

## T-Tube Drainage Versus Primary Duct Closure After Open Common Bile Duct Exploration In Management of Choledocholithiasis

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### ABSTRACT

**Objective:** To determine the outcomes of T-Tube drainage versus Primary Duct Closure after open common bile duct exploration in management of choledocholithiasis.

**Study Design:** Quasi-Experimental study.

**Place and Duration of Study:** Department of Surgery, Combined Military Hospital, Kharian Pakistan, from Aug 2019 to Jul 2022.

**Methodology:** All patients aged 26-64 years of either gender and undergoing open Common Bile Duct exploration for choledocholithiasis, were recruited in the study. Group-A consisted of 30 patients who underwent T-tube drainage, while Group-B consisted of 30 patients who underwent primary ductal closure.

**Results:** Total 60 patients were included in the study ranging from 26–64 years. There were 49(81.6%) females and 11(18.3%) males. Operative time in Group-A was 118.2±5.06 minutes, whereas, in Group-B it was 100.37±2.93 minutes. The duration of sub hepatic drain in Group-A was 16.37±1.75 days, and in Group-B was 7.47±2.71 days. In Group-A, hospital stay was 17.07±1.92 days, and in Group-B, the average hospital stay was 9.61±2.63 days. The total number of complications in Group-A was 05(16.7%). Total complications in Group-B were 02(6.67 %).

**Conclusion:** Primary closure of CBD is a safe and effective alternative to T-tube drainage in selective patients. Our study recommends the use of the primary closure technique strongly except for cases where the distal patency of CBD is doubtful.

**Keywords:** Common bile duct, Choledocholithiasis, Primary duct closure, T-Tube drainage.

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### INTRODUCTION

The term “Choledocholithiasis” is interpreted as the presence of gallstones in the extra hepatic biliary tree, which comprises of Common Hepatic Duct (CHD) and Common Bile Duct (CBD).<sup>1</sup> Choledocholithiasis is found in approximately 5% to 19% of patients with symptomatic cholelithiasis.<sup>2</sup> Biliary pancreatitis, obstructive jaundice and acute cholangitis are the potential complications linked with choledocholithiasis. In Pakistan, one study published in 2004 found the total incidence of gall stone disease to be 9.03%.<sup>3</sup> Another study published in 2021, found slightly higher prevalence of gallstone disease among people of Gujranwala.<sup>4</sup>

These CBD stones can be addressed with endoscopic techniques, laparoscopic or open common bile duct exploration.<sup>5</sup> Open CBD exploration is still one of the standard treatment options for choledocholithiasis, particularly in the cases where

Endoscopic Retrograde Cholangiopancreatography (ERCP) and advance laparoscopy is not successful or not available.<sup>6</sup>

After Open exploration, CBD can be closed with T-tube drainage, duct closure without T-tube drainage or choledochoduodenostomy.<sup>7</sup> T-tube drainage has been considered a fundamental, as it provided CBD decompression, a tract for future cholangiogram and removal of any residual stones. T-tube drainage corresponded with significant success rate.<sup>8</sup> However, T-tube is also linked with certain complications, including T-tube displacement, electrolyte imbalances, prolonged hospital stay, precipitation of CBD stone formation and stricture formation.<sup>9</sup> Moreover, T-tube removal is also linked with a few cases of biliary peritonitis, which is a life-threatening complication. The overall complication rate of T-tubes is estimated to be 11.29 %. However, recent studies have emphasized that primary duct closure curtails the hospital stay as well as the complications related to T-Tube drainage.<sup>10</sup> The study was conducted to determine the outcomes of T-Tube drainage versus Primary Duct Closure after open common bile duct exploration in management of choledocholithiasis.

