



MANAGEMENT OF COMMON BILE DUCT STONES – DIFFERENT MODALITIES

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ABSTRACT

Background and Objectives: “Management of Common Bile Duct-Different Modalities”, is a prospective study comparing the three different modalities viz. endoscopic retrograde cholangio pancreatography (ERCP), open CBD exploration and laparoscopic CBD exploration. The study was conducted with an objective to compare and contrast these different modalities and to study the advantage of ERCP over surgical methods.

Methods: 50 cases of common bile duct stones admitted in JSS Medical College Hospital, Mysore, were selected for the study. After pre procedure work up patients were subjected to either or combination of procedures namely ERCP, open CBD exploration, laparoscopic CBD exploration. The age/ sex distribution, the clinical presentation, the investigations, the treatment modalities, the complications and the outcome were evaluated.

Results: In this study of 50 patients, 39 patients underwent ERCP with successful stone extraction in 24 patients and in 7 patients incomplete duct clearance was obtained and 8 patients had failed ERCP. 22 patients underwent open CBD exploration with T tube closure in 18 and 3 patients underwent choledochoduodenostomy and in 1 patient trans duodenal sphincterotomy was performed. 4 patients underwent laparoscopic CBD exploration with 1 converted to open procedure. 3 patients underwent choledochotomy with extraction of stones and primary closure of CBD with ante grade biliary stenting.

Conclusion: Management of CBD stones in each patient needs to be individualized for different modalities depending upon the need and the indication. However the preferred method based on our study is subjecting the patient to pre operative ERCP followed by laparoscopic cholecystectomy.

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INTRODUCTION

Common bile duct stones have been a challenge to the surgeons since time immemorial. The common bile duct is explored in approximately 15% of all cholecystectomies and the stones are removed in 65% of these explorations. The incidence of concomitant common bile duct stones varies between 8% to 20%. Laparoscopic Cholecystectomy has superseded open cholecystectomy as the preferred method. One limitation of laparoscopic cholecystectomy as preferred to open cholecystectomy is in dealing with common bile duct stones. Laparoscopic CBD exploration is time consuming, needs more hard ware, is an intensive procedure, has steep learning curve and risks injury to Common bile duct. Another alternative in the management of patients with CBD stones is endoscopic retrograde cholangio pancreatography. Open methods of surgery followed so far are now giving way slowly to ERCP and Laparoscopy. This has brought down the morbidity and mortality rates. This study aims to compare different modalities of management of CBD stones and also morbidity and mortality rates.

Aims and Objectives

1. To compare and contrast the different methods of treatment of CBD stones
2. To study the advantage of non-operative method of CBD stone removal and its limitation, namely ERCP and Endoscopic sphincterotomy.
3. To study the outcome, morbidity, mortality of laparoscopic CBD exploration and open choledochoscopy.

MATERIALS AND METHODS

The present study is a prospective study of 50 cases of common bile

duct stones admitted in the JSS Medical college Hospital, Mysore during the study period from August 2005 to September 2007.

Inclusion criteria

All patients with the evidence of common bile duct stones undergoing-

- 1) Open CBD exploration
- 2) Laparoscopic CBD exploration
- 3) ERCP
- 4) Combination of above methods

Exclusion criteria

- 1) Those patients with CBD stones but not treated by any of the accepted modalities due to
 - a) Medical contraindications
 - b) Refusal to undergo ERCP and Surgical intervention.
- 2) Patients with Sclerosing Cholangitis

The data was collected in a proforma. The diagnosis was made with relevant clinical history, physical examination, relevant investigations – Liver function tests, ultrasound – abdomen, endoscopic retrograde cholangiogram, CT-scan abdomen. All patients were worked up for the therapeutic procedures with all routine lab investigations. Patients were subjected for the different procedures namely ERCP , open or laparoscopic CBD exploration, or combination of one or more above mentioned procedures, depending upon the need and or the indications. All patients were kept nil per oral for 6hours before the therapeutic procedures. Some patients received Inj. Mannitol 100ml on the day of surgical intervention. All patients received single dose of antibiotics before the above mentioned procedures. ERCP was done

