

Original Article

Comparative assessment between Primary Closure versus T-tube Drainage after Choledochotomy

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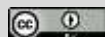
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Introduction: Conventional treatment of common cholelithiasis includes T-tube insertion after endoscopic retrograde cholangiopancreatography or common bile duct examination. The aim of this study is to demonstrate that treatment of patients with gallstones by laparoscopic common choledochotomy is safe and feasible with primary gallstone obstruction. **Objective:** To compare the clinical outcomes of primary closure and T-tube drainage after open common choledochotomy. **Methods & Materials:** This comparative study was conducted from January to June 2022 at the Department of Hepatobiliary Surgery, Enam Medical College and Hospital, Savar, Bangladesh. 50 patients were included in the study, of which 20 underwent primary closure. The patient underwent routine laboratory tests, including a complete blood count, liver function tests, coagulation tests, and abdominal ultrasound. **Results:** 50 patients were included in the study. The

mean age of patients who had primary closure done ($n=20$) was 46.0 ± 16.8 and there were 3 (15.0%) males and 17 (85.0%) females. After primary closure of the CBD, bile leakage was noted in one patient (5.0%), which subsided without any biliary peritonitis as compared to the T-tube group in which two patients (10.0%) had bile leakage. Postoperative jaundice was seen in one patient (6.6%) who had a T-tube because of a blockage of CBD. Not a single patient had a retained stone in both groups as well as no recurrence of CBD stones. The postoperative hospital stay after primary closure was $5.56 \pm$

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1.1 days as compared to after T-tube drainage which was 13.6 ± 2.3 days. The total cost of treatment in patients who underwent primary closure was USD194.5 \pm 41.5 but after T-tube drainage it was USD 548.6 \pm 88.5. The median follows up duration for both groups was 6 months. **Conclusion:** Primary CBD closure is a safe and cost effective alternative to routine T-tube drainage after open choledochotomy.

Keywords: Choledocholithiasis, Open Choledochotomy, Primary Closure.

INTRODUCTION

Conventional treatments for choledocholithiasis include endoscopic retrograde cholangiopancreatography and insertion of a T-tube after bile duct exploration. The use of a T-tube is not without complications. Choledocholithiasis occurs in approximately 10-15% of patients with gallstones^[1], and literature suggests that bile duct stones occur in approximately 7-15% of patients who undergo cholecystectomy^[2]. To avoid complications associated with the T-tube, primary biliary closure (CBD) was performed after the exploration. This pilot study is intended to evaluate the safety of primary CBD closure and serve as a basis for larger-scale implementation. There are two ways to remove CBD stones: endoscopically using endoscopic retrograde cholangiopancreatography (ERCP) and surgically, either open or laparoscopically. Open exploration of the bile duct has been the main treatment for almost 100 years. In some hospitals in developing countries, surgeons still perform this procedure because minimally invasive techniques such as ERCP are not available^[3]. Due to a lack of experienced endoscopists in smaller hospitals, patients must be transferred to larger centers for endoscopic diagnosis and treatment, which increases costs and reduces the burden on patients^[4]. Laparoscopic treatment of CBD stones is now well known^[5] but remains controversial. This operation requires skill

and equipment, so it is used by only a small number of surgeons^[6]. Moreover, the superiority of this procedure in the treatment of gallstones has not yet been proven, limiting its applicability^[7]. Therefore, open surgery is still the treatment of choice in many hospitals. The classical performance of bile duct exploration is accompanied by the problem of bile duct obstruction due to incision. Common choledochotomy followed by T-tube drainage is the traditional surgical treatment of common choledocholithiasis^[8]. T-tubes are used for postoperative bile duct decompression and have proven to be a safe and effective method, but they are not without complications, occurring in up to 10% of patients^[9]. The most common occurrence after resection is bile leakage, which occurs in 1-19% of cases^[6,10-12]. Some of these complications can be severe, such as bile leakage, urinary tract infection, and, especially in elderly patients, acute renal failure due to insufficient fluid intake and dehydration due to very large amounts of drainage. Moreover, biliary drainage for at least 3 weeks causes significant discomfort to the patient and delays return to work^[13-15]. Primary closure of the common bile duct after exploration is not new. Halsted was the first to describe the advantages of primary closure. There are numerous articles by various authors advocating direct closure of the levee immediately after exploration^[3,12,14,16,17]. The use of a chole-

