

# Primary closure of common bile duct after choledocotomy over feeding tube as a stent – A prospective study

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## Abstract

In the era of laparoscopic management of Cholelithiasis, choledocholithiasis is not routinely managed by laparoscopically because laparoscopic management of CBD stones demands skills and equipment, and is therefore used by few surgeons. Therefore open surgery is still a treatment of choice in many hospitals. The classical performance of bile duct exploration is associated with the problem of an incised bile duct closure. Choledochotomy followed by T-tube drainage is a traditional surgical treatment for choledocholithiasis but it is not exempt from complications, which are present in up to 10% of patients. The most frequent of these is bile leakage after removal, which is reported to occur in 1–19% of cases. Primary closure of the CBD after exploration is not new. Halstead first described the advantages of primary closure. In our hospital, open CBD exploration is still the treatment chosen for CBD stones. In this study, our aim was to assess the outcome of primary closure of common bile duct over feeding tube after choledochotomy.

**Keywords:** Choledocholithiasis, feeding tube, primary closure.

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## INTRODUCTION

In the era of open Cholecystectomy, open common bile duct (CBD) exploration was the procedure of choice for CBD stones. However, with the availability of laparoscopic Cholecystectomy (LC) for Cholelithiasis, the treatment for CBD stone has changed and various options are now available. These include Endoscopic Retrograde Cholangiopancreatography (ERCP), laparoscopic CBD exploration (LCBDE) or open CBD exploration. Laparoscopic CBD exploration has all the advantages of minimal access and is also most cost effective compared to the other options<sup>13</sup>.

Choledocholithiasis develops in about 10–15% of patients with gallbladder stones<sup>4</sup> and literature suggests that common bile duct (CBD) stones are encountered in approximately 7–15% of patients undergoing Cholecystectomy<sup>5</sup>. Open exploration of the bile duct was the principal treatment for almost 100 years. In some hospitals of developing countries, surgeons are still performing this procedure because minimally invasive techniques like ERCP are not available<sup>6</sup>. Due to the lack of experienced endoscopists at smaller hospitals, patients need to be transferred to a larger centre for endoscopic diagnosis and treatment, which increases costs and patient discomfort<sup>7</sup>. The laparoscopic management of CBD stones is well known these days,<sup>8</sup> but remains controversial. This procedure is demands skills and equipment, and is therefore used by few surgeons<sup>9</sup>. Moreover, the superiority of this procedure for the treatment of CBD stones has not yet been proven, which limits its applicability<sup>10</sup>. Therefore open surgery is still a treatment of choice in many hospitals. The classical performance of bile duct exploration is associated with the problem of an incised bile duct closure. Choledochotomy followed by T-tube drainage is a

traditional surgical treatment for choledocholithiasis<sup>11</sup>. Although it is true that the T-tube has been used and has proven to be a safe and effective method for postoperative biliary decompression, it is not exempt from complications, which are present in up to 10% of patients<sup>12</sup>. The most frequent of these is bile leakage after removal, which is reported to occur in 1–19% of cases<sup>9,13–15</sup>. Some of these complications are serious, such as bile leak, tract infection or acute renal failure from dehydration due to inadequate water ingestion or a very high outflow, particularly in elderly patients. In addition, having bile drainage in place for at least 3 weeks causes significant discomfort in patients and delays their return to work<sup>16–18</sup>. Primary closure of the CBD after exploration is not new. Halstead first described the advantages of primary closure. There are many papers reported by different authors who support the direct closure of the duct immediately after exploration<sup>6,15,17,19,20</sup>. With the help of a choledochoscope during surgery, direct visualization of the CBD is possible and retained stones are not a problem. In our hospital, open CBD exploration is still the treatment chosen for CBD stones. In this study, our aim was to assess the outcome of primary closure of common bile duct over feeding tube after choledochotomy.

## MATERIAL AND METHODS

A prospective randomized study was done in between January 2013 to January 2015 on 25 patients of CBD STONE admitted in the Department of General Surgery, Mahatma Gandhi Medical College, Jaipur. All routine workup was done preoperatively. Cases were operated randomly by two different procedures.

### Inclusion Criteria

The patients were evaluated with routine investigations including full blood counts, liver function tests, coagulation screening and abdominal ultrasonography. The criteria for choledochotomy were obstructive jaundice, CBD stones suggested by ultrasound, or the presence of stones in the CBD palpated preoperatively.