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## METHODOLOGY

The quasi-experimental study was conducted in Department of General Surgery, Combined Military Hospital, Kharian, Pakistan from August 2019 to July 2022, after obtaining approval from the Institutional Ethical Review Committee (Certificate No. 512, dated 30-07-019). Sample size was calculated using WHO calculator, with anticipated proportion of bile leak in Group-A as 2.4% and anticipated proportion in Group-B as 2.6%.<sup>9</sup>

**Inclusion Criteria:** Patients aged 26 to 64 years, of either gender with choledocholithiasis were who had CBD stone verified by abdominal USG or magnetic resonance cholangiopancreatography (MRCP), with no stones in intrahepatic biliary channels, a CBD diameter greater than 8 mm and no distal common bile duct obstruction were included.

**Exclusion Criteria:** Patients with history of pancreatitis, cholangitis, Mirizzi syndrome, cholangiocarcinoma or stricture in any part of biliary tree, pregnant women and those with history of previous biliary surgery are also excluded from study.

The total sample size came out to be 60 cases with 30 patients in each group. Informed Consent was taken from all the participants of the study. Patients were recruited using non-probability convenience sampling, and written, informed consent was sought prior to data collection. Patients were split into two groups using the lottery method. Patients in Group-A underwent open CBD exploration and T-tube drainage, whereas Group-B patients underwent primary ductal closure (Figure). All selected patients underwent a cholecystectomy followed by exploration of CBD by longitudinal supraduodenal choledochotomy using stay sutures. After achieving ductal clearance, CBD was irrigated with normal saline to establish distal patency. Free flow of saline into duodenum was ensured. 12 F gauge T-tube was placed in Group-A patients. T-tube cholangiogram was performed on 14th post-operative day. T-tube was removed after getting a clear bile flow into duodenum on cholangiogram. Primary closure of CBD was carried out with No. 3-0 PDS (polydioxanone) suture in Group-B patients. Sub hepatic drain was placed in all the patients.

Outcomes were evaluated in terms of bile leakage or peritonitis. Bile leakage was examined by the output of sub hepatic drain or sub hepatic collection and biliary peritonitis was detected by abdominal pain, fever, tachycardia, rising Total Leukocyte Count

and any intra peritoneal collection. Sub-hepatic drain time was counted in days. Operative time was estimated in minutes, commencing from time of incision to the completion of operation. Hospital stay was numbered in days beginning from the day of operation till discharge of patient. The patients were followed up at 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 28<sup>th</sup> day of discharge from hospital. Skin stitches were removed on 10th post-operative day.

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Quantitative variables including age of patients, operation time, duration of hospital stay and days of sub-hepatic drain, were interpreted using mean and Standard Deviation and student t-test, while qualitative variable including wound infection and biliary leakage, were expressed as frequencies and percentages, and Chi-square test was applied. The *p*-value of  $\leq 0.05$  was perceived as significant.

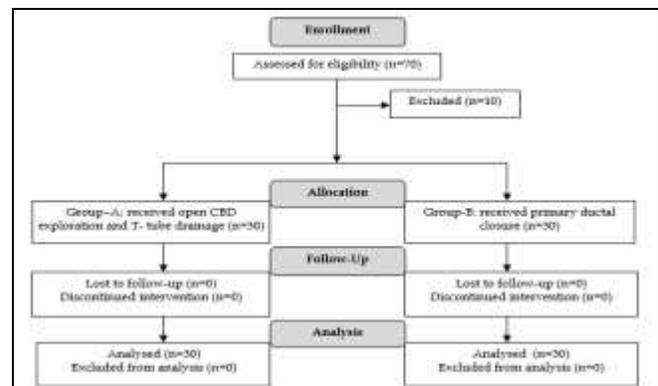


Figure: Patient Flow Diagram (n= 60)

## RESULTS

Out of 60 patients, 49(81.6%) were female and 11(18.3%) were male. Minimum and maximum ages were 26 and 64 years and mean age was  $47.05 \pm 8.26$  years. The total procedure time for Group-A was  $118.2 \pm 5.06$  minutes, whereas, for Group-B mean procedure time was  $100.37 \pm 2.93$  minutes. According to *p*-value ( $<0.001$ ) mean operative time was lesser for primary ductal closure patients in Group-B, as compared to T-tube drainage patients in Group-A. In Group-A, the duration for sub hepatic drain was  $16.37 \pm 1.75$  days (ranging from 15 to 20 days) and duration span of drain in Group-B was  $7.47 \pm 2.71$  days (ranging from 05 to 14 days). This data illustrates that time span for sub hepatic drain was significantly ( $p < 0.001$ ) short for Group-A (Primary closure) as

compared to Group-B (T-Tube drain). In Group-A, the average duration of hospital stay was 17.07±1.92 days (ranging from 15-21 days) and in Group-B, the average hospital stay was 9.6±2.6 days (ranging 06-15 days). The difference across both groups was statistically significant. This has been summarized in Table-I.

