Comparative Study Between Intraoperative ERCP versus Laparoscopic CBD exploration in management of patients with concomitant gall bladder stone with stones in CBD

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Abstract

Objective: to compare outcome of two single-stage approaches: laparoscopic cholecystectomy plus laparoscopic exploration on common bile duct versus laparoscopic cholecystectomy plus intraoperative endoscopic retrograde cholangiopancreatography (ERCP) in patients with concomitant gall bladder stone with common bile duct stones.

Background: With refinements in technique and expertise in field of minimal access surgery; Single-stage approaches may shorten length of hospital stay and can be more efficacious for confirming common bile duct (CBD) stone clearance.

Patients and methods: This study included a total of 60 patients with a clinical diagnosis of choledocholithiasis. Thirty patients were operated upon by laparoscopic cholecystectomy with intraoperative ERCP while the other thirty patients were managed by laparoscopic cholecystectomy with laparoscopic common bile duct exploration. Follow-up period was 6 months.

Results: Mean duration of cholecystectomy was significantly higher in group A (0.74 h) compared to group B (0.55 h). P value was 0.007. Intraperitoneal collection was significantly higher in group B (30.0%) compared to group A (0.0%). P value was 0.002. There were no significant differences between both groups as regard pancreatitis (P value = 0.112), perforation (P value = 1.0), missed
stone (P value = 1.0) and recurrence of stone (p value = 0.254). No bleeding was reported in both groups.

**Conclusion:** the two reported procedures can be used for treating cholelithiasis with CBD stones. However, we recommend the use of intraoperative ERCP as a preferred option for management of patients with gallbladder stones and preoperatively diagnosed CBD stones when facilities for endoscopic therapy are readily available.

**Keywords:** CBD, Intraoperative ERCP, Laparoscopic CBD exploration, Outcomes.

**Introduction:**

The incidence of gallstones varies from 6%-10% in adult population. Three percent to 14.7% of patients of gallstones have concurrent common bile duct (CBD) stones as well. Common bile duct (CBD) stones are the most common cause of obstructive jaundice and cholangitis. Primary CBD stones are rare, comprising about 15% of the cases, rest being secondary (1-3). About 10–18% of patients with gallbladder stones will have CBD stones at the time of cholecystectomy. (4&5)

The diagnosis of choledocholithiasis can be preoperative, intraoperative or postoperative. Transabdominal ultrasonography (sensitivity 20–80%), MRCP (sensitivity 81–100%, specificity 92–100%), ERCP/ EUS (sensitivity 88–97%, specificity 96–100%) are the primary imaging modalities that can detect CBD stones besides showing dilated biliary ductal system. Other imaging modalities available are intra-operative laparoscopic ultrasonography and helical CT cholangiography. (6-8)

“Gold Standard” for management of gallstones is laparoscopic cholecystectomy (LC) but there is no consensus for treatment of CBD stones. In
the era of open surgery, treatment was straight-forward; open cholecystectomy with open CBD exploration though it carried high morbidity and mortality.\(^{(9)}\)

With advent of non invasive & minimal invasive techniques, option of intraoperative endoscopic retrograde cholangio-pancreatography (ERCP) with laparoscopic cholecystectomy emerged as adequate treatment. Major disadvantage; it is associated with life threatening complications like pancreatitis, bleeding and duodenal perforation. It has also been reported that sphincterotomy may cause papillary stenosis and increased risk of bile duct cancer.\(^{(9)}\)

With refinements in technique and expertise in field of minimal access surgery, many centers in the world have started offering one stage management of choledocholithiasis by LC with laparoscopic CBD exploration (LCBDE).\(^{(10)}\)

Only few randomized trials are available comparing intraoperative ERCP with LC with single stage LC and LCBDE. There is no consensus even for the technique of LCBDE. Various modalities have been tried for entering into CBD [transcystic (TC) vs transcholedochal (TD)], for confirming stone clearance [intraoperative cholangiogram (IOC) vs choledochoscopy], and for closure of choledochotomy (T-tube vs biliary stent vs primary closure).\(^{(11)}\)

