

PRIMARY CLOSURE WITH T-TUBE DRAINAGE AFTER COMMON BILE DUCT EXPLORATION FOR CHOLEDOCHOLITHIASIS: A COMPARATIVE STUDY IN TERTIARY CARE HOSPITAL OF NORTH EAST INDIA

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Abstract

Background: After a surgical choledochotomy, T-tube drainage used to be the norm, but some centers now choose to predominantly close the common bile duct. This study's objectives were to evaluate the safety of primary closure for potential future use and compare the clinical outcomes of primary closure versus T-tube drainage following open choledocotomy. **Materials and Methods:** This study was carried out in the Department of General Surgery at tertiary care medical college and hospital of north east region of India. In this study, 35 patients between the ages of 25 and 70 underwent primary closure on 15 (Group-A) of them, and 20 (Group B), T-tube implantation. Purposive, non-probability, quasi-experimental sampling was used. Operating time, length of hospital stay, sub hepatic drainage, and postoperative complications were the primary outcome measures. Data analysis was done using SPSS software. P value of 0.05 or less was considered statistically significant. **Result:** The mean hospital stay for patients in Group A was 4.11 days, compared to 6.20 days for patients in Group B. In Group-A, the overall complication rate was 53.3%. In Group-A, there was no need for re-exploration. 90% of Group B's complications were overall. **Conclusion:** After an open choledocotomy, primary closure of the common bile duct (CBD) is a safe and affordable alternative technique to routine T-tube drainage in India.

INTRODUCTION

The formation of stones in the common bile duct (CBD) is referred to as choledocholithiasis (CDL). It occurs in about 10 to 15% of individuals with gallbladder stones, and research indicates that 07-15 percent of patients having cholecystectomy (CC) may develop CBD.^[1,2] These stones typically originate in the gallbladder (GB) and move into the CBD. There are two ways to remove CBD stones: first one surgically removed via an open or laparoscopic procedure, or second through Endoscopic Retrograde Cholangio-Pancreatography (ERCP).

Laparoscopic Cholecystectomy (LCC) plus Laparoscopic CBD Exploration (LCBDE; single-stage) are now the most widely used techniques, and it has the advantages of having a reduced rate of

surgical failure, fewer surgeries needed, more economic and a lesser duration hospital stay.^[3-5]

T-tube drainage (TTD) has been frequently used for CBD closure when LCBDE has been carried out using the Transductal method. Biliary Tract Decompression (BTD) to halt future leak of bile (BL), Postoperative Cholangiography (PC) when required, and Choledochoscope Excision (CE) of residual stones are some of its uses.^[6] The use of a T-tube, however, frequently causes a number of postoperative problems with a morbidity of 04–16.4 percent.^[7,8] Some surgeons advise using Primary Duct Closure (PDC) alone or PDC plus Internal or External biliary drainage (IBD or EBD respectively) for CBD closure after LCBDE to prevent these complications linked to T-tube use; in addition, when compared to the use of TTD, several clinical trials and meta-analyses have supported the use of PDC or PDC combined with other biliary drainage (PDC+BD) techniques; the former resulted in lower

postoperative morbidity, complications, more economic and a lesser duration hospital stay.^[9,10] The current study is necessary because the question of whether TTD is better than primary closure after laparoscopic exploration of the CBD in Indian settings remains unanswered in terms of safety, efficacy and feasibility, despite the fact that LCBDE is performed only in higher tertiary care centers, using fine instruments or a high-resolution camera, or both, which are introduced into the CBD usually through a cut in it. So we planned to compare the safety, efficacy and feasibility of primary closure of the CBD and TTD in CDL patients.

MATERIALS AND METHODS

Study Design

This retrospective study was carried out in the Department of General Surgery at tertiary care medical college and hospital of north east region of India.

Study Participants

This study comprised 35 CDL patients in total. The trial included all patients aged 25 to 70 years with CBD stones clinically palpable, preoperative USG imaging indications of CBD stones or dilated CBD. Patients were excluded with pathology in pancreatic organ, suppurative cholangitis, kidney failure, concomitant cerebrovascular disorders, severe psychiatric disease and carcinoma. Prior to surgery, the patients' data were assessed with routine investigations such as CBC, LFT, and KFT, X-ray chest USG-abdomen, ECG and MRCP.

Out of 35 patients, 34 had CC then CCL with CBD flushing with NS 0.9% concentration, and no distal obstruction in CBD. Patients were separated into two groups based on the proposed procedure, either Group A-primary duct closure (PDC) 15 patients or Group B- T-tube implantation (TTI) 20 patients.