In Group-A, two patients (6.66%) developed superficial wound infection, in Group-B, one case (3.33%) had superficial surgical site infection. Wound infections were superficial in all cases and responded to conservative measures. In Group-A, two cases (6.66%) developed biliary leakage, in Group-B, no patient developed biliary leakage. The cases of biliary leakage in Group-A were managed successfully without intervention, by keeping sub-hepatic drain for 20 days. In Group-A, one patient (3.33%) had post-operative jaundice, but his post-operative cholangiogram on 14th day, did not reveal any residual stone. In Group-B, one case (3.33%) had developed post-operative jaundice, but MRCP showed no residual stone in MRCP. Post-operative jaundice responded by conservative measures. The total number of complications in Group-A (T-Tube drainage) was 05 (16.7%). Total complications in Group-B were 02(6.67 %) (Table-II).

**Table-I: Comparison Of Surgical Outcomes Of T-Tube Drainage And Primary Ductal Closure (n=60)**

Surgical Outcomes	Group-A (n=30)	Group-B (n=30)	p-value
	Mean±SD	Mean±SD	
Operative Time (Minutes)	118.2±5.06	100.37±2.93	<0.001
Sub Hepatic Drain (Days)	16.37±1.75	7.47±2.71	<0.001
Hospital Stay (Days)	17.07±1.92	9.61±2.63	<0.001

**Table-II: Comparison Of Complications Of T-Tube Drainage And Primary Ductal Closure (n=60)**

Complications	Group-A (n=30)	Group-B (n=30)	p-value
	n (%)	n (%)	
Wound Infection	2(6.66%)	1(3.33%)	0.554
Biliary Leak	2(6.66%)	0	0.150
Post-Operative Jaundice	1(3.33%)	1(3.33%)	1.000
Total	5(16.7%)	2(6.67%)	0.229

None of the patients showed any clinical sign of biliary peritonitis in either treatment groups. No patient in the study developed acute cholangitis, hemorrhage, intra-abdominal abscess or acute pancreatitis. There was 0% mortality in this study. There was no recurrence of CBD stones seen on the

follow up of patients in both groups up to 6 months follow up.

**DISCUSSION**

Conventionally, the exploration of the CBD culminates in the placement of a T-tube. The T-tube drainage decompresses the biliary tree and diminishes the risk of bile leakage. It also serves as a tract for imaging of biliary tree by cholangiography. It also acts as a route for extraction of any residual stones.<sup>11</sup> In spite of, these promising advantages, complication rates of T-tube have been approximated to 11.29%.<sup>12</sup> The T-tube-related complications include T-tube displacement, biliary leakage, persistent biliary fistulas, CBD stenosis and recurrent CBD stones. Currently, there are plenty of concerns pertaining to the judiciousness of T-tube drainage. There is rising drift of opinion towards primary ductal closure. Many authors have endorsed primary closure of the CBD, as it is safe and is associated with a lesser complication rate.<sup>13</sup> The prerequisites for a safe primary ductal closure include distal patency, complete CBD clearance, normal pancreas and free flow of saline into duodenum.