dochoscope during surgery allows direct visualization of the common bile duct and residual stones are not an issue. In our institution, open cholecystectomy remains the first-line procedure for cholecystectomy stones. This study compares the short-term clinical outcomes of primary closure with those of T-tube drainage after common bile duct resection.

METHODS & MATERIALS

This comparative study was conducted at Hepatobiliary Surgery, Enam medical college Hospital, Savar, Bangladesh from January to June 2022. Fifty (50) patients were included in the study of which 20 patients underwent primary closure. The patients were evaluated with routine investigations including full blood counts, liver function tests, coagulation screening and abdominal ultrasonography. The criteria for choledochotomy were obstructive jaundice, CBD stones suggested by ultrasound, or the presence of stones in the CBD palpated preoperatively. Patients with pancreatitis, suppurative cholangitis and malignancy were excluded.

All patients received antibiotics before undergoing laparotomy. The Darcis duct was opened by a vertical incision above the duodenum between the sutures. Stones were removed and irrigated with saline to ensure patency. The duct's patency was confirmed by choledochoscopy. Subsequently, primary closure of the long duct was performed in 20 patients. After completion of cholangioscopy, patients were randomly assigned to undergo one of two surgical options: primary closure of the CBD or T-tube drainage. Intermittent 3/0 Vicryl sutures were placed. A T-tube was inserted into the CBD in 30 patients. All patients underwent subhepatic drainage. All patients who underwent T-tube drain-

age underwent T-tube cholangiography on postoperative day 7. After the patency of the CBD was confirmed and free flow of dye was present, the T-tube was clamped intermittently and removed on postoperative day 12. Ultrasound and liver function tests were performed postoperatively. Postoperative complications, postoperative hospital stay, and total treatment costs between the two groups were compared. Bile leakage was defined as yellow bile-like fluid leaking from the subhepatic drain or aspirating yellow bile-like fluid (300ml) under ultrasound guidance from the subhepatic peritoneal cavity after removal of the drain.

The data was analysed in statistical program SPSS version 21. Fisher's exact test of chi-squared was applied for categorical variables to calculate frequencies and percentages among the groups. Student's t-test was applied for continuous variable to compare the means (2 tailed) with median and range among the groups. All the parameters were calculated on 95% confidence interval. If the value of $p \leq 0.05$ it was considered statistically significant.

RESULTS

CBD exploration was performed in 50 patients, out of which 20 had primary closure of CBD after stone removal. A T-tube drain was placed in 30 patients. The mean age of patients who had primary closure was 46.0 ± 16.8 years (median, 48.5 years; range, 20–72 years) and that of T-tube drains was 41.9 ± 13.9 years (median, 40.0 years; range, 23–75 years). There were two males (15.0%) and 17 females (87.0%) in the primary closure group, and three males (16.6%) and 25 females (83.4%) in T-tube group [Table I]. Most of the patients in both groups presented with biliary colic (65.0% and

80.0%). Other clinical presentations were acute cholecystitis and jaundice, which were nearly of same frequency in each group. Out of 50 patients, eight patients had comorbidities like diabetes mellitus and hypertension (30.0% and 16.6%). Fourteen patients (90.0%) in the primary closure group had concomitant gallstones and 20 (66.6%) in the T-tube group as evident by preoperative abdominal ultrasound. Preoperative liver functions were compared between two groups. There was a significant difference in the

level of serum glutamic pyruvic transaminase (SGPT) between the two groups. Preoperative abdominal ultrasound showed the size of CBD and number of CBD stones, which was then confirmed during the operation. The mean diameter of CBD was 1.52 ± 0.36 cm (median, 1.45 cm; range, 1.2–2.3 cm) in patients who had primary closure and 1.64 ± 0.55 cm (median, 1.50 cm; range, 0.6–2.6 cm). The maximum number of stones (10) was noted in the T-tube drain group [Table I].

