Original Research Article

**PRIMARY CLOSURE VERSUS CLOSURE OVER T-TUBE AFTER OPEN CHOLEDOCHOLITHOTOMY**

**Abstract:**

**Background:** Choledocholithotomy followed by closure over a T-tube has long been a standard surgical treatment for choledocholithiasis. However, several authors have supported the primary closure of the duct immediately after exploration. This study was conducted to compare the clinical short-term outcomes of primary closure of common bile duct and T-tube drainage.

**Methods:** This prospective comparative study was conducted at the Department of Surgery, Mymensingh Medical College and Hospital, from January 2021 to June 2022. A total of 50 clinically diagnosed cases of choledocholithiasis patients after fulfilling the inclusion criteria were included and purposively divided in primary closure group (Group I, n=25) and closure over T-tube group (Group II, n=25). All patients were in evaluated by history, physical examination and investigation. The data was collected in a semi structured questionnaire. Finally data analysis was done by SPSS 26 version. A standard guideline was followed during post-operative management.

**Result:** The mean (±SD) age of patients were 48.5±8.60 and 48.20±9.86 years in primary closure and T-tube closure respectively with female predominance (72% and 60% primary closure and T-tube closure group respectively). There was a significant difference found between group-I & group-II regarding mean operative time (87.8±4.58 vs 102.2±3.82 mins, p<0.001) and length of hospital stay (5.64±1.36 vs 15.08±1.32 days, p<0.001). There was no significant difference between group-I and group-II patients regarding post-operative early complications. T-tube related complications were only seen in group-II.

**Conclusion:** Primary closure has similar post-operative complications but shorter duration of operation and length of hospital stay than T-tube closure in the treatment of CBD stone after open choledocholithotomy.

Key words*: primary closure,T-tube closure, choledocholithotomy*

**Introduction:**

Choledocholithiasis is the presence of stones in the common bile duct (CBD) (Abd Wahid et al, 2022). CBD stones are found in 6-12% of patients with stones in the gall bladder, either secondary i.e. migrate from the gall bladder (90%) or form primarily within the bile ducts themselves (10%) (Haisley and Hunter, 2019). To avoid serious complications that can occur in choledocholithiasis, these stones should be removed (Cianci and Restini, 2021). The conventional management of choledocholithiasis is surgical via a supraduodenal choledocholithotomy ( Khan et al, 2017). T-tube insertion is a common practice in open CBD exploration (Podda et al,2016). It has been the main treatment modality for CBD stones for many years.

T-tube placement is based on hypothesis that it provides postoperative decompression of the CBD, allows radiological visualization of the CBD and potential route for extraction of any retained stone (Seervi et al, 2020; khan et al, 2017; Barband et al, 2015).

But potential of complications exists with this therapeutic modality which include bile leakage and biliary peritonitis, bacteremia, cholangitis, wound infection, dislodgement of tube, obstruction and or fracture of the tube, retained T-tube and difficulty on removal of the tube, fluid and electrolytes imbalance due to continuous external drainage of bile (Khan et al, 2017). Moreover there may be persistent external bile discharge and skin excoriation after T-tube removal and patient may need to carry it for several days after removal (Zhu et al, 2011).Significant bile leak after T-tube removal can occur in 1-30% of cases. The duration of T-tube drainage is variable and can range from 7–45 days depending on individual preference (Pattanshetti et al, 2021).

Although not widely and routinely practiced, primary closure of the CBD after exploration is not new. This method claims to have no significant serious morbidity. Many advantages of primary closure include shorter hospital stay, associated with fewer postoperative complications, less need for reintervention than T-tube drainage and no pain due to T-tube (Khan et al,2017; Carvalho et al). Primary closure avoids T-tube insertion and disadvantages associated with the use of T-tube. Disadvantages of primary closure are loss of decompression of CBD and failure to extracts any retained stone (Gurusamy and Samraj 2009).

In absence of resources and training, open choledocholithotomy is advocated instead of laparoscopic one. And then the explored common bile duct (CBD) needs to be closed. The option lies between closure over a T-tube or primary closure. Each procedure has its own advantages and disadvantages. However, in many places, routine use of a T-tube following CBD exploration remains standard practice. On the other hand history of primary closure of CBD is also practiced to overcome adverse consequences of T-tube. This study was performed with the aim to compare the outcomes between primary closure and T-tube drainage after CBD exploration in terms of mean operation time, post-operative morbidity and hospital stay. So, this study may guide us towards the judicious and right pathway for the betterment of the patient.

**Materials and method:**

This prospective comparative study was conducted in Department of Surgery, Mymensingh Medical College Hospital. Mymensigh, Bangladesh from January 2021 to June 2022. Considering the inclusion and exclusion criteria 50 patients were selected purposively for the study.

