International Surgery Journal
Imam MN et al. Int Surg J. 2022 Jun;9(6):1151-1155
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20221317

Original Research Article

A prospective interventional study to compare T-tube placement and primary closure of common bile duct in patients undergoing choledocholithotomy

M. Nazar Imam[1], Vijay Shankar Prasad[1], Sana Sharfuddin[2], Babita Chettri[1]*

[1]Department of General Surgery, [2]Department of Obstetrics and Gynaecology, Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India

Received: 28 March 2022
Revised: 07 April 2022
Accepted: 28 April 2022

***Correspondence:**
Dr. Babita Chettri,
E-mail: dr.babitachettri@gmail.com

ABSTRACT

Background: Primary closure of common bile duct following choledocholithotomy is now being considered as other possibility to the traditional method. This study is designed to analyse the outcome of primary common bile duct repair in terms of mean operation time, duration of hospital stays and post-operative morbidity. The objective of the study was to assess feasibility of safe primary closure in order to achieve early discharge and define case selection for this purpose.
Methods: Study was conducted in Sikkim Manipal institute of medical sciences, gangtok on patients operated between January 2017 and April 2018. Primary closure was performed in 16 patients and choledochotomy with T-tube drainage was performed in 16. The primary endpoints were morbidity, the bile drainage quantity, operative time, post-operative stay, time until return to work and postoperative complications and hospital expenses were recorded for each group.
Results: Mean total duration of the surgery was 132.44 minutes in primary closure group while it was 146.31 minutes in T-tube group and this difference of around 14 minutes between two groups was statistically significant. Patients were discharged on the 9th day at average in the primary closure group, while in the T-tube they were discharged on the 13th day on average. This difference was statically significant.
Conclusions: Primary choledochorraphy is a safe option in selected patients undergoing choledocholithotomy, provided common bile duct patency and clearance can be confirmed intra-operatively.

Keywords: Choledocholithotomy, Primary closure, T-tube drainage

INTRODUCTION

Choledocholithiasis is the development of stones in the common bile duct. It develops in about 10–15% of patients with gallbladder stones and literature suggests that common bile duct stones are encountered in approximately 7–15% of patients undergoing cholecystectomy.[1,2] Usually such stones are formed in the gallbladder and migrate into the common bile duct. Obstruction to the flow of bile can lead to jaundice. Such stones are usually removed by inserting an endoscope (ERCP) before laparoscopic cholecystectomy, or as a part of laparoscopic common bile duct exploration with laparoscopic cholecystectomy.

Endoscopic removal of the common bile duct stone is the commonly used method to treat stones in the common bile duct where facilities are available.

Traditionally, a T-tube through an opening made in the common bile duct is used.[3-5] The top horizontal portion of the 'T tube' is inside the common bile duct while the long vertical bottom part is brought out of the abdomen and connected to an external bag for drainage. The cystic duct is sealed if the exploration is done through it. In addition to acting as a drain, which drains the bile from the common bile duct to the exterior, dye can be injected into the T-tube and an X-ray used to demonstrate any residual stones. Once the absence of residual stones is confirmed, the T-tube is removed. The build-up of bile along with the swelling can potentially prevent the healing of the bile duct resulting in a leakage of bile from the common bile duct into the abdomen. Uncontrolled bile leak can be potentially life-threatening if not recognized and treated.

The tiny hole left after T-tube removal in the common bile duct normally heals without a trace but, bile can leak through this hole raising the questions of the use of a T-tube after laparoscopic common bile duct exploration.

There are numerous reports of complications specifically associated with the use of a T-tube for biliary drainage.[6,7] These occur after both open and laparoscopic exploration of the common bile duct. In general, complications include fluid and electrolyte disturbances, sepsis, premature dislodgement, bile leak, localised pain, biliary peritonitis, prolonged biliary fistulae and late biliary stricture. It is important to note that the presence of a T-tube does not prevent bile leaks as they occur both when it is still in situ, as well as after its removal.[8,9] Previous studies comparing primary closure with T-tube drainage in open techniques showed a significant reduction in hospital stay and duration of operation with comparable complication rates.[10] Subsequently, Wu et al in a prospective randomised experimental animal study of different laparoscopic techniques of exploration and closure of the common bile duct, showed similar reduction in operating time.[11] They also reported that primary closure of the common bile duct resulted in a significant increase in stenosis.

The need for this arises because the question still remains whether T-tube drainage is better than primary closure after laparoscopic exploration of common bile duct in Indian settings in terms of efficacy, safety and feasibility although laparoscopic common bile duct exploration are performed only in highly specialized centres, using instruments or a camera, or both, which are introduced into the common bile duct usually through a cut in the common bile duct. So, we carried out our study with the objective of comparing the efficacy, safety and feasibility of primary closure of common bile duct and T-tube drainage in patients undergoing choledocholithotomy.

