ORIGINAL ARTICLE

Comparison of Primary Repair Versus T-Tube Placement After CBD Exploration in the Management of Choledocholithiasis

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ABSTRACT

Background: Choledocholithiasis is the formation of gallstones in the common bile duct. These stones are removed by performing common bile duct exploration. The choice lies between primary duct closure and T-tube drainage which is a standard practice after surgical choledochotomy.
Aim: To determine the safety and efficacy profile of primary repair versus T-Tube placement in the management of Choledocholithiasis.
Methods: This was a randomized trial. This study was carried out in Department of Surgery, Lahore General Hospital, Lahore. Total 40 patients were included in the study and randomly classified into two groups. In Group-A patients were treated with CBD exploration and primary closure, and in Group-B patients were treated with CBD exploration and primary closure with T-Tube.
Results: The mean age of patients in Group-A was 41.85±9.33 years and in Group-B 40.35±11.09 years. The mean operative time, post operative hospital stay and time for sub hepatic drain values were significantly short (p-value < 0.05) in group-A as compared to corresponding values of group-B.
Conclusion: Primary repair is more effective and safe in comparison to T-Tube placement for treating choledocholithiasis in terms of Leakage/biliary peritonitis, Time for subhepatic drain removal after surgery, Operative time and Post operative hospital stay. All these outcome parameters are of clinical significance for primary closure.
Keywords: Primary closure, CBD, T-Tube drainage, Hospital stay, Post operative time

INTRODUCTION

Cholecystectomy is the most common elective procedure performed by a general surgeon to treat cholelithiasis (gall bladder stones). Choledocholithiasis occurs in about 10–15% of patients with gall-bladder stone.[1] Common Bile Duct (CBD) stones are encountered in about 7–15% of patients undergoing cholecystectomy.[2] There are two common techniques for extracting CBD stones, either by endoscopic retrograde cholangiopancreatography (ERCP), or surgically, by an open or laparoscopic method. The conventional management by surgical intervening of CBD stones consists of a supra-duodenal choledocotomy and placement of a T-tube. The decision of drainage of T-tube is laid on the premise that it potentiates CBD decompression post operatively should exceed the happening of obstruction; it permits visualization of the CBD radiologically, and opens the pathway for getting rid of residing stones. The T-tube placement can variate in range of 7-45 days, considering person to person feasibility. It is advisable to have a T-tube cholangiogram done after the procedure to visualize any missed stones or biliary outflow.

In contrast to this, challenged facts about the placement of a T-tube and three randomised trials have depicted the advantage of primary repair over placement of T-tube. Persistent drainage of bile from inside can lead to fluid and electrolytes imbalance and dietary deprivations. Mostly cholangitis and wound sepsis are notable significant complications associated with T-tube placement. T- tube removal results in leakage of biliary fluid in about 1–30% of cases[3-10].

External loss of bile leak through T-tube may lead to slow process of wound healing, lack of appetite and constipation (post-choledocotomy acidotic syndrome). Complications like migration, fracture of tube, encrustation, hindrance in removal, and stricturing of duct are explained. The repeated formation of stones are thought to be more in T-tube drainage as the tube acts as a foreign body facilitating the precipitation of pigments and bile salts[11-16]. This study was undertaken to investigate the efficacy and safety of the primary closure of CBD without T-Tube. We hypothesized that primary repair is better in terms of lesser chances of bile leakage or biliary peritonitis, shorter operative time, early removal of sub hepatic drain and lesser post operative hospital stay as compared to T-Tube.

MATERIALS AND METHODS

This randomized control trail was conducted at the department of Surgery, Lahore General Hospital,

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Lahore, Using simple Random Sampling. All patients were divided into two groups using random number table. Patients of group-A were managed with CBD exploration and primary closure without T-Tube and groups-B received treatment mode of CBD exploration and primary closure over T-Tube. A total of 40 cases 20 in each group, were taken (the sample size was calculated by the following formula keeping the power of study equal to 90% and level of significance equal to 95%).

$$n = \frac{Z^2 \cdot p \cdot (1-p)}{e^2}$$

Where n is sample size, Z is the level of confidence (1.96), p is estimated frequency and e is the precision.

All patients between 20-65 years of age and of either sex were diagnosed to have CBD stones on USG. Patients with diagnosis of Cholecystitis or Acute Gall Bladder Disease, Cholangitis, Malignancy. Hepatic failure and Immunocompromised were excluded from study.

