



Hepatobiliary Surgery

PRIMARY CLOSURE VS T-TUBE DRAINAGE FOLLOWING LAPAROSCOPIC COMMON BILE DUCT EXPLORATION FOR CHOLEDOCHOLITHIASIS : A COMPARATIVE STUDY

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ABSTRACT

Background: Traditionally, Laparoscopic common bile duct exploration (LCBDE) was followed by removal of CBD stones and T-tube placement to drain the bile duct. However, T-tube drainage often lead to indwelling T-tube-related complications affecting patients' quality of life; or complications after T-tube removal which may require further interventions. Primary closure following LCBDE can avoid these T-tube related complications; however, the problems of bile leakage, residual CBD stones, and stricture still require attention. Therefore, this treatment remains controversial. This prospective study was performed to evaluate the safety and feasibility of primary closure as opposed to T-tube drainage following LCBDE for the treatment of choledocholithiasis. **Methodology:** 40 consecutive patients who underwent laparoscopic cholecystectomy (LC) with LCBDE via choledochotomy, for cholelithiasis with choledocholithiasis, were included in the study. 20 patients had primary closure (PC) done, whereas 20 patients underwent T-tube drainage (TD). The median follow up duration for both groups was 6 months. The peri-operative and follow-up outcomes of the two groups were compared. **Results:** After primary closure of the CBD, bile leakage was noted in 1 patient, which subsided without any biliary peritonitis, as compared to the T-tube group in which 2 patients had bile leakage. Postoperative jaundice was seen in 1 patient who had a T-tube, because of a blockage. Not a single patient had a recurrence of CBD stones in both groups. Residual stones were found in 1 patient after PC. None of the patients developed a biliary stricture in either group. There was no post-operative mortality in any group. Mean operating time was higher in TD than in PC. There was no significant difference between the two groups in the rates of conversion to open procedure (laparotomy). The postoperative hospital stay after PC was 5.1 ± 2.0 days as compared to after TD which was 7.2 ± 2.6 days. The total cost of treatment in patients who underwent PC was comparatively less than those who underwent TD. **Conclusion:** Primary CBD closure is a safe and more cost effective alternative to routine T-tube drainage after Laparoscopic CBD exploration, with shorter hospital stays.

KEYWORDS : Laparoscopic common bile duct exploration, choledocholithiasis, T-tube, primary closure**INTRODUCTION**

Choledocholithiasis has an incidence of 1-15% & is present in 5-30% of patients of cholelithiasis. It can lead to complications which may be life threatening, thus timely surgical intervention is required.[1]

In recent times, the management of CBD stones has risen from conventional open surgical approach to laparoscopic & endoscopic approaches. With the rapid advancement of minimally invasive surgical techniques, laparoscopic CBD exploration (LCBDE) has become a widely accepted surgical approach for patients with gallbladder and CBD stones

Traditionally, LCBDE was followed by T-tube placement to drain the bile duct. However, T-tube drainage often lead to indwelling T-tube-related complications affecting patients' quality of life; or complications after T-tube removal which may require further interventions. Primary closure following LCBDE can avoid these T-tube related complications; however, the problems of bile leakage, residual CBD stones, and stricture still require attention. Therefore, this treatment remains controversial.

AIMS & OBJECTIVES

This prospective cohort study was performed to compare the safety and feasibility of primary closure as opposed to T-tube drainage following laparoscopic common bile duct (CBD) exploration for the treatment of choledocholithiasis in terms of the peri-operative & follow up outcomes of the two groups

MATERIALS AND METHODS

Study design- prospective comparative study

Study population-

A total of 40 patients hospitalized in the department of general & minimal access surgery of Jaipur Golden Hospital, for choledocholithiasis with cholelithiasis, who underwent laparoscopic cholecystectomy(LC) with laparoscopic CBD exploration(LCBDE) via choledochotomy & subsequent choledochoscopy, from May 2022 to June 2023, were included in the study

Patient grouping-

These patients included in the study (n=40) were divided into 2 groups according to management protocol [Fig. 1]

20 patients had primary closure of CBD done and comprised the PC group (n=20) whereas 20 patients who underwent T-tube drainage comprised the TD group (n=20)