In Group A, 15 patients (42.8%) had primary closure, while 20 patients (57.2%) had T-tube insertion. CBD was repaired using Vicryl 3-0 round body interrupted sutures. A 12/14 F T-tube was implanted in group B patients. For monitoring any BL, a sub-hepatic drain was employed for seventy two hours. T-Tube Cholangiograms (TTC) and T-Tube Removal (TTR) were performed on tenth and fourteen day post-operative day respectively.

Statistical Evaluation

Purposive sampling was quasi-experimental, and non-probability. The primary outcome measures were operating time, hospital stay duration, and postoperative complications. The data was analysed using the statistical software SPSS version 21.0 for Windows and Microsoft Excel 2010. The Shapiro-Wilk test performed for normal distribution. A chi-square test was used to compare categorical data expressed as frequencies and percentages. The mean and standard deviation (SD) of normally distributed data were expressed and compared using the t test or analysis of variance. A P value of 0.05 or less was considered statistically significant.

Ethical Approval

The study was approved by Institutional Ethical Committee (Approval No. FAAMC&H/P.Est./I.E.C/26Pt.-/2022/90).

RESULTS

The demographic and clinical baseline characteristics of participants are shown in [Table 1]. The patients' average age was 48.6±11.43 years. There were more female patients than male patients, with a female to male ratio of 2.5:1.

[Table 2] shows that in Group B, subhepatic drainage continued until the sixth postoperative day, and the volume was substantially larger (P<0.001) than in Group A.

The numbers of patients experiencing postoperative complication is substantially greater (18) with more mean operating time in Group B (primary closure) patients which is considered statistically significant(P<0.001). The duration of stay in hospital, Drain carried time (DCT), and Return to normal activity (RNA) were statistically significantly (P<0.001) shorter in the group A when compared with the Group B [Table 3].

The postoperative problems in both groups were shown in [Table 4]. Some complications like T-tube blockage, T-tube site wound infection and BL after T-tube removal were seen only in Group B. These issues might be fully avoided in Group A due to the primary closure and avoidance of the T-tube. Other problems occurred at a higher rate in group B than in group A.

Table 1: Demographic and clinical baseline characteristics of the participants.

Groups	Sub-Groups	Group A (n=15) Primary closure	Group B (n=20) T-Tube Insertion
Gender	Male	4 (26.7%)	6 (30%)
	Female	11 (73.3)	14 (70%)
Age	Mean age (years)	48.4±12.63	48.75±10.77
Age groups (Years)	25-40	4 (26.7%)	3 (15%)
	41-55	7 (46.7%)	12 (60%)
	56-70	4 (26.6%)	5 (25.5%)
Preoperative Diagnosis	Chronic calculus cholecystitis with choledocholithiasis	12 (80%)	14 (70%)
	Acute calculus cholecystitis with choledocholithiasis	2(13.3%)	4 (20%)
	A calculus cholecystitis with choledocholithiasis	0	2 (10%)
	Choledocholithiasis (history of cholecystectomy in past)	1 (6.7%)	0

Symptoms	Abdominal pain	13 (86.6%)	18 (90.0%)
	Jaundice	12 (80.0%)	17 (85.0%)
	Acute cholecystitis	3 (20.0%)	4 (20.0%)
	others	3(20.0%)	3 (15%)

Table 2: Amount and Nature of Sub Hepatic Drainage during Postoperative Period

Post-operative days	Group A (Quantity (ml) and Nature)	Group B(Quantity (ml) and Nature)	p-value
First	98.7 ± 23.3 (Bilious)	132.9 ± 17.6 (Bilious)	<0.001
Second	58.6 ± 18.7 (Bilious)	97.7 ± 14.8(Bilious)	<0.001
Third	27.1 ± 6.4 (Serous)	65.5 ± 12.7 (Bilious)	<0.001
Fourth	13.6 ± 1.2 (Serous)	43.76 ± 9.9 (Serous)	<0.001
Fifth	Nil	22.7 ± 4.7 (Serous)	-
Sixth	Nil	12.7 ± 1.2 (Serous)	-
Seventh	Nil	Nil	-
Eighth	Nil	Nil	-
Ninth	Nil	Nil	-
Tenth	Nil	Nil	-

P value- <0.001- Highly significant

Table 3: Comparison of Postoperative Outcomes Variables of Two Groups.

Parameters	Group A (primary closure)	Group B (T tube insertion)	P-Value
Mean operating time (Minutes)	72.8 ± 5.4	90 ± 10.5	<0.001
Mean duration of hospital stay (days)	4.11 ± 1.1	6.20 ± 1.8	<0.001
Number of patients with post operative complication	8	18	<0.001
Return to normal activity (days)	12.87±1.19	18.80 ± 1.82	<0.001
Drain carried time (days)	3.9±1.8	6.5±2.7	<0.001

P value- <0.001- Highly significant

Table 4: Comparison of Postoperative Complications of Two Groups.