This study was conducted in line with recommendations from a recent Cochrane review that further randomized clinical trials are needed to validate existing data on the topic. Single-stage approaches may shorten length of hospital stay and be more efficacious. It was hypothesized that intraoperative ERCP would be no different to LBDE in terms of rates of bile duct clearance or retained stones in patients undergoing laparoscopic cholecystectomy.\(^{(12)}\)

**Patients and Methods:**

The current study is a prospective study where the patients were recruited from general surgery department, Benha university hospital & the gasrto-intestinal surgical center, Mansoura university. This study included a total of 60 patients
with a clinical diagnosis of choledocholithiasis. Thirty patients were operated upon by laparoscopic cholecystectomy with intraoperative ERCP while the other thirty patients were managed by laparoscopic cholecystectomy with laparoscopic common bile duct exploration.

Patients included in this study were between the ages of 18 and 80 years who were admitted or referred to the department, Patients with diagnosis of concomitant gall bladder stone with common bile duct stones, and listed for laparoscopic cholecystectomy, Common bile duct stones are confirmed by imaging or Patients with or without symptoms of biliary-type pain or obstructive jaundice.

Patients were excluded from this study if the CBD stone was [> 2cm], Patients with history of bleeding disorders, US or CT evidence of intrahepatic gallbladder, liver mass or abscess or periampullary neoplasm, clinical or US evidence of suppurative or necrotizing cholecystitis, gallbladder empyema, or perforation, Patients who underwent multiple prior laparotomies or morbid obesity, pregnancy, severe systemic organ dysfunction (chronic liver, renal or heart diseases) and immunosuppressed patients, were also excluded.

Enrollment of eligible patients began on August 2017 and took place till the end of the study on August 2018. Follow up was designed for 6-12 months duration. The participants who agree to share in this clinical study signed an informed consent after being fully informed about the technique and its circumstances. Patients were randomized into 2 groups by closed envelope technique, first group (Group A) underwent laparoscopic cholecystectomy with intraoperative ERCP, while second group (Group B) underwent laparoscopic cholecystectomy with laparoscopic common bile duct exploration. The study was conducted after approval of the Committee of Ethics in Faculty of Medicine, Benha University.
Clinical histories including presenting symptoms (pain & jaundice) and clinical examination were recorded for all patients. Investigations done were laboratory investigations, ultrasonography and MRCP.

All patients were administered parenteral vitamin K which would correct the deficiency, Antibiotic against Gram-negative bacilli which should achieve both therapeutic systemic levels and good penetration of the biliary system and Good hydration and mannitol as a prevention from renal failure.

**Operative procedure:**

All operations were carried out under general anesthesia. The operations were performed by staff surgeons using the same techniques and rules. First of all laparoscopic cholecystectomy was done then;

**For the first group (Group A):** endoscopic management of CBD stones was performed using a side viewing endoscope with patient in supine position, the patient is shifted to prone or semiprone position, The duodenoscope was introduced through a self-retaining mouth guard till it reached to second part of duodenum with the lens facing the papilla, with the tip in close proximity to the duodenal wall. For easier cannulation of the common bile duct (CBD), the scope was positioned so that the image of the papilla is in the upper portion of the video monitor; this allowed an upward approach to the papilla, which is more in line with the natural path of the CBD. A biliary sphincterotomy was generally performed initially to facilitate passage of the the stone through the distal bile duct.

Cannulation was done by passage of the cannulation device tip into the papillary orifice, followed by introduction of a guide wire under fluoroscopy into the CBD before the injection of contrast to confirm the position.