The median follow up duration for both groups was 6 months

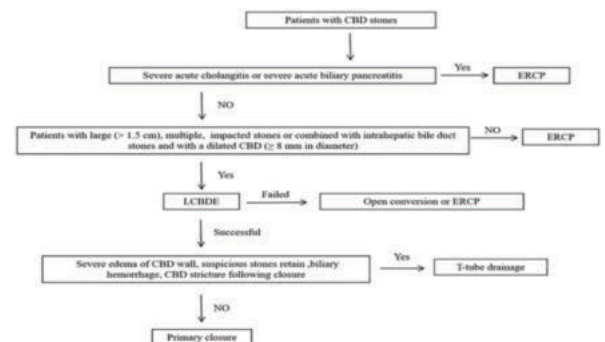


Fig 1 : Flowchart for the management of CBD stones (ERCP= endoscopic retrograde cholangiopancreatography)

Inclusion Criteria :

1. Definitive preoperative diagnosis of choledocholithiasis
2. CBD diameter ≥ 8 mm
3. Favorable general condition, good function of vital organs, and tolerance of general anesthesia

Exclusion Criteria :

1. Preoperative complications like gall bladder perforation requiring emergency surgery
2. Severe acute obstructive or suppurative cholangitis
3. Acute pancreatitis
4. Severe upper abdominal adhesions hindering insertion of laparoscopic devices or establishment of pneumoperitoneum
5. Tumor in the biliary tract
6. CBD stricture
7. Internal fistula of the biliary and digestive tracts
8. Malignancy

Data Collection:

The following data were collected for both groups of patients

Preoperative parameters:

age, sex, comorbidities, white blood cell (WBC) count, liver function parameters, CBD diameter, number of CBD stones, state of the gallbladder, and concomitant acute pancreatitis/severe acute cholangitis

Intraoperative parameters:

operating time and ratio of and reason for conversion to open surgery (laparotomy)

Postoperative parameters: hospital stay, post-operative complications and mortality

Follow-up parameters: residual/retained CBD stones, stone recurrence, biliary stricture, and carcinogenesis

The patients were evaluated with complete blood counts, liver function tests and coagulation profile. CBD stones were confirmed by preoperative abdominal ultrasonography ± magnetic resonance cholangiopancreatography (MRCP). The diagnosis and severity assessment of acute cholangitis were defined according to the Tokyo Guidelines based on a combination of clinical features, laboratory data and imaging findings. Once the diagnosis was confirmed, the initial treatment with adequate fluid replacement, intravenous analgesics and antibiotics, was provided to all patients.

Surgical Procedure:

The standard four-trocar operative technique was used for LCBDE. The operation was started with dissection of Calot's triangle. The cystic artery and cystic duct were clipped and cut off. After antegrade excision, the gallbladder was removed through the main operating port. Next, the supraduodenal portion of CBD was opened through a longitudinal incision made along its anterior wall, between two stay sutures; keeping the size of the incision at least as large as the diameter of the largest stone. A 5-mm flexible choledochoscope was inserted via this choledochotomy, for CBD exploration. Stones were extracted using saline irrigation or a Dormia basket. After complete removal of the stones, choledochoscopy was performed repeatedly to confirm the clearance of the intrahepatic/extrahepatic bile ducts and the condition of distal CBD and sphincter of Oddi.

In the PC group, the choledochotomy was closed using 4–0 PDS sutures in an intermittent fashion. In the TD group, a silicone T-tube of appropriate size (16–22 Fr) was inserted into the CBD, followed by closure using the same suture technique. Saline was flushed through the T-tube to rule out leakage. The abdominal cavity was repeatedly flushed with normal saline. The operation was completed after inserting a non-suction drain in the subhepatic space, which was removed after 72–96 hrs if there was no bile leakage postoperatively. At 6 weeks postoperatively, the T-tube drained patients underwent T-tube cholangiography followed by T-tube removal after confirming that no remnant stones or stenosis of the bilc duct was present.

