# Primary closure versus T-tube drainage for calculus obstructive jaundice

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**Received:** 12 February 2021
**Revised:** 10 March 2021
**Accepted:** 15 March 2021
**Published:** 12 October 2021

**The Egyptian Journal of Surgery** 2021, 40:656–662

**Context**
Choledochotomy followed by T-tube has long been a standard surgical treatment for choledocholithiasis. Till now, it is the first choice in many hospitals where minimal invasive procedures are not feasible, although it has many complications. To avoid these complications, primary closure of the common bile duct (CBD) after exploration is performed.
**Aims**
This study aimed to assess the safety of primary closure of CBD, which would help for its implementation on a wider scale.
**Settings and design**
This randomized controlled trial was conducted in outpatient clinic of the Surgical Department, Faculty of Medicine, Sohag University
**Patients and methods**
A total of 50 patients were recruited from the outpatient clinic at Sohag University Hospital during the period from July 2019 to December 2020. They were randomly assigned into two groups: group A patients underwent CBD exploration with primary closure, and group B patients underwent CBD exploration with insertion of T-tube.
**Statistical analysis**
used Descriptive analysis (frequency, percentage, mean, and SD), $\chi^2$/Fisher's exact test, and independent *t* test were applied.
**Results**
There was a significant difference between group A and group B cases regarding operative time and hospital stay. There was no significant difference between group A and group B cases regarding postoperative early and late complications.
**Conclusions**
Morbidity and length of hospital stay after primary closure of CBD after choledocholithotomy is significantly less compared with insertion of T-tube.

**Keywords:**
common bile duct, choledocholithotomy, primary closure, T-tube

Egyptian J Surgery 40:656–662

1110-1121

## Introduction

The incidence of gall bladder stone was estimated at 3–20%, worldwide. Gall bladder stones occur in the common bile duct (CBD), common hepatic duct, or right or left hepatic ducts. CBD stones (also called choledocholithiasis) developed in ~15% of people with gallstone, and surgical intervention is necessary for removal of stone. There are two options for management of stone in biliary tree depending on the stone size. Small stones can be removed by endoscopic retrograde cholangiopancreatography (ERCP) [1].

In cases of large stones and failure of ERCP, surgical intervention is the only resort. Surgical exploration of CBD (choledochotomy) can be done either open or by laparoscopically. After CBD exploration, stones are removed, and CBD is closed with T-tube. T-tube closure after open CBD exploration is used for drainage of CBD to reduce edema resulted from manipulation and instrument used for removal of stone, to decrease the intraluminal pressure of CBD and to visualize and extract the retained bile duct stones [2].

On the contrary, using T-tube has many potential complications: bacteremia, displacement of tube, obstruction, and fracture of tube. Furthermore, bile may be discharged after removal. Moreover, the patient may have to keep the tube for several days before removal [3–6]. All of these might lead to prolonged length of hospital stay [7]. It also causes psychological trauma to the patient, along with increased bed occupancy and hospital patient load [1]. Currently, primary closure of CBD after exploration has been described to decrease these complications via using T-tube closure technique [8].

Although it was thought that T-tube was used in many centers after CBD clearance, some authors found no significant difference in the morbidity or mortality between primary closure and T-tube drainage [6,9,10]. Others found a higher morbidity in terms of more biliary infection, discomfort from tube, and delayed hospital discharge [11]. This study was designed to assess the outcome of T-tube primary repair of CBD in terms of operating time, duration of hospital stay, and postoperative complications like wound infection, bile leak and pyrexia, and T-tube block.

## Patients and methods

This study was nonblinded RCT, conducted from July 2019 to December 2020. A total of 50 patients with CBD stones were recruited from the Surgical Department, Sohag University Hospital. Diagnosis of choledocholithiasis was carried out via preoperative radiology and MRCP. Patients with calicular obstructive jaundice with large stones (>1.5 cm) or small stones (<1.5 cm) after failure of ERCP were included. Exclusion criteria were patients with malignancy, renal failure, pancreatic pathology causing jaundice, and other severe comorbidities.

