

An Experience of Primary Common Bile Duct Closure after Open Choledochotomy as Compared to T-Tube Closure

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ABSTRACT

Objective: To evaluate the short and long term benefits and harms of the primary closure without and with T-tube drainage after open choledochotomy.

Study Design: Prospective, comparative randomized control study

Place and Duration of Study: This study was conducted at the Surgical Unit III of Peoples University of Medical and Health Sciences for women and Jinnah Medical Center Nawabshah from June 2013 to July 2017..

Materials and Methods: Seventy patients were randomly selected for the study, 32 underwent primary common bile duct closure (Group A) and in others T-Tube (Group B) was placed. Patients demographic, intraoperative findings, postoperative stay, complications and long term follow-up data were recorded and compared.

Results: Seventy patients were randomly selected in the study. The age range of patients was 22 to 75 years. In primary closure group A (n=32) four (12.5%) males and 28 (87.5%) females. In 2 patient (6.3%) bile leakage noted which subsided without any biliary peritonitis, as compared to the T-tube group B (n=38) six male and 32 females, five patients (13.5%) resulted bile leakage. No one patient had a retained stone in both groups and no jaundice in group A but postoperative jaundice was seen in two patients (5.3%) group B because of CBD blockage. The postoperative hospital stay in group A was 4.5±1.2 days and in B was 12.5±1.5 days. The total cost of treatment in group B was Rs/60000 ± 12000± (US\$ 500± 100) and group A was Rs/35000±5000 (USD 200±50). Follow up time was six months.

Conclusion: The primary closure might be much effective and safe as compared to T-tube drainage after open choledochotomy and less postoperative complications.

Key Words: open choledochotomy, choledocholithiasis, primary closure, T-tube drainage

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INTRODUCTION

Choledocholithiasis develops in about 03–15% of patients with gallbladder stones and literature suggests that common bile duct (CBD) stones occur in about 7–15% of patients who are undergoing cholecystectomy¹. The surgical technique to remove stones from the common bile duct (CBD) depends on anatomical characteristics, local experience, and size, location and number of stones. Most surgeons consider choledochotomy as an alternative to failed laproscopic exploration, and some use it exclusively. Commonly CBD is closed with T-tube drainage after choledochotomy, is associated with 11.3-27.5 % morbidity.

After choledochotomy and removing of stones from the common bile duct (CBD), and placing T-tube is suggested to be a classical method since the end of the 19th century. T-tube is supposed to drain bile outside the body to avoid bile peritonitis, and supposedly a route to evaluate and remove the retained CBD stones, and to reduce the chances of CBD stricture formation. There is debate by placing T-tube that it causes bile peritonitis before and after its removal, discomfort and prolonged out-patient care^{2,5}. In addition, having bile drainage in place for at least 3 weeks causes significant discomfort in patients and delays their return to work.^{6,8} The principal treatment of open exploration of the bile duct was for several decades. The open procedure is still performed in developing countries by surgeons because of non-availability of minimally invasive techniques like ERCP⁹. Due to the lack of experienced endoscopists at secondary care hospitals most of patients need to be transferred to a tertiary centers for endoscopic diagnosis and treatment, which increases cost and patient discomfort.⁸

When it comes to laparoscopic choledochotomy, albeit recent developments in instruments, due to technical demanding of choledochotomy and prolonged operation time, mostly in putting up the T-tube and closing the

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incision wound securely, there are limitations in adopting the procedure. Primary closure of the CBD after exploration is not new therefore open surgery is still a treatment of choice in many hospitals. Primary duct closure after open CBD exploration was first described by Halstead as early as 1917. Since then, the debate between primary closure and T-tube drainage continued even in the era of laparoscopic surgery. In the past few decades, numerous studies comparing primary with T-tube were published and revealed the feasibility and safety of primary closure^{9,11}. Many papers are reported by different authors, which support the direct closure of the duct immediately after exploration.^{7,9}, During surgery direct visualization with choledoscope of the CBD is possible and retained stones are not a problem in current era. In our setup, open CBD exploration is still the treatment of choice for CBD stones. In our study, we focused to compare short-term results of primary closure of CBD and T-tube drainage, and to assess the benefits of primary closure of CBD at a government and a private hospital in a developing country like Pakistan.

MATERIALS AND METHODS

This study was conducted at Surgical Unit III of Peoples University of Medical and Health Sciences for Women Nawabshah and Jinnah Medical Center Nawabshah. Seventy patients were randomly selected for the study, from June 2013 to July 2017. The patients were investigated with, complete blood counts, liver function tests, coagulation profile. The criteria for choledochotomy were (1) CBD stones were confirmed by preoperative MRCP or CT with no intrahepatic bile duct stone; (2) The diameter of CBD is more than 0.8 cm; (3) No obvious inflammatory changes of CBD are detected intraoperatively; (4) No. of stones is less than 8; (5) obstructive jaundice, (6) CBD stones suggested by ultrasound, and (7) the presence of stones in the CBD palpated during open cholecystectomy. Patients with pancreatitis, cholangitis and cholangiocarcinoma were excluded.

