ORIGINAL ARTICLE

A prospective study of 25 cases of management of common bile duct stones

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ABSTRACT

BACKGROUND: Gall stone is becoming a problem worldwide because of change in life style. Now a days, is a major cause of morbidity among the patients attending the surgical OPD. The last 30 years have seen major developments in the management of gallstone related disease. Endoscopic retrograde cholangiopancreatography has become a widely available and routine procedure, whilst open cholecystectomy has largely been replaced by a laparoscopic approach, which may or may not include laparoscopic exploration of common bile duct or LCBDE. In this case series, we have studied 25 cases of management of common bile duct stones according to the association with gall stones; pre-operative, intra-operative or post-operative identification of common bile duct stones and its management accordingly. OBJECTIVES: To study the various modes of clinical presentation of common bile duct stones. 2. To study the modalities of management of common bile duct stones. 3. To study the feasibility, success rate, safety and outcome of different modalities. 4. To conclude the outcome of a single-step procedure against combined procedures. METHODS & MATERIALS: Patient selection criteria: 1. Age:15 to 80 years of age 2. BMI of 30 as the upper limit 3. Blood pressure<140/90 mmhg 4. ASA grades 1,2,3 RESULTS: single stage approach preferably laparoscopic common bile duct exploration is adopted if resources are available, otherwise preoperative ERCP plus laparoscopic cholecystectomy is feasible. The length of hospital stay and morbidity is significantly reduced in single stage approach as compared to two stage approach of CBD stones. CONCLUSION: As far as management is concerned, single stage laparoscopic CBD exploration is the best modality. As median hospital stay is significantly lower and rate of complications like recurrence, biliary stricture, leakage, cholangitis and biliary pancreatitis is significantly lower. The LCBDE requires advanced laparoscopic equipment and surgical skills, its application is limited.

Keywords: ERCP; LCBDE; CBD STONE

INTRODUCTION

Gall stone is becoming a problem worldwide because of change in life style. Now a days, is a major cause of morbidity among the patients attending the surgical OPD. The last 30 years have seen major developments in the management of gallstone related disease. Endoscopic retrograde cholangiopancreatography has become a widely available and routine procedure, whilst open cholecystectomy has largely been replaced by a laparoscopic approach, which may or may not include laparoscopic exploration of common bile duct or LCBDE. In addition, new imaging techniques such as magnetic resonance cholangiography and endoscopic ultrasound offer the opportunity to accurately visualize the biliary system without instrumentation of bile ducts. As a consequence, clinicians are now faced with a number of potentially valid options for managing patients with suspected CBDS. It is well documented that the incidence of choledocholithiasis increases with age, and as life expectancy is rising, it is expected that the prevalence of advanced age patients with bile duct stones will correspondingly increase. In these elderly patients, complications of choledocholithiasis carry a more substantial morbidity and mortality rate. Indeed, the mortality of elderly patients increases sharply, particularly when infective complications ensue or when

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emergency procedures are required. Therefore several investigators have endorsed a non-operative therapeutic approach for the Management of choledocholithiasis in elderly patients with high operative risks. With reference to the above, therapeutic endoscopic retrograde cholangiopancreatography and stone extraction is considered the treatment of choice for elderly or high risk patients.

**The risk factors mainly include:**
1. Female
2. Fatty
3. 60 years
4. Eating low fiber diet
5. High cholesterol diet
6. Diabetes
7. Losing weight very quickly
8. Cholesterol lowering medium
9. Hormone replacement therapy

CBD stone is a disorder of varied presentation associated with various other factors and diseases. In short, it is essential to diagnose and treat such conditions in order to decrease mortality and morbidity.

**MATERIALS AND METHOD**
This observational prospective study has been carried out in 25 cases of common bile duct stones admitted to Dept. of General Surgery in P.D.U. Medical College and General Hospital Rajkot, from September 2013 to December 2015. All the patients were examined clinically and their history and physical examination were filled in perform.

**Patient selection criteria:**
1. Age: 15 to 80 years of age
2. BMI of 30 as the upper limit
3. Blood pressure < 140/90 mmHg
4. ASA grades 1, 2, 3

All the patients coming to O.P.D. are examined first time in the O.P.D. Investigated and the diagnosis is confirmed. Patient coming with the ERCP and CBD stents are included in the criteria. They undergo routine hematological investigations, chest x-ray, ECG etc. Patients coming with acute attack of cholecystitis along with CBD stones are treated conservatively advised to go for ERCP and followed up for Lap. Cholecystectomy. Patients coming with stents in situ will be selected for Lap Sos open cholecystectomy with CBD exploration and stent removal. Written and verbal instructions are given to each patient about the disease, need for surgery, surgical procedure, overnight fasting, sos requirement for open exploration, anesthesia risk. Preoperatively all patients are given third generation cephalosporin as an injectable antibiotic of choice and antihypertensive, anxiolytic and laxatives as per requirement. Adequate intraoperative and post operative care is taken. Patient will be discharged after following criteria.