### Sample size calculation

Sample size calculation was carried out using G*Power 3 software (IBM-SPSS-24 manufactured as IBM-Corporation, NY, USA, 2016). A calculated minimum sample of 50 patients with CBD stones was needed. Patients was randomly assigned into one of two groups: group A included 25 patients who underwent CBD exploration with primary closure, and group B include 25 patients who underwent CBD exploration with insertion of T-tube to detect an effect size of 0.3 [6] in the rate of postoperative complications, with an error probability of 0.05 and 80% power on a one-tailed test.

### Preoperative assessment

Baseline investigations including complete blood picture, renal function tests, radiograph chest (P/A), ECG, serum bilirubin, serum alkaline phosphatase, SGPT, SGOT, and ultrasonography upper abdomen were conducted. To rule out malignancy, contrast-enhanced computed tomography was done in selected cases.

### Recruitment and randomization

Written consent was obtained from all eligible patients scheduled for surgery after detailed explanation about the study objectives, procedure, risks, and benefits during the outpatient visit. The investigator did not undertake any diagnostic measures specifically required for the clinical trial until valid consent has been obtained. After completion of the baseline assessment, participants were randomly assigned to one of the two intervention groups (group A: 25 patients underwent CBD exploration with primary closure, and group B: 25 patients underwent CBD exploration with insertion of T-tube. Allocation was conducted by random digit allocation using IBM-SPSS [12] program with a fixed block size. Descriptive data about patients characteristics including age, sex, occupation, physical activity, smoking, relevant medications, BMI, and type of hernia were recorded.

### Operative technique

All selected patients underwent a cholecystectomy followed by choledochotomy. Then the stones were removed, and CBD was flushed with normal saline, ensuring no distal obstruction, and choledocoscope was used to rule out any retained stone. Primary closure was done in group A cases, and T-tube drainage was used in group B cases. Primary closure of CBD was done with continuous/interrupted suture no. 3-0/4-0 vicryl on an atraumatic needle. A subhepatic drain was kept in all patients. For group B patients, 12-F gauge T-tube was used. T-tube was removed on 14th postoperative day after satisfactory postoperative T-tube cholangiography (Figs 1–3). All patients were given preoperative and postoperative care along with antibiotics and followed up for 3 months.

