International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 10, October 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.10.2024.127

Original Research

Prospective Observational Study Comparing Primary Closure Of Common Bile Duct Versus T-Tube Drainage After Open Choledochotomy

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Received Date: 15 August, 2024 Accepted Date: 27 September, 2024

Abstract

Introduction: Choledocholithiasis, affecting 3% to 14.7% of cholecystectomy patients, can lead to complications such as biliary colic, jaundice, and pancreatitis. Treatment options include ERCP, laparoscopic CBD exploration (LCBDE), and open surgery, with LCBDE emerging as a preferred method for high-risk cases. This study aims to compare primary closure and T-tube drainage in open choledocholithotomy, focusing on safety, operative timing, hospital stay, infection rates, and bile collection.

Aim and Objectives: This prospective observational study evaluates the outcomes of primary closure versus T-tube drainage after open choledochotomy, examining safety, operative timing, duration of hospital stay, surgical site infections (SSIs), and bile collection.

Methodology: Conducted over one year at SMCH, this study will include 60 patients with obstructive jaundice or cholangitis due to common bile duct stones. Patients will undergo detailed pre-operative assessments and then be randomly assigned to either primary closure or T-tube drainage groups. Post-operative care will involve monitoring for SSIs, conducting cholangiograms for the T-tube group, and evaluating outcomes through statistical analysis using SPSS and GraphPad Prism.

Results: Early findings suggest lower incidences of bile collection and shorter hospital stays in the primary closure group compared to the T-tube drainage group, which required more interventions for SSIs. Data will be analyzed using chi-squared tests and t-tests to assess statistical significance.

Conclusion: This study aims to provide insights into the comparative efficacy of primary closure versus T-tube drainage after open choledochotomy. Preliminary results indicate that primary closure may offer benefits in reducing hospital stays and complications, potentially
influencing future treatment protocols for choledocholithiasis management. Further analysis will validate these findings and their implications for surgical practice.

Keywords: Fosfomycin, Escherichia coli, Urinary tract infection

INTRODUCTION

Choledocholithiasis, or common bile duct stones (CBDS), affects 3% to 14.7% of patients undergoing cholecystectomy and can present with symptoms like biliary colic, jaundice, cholangitis, or pancreatitis, or it may be asymptomatic. Treatment must be tailored to the clinical presentation, considering patient satisfaction, stone characteristics, and surgeon expertise. Options include ERCP, laparoscopic CBD exploration (LCBDE), or open surgery, each with its pros and cons. Secondary bile duct stones from the gallbladder, found in up to 15% of gallstone patients,

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pose risks like pancreatitis and cholangitis. Laparoscopic cholecystectomy, paired with ERCP in a two-step approach, has become the gold standard, offering benefits such as reduced pain, shorter hospital stays, and faster recovery. However, ERCP has a failure rate of 10% to 25% and challenges in cannulating the ampulla of Vater, often necessitating CBD exploration.

Laparoscopic surgeons have adopted LCBDE as an alternative to ERCP, especially in cases prone to ERCP failure. Identifying high-risk stones allows for early intervention, improving outcomes and reducing healthcare costs. Traditionally, T-tube drainage has been used in bile duct exploration to facilitate drainage and check for residual stones. However, bile accumulation and swelling can lead to bile leakage, a serious complication. Primary closure of the bile duct has shown benefits like shorter hospital stays and operation times, though questions remain about its superiority over T-tube drainage, particularly in India. This study aims to compare primary closure and T-tube drainage in open choledocholithotomy, focusing on safety, operative timing, hospital stay, infection rates, and bile collection.

AIMS AND OBJECTIVES

Aim

- Prospective Observational study comparing Primary closure of common bile duct versus T-tube drainage after open choledochotomy.

Objectives

To compare the Primary closure with T-Tube drainage after open choledochotomy in terms of-

1. Safety
2. Operative timing
3. Duration of hospital stay
4. Surgical site infection
5. Bile collection

MATERIALS AND METHODS

This prospective observational study will be conducted over one year in the General Surgery department of SMCH, focusing on patients with hyperbilirubinemia, obstructive jaundice, or cholangitis due to gallstone disease and common bile duct stones detected via ultrasonography or MRCP. A total of 60 patients undergoing elective open choledocholithotomy with a common bile duct diameter greater than 12 mm and failed ERCP will be included. Exclusion criteria include suspicion of malignancy, common bile duct strictures, choledochal cysts, a common bile duct diameter of less than 4 mm, refusal of surgery, or being unfit for surgery. The methodology involves detailed pre-operative assessments including clinical history, physical examination, and various baseline investigations like CBC, LFT, serum amylase, and lipase levels, as well as imaging studies such as ultrasonography, MRCP, and CECT in selected cases to rule out malignancy.