**Discharge criteria:**
1. Vital signs are normal.
2. Wound is clear.
3. Drains have been removed.
4. Patient taking all orally.
5. Minimal pain.
6. Ambulating.

Patients are followed up at regular intervals for any early or late complications or wound infection.

**RESULTS**
We have studied 25 cases of common bile duct stone presented at P.D.U. Hospitals, Department of surgery, Rajkot from September 2013 to November 2015. We examined the patients. Investigated & admitted patients according to clinical features of CBD stones. We also included Post-ERCP patient with CBD stent insitus planned for interval lap cholecystectomy.

**Table 3: Distribution According to Sex:**

<table>
<thead>
<tr>
<th>GENDER</th>
<th>NO. OF PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALE</td>
<td>13</td>
</tr>
<tr>
<td>FEMALE</td>
<td>12</td>
</tr>
</tbody>
</table>

There were 13 Males and 12 Female patients. So, no sexual predilection for CBD stones in our study was there.
There were 17 patients showed CBD size more than 10 mm on imaging modality like MRCP, CECT or Ultrasound examination. 5 patients had GB wall thickness more than 4 mm which suggested acute cholecystitis. 16 patients had presence of Gall stones out of which, 5 patients had acute cholecystitis, 7 patients had chronic calculouscholecystitis, 4 patients had asymptomatic gall stones. 4 patients had presented with CBD stent in situ which suggested recurrence of CBD stones following ERCP. They were asymptomatic and admitted for interval laparoscopic cholecystectomy. 19 patients had ALP elevation >200 IU/l, 6 patients had ALP<200IU/L Which means 76% of patients had strong predisposition of presence of CBD stones.

Graph-2

68% of patients had CBD size>10 mm, 20% of patients had acute cholecystitis, 64% of patients presented with associated Gall stones, 16% had presented with CBD stent in situ, which were asymptomatic came for interval laparoscopic cholecystectomy, 76% patients had ALP elevation more than 200 IU/l. In our study, median age of patients with CBD Stones is 61 years. According to study by Faris and Hunt, as the diameter of CBD increases probability of stone increases.

Distribution of patients according to clinical presentation: 8 patients had presented with features of acute cholangitis; pain in righthypochondriac region with Fever andJaundice. That means 32% patients presented with cholangitis. 5 patients had presented with obstructive jaundice with mild pain in RHC. That means 20% patients had predominant jaundice as their clinical presentation. 4 patients had presented with stent in situ,they were asymptomatic except occasional complaint of flatulent dyspepsia 1 patient had presented in emergency as severe abdominal guarding,biliary peritonitis and GB perforation with features of cholangitis. 7 patients had presented with Biliary colic, Jaundice, Recurrent attacks of chronic calculouscholecystitis.

Table:Distribution According To Mode Of Presentation

<table>
<thead>
<tr>
<th>Mode of presentation</th>
<th>No. of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholangitis</td>
<td>8</td>
<td>32%</td>
</tr>
<tr>
<td>Jaundice</td>
<td>5</td>
<td>20%</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>4</td>
<td>16%</td>
</tr>
<tr>
<td>Peritonitis</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Biliary colic</td>
<td>7</td>
<td>28%</td>
</tr>
</tbody>
</table>

Management of patients according to
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clinical presentation, physiological status, No. and location of CBD stone, CBD size, Presence of Gall stones and Anesthetic Fitness for surgery. Patients with cholangitis were treated conservatively with antibiotics, analgesics. They were sent for ERCP and followed up for interval cholecystectomy. Patients with predominant jaundice were treated according to the patient’s physiological status. Number, size and location of stones, Diameter of CBD, association of Gall stones and resources availability. Those who present with larger CBD stone, multiple stones with cholangitis, and CBD size more than 10 mm are selected for open CBD exploration with complete or partial cholecystectomy with surgical biliary drainage procedures like choledochoduodenostomy if impacted stone, Ampullary stenosis or Biliary sludge is found intraoperatively. Open exploration of common bile duct is done, which is either closed primarily, over 'T' Tube or choledochoduodenostomy is done. 10 patients had selected for open exploration of CBD with 5 patients had undergone choledochoduodenostomy, and 5 patients had open CBD exploration and closure with 'T' Tube. 14 patients were undergone preoperative ERCP followed by laparoscopic cholecystectomy that is 56% match with the findings of gall stones in 64% patients. 1 patient was undergone lap converted to open exploration of CBD with primary closure of CBD. Graph: Different Modalities Of Management.

