



# International Journal of Surgery Science

E-ISSN: 2616-3470  
P-ISSN: 2616-3462  
© Surgery Science  
www.surgeryscience.com  
2019; 3(2): 77-81  
Received: 16-02-2019  
Accepted: 20-03-2019

**Dr. Ravi MJ**  
Assistant Professor,  
Department of Surgery, VIMS,  
Ballari, Karnataka, India

## The efficacy of endoscopic and surgical management of CBD stones in terms of outcome, morbidity and mortality

**Dr. Ravi MJ**

**DOI:** <https://doi.org/10.33545/surgery.2019.v3.i2b.17>

### Abstract

Laparoscopic Cholecystectomy has superseded open cholecystectomy as the preferred method.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 harder ware, is an intensive procedure, has steep learning curve and risks injury to Common bile duct. The data was collected in a proforma approved by the guide. 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, ECG, chest Xray and fitness for the procedure was taken from the physicians where ever necessary. In this study of 60 patients, 34 patients had no complications. 3 patients had wound infection. In 4 patients along with wound infection cholangitis and sepsis (1 each), pancreatitis in one patient and bile leak in one patient was observed. Each of the 5 patients had pancreatitis and sepsis. Cholangitis was observed in 3 patients and 2 patients had bile leak through t-tube tract following its removal which persisted for 6 and 7 days respectively. Cholangitis along with pancreatitis, sepsis, bile leak was observed in 1, 1, 2 patients respectively.

**Keywords:** Laparoscopic cholecystectomy, surgical management, CBD stones

### 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 Laparoscopic Cholecystectomy has superseded open cholecystectomy as the preferred method.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 [1]. Open methods of surgery followed so far are now giving way slowly to ERCP and Sphincterotomy. This brought down the morbidity and mortality rates. Ours is a teaching hospital where open methods of CBD stone management are being done and ERCP as a tool of management has recently been introduced. This study is to compare different modalities of management of CBD stones in our hospital as also morbidity and mortality rates. Study will also encompass the even newer modalities of treatment like laparoscopic CBD exploration which has also been introduced in our hospital [2].

Historical aspects of the management of bile duct stones have been reviewed by Morgenstern [1], after Dr Karl Langenbuch, first cholecystectomy in 1882. Within a decade, cholecystectomy was being combined with exploration of the bile duct in selected patients with jaundice or cholangitis. By 1900, additional surgical procedures had been described including cholecysto-enterostomy, choledcho-duodenostomy, and operative sphincteroplasty. At a similar time, operative drainage of the bile duct using a T-tube was described by another German surgeon, Dr Hans Kehr. The first description of operative cholangiography has been attributed to Dr P Mirizzi in Argentina. In 1931, he described the intraoperative injection of lipiodol through the cystic duct. This procedure increased the detection of unsuspected bile duct stones and decreased

**Correspondence**  
**Dr. Ravi MJ**  
Assistant Professor,  
Department of Surgery, VIMS,  
Ballari, Karnataka, India

the frequency of unnecessary bile duct explorations. Subsequently, percutaneous trans hepatic cholangiography was described but the procedure was not widely adopted until the introduction of the Chiba needle by Dr K Okuda in Japan in 1973. More recently, sophisticated radiological equipment has been installed in operating suites to provide both fluoroscopic and static images of the bile duct [3].

Developments in radiological techniques were associated with the evolution of endoscopic techniques for direct visualization of the bile duct. Although rigid choledochoscopy had been described in the 1940s, it was not until the 1960s that optical systems were good enough to promote their widespread use. Within a decade, some of these instruments had been replaced by flexible fiber optic choledochoscopes. Flexible choledochoscopes have also been used to extract retained bile duct stones through the T-tube tract, and to perform diagnostic and therapeutic procedures after percutaneous trans hepatic passage into the bile duct.

Another major step forward was the introduction of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy. Although sphincterotomy was first described in 1973, the procedure became widely available only in the early 1980s. Subsequently, sphincterotomy became a common procedure for patients with bile duct stones prior to cholecystectomy, and became the procedure of choice for removal of bile duct stones after cholecystectomy [4].

Laparoscopic cholecystectomy was introduced in the late 1980s, and by the mid-1990s replaced open cholecystectomy as standard treatment for gallbladder stones. A particular concern, however, was the development of complications in patients with coexisting bile duct stones. Initially, many patients underwent ERCP prior to laparoscopic cholecystectomy to exclude bile duct stones. Subsequently there was a more rational use of ERCP as well as the development of laparoscopic exploration of the bile duct.