With the patient in the prone or semiprone position either on a dedicated fluoroscopy table or under a portable C-arm device, a cholangiogram was obtained.
Once this was done, devices such as a stone extraction balloon or a stone basket (with or without stone crushing capacity) was passed over the guide wire in the bile duct to help deliver the stone. Fluoroscopic imaging was also typically performed after intervention to assess the adequacy of the treatment (e.g., to look for residual filling defects in a bile duct after stone extraction). Temporary stenting of the common bile duct was done if the stone clearance was incomplete. Fig. (1)

Fig. (1): Steps of intraoperative ERCP in Group (A).

**For the second group (Group B):** Laparoscopic CBD exploration was done. After dissection of the gallbladder neck and identification of the cystic duct, a surgical clip was placed on cystic artery & another one on the cystic duct at the level of the gallbladder. Intraoperative cholangiogram was done by making a small cystic duct incision which was fashioned just below the clip and its lumen was identified. A 5 Fr. cholangiogram catheter was inserted percutaneously in a location that would facilitate further access to the cystic duct and common bile duct if necessary. Most commonly the catheter would be positioned close to the costal margin, between the mid epigastric and lateral ports. Once in the abdomen, the catheter was flushed with saline to clear it of air. A dissector was used to advance the catheter into the ductotomy and was then secured with a non-occlusive surgical clip. Contrast was then injected through the catheter under fluoroscopy.

If stones were found in the common bile duct or hepatic ducts, a decision was made on how to proceed. Transcystic removal was tried first for removing
these stones utilizing a Fogarty balloon catheter. Using graspers, a 4-Fr. Fogarty was inserted transcystically into the common bile duct past the stones. The balloon was then inflated and the catheter was slowly withdrawn from the cystic duct using graspers.

A stone retrieval basket was inserted through the cholangiogram catheter into the common bile duct. The basket was then opened under fluoroscopic guidance past the stone. The basket was then slowly withdrawn and closed. If transcystic removal failed choledochotomy was made in the supraduodenal part using harmonic scalpel or unipolar cautery hook.

Stones were expressed out by gentle milking of the common duct and using balloon or a dormia basket followed by flushing of the entire ductal system with copious amounts of normal saline. Ductal clearance was confirmed by repeated cholangiogram. After ensuring CBD clearance, choledochotomy was closed either primary using absorbable suture (3-0) sutures or closed over T-tube which was inserted via mid clavicular port into the CBD through the choledochotomy site. The cholecystectomy was then completed in the usual fashion by dissecting between the gall bladder & its bed on the liver beginning from cystic duct till the fundus until it became completely free then it was put in retrieval bag that then be removed through the epigastric port. Lastly, a drain was put in morison pouch, removal of trocars & closure of trocars' sites. **Fig. (2)**

**Fig. (2): Steps of laparoscopic CBD exploration in Group (B).**
Post operative management:

Success was defined by removal of CBD stones and gallbladder by the intended approach in both the groups. All patients was received broad spectrum antibiotic, analgesics, proton pump inhibitors, antiedememous & IV fluids, daily laboratory investigations were done for all patients including CBC, liver function, kidney function & amylase, daily examination of patients were done searching for presence of primary symptoms and signs (pain & jaundice) & clinical picture of complications (eg: fever, tachycardia, hypotension & abdominal tenderness & rigidity) and daily follow up of drains for early detection of bleeding or biliary leakage. Primary outcome which was the success rate of CBD clearance but Secondary outcomes which were duration of the surgery, conversion to open procedure and its reasons, Intra-operative and postoperative complications, duration of hospital stay or condition on follow up visits.

Postoperative complications includes bile leak / fistula, perforation, bleeding, wound infection, acute cholangitis and acute pancreatitis. Length of hospital stay is calculated in number of days patient have to spend in the hospital following the first intervention till the discharge. Follow-up was done for 8 months.

Statistical analysis: The collected data and results were tabulated in suitable figures. Quantitative data was summarized using mean and Standard Deviation while qualitative data was summarized using frequency and percentage. Data was analyzed by the aid of Statistical Package for the Social Sciences of (SPSS) using suitable statistical tests.