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under local anaesthesia (Xylocaine 4%) with sedation (Inj.Midazolam) where as General anaesthesia was employed for surgical intervention. Patients subjected for endoscopic procedure underwent ERCP and extraction of stones with or with out sphincterotomy. Stones were extracted using balloon or baskets. Stenting was done if required. Patients subjected for surgical intervention underwent either open or laparoscopic CBD exploration. CBD closure was performed primarily with antegrade stenting or with T-tube. Some patients underwent transduodenal sphincterotomy / plasty or choledochoduodenostomy. All patients were monitored for post ERCP and post surgical complications. Patients were kept nil per oral for 4 hours following endoscopic procedure and for day or two for post surgical procedures depending upon the patients condition. All patients received post operative antibiotics and were continued for a longer period in patients having developed complications. Analgesics and routine post operative care was given for all patients. All patients with T-tube in situ underwent T-tube cholangiogram between 10th -14th post op days. T-tube was removed after confirming the patency of the bile duct. Patients were observed for bile leak and necessary measure were taken depending upon the need. Patients with biliary stent in situ were advised stent removal 4 to 6 weeks after the procedure. Patients were discharged when fit and were asked for regular follow up. Advice regarding the diet was given at the time of discharge.

Statistical Methods Applied

Following statistical methods were applied in the present study

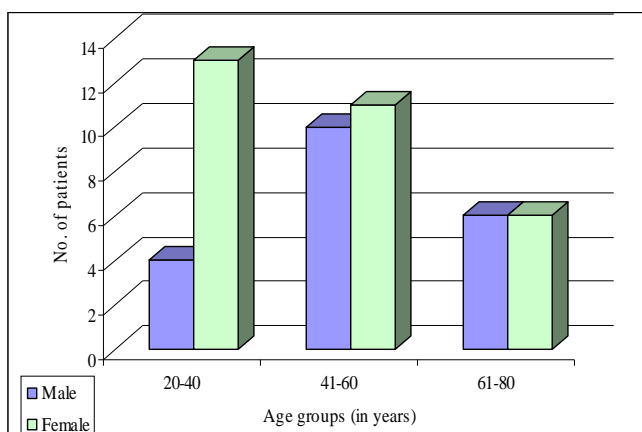
- 1) Cross tabs procedure (Contingency coefficient test)
- 2) Descriptive statistics.

Observations and Results

A study of 50 new cases of common bile duct stones was conducted from Aug-2005 to Sep-2007 in J.S.S hospital, Mysore and the following observations were made.

Age and Sex Distribution

In this study of 50 cases 30 female patients and 20 male patients were diagnosed of having common bile duct stones. The maximum distribution was seen in the age group of 41 to 60, accounting for 42%. The youngest patient being 21 year old and the oldest of 78 years old. It was observed that the occurrence of CBD stones was more in females compared to males, ratio being 1.5 to 1

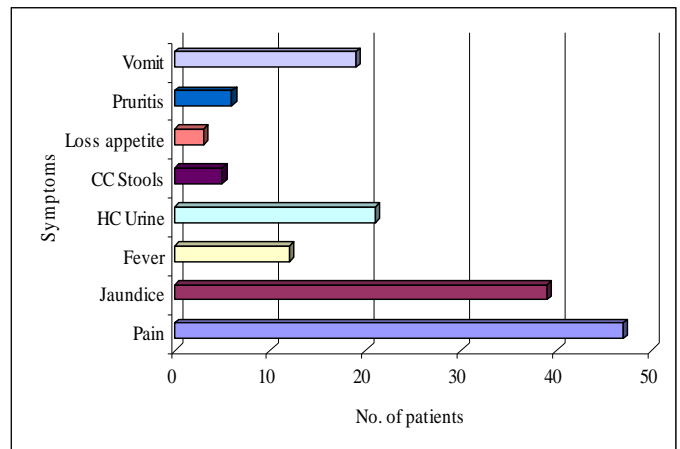


Graph 1. Age and sex distribution

Symptoms

In the study of 50 patients, pain was the predominant symptom found in 47 patients (94 %) where as 39 patients had jaundice (78%). 9 patients presented with classical Charcot’s triad of pain, jaundice, fever (18%). 12 patients presented with fever and loss of weight/

appetite was observed in 3 patients. The other symptoms were passing high colored urine, clay colored stools and pruritis seen in 21(42%), 5(10%), 6(12%) respectively. 19 patients had history of vomiting.



