



Primary Closure Versus T-tube Drainage After Open Choledochotomy

M. Ambreen, A.R. Shaikh, A. Jamal, J.N. Qureshi, A.G. Dalwani and M.M. Memon, Department of Surgery, Liaquat University of Medical and Health Sciences, Jamshoro, Sindh, Pakistan.

BACKGROUND: Choledochotomy followed by T-tube has long been a standard surgical treatment for choledocholithiasis. It is still a preferred choice in many hospitals where minimal invasive procedures are not feasible. The use of T-tube is not without complications. To avoid the complications associated with T-tube, we have performed primary closure of the common bile duct (CBD) after exploration. This pilot study assesses the safety of primary closure of CBD, which would help form a basis for implementation on a wider scale.

OBJECTIVE: To compare the clinical results of primary closure with T-tube drainage after open choledochotomy and assess the safety of primary closure for future application on a greater mass.

PATIENTS AND METHODS: This comparative study was conducted at surgical unit IV Liaquat University of Medical and Health Sciences, Jamshoro, from January 2007 to December 2007. Thirty-five patients were included in the study of which 16 patients underwent primary closure.

RESULTS: Thirty-five patients were included in the study. The mean age of patients who had primary closure done ($n = 16$) was 46.0 ± 16.8 and there were two (12.5%) males and 14 (87.5%) females. 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. Postoperative jaundice was seen in one patient (5.3%) 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 ± 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 USD548.6 \pm 88.5. The median follow 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. [*Asian J Surg* 2009;32(1):21-5]

Key Words: choledocholithiasis, open choledochotomy, primary closure

Introduction

Cholelithiasis develops in about 10–15% of patients with gallbladder stones¹ and literature suggests that common bile duct (CBD) stones are encountered in approximately 7–15% of patients undergoing cholecystectomy.²

There are two methods for extracting CBD stones either endoscopically, by endoscopic retrograde cholangiopancreatography (ERCP), or surgically, by an open or laparoscopic method.

Open exploration of the bile duct was the principal treatment for almost 100 years. In some hospitals of

Address correspondence and reprint requests to Dr Ambreen Muneer, Assistant Professor, Department of surgery, Liaquat University of Medical and Health Sciences, Jamshoro, Sindh, Pakistan.
E-mail: banglani_90@hotmail.com • Date of acceptance: 7 August 2008

developing countries, surgeons are still performing this procedure because minimally invasive techniques like ERCP are not available.³ Due to the lack of experienced endoscopists at smaller hospitals, patients need to be transferred to a larger centre for endoscopic diagnosis and treatment, which increases costs and patient discomfort.⁴ The laparoscopic management of CBD stones is well known these days,⁵ but remains controversial. This procedure is demands skills and equipment, and is therefore used by few surgeons.⁶ Moreover, the superiority of this procedure for the treatment of CBD stones has not yet been proven, which limits its applicability.⁷ Therefore open surgery is still a treatment of choice in many hospitals.

The classical performance of bile duct exploration is associated with the problem of an incised bile duct closure. Choledochotomy followed by T-tube drainage is a traditional surgical treatment for choledocholithiasis.⁸ Although it is true that the T-tube has been used and has proven to be a safe and effective method for postoperative biliary decompression, it is not exempt from complications, which are present in up to 10% of patients.⁹ The most frequent of these is bile leakage after removal, which is reported to occur in 1–19% of cases.^{6,10–12} Some of these complications are serious, such as bile leak, tract infection or acute renal failure from dehydration due to inadequate water ingestion or a very high outflow, particularly in elderly patients. In addition, having bile drainage in place for at least 3 weeks causes significant discomfort in patients and delays their return to work.^{13–15}

Primary closure of the CBD after exploration is not new. Halstead first described the advantages of primary closure. There are many papers reported by different authors, which support the direct closure of the duct immediately after exploration.^{3,12,14,16,17} With the help of a choledochoscope during surgery, direct visualisation of the CBD is possible and retained stones are not a problem. In our hospital, open CBD exploration is still the treatment chosen for CBD stones. In this study, our aim was to compare the clinical 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 hospital in a developing country.