Results:

There were no significant differences between both groups as regard age and gender. P values were 0.191 and 0.605 respectively. Tab. (1).
Tab. (1): Demographic characteristics in both groups:

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>Mean ±SD</td>
<td>50 ±14</td>
<td>54 ±15</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Males n (%)</td>
<td>15 (50.0)</td>
<td>13 (43.3)</td>
</tr>
<tr>
<td></td>
<td>Females n (%)</td>
<td>15 (50.0)</td>
<td>17 (56.7)</td>
</tr>
</tbody>
</table>

There were no significant differences between both groups as regard jaundice, pain and associated co-morbidities. P values were 0.584, 0.095 and 0.573 respectively. Tab. (2).

Tab. (2): Clinical characteristics in both groups:

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Jaundice</strong></td>
<td>Yes n (%)</td>
<td>19 (63.3)</td>
<td>21 (70.0)</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td>Yes n (%)</td>
<td>22 (73.3)</td>
<td>27 (90.0)</td>
</tr>
<tr>
<td><strong>Co-Morbidity</strong></td>
<td>Yes n (%)</td>
<td>10 (33.3)</td>
<td>8 (26.7)</td>
</tr>
</tbody>
</table>

Mean duration of cholecystectomy was significantly higher in group A (0.74 h) compared to group B (0.55 h). P value was 0.007. Mean duration of CBD exploration in group B was 2.51 hours. Mean duration of ERCP in group A was 0.65 hours. Total duration was significantly higher in group B (3.07 hours) compared to group A (1.39 hours). P value was <0.001. Tab. (3), Graph (1).

Tab. (3): Duration of surgical procedures in both groups:

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of</strong></td>
<td>Mean ±SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cholecystectomy (h)</td>
<td>0.74 ±0.33</td>
<td>0.55 ±0.15</td>
<td>0.007</td>
</tr>
<tr>
<td>CBD exploration (h)</td>
<td>Mean ±SD</td>
<td>2.51 ±0.77</td>
<td></td>
</tr>
<tr>
<td>ERCP (h)</td>
<td>Mean ±SD</td>
<td>0.65 ±0.27</td>
<td></td>
</tr>
<tr>
<td><strong>Total duration</strong></td>
<td>Mean ±SD</td>
<td>1.39 ±0.52</td>
<td>3.07 ±0.83</td>
</tr>
</tbody>
</table>
Graph (1): Mean total surgical duration in both groups.

Mean hospital stay was significantly higher group B (10 days) compared to group A (4 days). P value was <0.001. Tab.(4), Graph (2).

Tab. (4): Post-operative hospital stay in both groups:

<table>
<thead>
<tr>
<th>Hospital stay (days)</th>
<th>Mean ±SD</th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD</td>
<td>4 ±2</td>
<td>10 ±5</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Graph (2): Post-operative hospital stay in both groups.
Intraperitoneal collection was significantly higher in group B (30.0%) compared to group A (0.0%). P value was 0.002. There were no significant differences between both groups as regard pancreatitis (P value = 0.112), perforation (P value = 1.0), missed stone (P value = 1.0) and recurrence of stone (p value = 0.254). No bleeding was reported in both groups. Tab. (5), Graph (3).

Tab. (5) Post-operative complications in both groups:

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes n (%)</td>
<td>4 (13.3)</td>
<td>0 (0.0)</td>
<td>0.112</td>
</tr>
<tr>
<td>Intraperitoneal collection</td>
<td>Yes n (%)</td>
<td>0 (0.0)</td>
<td>9 (30.0)</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes n (%)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>-</td>
</tr>
<tr>
<td>Perforation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes n (%)</td>
<td>0 (0.0)</td>
<td>1 (3.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>Missed stone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes n (%)</td>
<td>4 (13.3)</td>
<td>5 (16.7)</td>
<td>1.0</td>
</tr>
<tr>
<td>Recurrence of stone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes n (%)</td>
<td>6 (20.0)</td>
<td>2 (6.7)</td>
<td>0.254</td>
</tr>
</tbody>
</table>