Graph 2. Symptoms

Investigations

Liver Function Tests

Liver function tests were altered in all 50 patients, but special mention was made towards the alkaline phosphatase, as a marker for obstructive jaundice which was elevated in 48 of 50 patients (96%).

Ultrasound-Abdomen

In this study ultrasound abdomen detected the presence of common bile duct (CBD) stones in 40 of 50 patients (80%). Size of the stone was mentioned 22 patients. Out of 22 patients 8 patients had single stone in the CBD whereas 14 patients were found to have multiple calculi. CBD dilatation was found in 36 patients, out of which no mention was made about the size of duct in 3 patients, 10 patients were found to have duct dilatation of less than 10mm and rest 23 patients showed duct dilatation of more than 10mm. In 13 patients no duct dilatation was found and in 1 patient USG findings were inconclusive (Table 4).

Table 4. USG Findings

USG-Findings	No. of Patients
Duct dilatation	03
Duct dilatation <10mm	10
Duct dilatation >10mm	23
Inconclusive	01
No dilatation	13

Diagnostic Endoscopic Retrograde Cholangiogram (ERC)

In this study, 39 patients underwent diagnostic ERC, out of which 37 patients had successful cannulation of CBD (94.87%) and in 2 patients CBD couldn’t be cannulated. Out of 37 cholangiograms, 20 patients showed single filling defect and 17 patients showed multiple filling defects (Table 5).

Table 5. Diagnostic ERC findings

Diagnostic ERC	No. Of Patients
Not done	11
Failed cannulation(failed cann)	02
Filling defects multiple(fill def multi)	17
Filling defect single(fill def single)	20
Total	50

37 patients were diagnosed to have CBD stones on ERC. Of 37 patients 23 patients were having stones measuring less than 10mm

(62.16%), in 12 patients stones measuring between 10mm to 20 mm (34.43%) and in 2 patients more than 20mm (5.40%).

CT Scan – Abdomen

Two patients underwent CT scan abdomen. One of these two patients had failed ERCP because of failure to cannulate the CBD and in the another patient ERCP was not attempted because USG abdomen showed very large stones in the terminal CBD. In these two patients CT scan showed dilated CBD along with intra hepatic biliary dilatation with stones in the CBD.

Therapeutic Endoscopic Retrograde Cholangiography

Out of 50 patients, 39 patients underwent ERC and in 11 patients ERC was not attempted. In 24 patients stones were extracted successfully with complete clearance of CBD. In 2 patients CBD could not be cannulated. 8 patients had failed ERC. 6 of these patients had stones measuring more than 12mm and in 2 patients impacted stones were the cause for failure. In 7 patients complete CBD clearance could not be achieved as these patients were having multiple CBD stones and stones measuring more than 12mm (Table- 6).

Table 6. Therapeutic ERC Findings

Therapeutic ERC	No. of Patients
Successful removal of stones (SRS)	24
Failed ERCP (Failed)	08
Incomplete extraction of stones	07
Not done	11
Total	50

CC- 0.397 p value- 0.156

Open Common Bile Duct Exploration

Table 7. Open CBD Exploration

Open CBD Exploration	No. of Patients
Not done	28
Closure with T-tube (TTU)	18
Trans duodenal sphincterotomy (BS)	01
Choledochoduodenostomy (CD)	03
Total	50

22 Patients underwent open CBD exploration. In all patients stones were extracted successfully. In 18 patients T- tube closure was done following supra duodenal choledochotomy. One patient underwent trans duodenal sphincterotomy and extraction of stone. 3 patients underwent choledochoduodenostomy. One of these patient was found to have associated distal CBD stricture. Remaining two patients were having hugely dilated CBD (more than 20mm). In remaining 28 patients CBD exploration was not attempted (Table 7).