Surgical procedures will involve standard supraduodenal anterior choledochotomy for common bile duct exploration and stone removal, with the use of a flexible choledochoscope to ensure clearance of the biliary tract. Patients will be divided into two groups: Group A will have the choledochotomy closed with 3/0 vicryl continuous sutures, while Group B will have a T-tube inserted into the choledochotomy, which will be closed with No. 3-0 polygalactin sutures. Post-operative care will include antibiotics, LFT on the second day, and follow-up ultrasounds before discharge. Group A patients will be followed up at two weeks and one month, while Group B patients will undergo a T-tube cholangiogram on the tenth post-operative day, with T-tube removal on the fourteenth day if the cholangiogram confirms no residual stones. Statistical analysis will be conducted using SPSS and GraphPad Prism, employing t-tests, chi-squared tests, and p-value determination to assess the significance of the results, with a p-value of ≤ 0.05 considered statistically significant.

RESULT

In this study, we aim to evaluate and compare the outcomes of primary closure versus T-Tube drainage after performing open choledochotomy. Patients assigned to the T-Tube drainage group will undergo a cholangiogram between the seventh and fourteenth postoperative day to assess the bile duct's integrity and detect any potential issues. If the cholangiogram results indicate a clear and unobstructed bile duct, the T-Tube will be safely removed. In cases of surgical site infections (SSIs), a range of treatments will be employed depending on the severity. Mild infections will be managed conservatively with antibiotics and appropriate wound dressings, while more severe or persistent infections may require surgical intervention, such as debridement, to ensure proper healing.

The study will thoroughly analyze critical outcomes, including the incidence of bile leaks, the frequency of SSIs, and the necessity for additional surgical procedures. These outcomes will be statistically examined using chi-squared tests for categorical variables and t-tests for continuous variables to determine any significant differences between the two groups. A p-value of less than 0.05 will be considered indicative of statistical significance, providing valuable insights that could influence and improve future treatment strategies for patients undergoing open choledochotomy.

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Table 1: Demographic and Baseline Characteristics

Characteristic	Primary Closure	T-TubeDrainage	Total	Percentage(%)
TotalPatients	30	30	60	100%
Age(mean± SD,years)	55 ± 12	57 ± 11	-	-
Gender				
-Female	18	17	35	58.3%
-Male	12	13	25	41.7%
BMI(mean ± SD, kg/m²)	25.3 ± 4.2	26.1 ± 3.8	-	-

Table 2: Postoperative Bile Collection Detected by Ultrasound whole abdomen

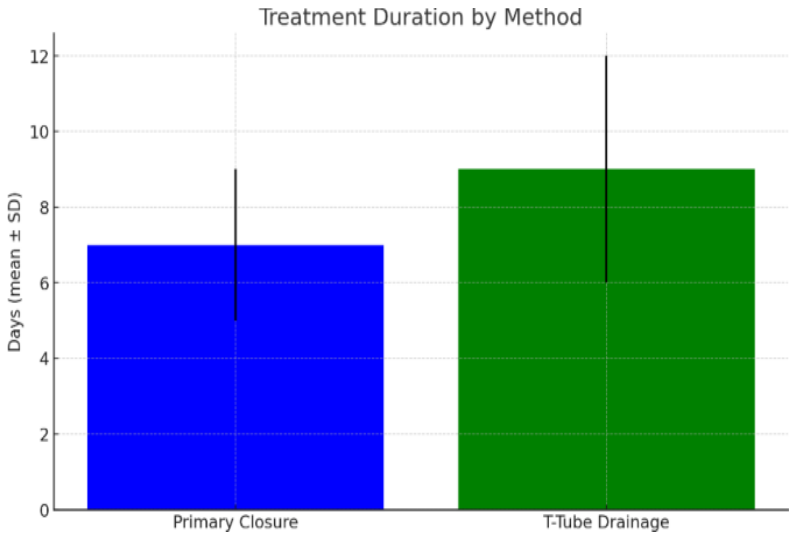
Outcome	Primary Closure	T-TubeDrainage	Total	Percentage(%)
NoCollection	29	27	56	93.3%
BileCollection	1	3	4	6.7%

Table 3: Surgical Site Infection Rates and Management

Outcome	Primary Closure	T-Tube Drainage	Total	Percentage(%)
No Infection	28	25	53	88.3%
SSI Managed Conservatively	1	2	3	5%
SSI Requiring Surgical Intervention	1	3	4	6.7%

Table 4: Duration of Hospital Stay

Outcome	Primary Closure	T-Tube Drainage	Total	Percentage(%)
Days(mean±SD)	7 ± 2	9 ± 3	-	-