Outcomes were measured as leakage or biliary peritonitis that was checked by applying two methods; by bile drainage through subhepatic drain and biliary peritonitis which is manifested by abdominal pain, fever (>99F), tachycardia, tenderness, raised TLC (>10,000/uL) and collection on USG abdomen. Sub-hepatic drain time was calculated in terms of days from the day of operation to the day of removal of drain. Operative time was counted in minutes and started from time of incision till the end of procedure and Hospital stay was counted in terms of days from the date of surgery of a patient till discharge. All the patients were kept in postoperative recovery room for 4 hours until they were fully conscious. They were kept in the ward till they were pain free and mobile. Device was removed when drain was nil. The patients were followed up at 7^{th}, 14^{th}, 21^{st} and 30^{th} day of the discharge for the outcome parameters. The skin stitches were removed at 7^{th} day of surgery.

The collected data were entered in SPSS version 18 and analyzed through it. Mean and standard deviation were calculated for quantitative variables like age, time of surgery, hospital stay and time for sub-hepatic drainage. Qualitative variables, like biliary peritonitis and biliary leakage were described as frequency distribution table. Student t-test was applied for quantitative variables and Chi-square test was applied for qualitative variables like sex, infection and leakage. P-value ≤ 0.05 was considered as significant.

RESULTS

Mean age of Group-A patients was 41.85±9.33 years. Minimum and maximum ages were 28 and 60 years respectively. In Group-B mean age of patients was between 40.35±11.09 years. Minimum and maximum ages of patients were 28 and 65 years respectively. In Group-A gender distribution shows that 2 male and 18 female patients were selected. While in Group-B gender distribution shows that 5 patients were male and 15 patients were of female gender. Female patients were dominating male patients in both treatment groups. For Group-A mean operative time was 101.05±4.96 minutes while for Group-B mean procedure time was 117.05±8.12 minutes. According to p-value (<0.001) mean operative time was short for group-A (Primary closure) as compared to group-B (T-Tube drain). Mean time of hospital stays in Group-A was 6.40±1.39 days. Minimum and maximum hospital stay ranged between 4 and 10 days. In Group-B mean hospital stay time was 12.10±3. Minimum and maximum hospital stay was 9 days and 22 days respectively; p-value of <0.001 indicates that mean hospital stay was significantly short for group-A (Primary closure) as compared to group-B (T-Tube drain). None of the patients had Biliary Peritonitis in both treatment groups. In Group-A mean time for sub hepatic drain was 5.20±1.23 days and in Group-B 10.80±1.85 days. In Group-A minimum and maximum time for sub hepatic drain was 3 and 8 days while in Group-B it was 8 and 15 days respectively. Analysis of data shows that time for sub hepatic drain was significantly (p<0.001) short for group-A (Primary closure) as compared to group-B (T-Tube drain) (Table 1).

Table-1: Comparison of age, gender and treatment outcome in both study groups

		Treatment Group		p-value
		Group-A	Group-B	
Age (years)	Mean ± S.D	41.85±9.33	40.35±11.09	> 0.05
Gender	Male [n (%)]	2 (10%)	5(25%)	> 0.05
	Female [n (%)]	18 (90%)	15 (75%)	
Operation time (hours)	Mean ± S.D	101.05 ± 4.96	117.05 ±8.12	< 0.001
Hospital stay (days)	Mean ± S.D	6.40 ± 1.39	12.10 ± 3.0	< 0.001
Biliary Peritonitis	Yes [n (%)]	0 (0%)	0 (0%)	---
	No [n (%)]	20 (100%)	20 (100%)	
Sub hepatic drain (days)	Mean ± S.D	5.20 ± 1.23	10.80 ± 1.85	< 0.001

***Group-A*=** Primary Repair ***Group- B*=** T-Tube

DISCUSSION

Symptomatic gallstone disease is a very common indication for abdominal surgery. Choledocholithiasis is a complex procedure with significant morbidity and mortality[14].

In present study mean hospital stay in Group-A was 6.40±1.39 days and in Group-B mean hospital stay was 12.10±3 days. Hospital stay was shorter in patients who were treated with primary closure as compared to that of T-Tube. i.e., (p-value≤ 0.000)

These results are in agreement with studies conducted by Saeed *et al.,* (2012)[17] Ahmad *et al*, (2008)[14], Ambreen *et al* (2009)[18], Zhang *et al* (2004)[19]. Another study conducted by Makinen and Nordback showed little hospital admission span in T-tube group (not statistically important)[20].