In our study, mean operative time in Group-A (T-tube drainage) was 118.2±5.06 minutes, and mean procedure time of Group-B (Primary closure) was 100.37±2.93 minutes. Statistical analysis revealed that mean operative time was reduced in patients who had primary closure as opposed to those who underwent T-tube drainage. Khan *et al.* presented that the overall procedure duration was evidently longer in the T-tube Group-As compared to primary repair group and is in resemblance with the findings of our study.<sup>14</sup>

The time span for sub hepatic drain in Group-A was 16.37±1.75 days and in Group-B it was 7.47±2.71 days. In Group-A minimum and maximum time for sub hepatic drain was 15 and 20 days while in Group-B this duration was 5 and 14 days respectively. This data illustrates that sub hepatic drain was kept for longer period in group-A (T-Tube drainage) as contrast to Group-B (Primary ductal closure). Khan *et al.* expressed in their study that the sub hepatic drain was kept for longer duration in the T-tube drainage patients, and this finding is also in accordance with our study.<sup>14</sup>

Mean hospital stay in Group-A was 17.07±1.92 days and in Group-B mean hospital stay was 9.6±2.6 days. Patients who were treated with primary ductal closure were found to have a shorter hospital stay. Similar results were replicated in the studies

conducted by Ambreen *et al.*<sup>15</sup> and Gad *et al.*<sup>16</sup>, with Primary closure patients spending less time in hospital post operatively.

T-Tube drainage has been linked with significant complications. Therefore, primary repair of CBD without T-tube has been favored in literature. Wang *et al.*<sup>12</sup> in their study cited the overall complication rate of T-tube to be 11.29 %, which is similar to our complication rate of 9.98%. Two patients (6.66%) in Group-A, and one patient (3.33%) in Group-B, developed superficial wound infection. Surgical site infections resolved completely using conservative measures. Deo *et al.* in their study estimated the superficial surgical site infection rate to be 10%.<sup>17</sup>

Biliary leakage occurred in two cases (6.66%) in Group-A, but in none in Group-B. Both the patients of biliary leakage presented as sub hepatic collection and were managed conservatively by keeping sub-hepatic drain for 20 days. Yildirim *et al.* in their study estimated the biliary leak to be 5.1 % in patients undergoing open CBD exploration.<sup>18</sup> One patient (3.33%) in Group-A manifested post-operative jaundice, but his post-operative cholangiogram 02 weeks after surgery, revealed no residual stone in bile duct. In Group-B, post-operative jaundice was also observed in one patient (3.33 %). However, post-operative MRCP did not disclose any residual stone in CBD. Post-operative jaundice in both patients improved with medication. The total number of complications in Group-A (T-Tube drainage) was 05(16.7%). Total complications in Group-B were 02(6.67 %). The overall complication rate in our study for both groups was 9.98 %. Tan *et al.* in their study demonstrated the overall complication rate to be 7.4%.<sup>19</sup>

In both treatment groups, no clinical sign of biliary peritonitis was recognized post operatively. Acute cholangitis, intra-abdominal abscess, hemorrhage or acute pancreatitis were not reported in any patient. No mortality was observed in this study. Up to a 6-month follow-up, neither group of patients presented with recurrence of CBD stones. In their study, Qin *et al.* did not notice any complication like biliary peritonitis, cholangitis, pancreatitis or residual stone, which is in resemblance with the results of our study.<sup>20</sup>

According to our experience in this study, we found that primary closure did not enhance the incidence of post-operative biliary leakage. Procedure time, hospital stay and duration of sub hepatic drain

were curtailed in Primary Duct Closure group. Additionally, with Primary Closure, we could absolutely avert the complications linked to T-tube. As a result, we can draw the conclusion that primary closure, which does not require a post-operative cholangiogram, is a practical, safe, and an economical alternative. If the diameter of the CBD is greater than 08 mm and distal CBD's patency is established, Primary Duct Closure should be recommended in most cases after CBD exploration.

### CONCLUSION

In open CBD exploration for choledocholithiasis, carefully selected individuals can undergo primary closure of the CBD. Hospital stay, operative time and drain duration are significantly lower in primary closure Group. It also eliminates the requirement of post-operative cholangiogram. We have concluded that Primary Closure of CBD is safe and effective alternative to T-tube drainage.

**Conflict of Interest:** None.

### Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

FSM & IA: Conception, study design, drafting the manuscript, approval of the final version to be published.

WA & YA: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

AM & MAZ: Data interpretation, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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