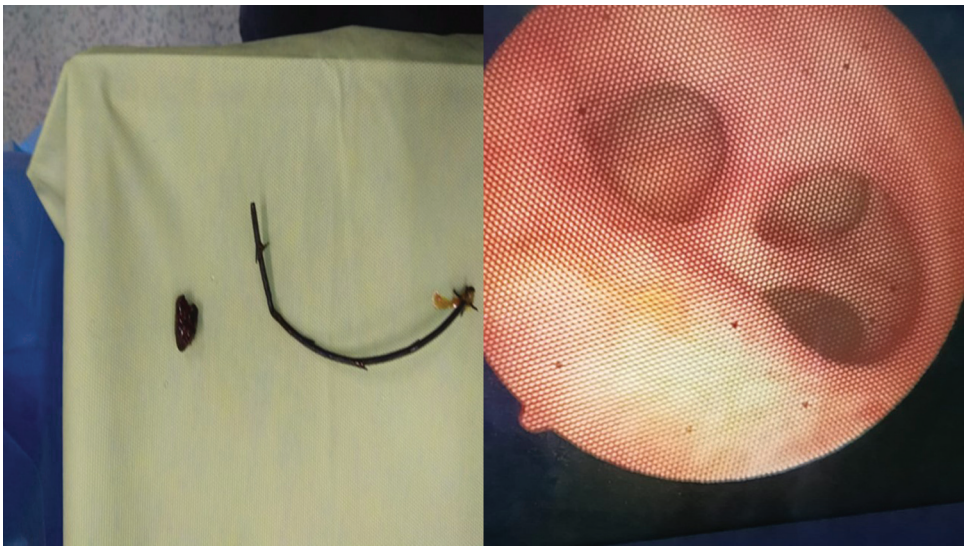
### Statistical analysis

Data were verified, coded by the researcher, and analyzed using SPSS, version 24 [12]. Descriptive statistics: means, SDs, medians, and percentages were calculated. Test of significances included the following: $\chi^2$/Fisher's exact test was used to compare the difference in distribution of frequencies among different groups. For continuous variables, independent $t$ test analysis was carried out to compare the means. A $P$ value less than 0.05 was considered significant.

### Ethical considerations

Approval for this study was obtained from institutional review board (IRB) of Faculty of Medicine, Sohag University before study execution. In addition, all participants received a written consent form. The informed consent was clear and indicated the purpose of the study and their freedom to participate or withdraw at any time without any obligation. Furthermore, participants' confidentiality and

**Figure 1**



Choledocoscope picture of CBD, stent, and stone removed from CBD. CBD, common bile duct.

**Figure 2**

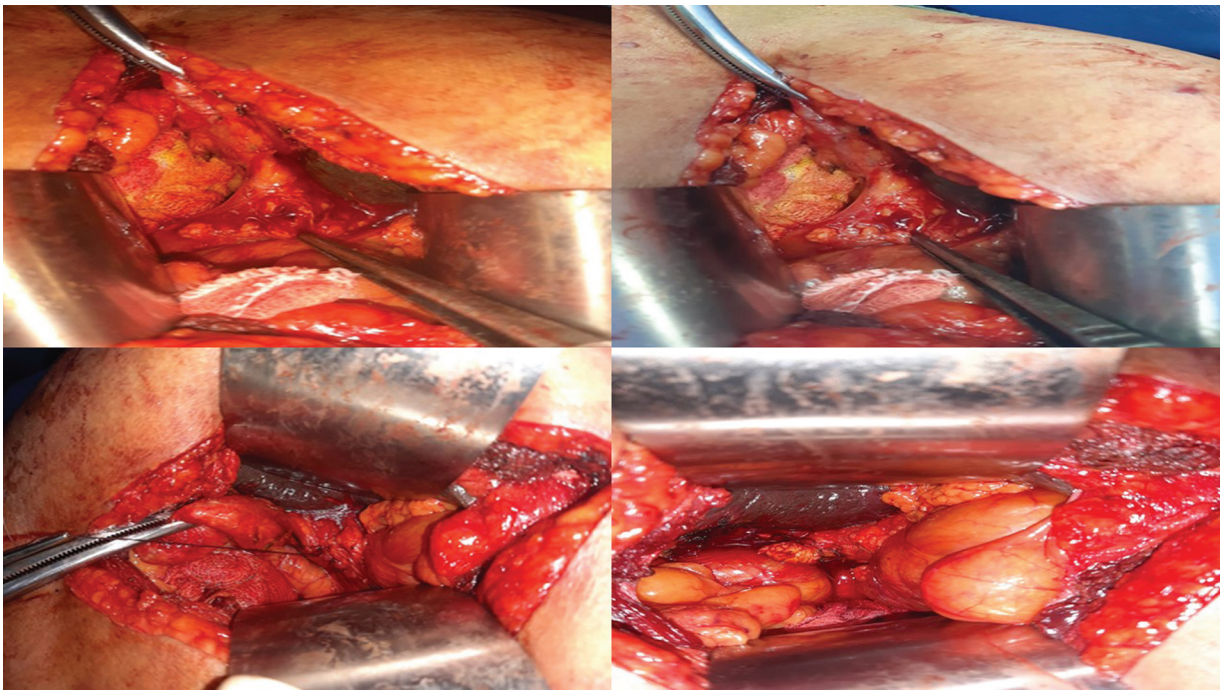
T-tube cholangiography study.

anonymity were assured by assigning each participant with a code number for the purpose of analysis only. The study was not based on any incentives or rewards for the participants and abided to the guidelines of Helsinki Declaration and the CONSORT guidelines.