Prophylactic antibiotics were used at the time of induction of anaesthesia. The CBD was explored through a supraduodenal longitudinal incision. Stones were removed and patency of CBD was confirmed by flushing of saline through 8FR feeding tube. Then CBD was closed with 4/0 Vicryl continuous sutures without placing T-tube in 32 patients and T-tube in 38 patients randomly selected. A sub hepatic drain was kept in all patients. The primary closure group was discharged on average 4th postoperative day after confirming no leakage and drain was removed. T-tube cholangiography was done on the 10th postoperative day in all T-tube drained patients; T-tube was removed on 12th postoperative day, after confirmation by free flow of dye into duodenum. Comparison of postoperative complications, hospital stay and the total

cost of treatment of both groups was done. The data was analyzed in statistical program SPSS version 11.0. Fisher's exact test or the Chi-square test was used for categorical variables to calculate frequencies and percentages between the groups. The Student's t-test was used to compare the means of the continuous variables between 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 was explored in 70 patients, out of which primary closure was done in 32 and T-tube was placed in 38 patients after stone removal. The mean age of group A patients was 50.0 ± 17 years (median, 49 years; range, 22–75 years) and group B patients was 43 ± 15 years (median, 41.0 years; range, 23–75 years). Four males (12.5%) and 28 females (87.5%) group A, and six males (15.7%) and 32 females (84.2%) group B (Table 1). Biliary colic was the most common presentation in both groups 22 (68.75%) and 32 (84.21%) respectively. Acute cholecystitis and jaundice were other presentations, nearly of same frequency in both groups. Twenty one patients had comorbidities like diabetes mellitus and hypertension 09 (28.12%) and 13 (34.21%) respectively in both groups. 18 patients (56.25%) in group A had concomitant cholelithiasis and 25 (65.7%) in group B has reported on ultrasonography.

LFT were compared between two groups. The level of serum glutamic pyruvic transaminase (SGPT) was significantly different between the two groups. Preoperative ultrasonography revealed the size of CBD and number of CBD stones, which was then confirmed during the operation. The mean diameter of CBD was $1.5 \text{ cm} \pm 0.47 \text{ cm}$ (median, 1.51 cm; range, 1.3–2.5 cm) in group A and $1.52 \pm 0.54 \text{ cm}$ (median, 1.49 cm; range, 0.7–2.8 cm) in group B. The maximum number of stones (46) was noted in group B (Table 1).

Thirty patients in group A did not suffer any complication. Two patients had a bile leakage that subsided on the fourth postoperative day and no biliary peritonitis. The total complication rate in group A was 6.3%

In group B, seven patients had biliary complication, (15.78%). After removal of T-tube bile leakage noted in five (13.15%) aspirated under ultrasound guidance. In these patients, the T-tube was removed on the fourteenth postoperative day. Postoperative jaundice noted in two because of a blockage T-tube. The jaundice subsided after removal of T-tube. There was no any recurrence of CBD stones up to 6 months follow up and postoperative ultrasonography was almost normal (Table 2).

The mean postoperative hospital stay in group A was 4.5 ± 1.2 days (median, 4 days; range, 3.5–6.5 days), compared to group B was 12.5 ± 1.5 (median, 14 days; range, 6–17 days). The total cost of treatment in group

B was Rs/=60000 ± 12000s+/- (US≠ 500± 100) and group A was Rs/=35000+/-5000 (US≠ 200±50).The mean follow-up duration in group A was 5.5±0.4

months (median, 5.0 months; range,(3–7 months) and in group B it was 5.6±0.4 months (median, 6.0 months; range, (3.5–5.5 months) (Table 3).

