Choledochoscopy versus Intra-operative Cholangiogram for detection of common bile duct clearance during laparoscopic common bile duct exploration

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Abstract: Objective: To compare between the Intra-operative Cholangiogram (IOC) and choledochoscopy as regardcommon bile duct (CBD) clearance in patients who underwent laparoscopic common bile duct exploration (LCBDE). **Study design**: Prospective comparative study. **Patients and methods**: Forty patients with the mean age 43 ± 13.2 (range 23-67) years presented with gall bladder stones and CBD stones (CBDS) as diagnosed by abdominal Ultra Sound (US), clinical presentation, laboratory and radiological investigations. All patients underwent LCBDE and then divided into two groups. Group I; 20 patients allowed for intra-operative cholangiography and group II; 20 patients allowed for choledochoscopy. **Results**: In group I, two patients (10%) had false-positive results; one patient (5.55%) had false-negative results; operative time was 195 ± 25.3 minutes. In group II, no false-positive or false-negative results; operative time was shorter 175 ± 22.8 minutes. **Conclusion**: During LCBDE; we recommend choledochoscopy rather than intra-operative cholangiogram for detection of CBDS clearance. Choledochoscopy result in less false-positive and false-negative results and less time consuming.
[SamehGabrAttia. **Choledochoscopy versus Intra-operative Cholangiogram for detection of common bile duct clearance during laparoscopic common bile duct exploration.** *Life Sci J* 2015;12(8):106-110]. (ISSN:1097-8135). http://www.lifesciencesite.com. 18

Keywords:CBDS, LCBDE, Cholangiogram, Choledochoscopy, CBD clearance.

Introduction

In about 10% to 18% of patients presented with gall bladder stones there are CBDS[(1)].CBDS may be asymptomatic or associated with biliary colic, obstructive jaundice, biliary pancreatitis, cholecysto-intestinal fistula and cholangitis [(2-3)].

In the past, the standard treatment for patients suffering from gallstones and CBDS was open cholecystectomy andopen exploration of CBD[(4)]. With the advancement of laparoscopic and endoscopic techniques, several alternatives treatments such as endoscopic retrograde cholangiopancreatography (ERCP) with stone extraction and laparoscopic cholecystectomy have been developed to treat the gall stones and CBDS either in two separate sessions or in the same single session[(5)].

LCBDE has the advantages of minimal invasive surgery, but it requiresadvanced surgical skills[(6)].

IOC during laparoscopic cholecystectomy was done routinely or selectively to detect common bile duct stones [(7)]. Choledochoscopy was introduced in the field of CBD exploration to visualize the CBDS and also to confirm complete removal of the stones[(8, 9)].

Limited studies were performed to compare between IOC and choledochoscopy to assess CBD clearance after LCBDE [(10)].

2. Materials and Methods

Population

Thiswas a prospective comparative study, carried outat the Department of Surgery, Al-Azhar University Hospitals for three years from June 2012 to June 2015.It was carried out on forty patients whounder went LCBDE then divided into two groups. Group I; 20 patients allowed for IOC and group II; 20 patients allowed for choledochoscopy to assess CBD clearance at the end of LCBDE.

Inclusion Criteria

Forty patients with the mean age 43 ± 13.2 (range 23-67) years presented with gall bladder stones and CBDS as diagnosed by abdominal Ultra Sound (US), Magnetic Resonance Cholangiopancreatography (MRCP) with CBD 9 mm or more in diameter,clinical presentation (biliary colic, obstructive jaundice or history of jaundice) and laboratory investigations(elevated Bilirubin level & elevated serum Alkaline Phosphatase). The characters of patients included in both groups are specified in (Table1).