Laparoscopic CBD Exploration

In 4 patients laparoscopic CBD exploration was attempted. 3 patients underwent supraduodenal choledochotomy and choledochoscopy with extraction of stones using basket. Ante grade stenting of the common bile duct and primary closure was done. One patient had failed laparoscopic extraction of stones, because of large sized impacted distal CBD stone, was converted to open CBD exploration with extraction of stones through supraduodenal choledochotomy and T-tube closure was done

Outcome

In this study of 50 patients 49 patients were treated successfully with complete clearance of Common Bile Duct with one or more methods of stone extraction. In one patient ERC was attempted with incomplete clearance of duct and surgery was advised. Patient refused for the same. There was no mortality in this study

Complications

In this study of 50 patients, 26 patients had no complications. Cholangitis, Pancreatitis, and Sepsis following ERCP was observed in 2, 4, 4 patients respectively. 5 patients had superficial SSI following open CBD exploration and 2 patients had bile leak following T tube removal and 2 more patients had cholangitis with bile leak which was managed successfully by conservative treatment. Along with wound infection cholangitis, sepsis, pancreatitis was observed 2, 2, 1 patients respectively (Table 8).

Table 8. Complications

Complications	No. of Patients
No complications	26
Cholangitis (Cho)	02
Pancreatitis (Pan)	04
Sepsis (Sis)	04
Bile leak (BL)	02
Wound infection	05
Wound infection with Cholangitis	02
Wound infection with Pancreatitis	01
Wound infection with Sepsis	02
Total	50

DISCUSSION

In a series of 2455 patients of choledocholithiasis by Wani *et al.* (1983-1992)¹ the male to female sex ratio was 1:4.4 and maximum incidence was in the age group of 31–40 years. The classical presentation of choledocholithiasis is a triad of jaundice, pain in abdomen and fever with or without chills as described by Charcot in 1877. In a series of 2455 patients of choledocholithiasis by Wani *et al.* (1995)¹ the symptoms were pain in abdomen 94.90%, fever with rigors 13.44% and jaundice 43%. According to Lahey Clinic study (1958) of choledocholithiasis, pain occurred in 95% of patients, fever in 50% of patients and jaundice in 43% of patients. Liver function tests may be entirely normal in patients with common bile duct stone². Approximately 5% of patients with normal serum liver enzymes will harbour common bile duct stone at time of cholecystectomy (Jones and Soper, 1996)³. Lillemoe *et al.* (1995)² found common bile duct stone in 33% patients when serum bilirubin was greater than 1.2 mg/dl. Serum alkaline phosphatase is useful indicator and incidence of common bile duct stone is 46% when serum alkaline phosphatase is above 200 IU/L (Lillemoe – 95).² USG is the best non invasive, cheap and easily available investigation. In his series of 2455 patients, Wani *et al.* (1995)¹ has detected 73.72% patients of common bile duct calculi on USG. Sensitivity can be increased between 80% to 100%, when endoscopic ultrasound is used (Tierny *et al.*, 1995)². Amouyal *et al.* (1995) found endoscopic ultrasonography (EUS) to have sensitivity and specificity of 100% in common bile duct stone detection. Overall USG is only 55 to 88% accurate in documenting the presence or absence of common bile duct stones (Tierny *et al.*, 1995)² Reported sensitivity of CT scan for CBD stones was 75 – 80% according Tierny and Lillemoe *et al.* (1995)².

Management

Therapeutic ERCP

Results from the centres around the world (Cotton 1974, Safrany 1978, Reiter *et al.*, 1978, Nakajima *et al.*, 1979, Siegel 1981, Geenen *et al.*, 1981, Cotton & Vallon *et al.*, 1981, Seifert *et al.*, 1982, Leese *et al.*, 1985, Schumacher *et al.*, 1998)⁴ with individual and collected series of from 430 to 7885 patients range 78% to 98% for duct clearance with median value of 88%.

Open CBD Exploration

Traditional open surgery is an effective and safe option for management of choledocholithiasis (Jean Moreaux, 1995)⁵.

Cholecystectomy with common bile duct exploration was considered as gold standard. Common bile duct exploration should be done selectively in following conditions (Gadaez T., 1991)⁶.

- 1) Palpable common bile duct stone
- 2) Jaundice with cholangitis
- 3) Stone demonstrable in intraoperative cholangiography
- 4) Preoperative demonstration of common bile duct stone.