METHODS

The study was conducted in Sikkim Manipal institute of medical sciences, Gangtok on patients operated between January 2017 and April 2018.This study was designed as a prospective interventional study. Sample size was calculated assuming the mean operation time in primary closure group 1 as 100.6 minutes and in T-Tube group as 125.1 minutes with respected standard deviations of 20 and 25 respectively, as per previous study by El-Geidie et al. The other parameters considered for sample size calculation were 80% power of study and 5% alpha error. Thirty-two such patients were included in the study. The same group of patients was studied before and after choledocholithotomy. Due approval of the institution ethics committee (IEC)- Sikkim Manipal institute of medical science was obtained before commencing the study.

Selection criteria

Inclusion criteria

Patients with cholelithiasis and common bile duct stones (proven pre-operatively) or having common bile duct stones only.

Exclusion criteria

Grossly thickened bile-duct wall / recent cholangitis. Equipment or other technical failure leading to ergonomic difficulties. Any deviation of standard surgical protocol for choledocholithotomy. Presence of intra-hepatic stones. Biliary strictures. Choledocholithiasis with pregnancy. Suspicion of malignancy at presentation. Older than 80 years old, patients with history of laparotomy, history of heart failure, renal failure, cerebrovascular accidents and myocardial infarction.

Standard procedural method

All enrolled patients were given prophylactic antibiotics. Biliary tree was approached via a right sub-costal incision. Common bile duct was confirmed by aspiration of bile. A longitudinal supraduodenal choledochotomy was done between stay sutures placed on common bile duct. Stones was retrieved with Desjardin forceps, or was milked out, and common bile duct was being irrigated with normal Saline. Proximal and distal patency was checked in all cases. Rigid ureteroscope was used to check for complete clearance and patency of both proximal and distal bile duct. Confirmation of patency of common bile duct was done by intra- operative cholangiogram. Patients with common bile duct diameter more than 15 mm was included in the primary closure group. The choledochotomy was closed primarily with interrupted 4-0 absorbable sutures (4-0 polydioxanone). At the end of the procedure, a single 30F sub-hepatic drain was placed. Those with common bile duct diameter less than 15 mm was included in the T-tube drainage group. A silicone t-tube of appropriate size (14-16 French size) was inserted into the common bile duct and common bile duct incision was closed using interrupted sutures (4-0 polydioxanone). Saline was flushed through the T-tube to rule out leakage. At the end of the procedure, a single 30F sub-hepatic drain was placed.

Cholecystectomy was performed after ligation and division of cystic duct and artery. Closure of abdominal wall was done in 2 layers using polyglactin 2-0 sutures. Drain / T-tube was secure in situ with silk 1-0. The day after the surgery, patients was ambulated, and oral intake was started on post-operative day 1 and gradually shifted to full diet as per tolerance. Post-operative parameters were recorded. T-tube cholangiogram was performed on 10^{th}-12^{th} post-operative day prior to removal; and sub-hepatic drain was removed on the next day in the T-tube group.

Study parameters

Intra operative parameters

Total Duration of surgery (minutes). Common bile duct clearance method = sounding/flushing, Cholangioscopy. Confirmation of patency: intra-operative cholangiogram. Common bile duct closure method: primary closure / T-tube drainage.

Post-operative parameters

Post-operative complains nausea/vomiting, pain based on visual analogue scale was recorded in each group. Post-operative Day 3 total bilirubin, direct bilirubin and alkaline phosphate values was recorded. Daily drain output in primary closure group and drain output including T –tube bile output was in T- tube group. In the T-tube group, T-tube cholangiogram was performed on the 9-12th postoperative day and tube was removed after confirmation of free flow of contrast with no residual stone. If there was an insignificant output from drain, it was removed, and patients were discharged. Hospital stay defined as postoperative admission days was recorded in each group. Postoperative complications: bile leak, biliary peritonitis after t-tube removal, biliary peritonitis after drain removal, surgical site infection and hospital expenses (₹) was recorded for each group.

Statistical methods

The data collected were tabulated and analysed by Statistical package for social sciences (SPSS) software version 21.0 for windows as well as Microsoft excel 2016 with inbuilt statistical analysis tool. Different statistical aggregates like mean, median and mode were used to analyse numerical (scale) variables.

Frequency distribution were used in case of non-numerical variables (nominal and ordinal) variables. Appropriate statistical methods were used to determine the significance of differences between various comparisons.

