Common bile duct repair after exploration with versus without T-tube: a prospective randomized comparative study

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Received: 23 June 2022
Revised: 07 July 2022
Accepted: 03 August 2022
Published: 05 April 2023

The Egyptian Journal of Surgery 2023, 41:1024–1029

Background
In common bile duct (CBD) exploration, closure of the bile duct on a T-tube (TT) was the standard technique for decades. Owing to its adverse effects and the new minimal invasive modalities in confirmation of CBD clearance, the theory of primary repair was raised strongly. However, the safety of the patients makes the debate still present between TT and primary repair.
Patients and methods
The study enrolled two groups of patients (35 patients in each group): group 1 for primary repair of CBD and group 2 for TT based repair. Operative time, postoperative hospital stay, and biliary complications were compared between the two groups.
Results
In this study, it was found that patients who underwent primary closure (PC) had significantly lower operative time (111.04 ± 5.55 vs. 121.15 ± 6.11 min; $P<0.001$). TT repair group had significantly shorter hospital stay (8.56 ± 2.01 vs. 2.50 ± 0.50 days; $P<0.001$) in comparison to those who underwent PC of CBD. Both groups had insignificant differences regarding intraoperative blood loss ($P=0.15$). These reported complications showed no significant differences between both groups ($P>0.05$). The overall complications rate was four (11.4%) and five (14.3%) patients in PC and TT groups, respectively.
Conclusions
Each case with CBD exploration should be individualized regarding methods of closure either TT insertion or PC based on the experience of the surgeon and availability of equipment.

Keywords:
cholangiogram, choledocholithiasis, primary closure, retained stone, T-tube

Egyptian J Surgery 2023, 41:1024–1029

1110-1121

Introduction

Choledocholithiasis occurs in 15% of the general population. In patients who undergo cholecystectomy for gall bladder stones, 10–18% also have common bile duct (CBD) stones. Medical treatment, endoscopic retrograde cholangiopancreatography (ERCP), and surgical management by CBD exploration are variable modalities for choledocholithiasis management [1,2].

The era of endoscopy in all medical branches leads to rising up of new surgical techniques. In CBD exploration, the appearance of choledoscope side to side with cholangiogram, dormia basket, or Fogarty catheter has markedly helped surgeons to do a complete assured extraction of choledocholithiasis [3,4]. In view of the above, the primary closure (PC) of CBD after its exploration was thought to be the golden substitutional technique after decades of dependence on T-tube (TT) as a gold standard, especially that external loss of bile leak through TT may lead to the slow process of wound healing, lack of appetite, and constipation (postcholedocotomy acidotic syndrome) [4–6].

TT is preferred in some conditions (if the surgeon is not sure about residual stones, if equipment is not available, CBD diverticula, risky patients whether owing to immunocompromised general condition or with low healing power such as hypoalbuminemia, postchemotherapy or radiotherapy, on corticosteroid therapy, and for edema caused by CBD manipulation during choledotomy is revealed). If the surgeon is sure about CBD clearance and there are no other risk factors, PC is indicated [5,6].

The argument about proper intraoperative evaluation, risk of leak, and patient safety in PC is still present.

So, research studies are still in a debate about which is the gold standard PC or repair over TT for closure of choledotomy after CBD exploration [5,6].

In our study, we aimed to assess the benefits and drawbacks of TT drainage versus PC without a biliary stent in choledocholithiasis management.

Patients and methods

Study setting and design

A randomized controlled trial was conducted at the Department of General Surgery of Assiut University Hospital. The study was performed in the period between March 1, 2019 and May 30, 2021. This study protocol was approved by the Institutional Review Board of Assiut University and conducted under code of good practice and the guidelines of the Declaration of Helsinki, 7th revision, 2013 (IRB No. 17101253) and the study was registered on clinicaltrials.gov with NCT04108780.

Written informed consent was obtained from the patients. The study was approved by the Department of surgery, Faculty of Medicine, Assiut University.