- Radiographic/sonographic evidence of dilated ductal system.
- Radiographic/sonographic visualization of common bile duct stone.
- Inability to clear CBD stone by ERCP.

### Management protocol for suspected CBD stone

**Transcholedochal Approach:** After opening up of the Calot's triangle, the anterior surface of the CBD was dissected carefully, two fine 000 silk sutures are placed a few millimeters apart in its wall just below the entrance of cystic duct into common bile duct. The common duct is opened between the stay sutures with a sharp scalpel for about 1 cm. The opening is made parallel to the long

axis of the duct, avoiding a blood vessel commonly found in its anterior wall. The duct is held open and explored with a metal probe, such as Bakes dilator, which is directed downward to Vater's papilla and into the duodenum if possible. The stones were retrieved by spontaneous evacuation while incising the bile duct, blunt instrumental pressure with atraumatic forceps and milking, stone forceps or irrigation and suction. After stone removal, a feeding tube, No. 8 or 10 French, is inserted towards the liver, and warm saline is injected as the tube is withdrawn. The feeding tube is directed downward. A sudden increase in resistance will be encountered when it passes through Vater's papilla into the duodenum. Saline is gently injected, and if the tip of the tube is in the duodenum, the duodenum will balloon out. Once ductal patency has been established, the upper limb of feeding tube shortened and lower end can be felt clearly in the duodenum and gently left inside the common bile duct. The opening in the duct closed securely with fine 000 absorbable sutures. The gall bladder is then removed. Primary closure of CBD was done in cases where the ampulla was not violated and complete stone clearance was achieved. A sub hepatic drain was placed in all cases which was removed on 2nd postoperative day if drain was <30 ml/ day. Patients were discharged home on the 3rd or 4<sup>th</sup> postoperative day. We study the postoperative complications, postoperative hospital stay of treatment of all patients. Bile leakage is defined as any yellow bile-like fluid coming out of the sub hepatic drain or after the removal of the drain aspiration of yellow colored bile like fluid under ultrasound guidance from sub hepatic peritoneal space (300 mL).

## OBSERVATION AND RESULTS

A prospective cross sectional study was carried out in the Department of General Surgery of Mahatma Gandhi Medical College and hospital, Sitapura, Jaipur, over a period of 18 months (January 2013 to July 2015). A total of 25 patients were enrolled in this study with the aim to assess the outcome of primary closure of common bile duct over feeding tube after choledochotomy. The primary closure of the CBD was performed in 25 patients. Postoperatively, ultrasound and liver function tests were done. We study the postoperative complications, postoperative hospital stay of treatment of all patients.

### Demographic characteristics of patients

(Table no. 1) the demographic parameters of patients under study. The mean age of patients was 48.5±16.8 years, though variation in age was 25 to 72 years. Sex ratio (M: F) was 10:15. Twenty three patients (92%) were married. As for their education only 4 (16%) patients had college education, equal number 4 (16%), had completed

high school and rest were partially literate. Regarding employment status, 8 (32%) were employed, 5 (20%) were retired from service and balance were unemployed patients. In our study the mean age was  $48.5 \pm 16.8$  years and M: F ratio was 2:3 is comparable to study done by Ambreen M *et al*<sup>26</sup>. Females are more prone to males<sup>26</sup>.

#### Clinical Examination of studied population

Table no. 2 shows clinical examination of patients was carried out and the outcome was recorded. Jaundice was noticed in 13 (52%), Acute Cholecystitis 10 (40%), Biliary Colic 16 (64%) and Co-morbidities were diagnosed in 8 (32%) of patients.

#### Radiological Investigation of enrolled patients

Radiological Investigation of all the 25 patients was carried out. In addition MRCP examination of 3 (12%) patients was also conducted. The mean of number of CBD stones observed during examination in each patient was  $2.2 \pm 1.52$  and the mean diameter of CBD stones, was  $1.52 \pm 0.36$ . (Table no. 3)

#### Investigation of liver functioning of patients

Table no. 4 shows pre-operative liver function of each of the 25 patients was examined. Total bilirubin level was measured, the mean value of which was found to be  $4.3 \pm 3.64$  (mg/dL). Similarly the mean values of alkaline phosphate and serum glutamic pyruvic transaminase (SGPT) were also measured and recorded, the same were found to be  $565.25 \pm 319.50$  U/L and  $142.37 \pm 150.09$  U/L respectively.