Student's t-test

For difference between means of different data arrays paired or unpaired two-tailed Student's t-test was employed, depending on the circumstance.

Chi-square ($\chi 2$) test

Chi-square ($\chi 2$) test was used for evaluation of the significance of difference in distribution of different data arrays.

Mann-Whitney U-test

U- test was used for evaluation of the significance of difference in means and medians of a given parameter between the two groups.

Irrespective of the method used, differences between various parameters among different groups or subgroups were considered significant if the p value was less than 0.05.

RESULTS

Demographic parameter

In primary closure group 2 (12.5%) were male and remaining 14 (87.5%) were female. In T-tube group 10 (62.5%) were male and remaining 6 (37.5%) were female.

The difference in the proportion of gender between groups was statistically significant (p value 0.003). The mean age was 40.81±15.08 in primary closure group and it was 47.5±11.66 in T-tube, the difference between two groups was statistically not significant (p value 0.171). (Table 1).

Table 1: Comparison of demographic parameter between the two study groups.

Demographic parameter	Group		P value
	Primary Closure	T- tube	
Age (Mean±SD)	40.81±15.08	47.5±11.66	0.171
Gender			
Male (%)	2 (12.5)	10 (62.5)	0.003
Female (%)	14 (87.5)	6 (37.5)	

Mean total duration of the surgery and hospital stay

The mean total duration of the surgery was 132.44±10.06 minutes in the primary closure group, and it was 146.31±5.62 min in the T-tube group. The difference between two groups was statistically significant ($p<0.001$).

The patients were discharged on the 9th day at average in the primary closure group, while in the T-tube they were discharged on the 13th day on average. This difference was statically significant ($p<0.001$) (Table 2 and 3).

Table 2: Comparison of total duration of the surgery (minutes) between the two study groups.

Parameter	Group		Independent sample T-test p value
	Primary Closure (Mean ±SD)	T- tube (Mean ±SD)	
Total duration of the surgery (minutes)	132.44±10.06	146.31±5.62	<0.001

Table 3: Comparison of duration of hospital stay between the two groups (n=32).

Post-operative hospital stays (days)	Group		Independent sample T-test p value
	Primary closure	T- tube	
Mean±SD	9.00±0.81	12.87±1.40	Independent sample t-test p<0.001
Median (IQR)	9 (8.25 to 10)	13 (12 to 14)	Mann Whitney U test p<0.001

Table 4: Comparison of hospital expenses between the two study groups (n=32).

Parameter	Group		Mann-Whitney U-test p value
	Primary Closure (Mean ±SD)	T-tube (Mean ±SD)	
Hospital expenses	₹ 39203.75± 6369.84	₹ 43153.13± 4841.85	0.032

Hospital expenses

The mean hospital expense in the primary closure group was lower at ₹ 39203.75±₹6369.84 than ₹ 43153.13±₹ 4841.85 of the T-tube group, the difference being statistically significant (p=0.032) (Table 4).

This correlates with a significant (p=0.004) positive correlation (Pearson correlation r=0.492) between duration of hospital stay and total expense.

DISCUSSION

The gender proportion observed in our study was at variance with that reported Ambreen et al and Williams et al who reported that the difference in sex distribution was statistically insignificant in the two groups.[10,13]

In our study, the mean total duration of the surgery was 132.4 minutes in primary closure group while it was 146.3 minutes in the T-tube group. This difference of around 14 minutes between two groups was statistically significant with a p<0.001.[14] Similar to our study Mokarram et al also reported a significantly higher duration of surgery by about 30 minutes in T tube compared to primary closure. Thus, it can be concluded that the duration of surgery is lesser if CBD is closed primarily.

Mokarram et al reported a higher mean duration of stay at hospital by about 6 days in the T-tube group (13.4 days) compared to primary closure group (7.0 days).[14] Ambreen et al13 also reported a higher duration of stay in the T-tube group by a mean of 8.5 days. Similarly, in our study, the median duration of stay was more by about 4 days (p<0.001) in the T-tube group (13 days) compared to the primary closure group (9 days). Thus, it can be firmly asserted that following choledocholithotomy, primary CBD closure offers a better chance of earlier discharge from hospital.

The mean total hospital expense of ₹ 43,153 in the T-tube group was significantly (p=0.032) higher by ₹ 3,950 than the ₹ 39,203 of the primary closure group.

Ambreen et al, similar to our study, too reported a significantly higher cost of treatment in the T-tube group (nearly 3 times higher in their study) compared to the primary closure group (p<0.001).[13] In a developing country like India, with an annual per capita income of $1670 in 2016 (compared to a world average of $10321) this difference in expenditure has significant implication not only for the family of the patient, but also has major impact on public health.