Patient selection

All patients were above 18 years old with dilated CBD (based on abdominal ultrasound, the abdominal computed axial tomography, and magnetic resonance cholangiopancreatography) with stone(s) inside and ERCP failed to extract the stone(s) were included. Patients with markedly dilated CBD (>2 cm) or who had a noncholedocholithiasis cause of biliary obstruction were excluded. Based on previously mentioned inclusion criteria, the reported frequency of bile leak after CBD exploration was 4.1% [7]. The minimum required number of patients was 61 patients with the following assumptions: 5% alpha error and 80% power. To avoid any possible effect of patient dropout, 70 patients were enrolled.

Randomization

Block randomization was performed through sequentially numbered opaque envelopes using a random number table (1 : 1 ratio), where patients were subdivided into two groups, with 35 patients in each group: PC group and TT drainage group.

Methodology

All participants were evaluated with complete history taking and physical evaluation. Baseline laboratory data were recorded such as complete blood count, serum creatinine, liver function tests, and international randomized ratio. In addition, recording of findings in different biliary imaging was done.

Surgical techniques

The operation was started with cholecystectomy, and then the anterior aspect wall of CBD was meticulously dissected by pinch burn technique at the supraduodenal part of the CBD. A Dormia basket (Cook, Bloomington, Indiana, USA) was used for CBD stone extraction.

After complete clearance of the CBD, the choledochotomy was closed primarily with interrupted vicryl 4-0 sutures in the PC group. For patients in TT drainage group, a latex rubber TT of appropriate size (14–20 Fr) was inserted into the CBD incision. Interrupted vicryl 4-0 sutures were used. An intraoperative cholangiogram was done in both techniques to confirm CBD clearance of stones.

A single intrahepatic suction drain was placed near the CBD incision in all patients. Operative time was counted in minutes and started from time of incision till the end of the procedure.

Follow up

All patients were routinely assessed for complications in the ward and 12 weeks after discharge. The patients were followed up on 7th, 14th, 21st, and 30th day of the discharge for the outcome parameters. Follow-up assessment depended mainly on ultrasound, liver function tests in the outpatient clinic, and magnetic resonance cholangiopancreatography or ERCP if indicated.

Statistical analysis

Recorded data were analyzed using the Statistical Package for Social Sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean±SD and compared with the Student *t* test. Qualitative data were expressed as frequency and percentage and compared with χ^2 test. The level of confidence was kept at 95%; hence, *P* value was significant if was less than 0.05.

Results

A total of 70 patients were enrolled in our study: 35 patients (group 1) had PC of CBD and 35 patients (group 2) had repair on TT. The mean age of the PC group was 43.03 ± 8.81 years, and the majority (62.9%) of them exceeded 40 years old, and also, the majority (25.7%) of them was males. However, the mean age of the TT group was 44.34 ± 7.58 years and majority (60%) of them exceeded 40 years old, and also, the majority (68.5%) of them were males.

Diabetes mellitus, hypertension, ischemic heart disease, and chronic kidney disease were present in 10 (28.6%),

nine (25.7%), two (5.7%), and three (8.6%) patients of the PC group, respectively, and present in 14 (40%), 11 (31.5%), seven (20%), and four (11.4%) patients of the TT group, respectively. There were no significant differences between both groups (P>0.05) regarding demographic data (Table 1 and Fig. 1).

Operative data and hospital stay among studied groups

It was found that patients who underwent PC had significantly lower operative time (111.04 ± 5.55 vs. 121.15 ± 6.11 min; P<0.001) compared with the TT repair group, and the TT repair group had significantly shorter hospital stay (8.56 ± 2.01 vs. 2.50 ± 0.50 days; P<0.001) in comparison with those who underwent PC of CBD. Both groups had insignificant differences regarding intraoperative blood loss (150 ± 25 vs. 200 ± 10 ml; P=0.15) (Table 2, Figs 2 and 3).