Table I: Demographic characteristics of patients (N=50)

	Group (n = 50)						p-value
	Primary closure (n=20)	Median	Range (Min–Max)	T-tube drain (n=30)	Median	Range (Min–Max)	
Age (yr)	46.0 ± 16.8	48.50	20–72	41.9 ± 13.9	40.0	23–75	NS
Gender							
Male	3 (15.0%)	–	–	5 (16.6%)	–	–	NS
Female	17 (85.0%)	–	–	25 (83.4%)	–	–	
Symptoms							
Biliary colic	13 (65.0%)	–	–	24 (80.0%)	–	–	NS
Acute cholecystitis	8 (40.0%)	–	–	10 (33.3%)	–	–	
Jaundice	10 (50.0%)	–	–	13 (43.3%)	–	–	
Co-morbidities	6 (30.0%)	–	–	5 (16.6%)	–	–	NS
Concomitant gallstones	18 (90.0%)	–	–	20 (66.6%)	–	–	NS
Preoperative liver function							
Total bilirubin (mg %)	2.2 ± 1.64	2.0	0–5	1.7 ± 1.97	1.0	0–8	NS
SGPT (U/L)	149.37 ± 152.09	96.0	20–600	55.42 ± 59.66	37.0	6–250	0.01
Alkaline phosphatase (U/L)	584.250 ± 319.50	725.0	99–1,050	3.9 ± 2.81	480.0	120–950	NS
Number of CBD	2.2 ± 1.52	2.0	1–6	460.578 ±	4.0	1–10	0.03

stones				259.56			
CBD diameter (cm)	1.52 ± 0.362	1,450.0	1.2–2.3	1.64 ± 0.555	1.50	0.6–2.6	NS

Fifteen patients in the primary closure group did not suffer any complication. One patient had a bile leakage that subsided on the third postoperative day. There was no biliary peritonitis. The total complication rate in this group was 5.0%. In the T-tube drain patients, biliary complication occurred in three patients, accounting for 6.6%. Two patients had bile leakage (10.0%) after removal of the T-tube that was managed by ultrasound

guided aspiration. In both of these patients, the T-tube was removed on the twelfth postoperative day. One patient had post-operative jaundice because of a blockage of the duct caused by the T-tube. The T-tube was removed and jaundice gradually subsided. There was not any recurrence of CBD stones seen up to 6 months follow up and postoperative ultrasound findings were almost normal [Table II].

Table II: Postoperative complications (n=50)

	Group (n= 50)		p-value
	Primary closure (n =20)	T-tube drain (n =30)	
Bile leakage	1 (5.0%)	3(10.0%)	NS
Postoperative jaundice	0	2(6.6%)	NS
Retained stone	0	0	–
Recurrence of	0	0	– CBD stones

The mean postoperative hospital stay in the primary closure group was 5.1±1.1 days (median, 5.0 days; range, 4–7 days), compared to the T-tube drainage group which was 13.6 ± 2.3 (median, 15.0 days; range, 7–18 days). The mean duration of

follow-up in the primary closure group was 5.62 ± 0.7 months (median, 6.0 months; range, 4–6 months) and in the T-tube drain group it was 5.7±0.5 months (median, 6.0 months; range, 4–6 months) [Table III].