Exclusion criteria

(1) Patients including in American Society of Anesthesiologists (ASA) score> 3[(11)]; (2) Patients with CBD diameter less than 9 mm (the used Choledechoscopy diameter is 9 mm); (3) suppurative cholangitis (body temperature > 38.5, with rigor and right upper-quadrant abdominal pain and tenderness); (4) acute pancreatitis (serum amylase 3 times higher than normal); (5) History of upper abdominal surgery; (6) decompensated liver disease; and (7) Bleeding tendency.

Table (1) Characteristics of the patients

Groups Parameters	Group I	Group II	Total
Sample size	20	20	40
Age (years)	42 ± 8.2 (25-67)	44 ± 11.4 (23-63)	43 ± 13.2 (23-67)
Sex: M/F	13/7	15/5	28/12
Jaundice	15 (75%)	16(80%)	31(78.5%)
Elevated bilirubin level	18(90%)	17(85%)	35(82.5%)
CBD diameter (mm)	11.8 ± 3.5	12 ± 4.2	12 ± 3.1

Study Protocol

All patients referred from outpatient clinics were admitted to the surgical department. The study was approved by the Local Ethics Committee of the surgery department. All patients were interviewed using a standardized questionnaire and underwent a physical examination. The questionnaire inquired about the history in terms of onset, course, duration, previous abdominal operations, and manifestation of decompensated liver disease.

A complete physical examination (general and local) was performed for all patients. Routine preoperative investigations including complete laboratory tests, serum Alkaline phosphates, total & direct Bilirubin level, prothrombin time & concentration, Radiological investigation including (abdominal US and MRCP), and Electro-Cardio Gram (ECG) were performed for all patients.

LCBDE was planned for all cases. Patients were completely counseled on the procedures, outcome, and possible complications. A written consent was obtained.

Statistical Analysis: Were performed by using statistical software SPSS (Statistical program for social science). Categorical variables were compared by using the Chi-square test. When two variables were dichotomous, the Fisher exact test was used. To evaluate continuous variables, the student t test was used. Statistical significance was defined as a p value < 0.05.

The procedures

Patients were admitted three days before surgery for Vitamin k injection in patients presented with jaundice or increased prothrombin time. Assessment for general anesthesia was performed. Preoperative preparation such as showering, sedation, and fasting for at least 8 hours before surgery were performed. An intravenous antibiotic(third- generation cephalosporin) was administered at the induction of anesthesia as prophylaxis. The operations were carried out under general anesthesia. The patients were placed on the operating table in the supine position. All forty patients underwent LCBDE through transcholedochal approach at the junction of cystic duct with CBD by direct puncture of the CBD with a 23-G scalp vein set. The stones were removed by dormia basket or atraumatic forceps with gentle manipulation. At this point in the operation, the patients were divided into two groups

Group I;

After removal of CBDS, the patient underwent IOC to assess the clearance of CBD from stones, through cystic duct (after closure of choledochotomy) by insertion of 8-10 F Ryle tube, 10 ml saline was injected to expel the air after which small amount of Urografinwas injected into the CBD. CBD was visualized by C-arm-X-ray image to detect a possible filling defect.

Group II;

We use acholedochoscopy for detection of ductal clearance or a 10 Frureter scope through previous choledechotomy. It was introduced over straight guide wire through a 5-mm port situated at the highest point in the epigastrium in the right paramedium plan to visualize the distal part of CBD and through the umbilical port to visualize the proximal part of CBD. If any stones remained they will be removed using dormia basket under direct vision. The choledochotomy was closed with 4/0 polygalactin sutures without endobiliary stent.

During surgery, the procedure followed was meticulous and precise. It was ensured that all the recommended precautions were taken (careful dissection, adequate hemostasis, and careful identification of CBD). Lastly cholecystectomy was done in both groups and abdominal drain was placed in all patients. The patients kept fasting postoperatively for about 12-24 H.

Operative time, number of CBDS and their size, CBD clearance from the stones, rate of conversion to open CBD exploration, false-positive, false-negative results for ductal clearance and any intraoperative complications were evaluated. Hospital stay and any postoperative complications as pancreatitis, bile leak, or intra-abdominal collection were also evaluated.