**Inclusion criteria:**

• Diagnosed cases of choledocholithiasis.

• Patients age more than 18 years.

**Exclusion criteria:**

• Associated acute pancreatitis.

• Hepaticolithiasis .

• Sepsis.

• Patient with biliary stricture

The study population was divided into two groups:

**Group-Ⅰ** consisted of 25 patients with primary closure

**Group-Ⅱ** consisted of 25 patients with closure over T-tube.

Preoperative evaluation by detail history and clinical evaluation then relevant investigations were done to confirm the fitness for reversion and fitness for anaesthesia. The surgical management was done as primary closure (Group I) and closure over T tube (Group II). Prophylactic I.V. antibiotic was administered just before giving incision. All patients were operated under General anaesthesia. All patients were followed up postoperatively with daily routine examinations according to SOAP protocol that include question about abdominal pain, fever, abdominal examination, status of jaundice, T tube bag collection, sub hepatic collection, wound checking etc. Postoperative care was performed according to the findings of the clinical examination and the principles and standard of the department. Postoperative complications, death and so forth were evaluated. Data were collected using a data collection sheet containing all the variables of interest.

All data were analyzed SPSS 26.0 (Statistical Package for Social Sciences) for Windows. Categorical data was reported as numbers and percentage (%) and quantitative data expressed as mean and standard deviation. Significant test of categorical variables was performed with Chi-square test and quantitive data by unpaired t-test with 95% confidence interval to make inference. A p value <0.05 was considered statistically significant.

**Results:** The present prospective comparative study was carried out at the Department of Surgery in Mymensingh Medical college Hospital. The study population was divided into two groups each containing 25 patients. The mean age of the patient were 48.5±8.60 and 48.20±9.86 years in Primary closure and T-tube closure groups respectively.(Table-1) Female patients are predominant in both groups. The male female ratio was 1:2.1.(Figure-1) In primary closure group 72% patients are female and 28% patients are male. In T-tube closure group 60% patients are female and 40% female. No significant association was found between two groups regarding pain, fever and jaundice (p>0.05).

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| --- | --- | --- | --- |
| **Age group** | **Group I**  **n=25**  **n(%)** | **Group II**  **n=25**  **n(%)** | **p-value** |
| 30-40 | 3(12.0%) | 6(24.0%) |  |
| 41-50 | 14(56.0%) | 11(44.0%) |  |
| 51-60 | 6(24.0%) | 5(20.0%) |  |
| >60 | 2(8.0%) | 3(12.0%) |  |
| Mean±SD | 48.5±8.60 | 48.20±9.86 | 0.915 |

**Table-1 age distribution of the patients**

Most common clinical presentation was obstructive jaundice and right upper abdominal pain. Jaundice was present 17(68%) and 20(80%) patients in the Primary closure and T tube closure group respectively, (p value 0.33).The mean CBD diameter is 15.09±0.67 mm in primary closure group and 14.77±0.97 in T-tube closure group. The mean CBD diameter was not statistically significant between primary closure group and T-tube closure group (p=0.180).

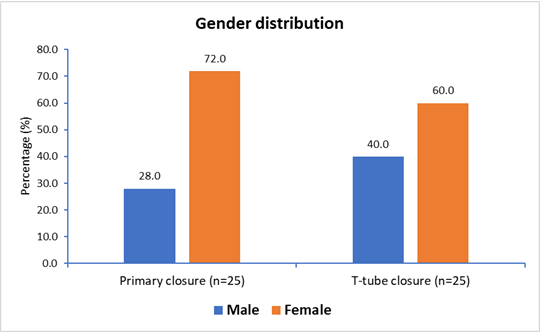


Fig-1 Gender distribution of the patients

Most common clinical presentation was obstructive jaundice and right upper abdominal pain. Jaundice was present 17(68%) and 20(80%) patients in the Primary closure and T tube closure group respectively, (p value 0.33).The mean CBD diameter is 15.09±0.67 mm in primary closure group and 14.77±0.97 in T-tube closure group. The mean CBD diameter was not statistically significant between primary closure group and T-tube closure group (p=0.180). No significant difference was found in overall post-operative complications rate between two groups (p>0.05). (Table-2)

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| --- | --- | --- | --- |
| **Post-operative complications** | **Group-Ⅰ**  **n=25**  **n(%)** | **Group-Ⅱ**  **n=25**  **n(%)** | **p-value\*** |
| Bile leakage | 3(12.0%) | 3(12.0%) | 1.000 |
| Retained stone | 0(0.0%) | 0(0.0%) | - |
| Surgical Site infection | 4(16.0%) | 5(20.0%) | 0.712 |