Table III: Hospital stay, cost of treatment and follow up duration (n=50)

	Group (n = 50)						p value
	Primary closure (n=20)	Median	Range (Min–Max)	T-tube drain (n=30)	Median	Range (Min–Max)	
Hospital stay (day)	5.1 ± 1.1	5.0	4–7	13.6 ± 2.3	15.0	7–18	0.008
Cost of treat- ment	194.5 ± 41.5	187.5	150–262.5	548.6 ± 88.5	600	300–712.5	<0.001
Follow up dura- tion (month)	5.62 ± 0.7	6.0	4–6	5.7 ± 0.5	6.0	4–6	NS

DISCUSSION

Cholelithiasis occurs in approximately 10-15% of patients^[18]. Ludwig Courvoisier was the first to successfully remove a bile duct stone in 1890, laying the foundation for modern bile duct examination. For generations, surgical exploration of the bile duct to remove bile duct stones at the time of cholecystectomy has been considered the gold standard against which all other treatments are based^[19,20]. Halsted (1919) recommended closure of the bile duct after choledocholithotomy and drainage of the bile duct using a small tube through the cystic duct. The tube should be left in place for 3-4 days and then fixed with a clamp. If bile flow did not stop, the tube had to be removed^[21]. However, retained stones were very common until Mirizzi introduced intraoperative cholangiography in 1932, which significantly reduced the frequency of missed stones and mortality^[22,23]. The next improvement in bile duct examination techniques was the introduction of cholangioscopy, which, according to Bakes, uses a speculum with a mirror and reflected light

from the surgeon's headlamp^[24]. In 1958, a commercially available choledochoscope with an optical system, a light source, and an irrigation channel surrounded by a rubber cover became available^[25]. Symptomatic cholelithiasis is a very common indication for abdominal surgery^[26]. Before the laparoscopic era, cholecystectomy and gallstones were removed in a single operation. This approach has been shown to be effective, with a morbidity rate of less than 15% and a mortality rate of less than 1% in patients up to 65 years of age^[27]. Even in the era of minimally invasive surgery, laparotomy for bile duct examination may still be the procedure of choice in some hospitals in developing countries. In this study, laparotomy was performed to explore the CBD and cholangioscopy after choledochotomy ensured clearance of the duct. According to studies on CBD for choledocholithiasis, intraductal drainage using a T-tube is the standard method^[28]. The use of a T-tube is not without complications, and there have been many reports of complications due to the T-tube^[8,10,29–32]. In our study, there were two cases of

bile leakage in our patients. In our study, we had two cases of bile leakage in patients in whom the T-tube was used (10.0%), and one case among the 17 patients (6.2%) in whom primary closure of the CBD was done. Yamazaki et al.^[5] reported an incidence of 11.7% and 5.8% respectively, and an overall incidence of leakage was reported to be 14.3–38%. On the other hand, after primary closure, there were no bile leakage cases reported by other authors^[16,17]. There was no major complications noted in any of our patients. There have been reports of intraperitoneal leakage with subsequent biliary peritonitis^[1,3,8]. The reason for this was probably because we performed cholangioscopy and did not explore the lower end of the CBD. These measures reduced the risk of bile leakage. There was a significant difference in postoperative hospital stay and total treatment costs between our two groups. The group that underwent primary closure had a shorter hospital stay and no burden due to T-tubes. Patients who had T-tubes placed incurred additional costs for postoperative cholangiography. Although not mentioned in this study, other complications of T-tube drainage are also listed in the literature: biliary sepsis, bile duct trauma at removal, bile leakage causing bile peritonitis, tube debris retention and stricture formation, fluid and electrolyte disturbances, early bile leakage dislocation, and long-term bile duct fistula^[33,34].

Conclusion:

Open choledochotomy allows for primary closure of the CBD in selected patients safely and with improved patient care. Cholangioscopy ensures clearance of the CBD and obviates the need for a T-tube. Patients have fewer hospital stays and significantly lower average costs of treatment

than those with a T-tube. From this study, we conclude that primary CBD closure is safe and effective after open surgery for CBD stones, with shorter hospital stays and lower costs.

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