Moreaux Jean (1995)⁵ believes that 'T' tube drainage is the most effective method where CBD diameter is less than 1.5 cms. Alternatives to 'T' tube drainage are transduodenal exploration, Choledochoduodenostomy and primary closure (Gillat *et al.*, 1985)⁷. Commonest indications for Choledochoduodenostomy procedure suggested are: (Ray and Pai 1994)⁸

- a) Impacted distal common bile stone
- b) Multiple intrahepatic and CBD stone
- c) Postoperative retained stone
- d) Stenosis of lower end of CBD
- e) Papillary stenosis

Laparoscopic CBD Exploration

Introduction of laparoscopic cholecystectomy in 1989 by Touret in France and Reddik in the United States brought revolutionary change in treatment options in biliary tree surgery. The options available for extraction of CBD stones are-

- 1) Laparoscopic cholecystectomy and transcystic duct common bile duct exploration.
- 2) Laparoscopic choledochotomy Laparoscopic CBDE, a technically demanding operation, is possible at the time of laparoscopic cholecystectomy in the majority of cases, with a low complication rate and a short length of hospital stay (Stoker, 1995)⁹

Complications

Related to Open and Laparoscopic CBD exploration

Gillat *et al.*, (95)⁷ have reported high incidence of septicaemia, bile leak, biliary peritonitis and thromboembolism with 'T' tube drainage. The use of T-tube is associated with complications like bile leak, dislodgement, breaking of the T-tube, formation of encrustations leading to difficulty in removal of tube, duct stricture, cholangitis, trauma to duct and subsequent biliary leak during tube removal and delayed healing of the CBD wound^{10,11}. Primary closure of CBD is more safe and physiological and the procedure of choice following routine choledochotomy¹². Cubillos L. *et al.*, a (1968-1982 study)¹³ analysed a series of 125 patients of choledocholithiasis, post-operative complication rate was 42.5%, which includes wound infection 27%, cholangitis 1.6%. Lygidaki's (1981) found incidence of postoperative complication in 2.8 to 5.1% of cases which included biliary leak, biliary peritonitis and wound infection.

Related to Endoscopy

Freeman *et al.*, 1996, Vander *et al.*, 1996 have reported early complications of 8-10%. Leese *et al.* reported higher complication rate during early experience of 394 procedures, carries over all morbidity of 10.4% with subsequent group of 300 cases to under 6%. Acute haemorrhage (2-2.9%), Acute Pancreatitis (1.5-5.4%), Cholangitis (1-2.7%), Perforation (0.3-1%). Emergency surgery required in 1-2.5% of cases for bleeding, cholangitis, perforation and pancreatitis in descending order of frequency. Statistically significant risk factors for complications include difficulty in cannulation, pre-cut sphincterotomy, suspected dysfunction of sphincter of oddi, greater than 2 cannulations, failed biliary access or drainage and technical skill of endoscopist rather than age or general medical condition of the patient as reported by Freeman *et al.*, 1996, Vander *et al.*, 1996, Neoptolemos *et al.*, 1989.⁴

Limitation of ERCP

Factors influencing the extraction of stones:⁴

Size, number, consistency, shape and location of stones, ductal factors (contour, diameter at the level of and distal to the stones and the presence of co existing pathology such as stricture or tumor). Stones that appear larger than the endoscope on radiographic imaging (usually greater than 15mm), large number of stones, stones that are hard in consistency, stones that are square, piston or faceted in shape that tightly fit the bile duct or that are packed against each other, intra hepatic stones or stones that are located proximal to the stricture or narrowed distal bile duct or in a sigmoid shaped duct are likely to be more difficult to extract and therefore requires adjuvant techniques to remove them.

Conclusion

However the preferred method based on our study is subjecting the patient to pre operative ERCP followed by laparoscopic cholecystectomy. ERCP achieved success rate of 92.08% for the stones measuring less than 12mm. The major limitations being the size of stones (measuring more than 12mm) and impacted stones. This treatment modality had low morbidity compared to surgical methods and no mortality, with the added advantage of shorter duration of hospital stay. The disadvantage is that the patient needs to be subjected for surgical management of gall stones at another setting. Open CBD exploration had attained success rate of 100% in clearing the CBD stones, but at the cost of higher morbidity compared to ERCP and longer duration of hospital stay. Laparoscopic CBD exploration had success rate of 75% in our study with low morbidity and no mortality. The duration of hospital stay was less compared to open CBD exploration but more compared to ERCP. This procedure has an added advantage of single stage treatment for both gallbladder stones and CBD stones, so as the open CBD exploration. The disadvantage is being that the procedure is time consuming, needs more hard ware, is an intensive procedure, has steep learning curve and risks injury to common bile duct although no bile duct injury was documented in our study.

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