**Table-2 Postoperative complications of two groups**

The mean duration of operation (minutes) was significantly lower in primary closure group compared to T tube closure group (87.8±4.58 vs 102.2±3.82, p<0.001).The median postoperative hospital stay in the primary closure group was 5.64+-1.36 days (IQR-5-9) compared to the T-tube closure group which was 15.08+-1.32 days which was statistically significant (p<0.001).(Table-3)

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| --- | --- | --- | --- |
| **Duration of operation (min)** | **Group-Ⅰ**  **n=25** | **Group-Ⅱ**  **n=25** | **p-value\*** |
| Mean±SD | 87.8±4.58 | 102.2±3.82 | <0.001 |
| Range (min-max) | (80 – 95) min | (95 – 105) min |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Postoperative hospital stay (days)** | **Group-Ⅰ**  **n=25** | **Group-Ⅱ**  **n=25** | **p-value\*** |
| Mean±SD | 5.64±1.36 | 15.08±+1.32 | <0.001 |
| Range (min-max) | (5 – 9) days | (14 – 18) days |  |

**Table-3 Mean operative time and mean duration of hospital stay of the patients**

**Discussion:**

Open CBD exploration has been the principal treatment for almost 100 years and still is considered the gold standarad for the removal of CBD stones. T-tubes are usually inserted for biliary decompression and stenosis and this tactic has been the modality of choice for many years. Although T-tube insertion is proved to be a harmless and effective method for postoperative biliary decompression, potential of complications exists with this therapeutic modality which include bile leakage and biliary peritonitis, bacteremia, cholangitis, wound infection, dislodgement of tube, obstruction and or fracture of the tube, retained T-tube and difficulty on removal of the tube, fluid and electrolytes imbalance due to continuous external drainage of bile (Zhen et al, 2020; Ambreen et al, 2009) .

The most common age group in our study was 41-50 years with 25(50%) patients belonging to this age group where 14(56%) and 11(44%) patients belonged to primary closure and T tube closure group respectively. This Study also showed female patients are predominant in both groups. ). Similar results were reported in a study by Asaduzzaman et al, (2017) where the mean age of patients in primary closure was 42.1 years and that of T-tube group was 40.1, (PV=0.71). There were three males (20%) and 12 females (80%) in the primary closure group, and four males (26.7%) and 11 females (73.3%) in T-tube group.

The mean operation time for Primary closure was 87.8±4.58 minutes ranging from 80 to 95 minutes, for T tube closure was 102.2±3.82 minutes ranging from (95 – 105) mins. Mean operating time was significantly higher in T tube closure group compare to primary closure group (p<0.001). In accordance with Khan et al, (2017) operative time was short for primary closure group (Group A) as compared to T tube closure group (Group B). . In another study done by Masud et al, (2019) found the mean total duration of the surgery was 132.44±10.06 minutes in the primary closure group, and it was higher 146.31±5.62 min in the T-tube group.

In this study we found a statistically significant difference in postoperative hospital stay between two groups. Prolonged hospital stay is one of the important components of morbidity of any surgical procedure. We found that the median postoperative hospital stay in the primary closure group was 5.64±1.36 (5 – 9) days compared to the T-tube drainage group which was 15.08±+1.32 (14 – 18) days, (P value <0.001). This result is consistent with studies conducted by Abdulraheem et al, (2021), Saeed et al.

In this study primary closure showed good outcome equal to T tube closure group mostly in terms of postoperative complications, as we found surgical site infection was 4(16.0%) patients of primary closure group and 5(20.0%) patients in T tube closure group which was statistically insignificant (P = 0.712ns). There was no residual CBD stones and mortality in our study which is similar with the studies of Zhu et al, (2011), Barband et al, (2015) and Asaduzzaman et al, (2017).

The current study had some limitations. The study population was selected from one selected hospital in Mymensingh, so that the results of the study may not reflect the exact picture of the country. Sample size was small to infer the findings as a general rule.

**Conclusion:**

This study found that T-tube closure patients had a significantly longer mean duration of operation and higher length of hospital stay compared to the primary closure group. As Primary closure reduces extra hospital stay, early return to work is possible here. Overall post-operative complications were not statically significant but T tube related complications were only seen in the T tube closure group. So, primary closure can be considered as a safe and affordable alternative technique to routine T tube closure.

**CONSENT:**

Patient’s informed written consent was taken to publish her case for academic purpose.

**ETHICAL APPROVAL:**

As per international standards or university standards written ethical approval has been collected from Institutional ethical committee and preserved by the authors.

**DISCALIMER (ARTIFICIAL INTELLEGENCE):**

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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