DISCUSSION

In our study comparing primary closure and T-tube drainage for bile duct management, we enrolled 60 patients evenly split between the two techniques. The demographic analysis showed comparable age distributions with the primary closure group averaging 55 years (SD ± 12) and the T-tube drainage group at 57 years (SD ± 11). Gender distribution was also similar, with females constituting 58.3% of the participants across both groups. Additionally, the Body Mass Index (BMI) indicated that both groups were within the normal to slightly overweight range, with the primary closure group averaging a BMI of 25.3 (SD ± 4.2) and the T-tube group at 26.1 (SD ± 3.8). These characteristics suggest that the study groups were well-matched, allowing for a focused comparison of the surgical outcomes attributable to the different management techniques used.Gurusamy KS et al,[11] analyzed data from six trials involving 359 participants, with 178 undergoing T-tube drainage and 181 undergoing primary
closure after surgery, all of which had a high risk of bias. The mortality rates between the groups showed no significant difference, with 1.2% in the T-tube group (4 out of 178) and 0.6% in the primary closure group (1 out of 181), resulting in a relative risk (RR) of 2.25, but the confidence interval (95% CI of 0.55 to 9.25) suggests this might be due to chance. Serious complications were also similar, with 145 per 1000 patients in the T-tube group and 66 per 1000 in the primary closure group, yielding a rate ratio (RaR) of 2.19, though the confidence interval (95% CI of 0.98 to 4.91) indicates uncertainty. However, T-tube drainage was associated with longer surgeries (by

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about 29 minutes) and extended hospital stays (by approximately 4.72 days), both statistically significant, indicating higher resource use. None of the trials reported on quality of life or return-to-work timing. While no clear difference in mortality or serious morbidity rates was found between the methods, T-tube drainage demands more surgical time and longer hospital stays, though these results should be cautiously interpreted due to the high risk of bias in the trials.

In our study, we investigated the postoperative outcomes associated with two common interventions for bile duct surgery: primary closure and T-tube drainage. We aimed to compare the incidence of bile collections following these procedures. Out of the total participants, 56 did not develop any bile collections, representing 93.3% of the cohort. This indicates a high success rate for both techniques in preventing postoperative bile collections. Specifically, primary closure resulted in 29 cases without bile collections, while T-tube drainage accounted for 27 cases, underscoring the effectiveness of both methods in the majority of cases. However, bile collections did occur in a small fraction of the patients—4 out of 60, or 6.7%. Among these, 1 occurred in the primary closure group and 3 in the T-tube drainage group. This suggests a slightly higher risk of bile collection with T-tube drainage compared to primary closure, although the difference is not substantial. These findings
highlight the general reliability of both surgical techniques while also pointing to a marginal difference in the risk of postoperative complications such as bile collections.

In our study, we explored the postoperative outcomes associated with primary closure versus T-tube drainage in terms of infection rates. The results indicated that a substantial majority of the patients—53 out of 60, or 88.3%—did not develop any infections post-surgery, showcasing the general effectiveness of both methods in maintaining surgical site integrity. Specifically, primary closure led to no infections in 28 cases, and T-tube drainage in 25 cases. Despite this overall success, surgical site infections (SSIs) occurred in 7 cases, reflecting a minority but notable concern.Among the SSIs noted, 3 (5%) were managed conservatively without the need for further surgical intervention; 1 of these occurred in the primary closure group and 2 in the T-tube drainage group. More severe SSIs requiring surgical intervention were observed in 4 cases (6.7%), with 1 in the primary closure group and 3 in the T-tube drainage group. This pattern suggests a slightly higher risk of more severe infections requiring surgical intervention in patients who underwent T-tube drainage compared to those who had primary closure. These findings emphasize the importance of close monitoring and prompt management of SSIs, particularly in the context of T-tube drainage, to mitigate the need for additional surgical procedures.

In our study, we assessed the average recovery times following two different surgical interventions for bile duct management: primary closure and T-tube drainage. The results indicate a mean recovery duration of 7 days (with a standard deviation of 2 days) for patients undergoing primary closure. In contrast, the mean recovery time for those receiving T-tube drainage was slightly longer, at 9 days, with a standard deviation of 3 days. This variation in recovery times suggests that primary closure may facilitate a quicker postoperative recovery compared to T-tube drainage. The extended recovery period associated with T-tube drainage could be attributed to the more complex nature of the procedure or greater postoperative care requirements, including management of the drainage tube. These findings underscore the importance of considering postoperative recovery time when choosing between these surgical options, as shorter recovery times can enhance patient comfort and reduce hospital stay durations, potentially influencing the overall cost and efficiency of care.Omar MA et al.,[12]compared postoperative outcomes among three procedures: T-tube drainage (TTD), primary duct closure (PDC), and antegrade biliary stenting (ABS). Patients in the PDC and ABS groups experienced significantly lower pain scores from postoperative day 1 to 3 and required fewer opioids compared to those in the TTD group. The ABS group showed significantly lower total bilirubin levels on postoperative days 3 and 5, along with shorter hospital stays and drain-carrying times than the TTD group. Although there were no significant differences in treatment costs, patients in the PDC group returned to normal activities faster than those in the TTD and ABS groups. However, re-intervention rates were higher in the PDC and TTD groups compared to ABS, primarily due to procedures like ERCP and sphincterotomy. Readmission rates were lowest in the ABS group, and patient satisfaction was highest in the ABS and PDC groups compared to TTD.