Comparison of Average Hospital stay and Morbidity between single stage versus two-stage Approach for common bile duct stones: If single stage laparoscopic CBD exploration is contemplated, the average hospital stay is 3±2 days. But because of Lack of resources, we have not taken LCBDE into account. The risk of recurrence, post-operative CBD stricture as well as residual stones are lesser in open exploration group as compared to pre-operative ERCP plus Laparoscopic Cholecystectomy group.

2 patients out of 14 patients had presented with retained CBD stones following ERCP. Means 14.28% retained stones following ERCP. No retained stones following Open CBD exploration. 2 patients had to undergo lap converted to open cholecystectomy. 1 patient had Lap converted to open CBD exploration. The average length of hospital stay was 7±2 days in open exploration group. Except for 1 wound complication, there was no significant complication noted in open exploration group. Thus, single stage approach preferably laparoscopic common bile duct exploration is adopted if resources are available, otherwise pre-operative ERCP plus laparoscopic cholecystectomy is feasible. The length of hospital stay and morbidity is significantly reduced in single stage approach as compared to two stage approach of CBD stones.

DISCUSSION
There is no consensus regarding the Ideal management of concurrent Gall bladder and Common bile duct stones. Currently, the treatment protocol involves most commonly a sequential approach consisting of Endoscopic Sphincterotomy followed by laparoscopic cholecystectomy or a single stage laparoscopic procedure, including cholecystectomy and exploration of CBD. Prior to the development of minimally invasive surgery, when the surgical approach to CBD stones consisted of open choledocholithotomy, there was considerable morbidity (11-14%) and mortality (0.6-1%). With the advent of endoscopic and laparoscopic techniques, CBD stones were removed pre-operatively by endoscopy, which was followed by LC. With refinements in laparoscopic techniques, many centres are performing laparoscopic CBD exploration with acceptable results and outcome. Management of CBD stones depend upon pre-operative, Intraoperative or post-operative diagnosis during cholecystectomy. It is always better to diagnose pre-operatively on the basis of clinical features, laboratory investigations and imaging modalities. Presence of Jaundice, Elevated liver enzymes and
Dilated common bile duct >8mm in ultrasound is 99% suggestive of common bile duct stones. Therapeutic ERCP should be considered if high likelihood of CBD stones is there. If any of above 2 is present patient can undergo Magnetic Resonance cholangiopancreatography (MRCP). Its sensitivity and specificity almost approaches 100%. CBD should be imaged if there is intraoperative doubt of choledocholithiasis by cholangiography via transcystic approach. In cholecystectomised patients, Endoscopic management is the choice, if it fails then Laparoscopic or open exploration of CBD should be done.

COMPARISON WITH DIFFERENT STUDIES: Cochrane Hepato-biliary group controlled Trial Register, Cochrane Central Register of Controlled Trials(CENTRAL, Issue 7 of 12, 2013) in the Cochrane library, MEDLINE. We included all randomized clinical trials which compared the results from open surgery versus endoscopic clearance and laparoscopic surgery versus endoscopic clearance of CBD stones.

Open surgical clearance with ERCP:

<table>
<thead>
<tr>
<th></th>
<th>Open CBD Exploration</th>
<th>ERCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>8/371 patients (2.15%)</td>
<td>1/358 patients (0.3%)</td>
</tr>
<tr>
<td>Morbidity</td>
<td>56/371 patients (15%)</td>
<td>67/358 patients (19%)</td>
</tr>
<tr>
<td>Retained stones</td>
<td>20/313 patients (6%)</td>
<td>47/296 patients (16%)</td>
</tr>
</tbody>
</table>

In our study:

<table>
<thead>
<tr>
<th></th>
<th>Open CBD Exploration</th>
<th>ERCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0/11 patients (0%)</td>
<td>0/14 patients (0%)</td>
</tr>
<tr>
<td>Morbidity</td>
<td>2/11 patients (18.18%)</td>
<td>0/14 patients (0%)</td>
</tr>
<tr>
<td>Retained stones</td>
<td>0/11 patients (0%)</td>
<td>2/14 patients (18.28%)</td>
</tr>
</tbody>
</table>

It suggests that patients who underwent ERCP had significant no. of retained stones. Participants in open surgery group had significantly fewer number of retained stones compared to ERCP.

Single stage LC+LCBDE versus two stage pre-op ERCP+LC:

Five trials have been done with 580 participants.