## Results

The study was performed at Sohag University Hospital and included 50 patients. In group A, there were 13 males and 12 females, whereas in group B, there were eight males and 17 females. Age in both groups ranged from 32 to 68 years. The mean age was 47.7 and 55.7 years in groups A and B, respectively. All patients required cholecystectomy with choledocholithotomy, except six (24%) patients of group A and two patients in group B. In these patients, cholecystectomy was already done for cholelithiasis in the past, and they developed choledocholithiasis subsequently. In the group A, 16 patients had chronic cholecystitis with CBC stone and three patients had acute cholecystitis with CBD stone. In the group B, 22 patients had chronic cholecystitis with CBC stone, and only one patient had acute calculous cholecystitis with CBC stone (Table 1).

**Figure 3**



Operative picture of choledochotomy.

**Table 1 Description and comparison between both study groups regarding operative time**

| Group A (*N*=25) [*n* (%)] | Group B (*N*=25) [*n* (%)] | *P* value* |
|---|---|---|
| Chronic calculous cholecystitis with choledocholithiasis | | |
| 16 (64) | 22 (88) | 0.098 |
| Acute calculous cholecystitis with choledocholithiasis | | |
| 3 (12) | 1 (4) | 0.602 |
| Choledocholithiasis (history of cholecystectomy in past) | | |
| 6 (24) | 2 (8) | 0.247 |

*$\chi^2$ test was used to compare the frequency difference between groups.

Table 2 showed the postoperative complications in group A vs. group B. Although there were higher percentages of early and late complications in group B compared with group A, these differences did not yield any statistical significance ($P>0.05$).

Patients need to be hospitalized during T-tube in situ to avoid complications like blockage and dislodgement. They also needed T-tube cholangiogram, which is usually done at 10th day before removal. Hospital stay was significantly ($P<0.001$) longer (5.14±1.1 days) in group B compared with group A (8.11±1.1 days) (Table 3).

Moreover, T-tube insertion required manipulation, and it is time consuming. Operating time in group B was significantly ($P<0.001$) longer (88±11.5 min) in comparison with group A (71.9±5.8 min). Contrarily, in six patients of group B (where only choledocholithotomy was done), shorter operating time was recorded (58.3±3.9 min). The operating time difference between two groups was statistically significant (Table 4 and Fig. 4).

**Table 2 Postoperative early and late complications in groups A and B**

| Parameters | Group A (*N*=25) [*n* (%)] | Group B (*N*=25) [*n* (%)] | *P* value* |
|---|---|---|---|
| Wound infection | 2 (8) | 5 (20) | 0.415 |
| Drain site infection | 3 (12) | 4 (16) | 0.998 |
| T-tube site infection | 0 | 5 (20) | 0.086 |
| T-tube blocked | 0 | 3 (12) | 0.121 |
| Pyrexia | 3 (12) | 5 (20) | 0.699 |
| Bile leak | 4 (16) | 10 (40) | 0.115 |

*Fisher's exact test was used to compare the frequency differences.

**Table 3 Hospital stay and operation time difference in group A versus group B**

| | Group A (*N*=20) | Group B (*N*=20) | *P* value* |
|---|---|---|---|
| Hospital stay (days) | 8.11±1.1 | 15.14±1.1 | <0.001 |
| Operative time (h) | 71.93±5.8 | 88.00±11.5 | <0.001 |

*Independent *t* test was used to compare the differences in means between groups.