Graph (3): Distribution of post-operative complications in both groups.
Discussion:

Currently, a common practice when facing a patient with a preoperative diagnosis of gallstones associated with CBD stones is to do a preoperative ERCP followed by LC (pre-LC ERCP). Patients with stones identified on IOC are referred for treatment by post-LC ERCP. \(^{(13)}\) This approach is associated with two anesthesias and sometimes two hospital admissions, which definitely increase the hospital stay and costs. The time delay between diagnosis and ERCP may allow spontaneous passage of CBD stones exposing patients to an unnecessary ERCP. Also, there still is a possibility of LC conversion to open procedure even if ES succeeds. \(^{(14\&15)}\)

The study group was distributed as follow, 28 male (15 in group A & 13 in group B) & 32 female (15 in group A & 17 in group B). The mean age of the patients was 50 for group A & 54 for group B. Patients in this study presented by pain, jaundice or pain & jaundice together. 8 patients presented with jaundice only without pain and 15 patients presented by pain only while 37 patients presented by both pain & jaundice. 18 patients from the overall group study gave history of comorbidity. Our results are highly close to \(^{(16)}\) results who worked on bigger scale of 234 patients.

Duration of operation showed obvious difference between the two group as group A showed mean duration 1.4 hour while group B showed mean duration of the total operation about 3 hours. This difference is due to complicated and delicate procedure that needs high skill to be done is cases of common bile duct exploration. \(^{(13)}\) who worked on IO-ERCP showed longer mean total duration of operation of 112 min compared to 84 min only in our study. \(^{(17)}\) had nearly the same mean operation time as ElGeidie as the mean surgical time in his study was 119 min. while \(^{(18)}\) reported mean surgical time near to ours as it was 97.7 min. \(^{(13)}\) in another study compared 2 different techniques of ERCP showing mean surgical
duration using randez vous technique 125 min while it was 88min only while using the ordinary technique used in our study which is a very close number to ours.

Post-operative complications was registered in all patients with variation between the two groups according to type of complication. Group A showed 4 patients (13.3%) who suffered from post ERCP pancreatitis with elevated amylase while no patients in group B suffered from same complication. While \(^{(19)}\) reported postoperative morbidity in 9.8% of the study sample with 2.7% had postoperative pancreatitis & \(^{(13)}\) in his study showed only 4.5% morbidity rate. In contrast with \(^{(17)}\) who worked on IO-ERCP and showed no morbidity rate in his study results and \(^{(13)}\) in another study reported also no postoperative morbidities. There were no mortalities in our study against \(^{(19)}\) who had 5.9% mortality rate. On the other hand group B showed significant increase in post-operative intra-abdominal collection as 9 patients (30%) showed post-operative intra-abdominal collection while group A showed no patient suffering from this complication. \(^{(20)}\) who worked on CBD exploration on 50 patients reported leakage only in 2%. Lastly, only one case (3.3%) in group B showed CBD perforation which was managed by bypass hepaticojunenostomy compared to group A which was free from this complication. According to missed stones, there was no significant difference between two group as group A showed 4 patients (13.3%) with missed stones while group B showed 5 patients (16.7%). \(^{(17)}\) who worked on his study on IO-ERCP showed no missed stone in any of his patients while \(^{(21)}\) who worked on CBD exploration found 3.2% missed stones & \(^{(20)}\) reported 2%.

**Tranter & Thompson** \(^{(22)}\) who compared between the same two groups showed that the overall postoperative complications that occurred in patients underwent IOERCP was 13% with 1% mortality rate while in patients who underwent CBD exploration it was reported 8% with mortality rate 1%. While \(^{(16)}\) showed that the two groups had the same postoperative complication rate (5-10%).
**Conclusion:** the two reported procedures can be used for treating cholelithiasis with CBD stones. However, we recommend the use of intraoperative ERCP as a preferred option for management of patients with gallbladder stones and preoperatively diagnosed CBD stones when facilities for endoscopic therapy are readily available.

**References:**


