

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

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Abstract:

Background and aim of the work: Around 10-18% of people undergoing cholecystectomy for gallstones have common bile duct (CBD) stones¹. Treatment can be conducted as open cholecystectomy plus open common bile duct exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LCBDE), or pre- or post-cholecystectomy ERCP in two stages for CBD clearance¹. The aim of this study is to compare CBD clearance rate by each procedure in a well-equipped tertiary centers

Patients and methods: 250 cases of choledocholithiasis were included from general surgery department, Sohag and Assuit university hospitals and managed randomly by either conventional surgery, endoscopic, or laparoscopic procedures

Results: Ages of our patients were ranged from 20-60 years (mean 40 years), with slight female predominance (1.6: 1), most of them presented with calculi obstruction (54.3%), however other presentations are also encountered as colic, cholangitis, or accidental discovery in 14.3, 10, 21.5% respectively. Patients were categorized randomly into 3 groups:

Group I included 100 patients (40%) were treated by open choledocholithotomy and T tube insertion, the operative time was 90 (60-180) min. with success rate of the attempted procedures reaching 100%, and CBD clearance of stones was achieved in 95% of cases (5 cases of missed stones), hospital stay was 8 (5-12) days, with no mortality and morbidity rate reaches 15% in the form of wound infection, bile leak, and missed stone. The patient can return to work after 2 weeks (12-20 days).

Group II included 100 cases (40%) treated by endoscopic sphincterotomy and basket extraction in 45%, balloon in 25%, combined maneuver in 15%, mechanical lithotripsy in 13%, with failure of the technique in two cases (2%), the procedure time was about 30 (20-45) min. with success rate of attempted procedure 98% and CBD clearance of stones was achieved by 100%, with no mortality, and morbidity rate of 9% in the form of cholangitis (3%) and mild pancreatitis with hyperamylasemia (6%), the period of hospital stay was 1 (1-2) days, and patient return to work after 3 (2-5) days.

Group III included 50 cases (20%) treated by laparoscopic approaches either by trans-cystic approaches in 5 cases, or trans-choledochotomy approaches in 45 cases. Choledochoscopic exploration was done in almost all cases (45 cases) to detect, extract the stones and test CBD clearance, and conversion to open techniques in 1 case. The time needed for this procedure was 123 (70-292) min. with CBD clearance of stones in 96% (2 cases of missed stone), with no mortality, and morbidity rate 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 the work after 7 (5-10) days.

Conclusion: Both ERCP/LC and LCBDE were highly effective in CBD clearance, and equivalent in 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 procedure, and anesthesia risks. It is feasible, cost-effective, and ultimately should be available for most patients in each specialized center.

Keywords: LCBDE, choledocholithotomy, ERCP, sphincterotomy

Introduction and aim of the work:

Around 10% to 18% of people undergoing cholecystectomy for gallstones have common bile duct (CBD) stones¹. Symptoms caused by CBD stones consist of colic or may result from complications such as jaundice, cholangitis or pancreatitis². In case of symptomatic CBD stones, decompression of the common bile duct and removal of ductal stones is warranted. Decompression may be achieved by endoscopic methods such as endoscopic sphincterotomy, papillary dilatation, and nasal-biliary drainage².

Treatment of the bile duct stones can be conducted as open cholecystectomy plus open common bile duct exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC + LCBDE), or pre- or post-cholecystectomy ERCP in two stages usually combined with either sphincterotomy (commonest) or sphincteroplasty (papillary dilatation) for CBD clearance¹.

Laparoscopic CBD exploration (LCBDE) was postulated through transcystic approach in small sized stones, or via choledochotomy that allows more selective approach for removal of CBD stones; hence avoidance of unnecessary preoperative ERCP. It has the advantage of combining two procedures into a single minimally invasive operation³.

The majority of secondary biliary stones can be diagnosed at the time of cholecystectomy and cleared trans-cystically, otherwise choledochotomy approach or postoperative ERCP is needed, but choledochotomy should be avoided in ducts less than 7 mm 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 ERCP⁴. 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 CBD³.

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 patients⁵.

As surgical skill with laparoscopic exploration of the common bile duct increases, the need for routine preoperative ERCP will likely decrease, except in unique high-risk situations. Therefore, a single surgical procedure for common bile duct stone is needed⁵.