#### Outcomes of surgery

As for Postoperative complications, in majority of the cases (92%) everything had gone smooth and there were no complications. It was only in 2 (8%) of the cases that Bile leakage was observed. In none of the other cases problems like Postoperative Jaundice, Retained stones, Recurrence of CBD stones, or Sub phrenic abscess were detected or subsequently reported. (Table no. 5) Ambreen M *et al*<sup>26</sup> reported one patient (6.3%) of bile leakage after primary closure, which subsided without any biliary peritonitis as compared to the T-tube group in which two patients (10.5%) had bile leakage. Postoperative jaundice was seen in one patient (5.3%) who had a T-tube because of a blockage of CBD. Not a single patient had a retained stone in both groups as well as no recurrence of CBD stones. Some studies reveal the similar fact of primary closure. Yamazaki *et al*<sup>22</sup> reported an incidence of 11.7% and 5.8% respectively, and an overall incidence of leakage was reported to be 14.3–38%. On the other hand, after primary closure, there were no bile leakage cases reported by other authors<sup>19,20</sup>. There were no major complications noted in any of our patients. There have been reports of intraperitoneal leakage with subsequent biliary peritonitis<sup>6,11,21</sup>. No such complication occurred in our patients and no deaths occurred in our

study. The reason for this was probably that we used choledochoscopy and did not probe the lower end of the CBD. These measures reduced the risk of biliary leakage. This is comparable to the data seen in the meta analysis<sup>27</sup>.

#### Hospital Stay and Cost

The mean Hospital stay days were  $5.1 \pm 1.1$  and the mean of subsequent follow-up months was  $5.62 \pm 0.7$ . (Table no. 6). This is comparable to Ambreen M *et al*<sup>26</sup> study, where we had seen the postoperative hospital stay after primary closure was  $5.56 \pm 1.1$  days as compared to after T-tube drainage which was  $13.6 \pm 2.3$  days. The median follow up duration for both groups was 6 months. There was a significant difference in postoperative hospital admission days and the total cost of treatment between our two groups. Authors reported that in a group where primary closure was performed, they remained in the hospital for a shorter period and were not burdened by a T-tube. In patients where the T-tube has been kept in place, there was the additional cost of postoperative Cholangiography<sup>26</sup>. In a developing country like India, this difference in expenditure has a major impact on public health. Literature<sup>17</sup> suggests that early discharge from hospital means an early return to work, which further has an indirect effect on the expenses of the patient. Other authors reported similar results<sup>6,17</sup> except in Japan where the number of hospital admission days was higher<sup>22</sup>.

#### DISCUSSION

Cholelithiasis develops in about 10–15% of patients with gallbladder stones<sup>21</sup> and literature suggests that common bile duct (CBD) stones are encountered in approximately 7–15% of patients undergoing Cholecystectomy<sup>5</sup>. There are two methods for extracting CBD stones either endoscopically, by endoscopic retrograde cholangiopancreatography (ERCP), or surgically, by an open or laparoscopic method. Open exploration of the bile duct was the principal treatment for almost 100 years. In some hospitals of developing countries, surgeons are still performing this procedure because minimally invasive techniques like ERCP are not available<sup>6</sup>. Due to the lack of experienced endoscopists at smaller hospitals, patients need to be transferred to a larger centre for endoscopic diagnosis and treatment, which increases costs and patient discomfort<sup>7</sup>. The laparoscopic management of CBD stones is well known these days,<sup>22</sup> but remains controversial. This procedure is demands skills and equipment, and is therefore used by few surgeons<sup>9</sup>. Moreover, the superiority of this procedure for the treatment of CBD stones has not yet been proven, which limits its applicability<sup>23</sup>. Therefore open surgery is still a treatment of choice in many hospitals. The classical performance of bile duct