Complications	Group A (n=15)Primary closure	Group B (n=20)T tube insertion	P-Value*
Post-operative pyrexia	3 (20%)	4 (20%)	<0.001
Cholangitis	0	1 (5%)	<0.001
Septicemia	1 (6.7%)	2 (10%)	<0.001
Wound infection	2 (13.3 %)	3 (15%)	<0.001
T-tube site infection	Nil	1 (5%)	-
Drain tube site infection	2 (13.3%)	4 (20%)	<0.001
Bile leak after T-tube removal	Nil	2 (10%)	-
T-tube blockage	Nil	1 (5%)	-

P value- <0.001- Highly significant *Fisher's exact test was used to compare the frequency differences.

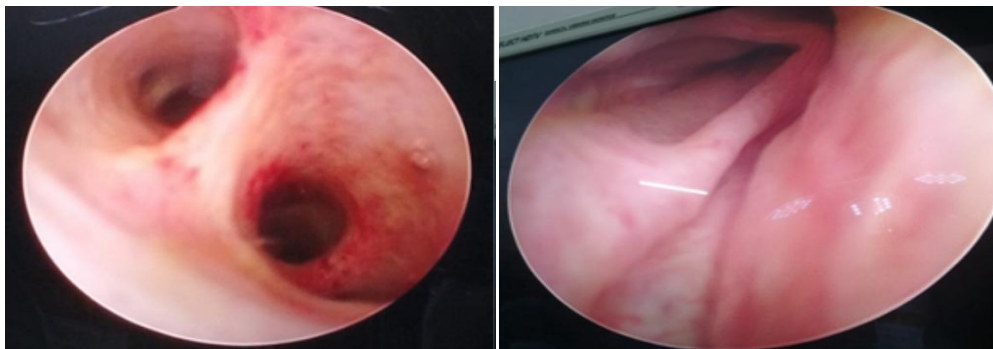


Figure 1: Choledochoscopy Before Primary Closure of CBD and to Ensure Total Ductal Clearance of CBD Stone

DISCUSSION

The male-female distribution observed in our study was similar to that shown by Ambreen et al and Williams et al.^[11,12] In contrast two other studies who found a statistically negligible difference in sex distribution between the two groups.^[13,14]

The findings of our investigation revealed that the PDC group required less time to operate than the TTI group, and the difference was statistically significant. The TTI group's long operative time may be ascribed to the time spent for T-tube

procedure. The finding was parallel to prior meta-analyses studies,^[15,16] as well as in a comparative research study.^[17] The results was not matching with a recent systematic review 18 which found that the TTI group's operative duration was statistically substantially longer than the PDC and ABS groups. The postoperative hospital stay is a major problem, and a lengthy stay benefits neither the patient nor the medical staff.^[16] our findings revealed that the PDC group had a less duration hospital stay than the TTI group. The similar finding was reported in several research 14, 15, 16, 17, 19 which

demonstrated that the PDC group had a statistically significant lower hospital stay than the TTD group. The less duration hospital stay for the PDC group in our study can be related to a variety of factors, including less analgesic demand for post operative pain, a quicker RNA, and a lesser DCT.

The safety of patients is always a top issue when using any technology. However, the use of T-tubes is frequently associated with an increased risk of problems (10% 15%).^[20] In our investigation, the combined results of overall postoperative problems revealed that the TTI group had a considerably greater incidence of complications than the PDC group. Biliary problems such as BL were common, as were T-tube complications and other complications such as cholangitis, septicemia, and wound infection. Previous research found no significant difference in the incidence of postoperative complications between the TTI and PDC groups.^[21,22] Another meta-analysis found a negligible difference in the occurrence of BL in the PDC group versus the TTI group and a significant difference in the occurrence of BL in the ABS group versus the TTD group.^[23]

The occurrence of BL is a reflection of the DCT in our investigation. The PDC group was significantly shorter than the TTI group. Our findings were similar with previous research that found the PDC to be superior to the TTI in terms of drain carried time.^[13,19,24,25]

Participants in the PDC group resumed RNA about 6 days sooner than those in the TTI group. This could be related to reduce surgical discomfort and analgesia, less hospitalization, less drain carrying time, and less time required for TTC & TTR. The findings for TTD and PDC were similar with previous research.^[16,26,27]

In our study, the TTI group had a higher percentage of wound infection than the PDC group. This result is roughly equivalent to the findings of Zhang et al,^[14] who discovered 28.6% of problems linked with T-tubes versus 11.1% in patients who underwent primary repair.

Limitation of the Current Study

For residual recurrent CBD calculi, follow up was not done for a longer period; small sample size, Single centered study and lack of randomization were some limitations in our study.

CONCLUSION

After an open choledocotomy, primary closure of CBD is a safe and affordable alternative technique to routine T-tube drainage in India in terms of post operative complications, RNA, BL and DCT.

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