All randomized clinical trials which compared the results from open surgery versus endoscopic clearance and laparoscopic surgery versus endoscopic clearance for CBD stones declare no significant difference in the mortality and morbidity between laparoscopic and endoscopic CBD clearance. Also there is no significant reduction in the number of retained stones and failure rates in the laparoscopy groups compared with the pre-operative and intra-operative ERCP groups. Moreover; there is no significant difference in the mortality, morbidity, retained stones, and failure

rates between the single-stage laparoscopic bile duct clearance and two-stage endoscopic management².

Patients and methods:

Study design: This prospective observational study was consisted of all consecutive patients who were referred for management of choledocholithiasis in surgery department, Assuit 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' prior recruitment to study.

The patients: From Jun 2014 to July 2016, patients with symptomatic choledocholithiasis at general surgery department, Assuit 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 female; and diagnosis of intra-hepatic stones in preoperative ultrasonography. Two hundred and fifty patients who fulfill all the criteria of the study were enrolled in the study protocols and thoroughly investigated and studied.

Randomization: was done with the permuted block method, using blocks of 10. Envelopes were drawn and opened by an operating room nurse that was not engaged in the study. Randomization was done 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 blind to the procedure used.

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

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

Conventional surgical approach includes open cholecystectomy plus choledocholithotomy and T-tube drain through choledochotomy incision with sub-hepatic drain in all cases **(Photo 1, 2)**.

Endoscopic treatment by pre- or post- cholecystectomy 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 **(Photo 3 - 8)**.

Laparoscopic CBD exploration was done with trans-cystic or trans-choledochotomy rout. Intra-operative cholangiogram was used in most of cases, and choledochoscope was used in choledochotomy cases to detect, extract, and assess CBD clearance. T-tube drain application was

practiced; however Direct CBD primary closure was also done in some cases, with sub-hepatic drain in all cases **(Photo 9 - 22)**.

Statistical analysis: Descriptive data will be expressed as mean & standard error of the mean, or as median and ranges for continuous variables and proportions for categorical variables. Statistical analysis will be performed using the Fisher's and chi-square tests. A p-value <0.05 was considered statistically significant.

Results:

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

Group I: includes 100 patients (40%) were treated by open choledocholithotomy and T tube insertion, the operative time was 90 (60-180) min. with success rate of the attempted procedures reaching 100%, and CBD clearance of stones was achieved in 93% of cases (7 cases of missed stones), hospital stay was 8 (5-12) days, with no mortality and morbidity rate reaches 13% **(Table 1)**, The patient can return to work after 2 weeks (12-20 days) post operatively.

Group II: include 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 success rate of attempted procedure 98% and CBD clearance of stones was achieved by 100%, with no mortality, and morbidity rate of 7% **(Table 3)**, the period of hospital stay was 1 (1-2) days, and patient return to work after 3 (2-5) days.

Group III: include 50 cases (20%) treated by LCBD either trans-cystic in 5 cases, or trans-choledochotomy in 45 cases **(Table 4)**. Choledochoscopy was done in almost all cases (45 cases), with conversion to open techniques in 1 case. The time needed for this procedure was 123 (70-292) min. with CBD clearance of stones in 96% (2 case of missed stone), with no mortality, and morbidity rate about 20% **(Table 5)**. The period of hospital stay was 3.2 (2-4) days with return to the 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 stones clearance **(Table 6)**.

Discussion:

Symptomatic gallstone disease is a very common indication for abdominal surgery⁶. Before the laparoscopic era, cholecystectomy and CBD stones were removed in a single procedure. This approach has been effective with morbidity below 15% and mortality below 1% in patients up to 65 years old⁷. In the era of minimally invasive procedure, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries, so therapeutic decision making is based on the local availability of expertise⁸, hence concomitant gallstones and CBDS were managed by

pre- or post-operative ERCP⁹. 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 the dilemma of depending on LCBDE, postoperative ERCP or traditional open choledochotomy¹⁰. 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 mortality³. Despite postoperative ERCP can indeed avoid the risk of preoperative ERCP to patients without CBDS, it necessitates another surgical procedure when it fails to remove the CBDS¹¹. Both preoperative and postoperative ERCP are likely to lead to some short-term and long-term complications¹⁰.