CONCLUSION

In this study, we compare the outcomes of primary closure versus T-Tube drainage following open choledochotomy. The T-Tube is removed based on favorable cholangiogram results between the seventh and fourteenth postoperative days, confirming an unobstructed bile duct. Surgical site infections (SSIs) are addressed according to severity, with mild cases treated conservatively using antibiotics and appropriate wound care, and severe cases potentially requiring surgical debridement. We specifically look at the incidence of bile leaks, SSIs, and the need for additional surgeries, employing chi-squared tests and t-tests to evaluate statistical significance, with a threshold set at $p < 0.05$. Early results indicate a lower incidence of bile collection and shorter hospital stays for the primary closure group. Conversely, the T-Tube

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drainage group shows a higher necessity for surgical interventions in response to SSIs. These insights could significantly influence and improve the surgical and postoperative treatment strategies for patients undergoing open choledochotomy.

BIBLIOGRAPHY

1. Abolfazl Shojaiefard, Majid Esmaeilzadeh, Ali Ghafouri, and ArianebMehrabi. Various Techniques for the Surgical Treatment of Common Bile Duct Stones: A Meta Review; Gastroenterol Res Pract. 2009; Published online 2009Aug 6;
2. Petelin JB. Surgical management of common bile duct stones; Gastrointest Endosc. 2002; 56(6 Suppl): S183–189;
3. Sahai AV, Mauldin PD, Marsi V, Hawes RH, Hoffman BJ. Bile duct stones and laparoscopic cholecystectomy: a decision analysis to asses the roles of intraoperative cholangiography, EUS, and ERCP. Gastrointest Endosc. 1999; 49(3): 334–343;
4. Cotton PB. Endoscopic retrograde cholangiopancreatography and laparoscopy cholecystectomy; Am J Surg; 1993; 165(4): 474–478;
5. Tai C, Tang C, Ha J, Chau C, Siu W, Li M. Laparoscopic exploration of common bile duct in difficult choledocho lithiasis; Surg Endosc. 2004; 18(6): 910–914;
6. Rhodes M, Sussman L, Cohen L, Lewis MP. Randomised trial of laparoscopic exploration of common bile duct stones in a postoperative endoscopic retrograde cholangiography for common bile duct stones; Lancet. 1998; 351: 159–161;
7. Tang C, Li M. Technical aspects in the laparoscopic management of complicated common bile duct stones; J Hepatobiliary Pancreat Surg. 2005; 12: 444–450;
8. Francesco A Polistina, Mauro Frego, Marco Bisello, Emy Manzi, Antonella Vardanega, and Bortolo Perin. Accuracy of magnetic resonance cholangiography compared to operative endoscopy in detecting biliary stones, a single center experience and review of literature; World J Radiol. 2015; Apr 28; 7(4): 70–78. doi: 10.4329/wjr.v7.i4.70
9. David P. Vogt, M.D., Robert E. Hermann, M.D. Choledochoduodenostomy, Choledochojejunostomy or Sphincteroplasty for Biliary and Pancreatic Disease; Ann. Surg.; February 1981; 261 pg.;
10. Gold MS, Maginot A, Gliedman ML (1985). Choledochoduodenostomy after previous gastrectomy or duodenal operations; Surg Gynecol Obstet.; 161:142– 144;
11. Gurusamy KS, Koti R, Davidson BR. T-tube drainage versus primary closure after open common bile duct exploration. Cochrane Database Syst Rev. 2013 Jun 21;(6):CD005640. doi: 10.1002/14651858.CD005640.pub3. PMID: 23794200.
12. Omar MA, Redwan AA, Alansary MN. Comparative study of three common bile duct closure techniques after choledocholithotomy: safety and efficacy. Langenbecks Arch Surg. 2022 Aug;407(5):1805-1815. doi: 10.1007/s00423-022-02597-3. Epub 2022 Jul 4. PMID: 35786738; PMCID: PMC9399200.