Table No 1: Demographic Characteristics of patients Group n=70

Variable	Primary closure (A) n= 32	Median	Range Min-Max	T-tube Drain (B) n=38	Median	Range Min-Max	p value
Age years	50.0 ± 17.0	51.5	22-75 +/- 13.9	43± 15	41	23-75	NS
Gender							Ns
Male	4 (12.5%)			6 (15.7%)			
Female	28 (87.5%)			32 (84.2%)			
Symptoms							
Biliary colic	22 (68.75%)			32 (84.21%)			Ns
Acute cholecystitis	15 (46.87%)			15 (39.47%)			Ns
Jaundice	20 (62.5%)			26 (68.42%)			Ns
Co-morbidities	09 (28.12%)			13 (34.21%)			Ns
Preoperative LFT							
Total Bilirubin (mg%)	2.5 ± 2.01	2.0	0-5	2.1 +/- 1.85	1.0	0-8	Ns
SGPT (U/L)	150.36 ±149.09	95.0	18-599	54.42 ±61	36.0	7-262	0.01
Alkaline Phosphatase (U/l)	579+/-326.30	724.0	100.0-950	4.1± 2.81	492.0	135-850	Ns
Number of CBD stones	3.1 ±1.60	2.5	2-7	46.0 ±10	4.0	1-10	0.03
CBD Diameter (cm)	1.53±0.4721	1.512.0	1.3-2.5	1.52±0.5458	1.49	0.7-2.8	Ns

Results are expressed as mean +/- standard deviation, median, and range. CBD=Common Bile Duct , Ns= Not Significant

Table No 2: Postoperative Complications (n=70)

	Primary Closure (n=32)	T-tube drainage (n=38)	p value
Postoperative bile leakage	2 (6.3%)	5 (13.15%)	Ns
Jaundice	0	2 (5.3%)	Ns
Retained stones	0	0	--
Recurrence of CBD Stones	0	0	--

Results are expressed as number and percentage, CBD=Common Bile Duct, Ns= not significant

Table No. 3: Hospital Stay , cost of treatment, and follow up duration

Variable	Primary closure (n= 32)	Median	Range Min-Max	T-tube Drain n=38	Medain	Range Min-Max	p value
Hospital Stay (days)	4.5± 1.2	4.0	3.5-6.5	12.5±1.5	14.0	6-17	0.008
Cost of treatment PKR/US≠	35000±5000 200±50.0 US≠	150.5 US≠	180-300 US≠	60000±12000 500±100 US≠	600 US≠	300-712.5	<0.001
Followup duration months	5.5±0.4	5.0	3-7	5.6±0.4	6.0	3.5-5.5	NS

Results are expressed as mean +/- Standard Deviation, median and range

DISCUSSION

In the era of mini-invasive surgery, laparoscopic cholecystectomy(LC) has been the standard therapy for symptomatic gallstones. However, debate continues regarding the best treatment for managing cholecystocholedocholithiasis, and a consensus has not been reached¹². In clinical practice, three major procedures, LC + endoscopic retrograde cholangiopancreatography (ERCP) endoscopic sphincterotomy, endoscopic

papillary balloon dilation, LC+ laparoscopic transcystic common bile duct exploration were applied for treatment of cholecystocholedocholithiasis.

The role of ERCP in diagnosis of CBD stones has been replaced by MRCP, however, it is widely used to remove CBD stones in one-stage or staged procedures. EST is associated with serious short-term complications, including bleeding, post-ERCP pancreatitis (PEP), and perforation of the digestive tract. In addition, EST may increase the incidence of

long-term complications such as biliary infection due to the dysfunction of the Oddi's sphincter after the procedure^{13,14,15}. In order to preserve (at least partly) the function of the sphincter of Oddi and avoid post-EST bleeding, Now a days, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries.

Symptomatic gallstone disease is a very common indication for abdominal surgery.¹⁶, and cholecystectomy and CBD stones were removed in a single procedure with morbidity below 15% and mortality below 1%¹⁷.

We ensured the duct clearance by choledocopy following choledochotomy. After exploration of CBD T-tube drain has been a standard practice.²⁴ The risk of complications with use of a T-tube is higher, there are many reports of complications with T-tube.^{19,20,21}

We faced five cases of bile leakage in group B(11%), and two cases among the 32 patients (6.2%) in group A. On the other hand, in group A has no bile leakage as reported by other authors.¹⁵ There was a significant difference in postoperative stay and the total cost of treatment between two groups. The group A remained in the hospital for a shorter period where as group B remained for longer duration and there was the additional cost of postoperative cholangiography.

There have been reports of intraperitoneal leakage with subsequent biliary peritonitis.^{9,19,22} but in our study there were no major complications and mortality. This may be because we used choledocopy and did not probe the distal end of the CBD. The risk of biliary leakage was reduced by these measures. In developing countries, this difference in complications and expenditure has a major impact on public health.

Literature⁷ suggests that early discharge and early return to work, has effect on the expenses of the patient. Other authors reported similar results^{23,24} except in Japan where the number of hospital admission days was higher.²⁵

CONCLUSION

In Developing countries like Pakistan due to deficiency of facilities and endoscopic expertise in remote areas, & in secondary care hospitals, open choledochotomy, with primary closure of the CBD rather than placing T-tube is safe and may be performed in selected patients with improved patient care. It has been concluded that, the primary closure might be much cost effective as the T-tube drainage after open choledochotomy with shorter hospital stay and less complications.

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