There is a definite reduction of hospital expense if primary choledochorraphy is done after choledocholithotomy, as compared to T-tube placement. The longer stay in the hospital and the additional cost of postoperative cholangiography contribute to the increased expense in T-tube group.

Limitation of the current study

The current study is applicable only to open choledocholithotomy; findings may be applicable to laparoscopic choledocholithotomy. Lack of genuine randomization as segregation into two groups was done on the basis of CBD diameter with a cut-off of 15 mm. Long term follow-up was not done for stone residual recurrent CBD calculi. The sample size included in this study is small. Single centred study.

CONCLUSION

Primary choledochorraphy is a safe option in selected patients undergoing choledocholithotomy, provided common bile duct patency and clearance can be

confirmed intra-operatively. It provides the advantages of avoiding inconvenience to the patient caused by a t-tube, avoidance of need for review T-tube cholangiogram, earlier sub-hepatic drain removal, earlier discharge from hospital and lesser cost of treatment. This study shows that primary closure of common bile duct has a significantly shorter operating time and lesser duration of stay at hospital as compared to insertion of t-tube.

Recommendations

Primary choledochorraphy after open choledocho-lithotomy can be considered as a safe option in selected patients in to order to try to expedite discharge of patient and reduce hospital cost. Further randomized studies are required to establish the validity of these findings and establish exact guidelines for case selection for primary repair of common bile.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Perez G, Escalona A, Jarufe N, Ibanez L, Viviani P, Garcia C et al. Prospective randomized study of T-tube versus biliary stent for common bile duct decompression after open choledocotomy. World J Surg. 2005;29(7):869-72.
2. Ahrendt SA PHBtITM. Sabiston Text book of Surgery. Philadelphia, WB Saunders. 2004.
3. Sheen-Chen SM, Chou FF. Choledochotomy for biliary lithiasis: is routine T-tube drainage necessary? A prospective controlled trial. Acta Chir Scand. 1990;156(5):387-90.
4. Croce E, Golia M, Azzola M, Russo R, Crozzoli L, Olmi S et al. Laparoscopic choledochotomy with primary closure. Follow-up (5-44 months) of 31 patients. Surg Endosc. 1996;10(11):1064-8.
5. Seale AK, Ledet WP. Primary common bile duct closure. Arch Surg. 1999;134(1):22-4.
6. Galán C, Alonso AC. Bile leakage after removal of T tubes from the common bile duct. Brit J Surg. 1990;77(9):1075-.
7. Gharaibeh KI, Heiss HA. Biliary leakage following T-tube removal. Int Surg. 2000;85(1):57-63.
8. Wills VL, Gibson K, Karihaloot C, Jorgensen JO. Complications of biliary T-tubes after choledochotomy. ANZ J Surg. 2002;72(3):177-80.
9. Marwah S, Singh I, Godara R, Sen J, Marwah N, Karwasra RK. Evaluation of primary duct closure vs T-tube drainage following choledochotomy. Indian J Gastroenterol. 2004;23(6):227-8.
10. Williams JA, Treacy PJ, Sidey P, Worthley CS, Townsend NC, Russell EA. Primary duct closure versus T-tube drainage following exploration of the common bile duct. Aust N Z J Surg. 1994;64(12):823-6.
11. Wu JS, Soper NJ. Comparison of laparoscopic choledochotomy closure techniques. Surg Endosc. 2002;16(9):1309-13.
12. El-Geidie AA. Is the use of T-tube necessary after laparoscopic choledochotomy? J Gastrointest Surg. 2010;14(5):844-8.
13. Ambreen M, Shaikh A, Jamal A, Qureshi J, Dalwani A, Memon M. Primary closure versus T-tube drainage after open choledochotomy. Asian J Surg. 2009;32(1):21-5.
14. Mokarram A, Kajla RK, Jajra D. A randomised controlled study for comparision of primary closure of common bile duct versus t-tube drainage in case of choledocholithiasis. Int J of Allied Med Sci and Clin Res. 2016;4(2):167-70.
15. World Bank. World Development Indicators: GNI. World Bank. International Economics Dept. Development Data. 2016. Available at: http://databank.worldbank.org/data/reports.aspx?source=2&series=NY.GNP.PCAP.CD&country=IND, WLD#advancedDownloadOptions. Accessed on 6 June 2018.

Cite this article as: Imam MN, Prasad VS, Sharfuddin S, Chettri B. A prospective interventional study to compare T-tube placement and primary closure of common bile duct in patients undergoing choledocholithotomy. Int Surg J 2022;9:1151-5.