Postoperative reported complications among studied groups

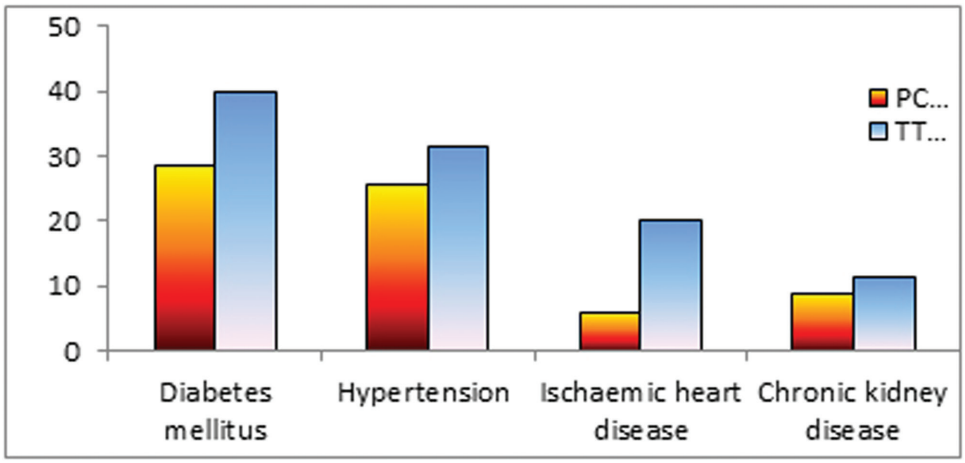
It was found that bile leakage was reported in three patients who underwent PC and one patient who underwent TT drainage. Two patients improved on conservative treatment and follow-up, and one patient needed an ERCP after 45 days postoperatively after the failure of medical treatment. Moreover, cholangitis was reported only in three patients from the PC group who responded well to the antibiotic, antispasmodics, ursodeoxycholic acid (Ursofalk), and good hydration. One patient in each group developed CBD stricture. Both of them are on follow-up in the outpatient clinic by liver function test, ultrasound, and magnetic resonance cholangiopancreatography. Wound infection occurred in three (8.6%) patients of the PC group and four (11.4%) patients of the TT group. They have been improved on frequent dressing with antibiotics based on culture and sensitivity of wound swab.

Table 1 Baseline data of studied groups

Variables	PC group (N=35)	TT group (N=35)	P value
Age (years)	43.03 ± 8.81	44.34 ± 7.58	0.77
Age group (years)			
<40	13 (37.1)	14 (40)	0.50
>40	22 (62.9)	21 (60)	
Sex			
Male	26 (74.3)	24 (68.5)	0.60
Female	9 (25.7)	11 (31.5)	
BMI (kg/m^2)	27.78 ± 9.45	25.68 ± 8.76	0.92
Diabetes mellitus	10 (28.6)	14 (40)	0.22
Hypertension	9 (25.7)	11 (31.5)	0.30
Ischemic heart disease	2 (5.7)	7 (20)	0.07
Chronic kidney disease	3 (8.6)	4 (11.4)	0.50
Residence			
Rural	27 (77.1)	24 (68.6)	0.29
Urban	8 (22.9)	11 (31.4)	
Smoking	20 (57.1)	16 (45.7)	0.23

Data are expressed as n (%) and mean±SD. PC, primary closure; TT, T-tube drainage. P value was significant if less than 0.05.

Figure 1



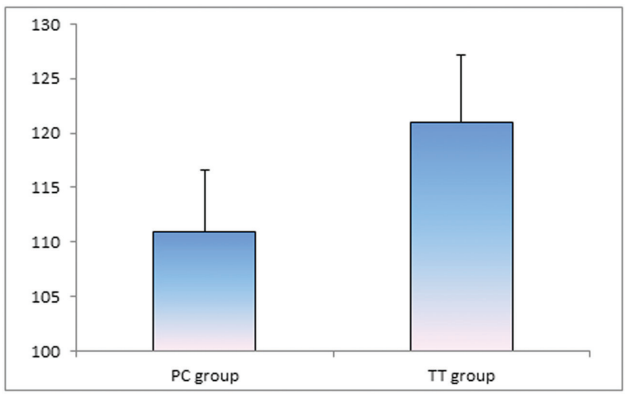
Comorbidities among enrolled patients.