exploration is associated with the problem of an incised bile duct closure. Choledochotomy followed by T-tube drainage is a traditional surgical treatment for choledocholithiasis<sup>11</sup>. Although it is true that the T-tube has been used and has proven to be a safe and effective method for postoperative biliary decompression, it is not exempt from complications, which are present in up to 10% of patients<sup>24</sup>. The most frequent of these is bile leakage after removal, which is reported to occur in 1–19% of cases<sup>9,13–15</sup>. Some of these complications are serious, such as bile leak, tract infection or acute renal failure from dehydration due to inadequate water ingestion or a very high outflow, particularly in elderly patients. In addition, having bile drainage in place for at least 3 weeks causes significant discomfort in patients and delays their return to work<sup>16–18</sup>. Primary closure of the CBD after exploration is not new. Halstead first described the advantages of primary closure. There are many papers reported by different authors who support the direct closure of the duct immediately after exploration<sup>6,15,17,19,20</sup>. With the help of a choledochoscope during surgery, direct visualization of the CBD is possible and retained stones are not a problem. In our hospital, open CBD exploration is still the treatment chosen for CBD stones. In our study we enrolled 30 patients underwent primary closure of common bile duct over feeding tube as stent tube that was comparable to other study (Tu Z *et al*<sup>6</sup>, Joshi MR *et al*<sup>25</sup>, Williams JA *et al*<sup>15</sup>). Some studies are mentioned below of primary closure vs T-tube drainage of CBD. Present study (2014) for 30 patients of primary closure to assess the outcome of primary closure of common bile duct over feeding tube after choledochotomy. This study was Prospective cross sectional study. Our results showed that primary closure of the CBD is performed safely in selected patients with improved patient care. Joshi MR *et al*<sup>25</sup> (2010) studied 71 patients in which 31- T tube drainage and 40- Primary closure and they conclude that Primary closure after the common bile duct exploration is safe and it helps to avoid the morbidities related to T-tube. Ambreen M<sup>26</sup> (2009) studied 35 patients 16- primary closure 19- T tube drainage to compare the clinical results of primary closure with T-tube drainage after open choledochotomy and assess the safety of primary closure for future application on a greater mass. That declares that Primary CBD closure is a safe and cost effective alternative to routine T-tube drainage after open choledochotomy. Tu Z *et al*<sup>6</sup> (1999) studied 19 patients for primary closure of the common bile duct that shows that Primary common bile duct closure is a safe alternative to routine biliary drainage. Seale AK *et al*<sup>17</sup> (1999) studied 89 patients of primary closure and show that primary closure of the common bile duct following mini Cholecystectomy is

safe and effective. Williams JA *et al*<sup>15</sup> (1994) studied 63 patients 37- primary closure 26- T-tube drainage and they carried out the results that Primary closure of the common bile duct is a reasonable alternative to T-tube drainage in selected cases.

**Table 1: Demographic characteristics of patients**

Demographic characteristics	Primary Closure (N=25)
Age (years)	48.5±16.8 (25-72)
Sex (M:F)	10:15
Married	23 (92%)
Local Resident	18 (72%)
Education Level	
Primary School	8 (32%)
Secondary School	9 (36%)
High School	4 (16%)
College and above	4 (16%)
Employment Status	
Employed	8 (32%)
Retired	5 (20%)
Unemployed	12 (48%)

**Table 2: Clinical Examination of patients**

Clinical Examination	Primary Closure (N=25)
Symptoms	
Biliary Colic	16 (64%)
Acute Cholecystitis	10 (40%)
Jaundice	13 (52%)
Co-morbidities	8 (32%)

**Table 3: Radiological Investigation of patients**

Radiological Investigation	Primary Closure (N=25)
USG	25 (100%)
MRCP	3 (12%)
No. of CBD stones	2.2±1.52 (1-6)
CBD diameter (cm)	1.52±0.36 (1.2-2.3)

**Table 4: Pre-operative liver function of patients**

Liver Function	Primary Closure (N=25)
Total bilirubin (mg/dL)	4.3±3.64 (1.9-12.5)
SGPT (U/L)	142.37±150.09 (35-550)
Alkaline phosphate (U/L)	565.25±319.50 (120-940)

**Table 5: Postoperative complication**

Complications	Primary Closure (N=25)
Bile Leakage	2 (8%)
Post-operative Jaundice	0 (0%)
Retained stones	0 (0%)
Recurrence of CBD stones	0 (0%)
Sub phrenic abscess	0 (0%)

**Table 6: Hospital stay and follow up of patients**

	Primary Closure (N=25)
Hospital stay (Days)	5.1±1.1 (4-7)
Follow up (months)	5.62±0.7 (4-6)

## CONCLUSION

In open choledochotomy, primary closure of the CBD is performed safely in selected patients with improved

patient care. Choledochoscopy ensures clearance of the CBD and eliminates the need for a T-tube. The number of hospital admission days is less and average cost of treatment is much lower than in the patients with a T-tube. From this study, we have concluded that after open surgery for CBD stones, primary closure of CBD is safe and effective with shorter hospital stays and lower costs.

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