Follow Up :

The patients of both groups were followed up by outpatient visits at 6, 12 and 24 weeks. In the TD group, T-tube cholangiogram was done at 6 weeks postoperatively, to check for residual stones, biliary stricture, and T-tube location. Both groups of patients underwent abdominal ultrasonography by a single sonographer and ultrasound device every 6 weeks to check for residual or recurrent biliary stones, biliary stricture, and carcinogenesis; if imaging revealed anything suspicious, MRCP or enhanced computed tomography was performed for further diagnosis.

Table 1: Demographic And Clinical Characteristics Of The Two Groups

Pre-operative Parameters	PC group (n=20)	TD group (n=20)	P value
Age (yrs)	48 ± 15	45 ± 17	0.55 NS
Sex (Male/Female)	2 (10%)/ 18 (90%)	4 (20%)/ 16 (80%)	0.37 NS
Co-morbidities	5 (20%)	3 (15%)	0.49 NS
Biliary colic	12 (60%)	16 (80%)	0.16 NS
Jaundice	7 (35%)	8 (40%)	0.74 NS

Fever	8 (40%)	10(50%)	0.52 NS
Concomitant gallstones	18 (90%)	19(95%)	0.54 NS
WBC count (x10 ³)	10.5± 2	8.6±5	0.12 NS
Total bilirubin (mg %)	3.2 ± 1.6	2.5 ± 1.9	0.42 NS
ALP (U/L)	195 ± 88.5	211 ± 87.8	0.56 NS
GGT (U/L)	220 ± 100.2	230 ± 96.4	0.75 NS
Number of CBD stones	2.5 ± 1.5	3.6 ± 2.3	0.08NS
CBD diameter (mm)	12 ± 2.6	10.5 ± 2.8	0.08 NS

RESULTS

Preoperative parameters-

Statistical analysis showed no significant differences in the demographic characteristics and/or clinical presentations between the two groups. [Table 1]

Preoperative And Follow-up Outcomes

The preoperative and follow-up outcomes are summarized in table 2. After primary closure of the CBD, self limiting bile leakage was noted in 1 patient, which regressed by 3rd postoperative day without any biliary peritonitis, as compared to the T-tube group in which 2 patients had bile leakage- one was managed conservatively with extended drainage and IV antibiotics, while the other developed a biliary collection that required USG guided drainage. Postoperative jaundice was seen in 1 patient of TD group, because of blockage of the duct by the T-tube; which gradually subsided on removing the T-tube. Mean operating time was higher in TD than in PC. There was no significant difference between the two groups in terms of the rates of conversion to open procedure (laparotomy). One patient had a residual stone following primary closure, which was detected on postoperative imaging and was removed by ERCP.

Table 2: Peri-operative And Follow Up Outcomes Of The Two Groups

Parameters	PC group (n=20)	TD group (n=20)	P value
Operating Time	112 ± 36 mins	145 ± 40 mins	0.009 HS
Conversion To Open	2(10%)	1(5%)	0.54 NS
Bile Leakage	1(5%)	2(10%)	0.54 NS
Post-operative Jaundice	0	1(5%)	0.31 NS
Residual Stones	1(5%)	0	0.31 NS
Recurrent Stones	0	0	-
Biliary Stricture	0	0	-
Post-operative Hospital Stay	5.1 ± 2 days	7.2 ± 2.6 days	0.007 HS
Post-operative Mortality	0	0	-
Total Cost Of Treatment (in Rs)	150024±23482	205345±32045	0.005 HS
Time Until Return To Work	12 ± 4 days	20 ± 7 days	<0.001 HS
Re-admission Within 30 Days	0	1(5%)	0.31 NS