Table 2 Operative data and hospital stay among studied groups

Variables	PC group (*N*=35)	TT group (*N*=35)	*P* value
Operative time (min)	111.04±5.55	121.15±6.11	<0.001
Intraoperative blood loss (ml)	150±25	200±10	0.15
Procedure			
Open	24 (68.6)	22 (62.9)	0.23
Laparoscopic	11 (31.4)	13 (37.1)	
Hospital stay (day)	8.56±2.01	2.50±0.50	<0.001

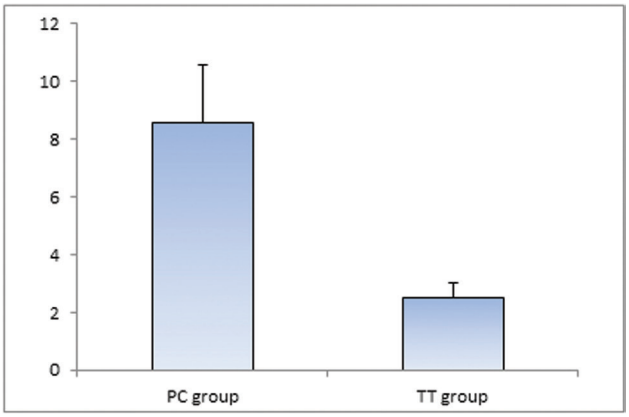
Data expressed as mean±SD and *n* (%). PC, primary closure; TT, T-tube drainage. *P* value was significant if less than 0.05.

Figure 2



Mean operative time among studied groups.

Figure 3



Mean hospital stay among studied groups.

Remnant stone was detected in only one patient from the PC group (2.9%), which was managed by ERCP. These reported complications showed no significant differences between both groups (*P*>0.05). The overall complications rate was four (11.4%) and five (14.3%) patients in PC and TT groups, respectively (Table 3 and Fig. 4).

Discussion

With the era of minimal invasive techniques and endoscopy like ERCP and choledoscope, the idea of PC of CBD in cases of CBD exploration appeared as a gold standard instead of the repair over TT. However, the debate is still present between teams supporting both techniques. In the current study, 70 patients underwent CBD exploration for choledocholithiasis to compare efficacy and safety of PC group and TT drainage (TT group). Those patients were randomly subdivided into two groups (PC group and TT group), and each group contained 35 patients.

In the current study, we reported that patients who underwent PC had significantly shorter operative time (111.04±5.55 vs. 121.15±6.11 min; *P*<0.001) but longer hospital day (8.56±2.01 vs. 2.50±0.50 day; *P*<0.001) in comparison with those underwent TT drainage. However, both groups had insignificant differences regarding intraoperative blood loss.

In a systematic review of three trials randomizing 295 participants (147 to TT drainage vs. 148 to PC), it was found that the operating time was significantly longer in the TT drainage group compared with the PC group (mean difference was 21.22 min). Moreover, the hospital stay was significantly longer in the TT drainage group compared with the PC group (mean difference was 3.26 days) [8].

This study was comparable with Hasabelnabi and colleagues and Pattanshetti and colleagues who reported that mean duration of hospital stay in PC group was 7 days, whereas it was 13.4 days in TT group, which indicates that PC of CBD is associated with significantly less stay at the hospital as compared with TT drainage. The authors reported that the mean operating time in the PC group was 65 min, whereas it was 95.25 min in the TT group [1,4].

Moreover, Anwar Zeb Khan and colleagues found that the mean hospital stay in group 1 was 6.40±1.39 days and in group 2 was 12.10±3 days. Hospital stay was shorter in patients who were treated with PC as compared with those who were treated with TT. Moreover, the authors demonstrated that the mean operative time in patients who were treated with PC and patients who were treated with TT insertion was 101.05±4.96 and 117.05±8.12 min, with a significant difference between both groups [2].

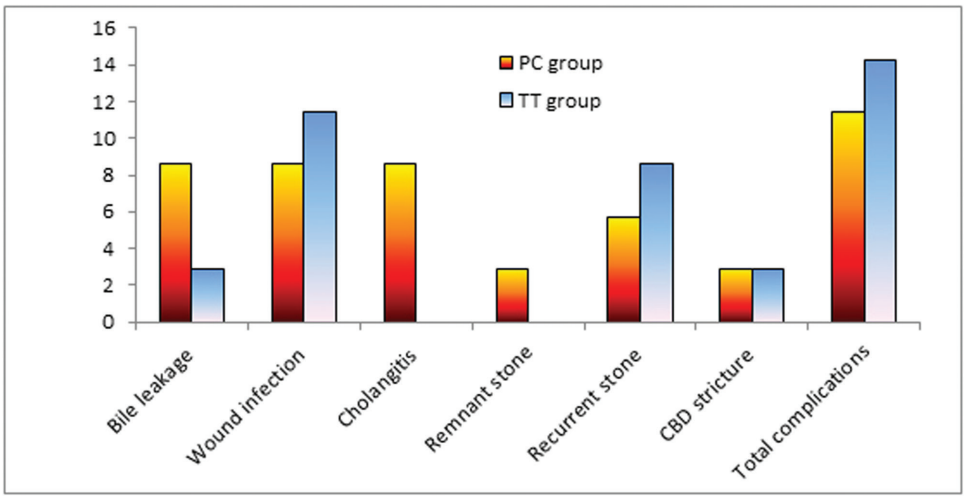
There are many reported studies that concluded TT drainage might increase the operating time and