Gurusamy in his study assessed the pros and cons of placement of T-tube drainage versus primary repair without biliary stent after open common bile duct exploration for common bile duct stones. The results indicate that hospital stay time was significantly longer in the T-tube drainage group compared with the primary closure group (MD 4.72 days; 95% CI 0.83 days to 8.60 days; five trials[21]. These results are consistent with the results of this study regarding the hospital stay in both treatment groups.

The outcome of primary repair of common bile duct after open choledochotomy was assessed in a local study. The findings of this study regarding the mean duration of hospital admission time (7.63±1.63 days)[22] are consistent with the results of the present study.

The application of a T-tube can lead to spasm or oedema of sphincter of Oddi to settle after the trauma of exploration. If the drainage of the duct is unsuccessful, it would result in creating of pressure in the extra hepatic ductal system, leading to outflow or mal repairing of duct with biliary peritonitis. Also it is used for detection and removal of retained stones through tube tract. Mean operative time in patients who were treated with primary closure and patients who were treated with t-tube insertion was 101.05±4.96 minutes and 117.05±8.12 minutes. Statistical analysis indicates that mean operative time was short in patients who were treated with primary closure as compared to that of T-tube.

Zhang reported no statistically significant difference in mean operative time for primary closure and t-tube drainage group. While in this study mean operative time was less for primary closure as compared to t-tube drainage group[19].

Gurusamy in his study reported that the duration of time of surgery was distinctly longer in the T-tube drainage group compared with the primary repair group (MD 28.90 minutes; 95% CI 17.18 to 40.62 minutes; one trial)[18]. These findings are in line with the results of this study. i.e., Primary repair had short operative time as that of T-Tube drainage group.
Haider in his study reported primary repair of CBD in terms of operating time was 95±7.0 minutes[19].

Williams *et al* observed no significant difference in the time of procedure between the two groups. i.e., Primary repair & T-Tube drainage (median operating time in both groups=120 minutes). Marwah *et al* observed a significantly lesser time span of procedure in the primary repair group compared to the T-tube group (mean 87.8 versus 116.7 minutes, P < 0.001)[10,23].

These findings reported by Williams and Marwah are in line with the results of this study results for mean operative time for open closure and T-tube drainage group.

Haider in his study reported that none of the patients experienced postoperative jaundice and biliary peritonitis[22]. Ambreen *et al.* found that after primary closure of the CBD, bile leakage was noted in one patient (6.3%), which subsided without any biliary peritonitis as compared to the T-tube group in which two patients (10.5%) had bile leakage.[14] However, Perez et al reported biliary peritonitis after removal of T-tube[1].

Williams & Marwah in his study reported that Bile peritonitis likely to develop in 1.0% of the patients of the primary repair group and 2.9% of the patients of the T-tube group. Out of three biliary peritonitis in the T-tube group, two occurred after removal of T-tube[10,23]. Biliary leakage, unrelenting biliary fistula, excoriation of epidermis and cholangitis caused by migration of microscopic creatures may prolong the hospital stay and delay recovery. T-tubes which are placed are uncomfortable, require continuous management and limit the patient's mobility because of the risk of dislodgment. Patients on free drainage with T-tubes are at risk of dehydration and electrolyte imbalance.

After the exploration of CBD and removal of residual stones, the option exists between primary duct repair and T-tube drainage. Recently, biliary stent insertion has also been used as a definite alternative to placement of T-tube drainage. T-tube drainage of the common bile duct is performed for the following reasons:

- CBD decompression after the procedure (if outflow obstruction occurs).
- visualization of common bile duct post operatively
- Convenient placement of a T-tube to extract common bile duct stones with a Burhenne steerable catheter.

However, the application of ERCP and choledochoscopy has reduced the importance of

these indications. Some researchers found no worth mentioning difference in the mortality or morbidity between primary repair and T-tube drainage, others found higher mortality, more biliary infection, and early morbidity after T-tube drainage. There have been reports of tube displacement causing common bile duct obstruction and biliary leakage following removal of T-tube. Furthermore, the hospital admission time is prolonged after T-tube drainage.

CONCLUSION

Primary closure of CBD is superior approach to that of T-Tube drainage in terms of short operative time (101.05 vs. 117.05 days), short post operative hospital stay (6.40 vs. 12.10 days) and time for sub hepatic drain (5.20 vs. 10.80 days). On the basis of these results it is conclusive as an open fact that Primary closure of CBD is safe and effective procedure, a definite alternative to T-tube drainage.

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