**Table 4 Operative time for both groups**

| Groups | Operating time (min) Mean±SD | *P* value |
|---|---|---|
| Group A | 71.9±5.8 | <0.001* |
| Group B | 88±11.5 | |

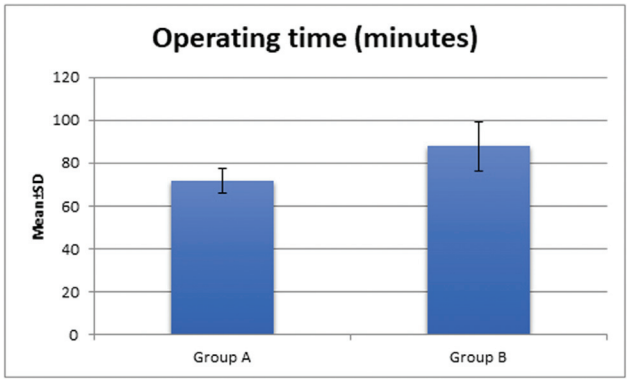
Independent samples *t* test. *Statistically significant difference (*P*<0.05).

## Discussion

It was proposed that choledocholithiasis is associated with cholelithiasis in ~10–15% of patients [13]. The foundation of modern CBD exploration was established by Ludwig Courvoisier as early as 1890, with first successful removal of CBD stones [14]. For generations, CBD exploration during cholecystectomy for removal of stone has been considered as the gold standard [15]. Halsted (1919) recommended closure of CBD after choledocholithotomy and drainage of CBD via a small tube through cystic duct. The tube should be left in place for 3–4 days, then clamped, and if the bile flow was uninterrupted, the tube should be removed [16]. However, residual stones were very common until Mirizzi introduced intraoperative cholangiography in 1932, and this procedure reduced the incidence of missed stones markedly, as well as mortality [17,18]. Next improvement in the technique of CBD exploration was the introduction of choledochoscopy, in which Bakes described a speculum with a mirror, which used reflected light from a surgeon's headlamp [19].

ERCP was introduced in 1968 by McCune, and over the next two decades, it revolutionized the diagnosis and management of diseases involving hepatobiliary tract [20]. Endoscopic interventions are currently established as the first-line therapy for choledocholithiasis [21]. The advantages of ERCP make it the prominent method for treating choledocholithiasis [22]. On the contrary, several limitations for ERCP were encountered, that is, large stone, impacted stones, or anatomical abnormalities, where surgical exploration of CBD is required, which can be done either using laparoscope (laparoscopic CBD exploration) or open surgery [23].

**Figure 4**




Operative time for both groups.

In both situations, after exploration and removal of stone from CBD, either T-tube is placed in common duct or primary closure can be done over biliary stent [22].

The present study was thus performed to compare the morbidity of T-tube placement over primary closure of CBD over stent placement. There were 12 females, represented 48% of the sample, and 13 males, represented 52% of patients. The patients' age ranged from 26 to 72 years in group A, and also 16 (64%) patients experienced chronic calculous cholecystitis with choledocholithiasis, three (12%) patients experienced acute calculus cholecystitis with choledocholithiasis, and six (24%) patients experienced choledocholithiasis history of cholecystectomy. Additionally, in group B, 22 (88%) patients had chronic cholecystitis with CBC stone and only one (4%) patient had acute cholecystitis with CBC stone and two (16%) patients had cholecystectomy done before and developed choledocholithiasis later.

In all cases, endoscopic stone extraction was attempted by endoscopist but failed. Either large (45%) or impacted stones (40%) were the main cause of the failure of endoscopic extraction. Other reasons of failure included difficulty in cannulation of the ampulla, or the procedure was abandoned because of bleeding during sphincterotomy (15%). Intraoperative post-exploratory rigid choledochoscopy was performed in all cases. Uses of intraoperative choledochoscopy can improve the cost–benefit of the bile duct exploration [24].