Postoperatively effective analgesia was ensured and all patients were subjected to close observation for early complications (e.g. wound hematoma, bile leak). After their discharge from hospital, patients were followed up on a weekly basis for 6 weeks. During follow up, patients were interviewed using the same standardized questionnaire as before, which included additional items related to surgery complications and results of abdominal ultrasonography.

3. Results

A total of 40 consecutive patients were included in the present study. They were between 23 and 67 years old with a mean age of 43 ± 13.2 years. The most common age group in this study ranged from 35 to 55 years old. Of these forty patients, 28 (70%) were men and 12 (30%) were women, with a male to female ratio of approximately (2.25-1). 31(78.5%) patients were presented with jaundice. 35 (82.5%) patients were presented with elevated bilirubin level. All 40 (100%) patients were presented with CBD diameter > 9 mm (12 mm +_ 3 mm).All forty patients underwent LCBDE and after stone extraction bydormia basket or atraumatic forceps, they grouped into two groups, 20 patients each. Group I underwent IOC and group II underwent intra-operative choledochoscopy to detect clearance of CBD.

Group I:

At the end of LCBDE, IOC was performed to determine CBD clearance. No filling defects were present in 18 patients (90%). In two patients of them, although there was no filling defect, the dye couldn't flow into the duodenum, and after injection of anti-spasmodic drugs (butylscopalamine) the dye appeared. In two patients out of the 20 (10%), there was a filling defect in CBD. Introduction of 10 Frcholedochoscopy was done through choledechotomytore move any stones remain in the CBD but no stones were found (false-positive results). The filling defect might be due to air bubbles.

During the follow up period, there was a missed stone in one out of 18patients (5.55%) (False-negative result).

The operative time recorded for group I was 195 ± 25.3 minutes. The stones extracted from the CBD were 1-9(4 ± 4.9) stones, 6 patients had single stone (30%) while 14 patients had multiple stones (70%). The size of the stones removed was 2-15mm (9.5mm). No intra-operative complications were observed (Table 2).

Group II:

After removal of the stones by LCBDE, a completion choledochoscopy check for all 20 patients was done to detect the clearance of CBD. Choledochotomy was the way for entrance of choledochoscopy. Any residual stones were extracted with a dormia basket under direct vision. One patient had impacted stone at the lower part of CBD; intracorporeal lithotripsy was done for stone fragmentation and then extracted with basket.

The operative time recorded for group II was 175 ± 22.8 minutes. The stones extracted from the CBD were 1-12(5 ± 5.2) stones, 8 patients had single stone (40%) while 12 patients had multiple stones (60%). The size of the stones removed was 1.5-17mm (10.2mm). One patient out of 20 (5%) was converted to open technique due to severe adhesion and failure to reach the calot's triangle and identificationof the CBD carefully, and this happened early at the beginning of the procedure. No intra-operative complications were observed and no false-negative result during the follow up period (Table 2).

Postoperative results

Postoperatively; rate of mortality was zero. Missed stone was present in one patient in group I (5%). Bile leak was observed in three patients in group I (15%), and in two patients in group II (10%), treatment was conservative. Postoperative hospital stay was 7.8 ± 5.7 days for group I and 7.2 ± 6.2 days for group II (Table 3).

Table (2) intraoperative results

Groups Parameters	Group I	Group II
False-positive results	2 (10%)	0 (0%)
Stone clearance	95%	100%
Number of extracted stones **Single/Multiple stones**	1-9 (4± 4.9) 6/14	1-12 (5± 5.2) 8/12
Size of extracted stones (mm)	9.5 (2-15)	10.2 (1.5-17)
Rate of conversion to open	0 (0%)	1 (5%)

Table (3) postoperative results

Groups Parameters	Group I	Group II
False-negative results	1 (5%)	0 (0%)
Missed Stones	1 (5%)	0 (0%)
Bile leak	3 (15%)	2 (10%)
Hospital stay (days)	7.8 ± 5.7	7.2 ± 6.2
Rate of conversion to open	0 (0%)	1 (5%)