### Methodology

The present study was a prospective study of 60 cases of common bile duct stones admitted in the Medical college Hospital.

The data was collected in a proforma approved by the guide. 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, ECG, chest Xray and fitness for the procedure was taken from the physicians where ever necessary.

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. All patients received single dose of antibiotics before the above mentioned procedures. ERCP was done 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 without 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 ante grade stenting or with T-tube. Some patients underwent trans duodenal sphincterotomy/ plasty or choledochoduodenostomy.

All patients were monitored closely 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 patient's 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 10<sup>th</sup> -14<sup>th</sup> 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. The age and sex distribution, clinical presentation, diagnostic modalities, different therapeutic modalities and associated complications- morbidity and mortality were all evaluated and compared with standard published literature.

### Statistical Methods Applied

Following statistical methods were applied in the present study

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

A brief description of each statistical method is given below

### Crosstabs procedure

The Crosstabs procedure forms two-way and multiway tables and provides a variety of tests and measures of association for two-way tables. The structure of the table and whether categories are ordered determine what test or measure to use.

Crosstabs' statistics and measures of association are computed for two-way tables only. If you specify a row, a column, and a layer factor (control variable), the Crosstabs procedure forms one panel of associated statistics and measures for each value of the layer factor (or a combination of values for two or more control variables). For example, if GENDER is a layer factor for a table of MARRIED (yes, no) against LIFE (is life exciting, routine, or dull), the results for a two-way table for the females are computed separately from those for the males and printed as panels following one another.

### Results

In this study, 59 patients underwent diagnostic ERC, out of which 57 patients had successful cannulation of CBD (96.610%) and in 2 patients CBD couldn't be cannulated. Out of 57 cholangiogram, 18patients showed single filling defect and 39 patients showed multiple filling defects.

**Table 1:** Diagnostic ERC findings

Diagnostic ERC	No. Of Patients
Not done	01
Failed cannulation (failed cann)	02
Filling defects multiple(fill def multi)	39
Filling defect single(fill def single)	18
Total	60

57 patients were diagnosed to have CBD stones on ERC. Of 57 patients 31 patients were found to have stones measuring less

than 10mm(54.4%), 20 patients were having stones measuring between 10mm to 20 mm(35.1%) and 6 patients were diagnosed to have stones measuring more than 20mm(10.5%).

**Table 2:** Size of Stone

Size of Stone	No. of Patients
<10mm	31
10mm to 20mm	20
>20mm	06
Total	57

In this study of 60 patients CT-Scan abdomen was advised in 3 patients. One of these three patients had failed ERCP because of failure to cannulate the CBD and in the another patient ERCP was not attempted because papilla edematous and bleeding, third had CBD calculi with Mirrizi's syndrome.

In this study of 60 patients, all the patients were diagnosed to have secondary common bile duct stones. None of the patients were found to have primary common bile duct stones or retained or recurrent common bile duct stones. The diagnosis was made either by ultrasound-abdomen, endoscopic retrograde cholangiogram, CT scan-abdomen or combination of one or more above mentioned procedures.

**Table 3:** Therapeutic ERC Findings

Therapeutic ERC	No. of Patients
Successful removal of stones (SRS)	45
Failed ERCP (Failed)	08
Incomplete extraction of stones	06
Not done	01
Total	60

Out of 60 patients, 59 patients underwent ERC and in 01 patients ERC was not attempted. In 45 patients stones were extracted successfully with complete clearance of CBD.4 of these patients had stones measuring between 11mm to 14mm. Mechanical Lithotripsy was used to reduce the size of the stones in these 4 patients. Stones were extracted using basket with or without endoscopic sphincterotomy. In 2 patients CBD could not be cannulated.8 patients had failed ERC. 4 of these patients had stones measuring more than 12mm and multiple and in 2 patients impacted stones and other 2 patients had edematous papilla. were the cause for failure. In 6 patients complete CBD clearance could not be achieved. All these patients were having multiple CBD stones and stones measuring more than 12mm.Smaller stones were extracted using basket. One patient had impacted large stone.