In group B, appropriate-size T-tube was inserted in CBD, and choledochotomy incision was closed using 3-0 Vicryl interrupted sutures to fit T-tube snuggly in the duct. In group A, interrupted 3-0 vicryl sutures were applied to achieve primary closure of duct.

Abdominal drain was placed in the subhepatic space in all patients. The criteria for primary closure included that the wall of the duct should be healthy enough to hold stitches, large enough to permit suturing without obstruction, and free passage of irrigating fluid was ensured [25].

The most important purpose of insertion of T-tube following choledocholithotomy is to provide decompression of the duct to prevent leakage of bile in subhepatic space. However, a large amount and nature of subhepatic drain discharge in both groups revealed that the purpose of T-tube is not well served as expected. The amount was more in T-tube-inserted patients, and bile leak (up to fifth postoperative day) and drainage were for longer period (up to seventh postoperative day), and hence drain could be removed on eighth day. However, in group A (primary closure of CBD), 24-h drainage amount was significantly less, and the discharge was serous from the fourth day, so that the drain could be removed on fifth postoperative day. With drain and T-tube both in situ, the patient was less mobile as compared with group A patients.

Regarding the incidence of complication, postoperative pyrexia was more prevalent in group B compared with group A (20 vs. 12%). Likewise, percentage of wound infection (20 vs. 8%) and drain site infection (16 vs. 12%) were higher in group B compared with group A. SSTI at T-tube insertion site was exclusively present in group B (20%). Following T-tube removal, significant bile discharge was present from site in 10 patients and stopped gradually, except for one patient who needed ERCP with stenting, where leakage incidence was high, and we should have referred the patient to ERCP earlier; however, there is no ERCP in our institute, and we had to refer the patient to a remote institute for ERCP. Our guidelines in the management of leakage were to use conservative treatment under full supervision in-hospital. In few cases, we had to refer them for ERCP intervention.

Although no obstructing calculus was seen, but probably dyskinesia was the reason of persistent discharge. Three patients had blockage of T-tube, leading to discharge from subhepatic drain and required irrigation of the T-tube. Moreover, other complications of T-tube drainage (biliary sepsis, bile duct trauma during removal, bile leakage leading to biliary peritonitis, retention of fragment of tube and stricture formation, fluid and electrolyte imbalance, premature dislodgment, and prolonged biliary fistula) [26] were not recorded in this study.In group B, the average operating time was 88±11.5 min, whereas in the group A, the average time of completion of surgery was 71.9±5.8 min. The difference in time was statistically significant. In six patients of group B (cholecystectomy done previously), the average operating time was 58.3±3.9 min. This indicated that T-tube insertion does take significantly longer time for completion of procedure and therefore may be associated with certain complications like wound infection [27]. Furthermore, prolonged hospital stay is one of the important components of morbidity of any surgical procedure. In group B, mean hospital stay was 15.2 ±1.1 days, whereas it was 8.1±1.1 days in primary closure (group A). The difference was statistically significant. Other studies have also observed prolonged hospital stay in T-tube insertion patients as compared with primary closure [9,26–29].

Recent evidence recommended primary closure after choledochotomy, to reduce the risk of T-tube-related complications and also to facilitate early discharge from hospital, early return to normal activity, and less hospital expense [9].

## Conclusion

It is concluded from the current study that morbidity and hospital stay after primary closure of CBD after choledocholithotomy is significantly less compared with insertion of T-Tube. Review of literature also indicates that primary closure of CBD is a safe and useful technique in the treatment of choledocholithiasis, as with the procedure, hospital stay, the risk of readmissions, and morbidity were lower than when T-tube is used.

#### Acknowledgements

The authors expressed their thanks for the help and support of the medical and administrative staff of the Surgical Departments, Sohag University Hospital. Moreover, we acknowledged the eminent role of the participants, as without their help, support, and approval, it would not be possible to finish this work.

#### Financial support and sponsorship

Nil.

#### Conflicts of interest

There are no conflicts of interest.

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