With the improvement in laparoscopic equipment and skills, LCBDE has been increasingly used to remove the CBDS ^{12,13,14,15,16,17,18,19}. Moreover, the use of single incision laparoscopic surgery (SILS) in CBDE was introduced by many centers ^{20,21,22,23,24,25}. Although LCBDE has a crucial advantage in that it simultaneously treats cholelithiasis and choledocholithiasis, thereby shortening hospital 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, due to the difficulty of laparoscopic manipulation and concerns for postoperative ductal stricture after suturing^{27,28}.

LCBDE is safe, efficient and cost-effective treatment; and associated with a high stone clearance rate ranging from 84 - 97%, postoperative morbidity rate of 4 -16%, and mortality rate of approximately 0 - 0.8 %²⁹. However, to decompress the bile duct and decrease biliary complications, T-tube drainage is routinely employed 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, T-tube drain was employed in most of laparoscopically treated patients by LCBDE (30 patients about 60%), ^{on the other hand}; primary CBD closure was also practiced in 20 patients (40% of cases) after retrieval of the stones, and ^{choledochorrhaphy} was done 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 shorten the total operative time.

CBD repair is one of the most challenging step during laparoscopic CBDE 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 use} choledochoscopy only without probing for the lower end of the CBD. These measures reduced the risk of post-operative biliary leakage, with a significant decreased in postoperative hospital admission and the total cost of

treatment; moreover 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 revealed that operative time was greatly reduced in endoscopic group, (20-45 min.), open surgery group (60-180 min.), versus laparoscopic group (70-292 min.) which was highly significant; these results were supported by previous data.

Concerning CBD clearance from stones in our study, it was 93% in surgery group with 7 cases of missed stones post-operatively, 100% in endoscopic group, versus 98% in laparoscopic group with 2 cases of missed stones post-operatively. Several studies have been reported on the safety and efficiency of CBD clearance of stones whether by ERCP and/or LCBDE. ERCP with sphincterotomy has been available in most major medical centers around the world for nearly 30 years, and 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% to 90%. Laparoscopic CBDE has been developed over the past 2 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 study demonstrated that LCBDE is equivalent in 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 LCBDE⁹. Furthermore, ERCP with retrograde passage of occlusion balloons permits better detection and removal of proximal ductal stones. Meta-analysis also demonstrated that single-stage (LC + LCBDE) management was as effective as two-stage (LC + ERCP) management, but one trial³⁸ was more strongly in favor of the single-stage (LC + LCBDE) management than any other included studies. One possible reason was that they abandoned ERCP at an earlier stage when they detected multiple and large stones in the CBD, and they favored a trans ductal approach if the bile duct diameter was large or if the stones were large and multiple. Another reason might be the use of intention-to-treat analysis¹⁰.

The difference in our results between laparoscopic and endoscopic clearance rate that was comparable in many studies may be explained due to relay on choledochoscope for detection, extraction of CBD stones and assessment of CBD clearance during laparoscopy versus cholangiogram that is used during ERCP. So intra-operative cholangiogram is very crucial in LCBDE and must be available to rely on for 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 P value= 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 P value = 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) management⁹. Other's data also suggested that single-stage management had the potential merit of a shorter hospital stay³⁹. 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, while other trials defined it as the entire duration from hospital admission to discharge^{9,10}.

The postoperative morbidity, and mortality in our study was 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 versus 70-292 min. for LCBDE) with P value = 0.000. in contradistinction to previous data demonstrating that total operating time were similar between the two-stage (LC + ERCP) and single-stage (LC + LCBDE) management with no statistically significant difference in this meta-analysis. When considering preoperative ERCP + LC vs LC + LCBDE and postoperative ERCP + LC vs 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 permit direct manual palpation and instrumentation of bile ducts using a variety of instruments, however it has its drawbacks in long maneuver time, invasiveness, increased mortality and morbidity, long hospital stay, and delayed return to work.

In the contrary, endoscopic management of choledocholithiasis has the advantage of minimally invasive maneuvers, could be done as outpatient clinic, less procedure time, less hospital stay, very low if no mortality and morbidity, rapid return of the patients to work, but the cost effectiveness and feasibility is still a problem. Moreover laparoscopic CBDE is a feasible minimally invasive procedure, with low morbidity and mortality, but it requires very high laparoscopic surgical skills, 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, so must be kept in mind during decision making for treatment of choledocholithiasis in all tertiary centers.

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