<table>
<thead>
<tr>
<th></th>
<th>LC+LCBDE</th>
<th>Pre-op ERCP+LC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>24/285 Patients (8.4%)</td>
<td>31/295 Patients (11%)</td>
</tr>
<tr>
<td>Morbidity</td>
<td>44/285 Patients (15%)</td>
<td>37/295 Patients (13%)</td>
</tr>
<tr>
<td>Retained stones</td>
<td>24/285 patients (8%)</td>
<td>31/295 Patients (11%)</td>
</tr>
</tbody>
</table>

In our study, only 1 Patient had undergone LCBE which converted to open CBD exploration so no comparison is possible. But 2/14 patients had retained stones following ERCP that undergone open CBD exploration.

Conclusion: Open bile duct surgery seems superior to ERCP in achieving CBD clearance based on the evidence available from the early endoscopy era. There is no significant difference in mortality and morbidity between laparoscopic bile duct clearance and endoscopic options. No significant reduction in the number of retained stones and failure rates in the laparoscopy groups.

Comparison in terms of complications of laparoscopic CBD exploration, ERCP and open choledocholithotomy for large CBD stones: A prospective study of 5530 patients by 60 months period and study of complications like biliary leakage, biliary stricture and recurrence of stones.

<table>
<thead>
<tr>
<th></th>
<th>Open CBDE</th>
<th>Endoscopic Sphincterotomy</th>
<th>LCBD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary Stricture</td>
<td>1.1%</td>
<td>0.65%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Recurrent Stones</td>
<td>7.9%</td>
<td>7.4%</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

1.6% patients had cholangitis, 0.3% had pancreatitis in endoscopic sphincterotomy group. Biliary leakage was noticed in 6% patients in LCBE group which was treated conservatively. Complications in terms of pancreatitis, wound infection, duodenal perforation bile leakage and residual stones were least in Lap. Choledocholithotomy as compared to ERCP and open choledocholithotomy.

Laparoscopic choledocholithotomy is technically demanding procedure because it requires fine endosuturing but at the same time more beneficial and result oriented than the other two methods.

Comparative study by Cuscheiri, et al between single stage and two-stage approach: It concluded the results as per outcome are almost same, although the length of hospital stay is shorter with LCBDE as compared to pre-operative EST+LC. Costi et al. performed a case-control study comparing a singlestage laparoscopic approach with sequential treatment. No difference emerged concerning early and late complications, mortality or laparotomies needed to accomplish cholecystectomy and CBD.
clearance. The post-operative hospital stay was shorter in the single stage group. Improved immediate outcome for patients undergoing a single stage group. Bansal et al. conducted a prospective randomized trial which compared single stage laparoscopic treatment with sequential treatment of CBD stones. 15 patients were randomized to each group and the two groups had comparable demographic and clinical profile. In group 1, There was a success rate of 93.5% in comparison with group 2, success rate of 86.7% (p=0.32, Fisher’s exact test). The complications were similar in the two groups. The results showed equivalent success rate in terms of morbidity and hospital stay. They concluded that laparoscopic approach is favorable because of smaller no. of procedures and hospital visits. In our study, there are no incidence of mortality during any procedure, 2 patients had presented with retained CBD stones after ERCP, that underwent open exploration of CBD. No definite complications were reported after surgical drainage procedure like choledochoduodenostomy.

**CONCLUSION**

Choledocholithiasis is a common problem, present in 10% of patients with symptomatic gall stones and up to 15% with acute cholecystitis. The diagnosis of CBD stone is important as it can lead to biliary colic, obstructive jaundice, cholangitis or pancreatitis. Ultrasound is the first investigation of biliary disease its sensitivity is variable from 58%-85% depending on the expertise of sonologist and equipments. CT cholangiography is highly sensitive (93%) and specific (100%). But because of its complications, MRCP is the gold standard investigation of choice for CBD stones (sensitivity and specificity approaching 100%). As far as management is concerned, single stage laparoscopic CBD exploration is the best modality. As median hospital stay is significantly lower and rate of complications like recurrence, biliary stricture, leakage, cholangitis and biliary pancreatitis is significantly lower. The LCBDE requires advanced laparoscopic equipment and surgical skills, its application is limited. So, in our institute, pre-operative ERCP was done for bile duct clearance following that interval laparoscopic cholecystectomy was performed. Few patients were selected for open CBD exploration and primary closure of CBD with total or partial cholecystectomy or bile duct with intestinal anastomosis. The conversion rate of laparoscopic to open cholecystectomy was 4-5%. There are no incidence of mortality or significant complications in the recent follow-up period.

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