally invasive techniques (endoscopy and laparoscopy) have a comparable efficiency, safety, and CBD stone clearance rate; this must be kept in mind during decision-making for the treatment of choledocholithiasis in all tertiary centers.

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Conflicts of interest

There are no conflicts of interest.

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