HS= highly significant, NS= not significant

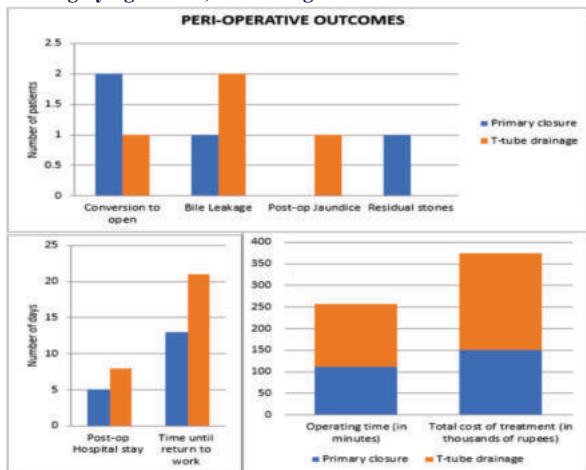


Fig 2 : Peri-operative Outcomes Of The Two Groups

DISCUSSION

It is known that insertion of a T-tube was meant to prevent bile leakage or bile duct stenosis or provide access to remove retained stones or

provide an effective biliary decompression in cases of incomplete stone removal after choledochotomy closure following LCBDE.[2] However, an indwelling T-tube has its own complications like drain site pain, fluid & electrolyte disturbances, bile leakage, premature dislodgement, retrograde biliary infection or wound infection or even sepsis. Even after removal, it can lead to localised pain, biliary peritonitis, persistent/prolonged biliary fistula or late bile duct stricture formation; which necessitate further intervention(s) or even re-operation. [3] Therefore, T-tube drainage not only fails to reduce postoperative complications but also increases the risk of postoperative complications. With respect to bile leak, which was the most common postoperative complication after T-tube drainage removal or its accidental dislodgement, the incidence between the two groups was not statistically significant. Our findings indicated that primary closure did not increase the risk of postoperative bile leak, while the insertion of T-tube did not prevent the occurrence of bile leakage. Some studies showed that slender CBD and inexperienced surgeons were the high risk factors for bile leakage after primary closure following LCBDE.[4] Hence, we employed a careful selection criteria before considering primary closure in the study patients. Primary closure was carried out only if : CBD stones were confirmed by preoperative MRCP or CT with no intrahepatic bile duct stone, CBD diameter ≥ 8 mm, number of stones ≤ 5 , no obvious inflammatory changes of CBD detected intraoperatively, normally functioning Oddi sphincter without residual stone confirmed by intraoperative flexible choledochoscopy, no biliary haemorrhage.[5,6]

There were no significant differences in the incidence of retained stones between the two groups. The incidence of retained stones went down to 5% (1 in 20) in the PC group, with the use of choledochoscopy \pm lithotripsy. So we felt it was unnecessary to use T-tube for cholangiography and extraction of residual stones, and residual stones could be removed by endoscopic sphincterotomy after primary closure.[7] There was no incidence of recurrence of biliary stones, or of development of biliary strictures or carcinogenesis in either group. The overall T-tube related complication rate experienced in our study was 20% (4 in 20) which is consistent with previous studies on the same.[8,9] There were no major complications or deaths encountered in our study patients.

As regards operating time, the study found that patients who underwent PC had shorter operating times than those with TD. This is understandable as additional time is needed to insert and place the T-tube, and the procedure is an extra step during surgery compared with primary closure. In our view, subsequent closure techniques after insertion of the T-tube were more complex to perform than primary closure.

In terms of postoperative hospital stay and total cost of treatment, the PC patients had significantly shorter hospital stay and less medical expenditure as compared to the TD group. TD patients need a longer time for postoperative recovery, to overcome T-tube related postoperative complications and in ensuring the patency of the T-tube. Absolutely, an extended hospital stay would increase the hospital expenses. The additional cost of T-tube cholangiography was also a contributing factor. Further, the burden of carrying around the T-tube, even after discharge from hospital, reduced the quality of life and prolonged the time to return to full physical activity, of the TD patients significantly.

CONCLUSION

Primary closure of the CBD without a T-tube drainage is a safe alternative to T-tube placement in the CBD after laparoscopic choledochotomy, as it minimizes the surgical trauma, dramatically improves the patients' quality of life after operation, hastens the patient's recovery, and reduces the need for hospitalization. The non-inferiority of primary closure is an important finding of this study. Primary closure is thus a safe and feasibly effective alternative to routine T-tube drainage in selected patients of choledocholithiasis undergoing LCBDE. However, larger RCTs that compare primary duct closure and T-tube insertion are still required to validate these observations. Also, it is necessary to prolong the follow-up duration to further evaluate the incidence of long term complications like biliary stricture and recurrent stones between the two groups.

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