**Table 4:** Open CBD Exploration

Open CBD Exploration	No. of Patients
Not done	45
Closure with T-tube (TTU)	13
Trans duodenal sphincterotomy (BS)	01
Total	59

14 Patients underwent open CBD exploration. In all patients stones were extracted successfully. In 13 patients T- tube closure was done following supra duodenal choledochotomy. One patient underwent trans duodenal sphincterotomy and extraction of stone. In remaining 45 patients open CBD exploration was not attempted.

**Table 5:** Laparoscopic CBD Exploration

Laparoscopic CBD Exploration	No. of Patients
Closure with ante grade stenting	01
Not done	59
Total	60

In 01 patient laparoscopic CBD exploration was attempted. patient underwent supraduodenal choledochotomy with extraction of stones using basket. Ante grade stenting of the common bile duct and primary closure was done.

**Table 6:** Out Come

Out Come	No. of Patients
Stones removed successfully	60
Incomplete clearance	00
Mortality	00
Total	50

In this study of 60 patients all patients were treated successfully with complete clearance of Common Bile Duct with one or more methods of stone extraction. There was no mortality in this study. In this study of 60 patients, 34 patients had no complications. 3 patients had wound infection. In 4 patients along with wound infection cholangitis and sepsis (1 each), pancreatitis in one patient and bile leak in one patient was observed. Each of the 5patients had pancreatitis and sepsis. Cholangitis was observed in 3 patients and 2 patients had bile leak through t-tube tract following its removal which persisted for 6 and 7 days respectively. Cholangitis along with pancreatitis, sepsis, bile leak was observed in 1, 1, 2 patients respectively.

**Table 7:** Complications

Complications	No. of Patients
Wound infection (WI)	03
Cholangitis (Cho)	03
Pancreatitis (Pan)	05
Sepsis (Sis)	05
Bile leak (BL)	02
No complications	34
Wound infection with Cholangitis	01
Wound infection with Pancreatitis	01
Wound infection with Sepsis	01
Wound infection with Bile leak	01
Cholangitis with Pancreatitis	01
Cholangitis with Sepsis	01
Cholangitis with Bile leak	02
Total	60

## Discussion

In 45 patients stones were extracted successfully with complete clearance of CBD.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 6 patients complete CBD clearance could not be achieved. All these patients were having multiple CBD stones and stones measuring more than 12mm. One patient had impacted large stone. In this study if the success rate of ERCP after excluding the stones measuring more than 12mm is considered then success rate will be 92.08% (24 out of 26 procedures).The overall success rate after excluding the cases with the incomplete clearance of duct, then it accounts for 82.75%.

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.

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) [5] with individual and collected series of from 430 to 7885 patients range 78% to 98% for duct clearance with median value of 88%. Our study results matches with the results mentioned above.

Traditional open surgery is an effective and safe option for management of choledocholithiasis [6].

Most of the common bile duct stones are formed in the gall bladder and migrate to the common bile duct. In absence of cholelithiasis CBD stones are uncommon. Hence cholecystectomy with common bile duct exploration was considered as gold standard but Sheridan [33] advised that common bile duct exploration in every case of choledocholithiasis should be avoided as it is associated with morbidity due to sepsis and retained stones and as common bile duct stones can be detected by by USG, ERCP or CT scan.

14 patients underwent open CBD exploration in our study. In all patients stones were extracted successfully. In 13 patients T-tube closure was done following supra duodenal choledochotomy. In all patients preoperative diagnosis of common bile duct stones was established by either USG, ERC, CT Scan. In 5 patients intra operative cholangiogram was done, as details were not available. Remaining 8 had no mention of cholangiogram was there.

Intraoperative cholangiography (IOC) was advised first in 1934 by Mirrizi's. It should be done selectively in patients undergoing cholecystectomy. Conventional wisdom learned from open cholecystectomy was to perform cholangiography selectively in patients with history of pancreatitis, dilated cystic duct or common bile duct, palpable common bile duct stone or abnormal serum liver enzymes.

In our study 100% duct clearance obtained following open CBD exploration which was confirmed by T-tube cholangiogram post operatively.

Moreaux Jean believes that 'T' tube drainage is the most effective method where CBD diameter is less than 1.5 cms.

One patient underwent trans duodenal sphincterotomy who had distal large impacted stone with tight sphincter.

In a series of 2610 patient of choledocholithiasis Ramirez *et al.* [8] has done surgical exploration of common bile duct with sphincterotomy in 22.6%. Endoscopic papillotomy is a safe alternative in elderly and in post-cholecystectomy common bile duct stone.