4. Discussion

Laparoscopic Cholecystectomy (LC) considered the first choice for treatment of calcularcholecystitis, but there is no concept on the ideal management of combined gall bladder stones and CBDS.Open approach for exploration of CBD was the preferred approach for CBDS. After that ERCP introduced itself as a minimally invasive procedure for diagnosis and treatment of CBDS, then the patient allowed to LC (either two or one stage procedures).The morbidity after ERCP as bleeding, pancreatitis, cholangitis…etc, and also mortality rate are not negligible [12].

Laparoscopic exploration of CBD has been developed over the past 2 decades to extract CBDS discovered incidentally during the course of LC [13]. Now it becomes the treatment of choice for CBDS [14].It is a popular minimally invasive method but generally requires laparoscopic skills that maynot be readily available [15].

At the end of LCBDE, detection of CBD clearance from stones can be determined by either IOC or choledochoscopy. So we do this study to evaluate and compare the accuracy of both maneuvers.

Our patients were grouped into two groups 20 patients each, the two groups were nearly similar as regard the preoperative parameters as age, sex, incidence of jaundice, CBD diameter and others. These parameters were compared with that in the other studies[7, 10].

In the present study, extraction of multiple stones was present in the most of patients (14 patients in group I and 12 patients in group II).The number of stones extracted in group I was 1-9 stones, theirsize was 2-15mm (9.5 mm) while in group II,the number of stones extracted was 1-12, and their sizewas1.5-17mm (10.2 mm). These results agreed with most literatures [9, 16]. Vindal *et al.* [11], in their studies on 132 patients also observed that most patients had multiple stones 1-25 (4.92 ± 4.801) with the size 2-22 (11.02 ±4.45) mm. The difference between the two studies in the number of the stones removed may be was due to the difference in number of patients (132 Vs 40).

The operative time for both groups in our study was 195 ± 25.3 and 175 ± 22.8 minutes respectively which was longer than that recorded in the literatures [11, 17, 18]. The reason of the longer operative time was due to using a mobile C-arm which resulted in time consuming during positioning in operating room. We observed also that, the operative time was longer in group I (IOC) than in group II (choledochoscopy) which was statistically significant.

Abnormal cholangiogram meanspresence of filling defect or absence of free flow of dye into the duodenum. In group I, two patients hadabsence of free flow of dye (10%) which relieved by antispasmodics (butylscopalamine). In other studies, glucagon reported to relieve the spasm of sphincter of Oddi and help the free flow of contrast [17-19].

Another two patients in group I had filling defect (10%) in whom choledochoscopy was done to confirm presence of stones and revealed absence of stones in CBD (false-positive results). These results were nearly similar to many published studies [20, 21], but Vindal *et al*.[11], observed lower incidence (3%).

The rate of CBD clearance in our study for group I was 95% and 100% for group II; this was due to direct vision of the interior of common bile duct by choledochoscopy and meticulous surgical technique. Topal *et al.* [9], in their series on 113 patients reported 91.8% rate of CBD clearance. 96% clearance rate was observed in a study performed by Thompson *et al.* [22]. Vindal *et al.* [11], reported a very high (100%) clearance rate.

As regard postoperative complications; 5 patients in both groups developed bile leak managed conservatively mainly by antispasmodics (transient spasm at sphincter of Oddi). One patient in group II converted to open surgery due to severe adhesion. Postoperative hospital stay was 7.8 ± 5.7 days for group I and 7.2 ± 6.2 days for group II. These results were compared with the series reported in the literature [23-24].

Conclusion

During LCBDE; we recommend choledochoscopy rather than intraoperative cholangiogram for detection of CBD Sclearance. Choledochoscopy result in less false-positive and false-negative results and less time consuming.

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8/23/2015