Table 3 Postoperative reported complications among studied groups

Variables	PC group (*N*=35)	TT group (*N*=35)	*P* value
Bile leakage	3 (8.6)	1 (2.9)	0.56
Wound infection	3 (8.6)	4 (11.4)	0.49
Cholangitis	3 (8.6)	0	0.12
Remnant stone	1 (2.9)	0	0.38
Recurrent stone	2 (5.7)	3 (8.6)	0.50
CBD stricture	1 (2.9)	1 (2.9)	0.74
Total complications	4 (11.4)	5 (14.3)	0.50

Data are expressed as *n* (%). CBD, common bile duct; PC, primary closure; TT, T-tube drainage. *P* value was significant if less than 0.05.

Figure 4



Reported complications among enrolled patients.

hospital stay in comparison with those who underwent PC [8–10].

We found that bile leakage was reported in three patients who underwent PC and one patient who underwent TT drainage. One patient in each group developed CBD stricture during follow-up. Three patients developed cholangitis in the PC group. Wound infection occurred in three (8.6%) patients of the PC group and four (11.4%) patients of the TT group.

In the current study, three patients who underwent PC developed cholangitis, but there were no significant differences between both groups. This was comparable to a previous study that revealed insignificant differences regarding cholangitis between both groups (1.1 vs. 2.9%; *P*=0.65) [11].

Remnant stone was detected in only one (2.9%) patient from the PC group. These reported complications showed no significant differences between both groups (*P*>0.05). The overall complications rate was four (11.4%) and five (14.3%) patients in PC and TT groups, respectively.

Nearly to the current results, Pattanshetti and colleagues stated that wound infection was present in only 15% of cases in the PC group, whereas it was 35% in the TT group. This result is also, nearly comparable to the study performed by Cai *et al.* [12], who noticed a complication rate of 28.6% among those who underwent TT in contrast to 11.1% in those who underwent primary repair [4].

Bile leakage after PC is a major criterion for assessing the safety of this procedure, and we experienced 3/35 (8.5%) cases. This is comparable to Dong *et al.* [7] who reported that 9/194 (4.6%) patients developed bile leak. The main reason for bile leakage might be moderate edema of the wall of the CBD and the sphincter of Oddi [9,10,12]. Similar to our findings, other studies also showed that PC of the CBD did not increase the risk of bile leakage after the operation. Hence, TT drainage is unnecessary for decompression of the biliary tract [3,12,13].

The main reasons for biliary leakage following PC might be the result of the thin wall thickness of the CBD in these three patients. PC of CBD is not recommended for patients with severe acute pyogenic

cholangitis and those with thin because the risk of bile leakage is relatively high [14].

CBD stricture is also a major complication of CBD exploration. PC of choledochotomy in CBD with a diameter less than 5 mm is related to postoperative stricture and therefore is suggested to be safe only if the diameter is more than 7–9 mm [5,14]. In the study, one patient in each developed CBD stricture during follow-up.

The main limitations of the current study are relatively small sample size, the study was conducted in only one center, and lastly, short-term follow-up of those patients. So, it is recommended to perform such studies in multicenters on a large sample size with a longer duration of follow-up.

Conclusion

Each technique has advantages and drawbacks regarding hospital stay, operative time, and postoperative complications. On the basis of these results and the priority of patient safety, the debate is still present and the need to future studies is warranted. We recommended that each case with CBD exploration should be individualized regarding methods of closure either TT insertion or PC based on the experience of the surgeon and availability of equipment.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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