McIver [9] advised CBD exploration by technique of choledochoscopy. This technique appears to be safest because it captures stone under direct vision without manipulation of the ampulla. In our study choledochoscopy performed using ureter scopes and stones were extracted using baskets. This method was utilized for both open and lap CBD exploration. However

not in all cases of open CBD exploration, choledochoscopy was performed, in most cases Desjardins forceps were used to retrieve the stones.

Betlatzky and Freund [10] consider choledochoduodenostomy as more physiological operation than choledochojunostomy, as near normal physiological passage of bile in duodenum is maintained. He also considered that choledochoduodenostomy has added advantage of simplicity and is easily performed operation in elderly patients with biliary stenosis and papillary stenosis.

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. Preoperative endoscopic sphincterotomy for choledocholithiasis never become a common practice until the introduction of laparoscopic cholecystectomy (Phillips, 1994). The options available for extraction of CBD stones are-1) Laparoscopic cholecystectomy and trans cystic duct common bile duct exploration-Stones can be retrieved using dormia basket.

Transcystic exploration and clearance of common duct is highly effective. Using transcystic technique, 80 to 90% of common duct stones can be cleared and its success significantly reduces the need for either a choledochotomy or subsequent ERC.

Baskets may be passed over the guide wire into common duct to dislodge and extract stone under fluoroscopic guidance. Choledocholithiasis usually results from stones migrating through the cystic duct into the CBD. Cystic duct is often of adequate diameter to accept a choledochoscopes and extract stone.

In our study 1 laparoscopic CBD exploration were attempted. In this patient stones were extracted successfully after performing choledochotomy and primary closure was done with ante grade biliary stenting.

Laparoscopic choledochotomy has been performed safely and effectively in experienced hands with shorter hospitalization and disability as compared to open CBD exploration.

It has been thought that with increasing expertise laparoscopic surgery, the use of these techniques will become widespread, but in fact there are large geographic areas where laparoscopic CBD exploration is not presently practiced. These procedures are clearly more difficult than simple laparoscopic cholecystectomy. 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

The use of T-tube is associated with complications like bile leak, dislodgement and even breaking of the T-tube, formation of encrustations leading to difficulty in removal of tube, duct stricture, cellulitis around the T-tube, cholangitis, trauma to duct and subsequent biliary leak during tube removal and delayed healing of the CBD wound.

The continuous external drainage of bile can sometimes lead to nutritional disturbances. Despite its obvious advantages and various reports in literature, primary duct closure is still not being performed routinely.

In this study of 60 patients, 34 patients had no complications. 7 patients had wound infection accounting for 42.30%. 5 patients had bile leak, accounting for 19.23%. Sepsis and cholangitis was observed in 4 patients each. (15.38%). Bile leak was observed following T-tube removal. In 3 patients bile leak persisted for 3 days, in the remaining 2 patients it persisted for 5 days and 7 days respectively. All these patients were treated conservatively. No mortality occurred in our study. All patients with complications were treated conservatively. None of the patients

required re operation.

T-tube drainage following choledochotomy is associated with increased bile infection and wound infection. Significant bile leak following T-tube removal is said to occur in 1.2%-30 % of cases.

The use of T-tube following routine choledochotomy is unnecessary and increases postoperative morbidity and mortality. Primary closure of CBD is more safe and physiological and the procedure of choice following routine choledochotomy.

In our study primary closure was employed with ante grade biliary stenting in 1 case of Laparoscopic CBD exploration with low morbidity and no mortality. This patient had cholangitis and sepsis. These complications were treated conservatively.

Tan KK <sup>[11]</sup> *et al.* reported 8% complications in laparoscopic CBD exploration of which the main were retained CBD stones and biliary leakage.

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.

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, precut sphincterotomy, suspected dysfunction of sphincter of oddi, greater than 2 cannulations, failed biliary access or drainage and technical skill of endoscopists 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 <sup>[12]</sup>.

In our study 4 patients had pancreatitis following ERCP, accounting for 10.25%, which is higher than the studies mentioned above. 2 patients had sepsis (5.1%) and cholangitis each (5.1%), which is slightly higher than in the quoted studies. However no perforations or acute hemorrhage recorded in our study and so as the mortality. All complications were treated conservatively and no patients required surgical intervention. All patients improved with conservative management.

### Conclusion

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.

Although no mortality was recorded in this study. Wound infections and the bile leak were the commonest complications which were treated conservatively.

Laparoscopic CBD exploration had successfully clearance of stones 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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