Patients and methods

This was a pilot project conducted at surgical unit IV Liaquat University Hospital, Jamshoro. Thirty-five patients,

admitted at Surgical Unit IV in Liaquat University Hospital, Jamshoro in the year 2007, were included in the study. 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 were given antibiotics before they were taken for elective open surgery. The CBD was opened through a supraduodenal vertical incision between stay sutures. Stones were taken out and saline flushing followed to ensure patency. We confirmed the clearance of the duct with a choledochoscope. Then primary closure of the CBD was performed in 17 patients. After completion of choledochoscopy, patients were randomly selected to undergo either one of the two surgical options: primary closure of CBD and T-tube drainage. Interrupted 3/0 vicryl sutures were applied. In 19 patients, a T-tube was inserted into the CBD. A sub hepatic drain was kept in all patients. T-tube cholangiography was done on the seventh postoperative day in all T-tube drained patients. Once patency of CBD was confirmed and there was a free flow of dye, the intermittent clamping of T-tube was done and the T-tube was removed on the twelfth postoperative day. Postoperatively, ultrasound and liver function tests were done. We compared the postoperative complications, postoperative hospital stay and the total cost of treatment between the two groups. Bile leakage is defined as any yellow bile-like fluid coming out of the sub hepatic drain or after the removal of the drain aspiration of yellow coloured bile-like fluid under ultrasound guidance from sub hepatic peritoneal space (300 mL).

The data was analysed in statistical program SPSS version 11.0. 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 35 patients, out of which 16 had primary closure of CBD after stone

removal. A T-tube drain was placed in 19 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 (12.5%) and 14 females (87.5%) in the primary closure group, and three males (15.7%) and 16 females (84.2%) in T-tube group (Table 1).

The clinical presentation of choledocholithiasis is listed in Table 1. Most of the patients in both groups presented with biliary colic (62.5% and 78.9%). Other clinical presentations were acute cholecystitis and jaundice, which were nearly of same frequency in each group. Out of 35 patients, eight patients had comorbidities like diabetes mellitus and hypertension (31.3% and 15.8%). Fourteen patients (87.5%) in the primary closure group had concomitant gallstones and 13 (68.4%) in the T-tube group as evident by preoperative abdominal ultrasound.

Preoperative liver functions were compared between two groups (Table 1). 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 1).

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 6.3% (Table 2).

In the T-tube drain patients, biliary complication occurred in three patients, accounting for 15.7%. Two patients had bile leakage (10.5%) 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 postoperative jaundice because of a blockage of the duct caused by the T-tube. The T-tube was removed and jaundice

Table 1. Demographic characteristics of patients

	Group (n=35)						p value
	Primary closure (n=16)	Median	Range (Min-Max)	T-tube drain (n=19)	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	2 (12.5%)	-	-	3 (15.7%)	-	-	NS
Female	14 (87.5%)	-	-	16 (84.2%)	-	-	
Symptoms							
Biliary colic	10 (62.5%)	-	-	15 (78.9%)	-	-	NS
Acute cholecystitis	6 (37.5%)	-	-	6 (31.5%)	-	-	
Jaundice	8 (50.0%)	-	-	8 (42.1%)	-	-	
Co-morbidities	5 (31.3%)	-	-	3 (15.8%)	-	-	NS
Concomitant gallstones	14 (87.5%)	-	-	13 (68.4%)	-	-	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 stones	2.2 ± 1.52	2.0	1–6	460.578 ± 259.56	4.0	1–10	0.03
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

Results are expressed as mean \pm standard deviation; median and range. CBD = common bile duct; NS = not significant.

gradually subsided (Table 2). There was not any recurrence of CBD stones seen up to 6 months follow up and postoperative ultrasound findings were almost normal (Table 2).

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) (Table 3).

The average cost of treatment for open CBD exploration and primary closure of the CBD was USD194.5 \pm 41.5 (median, USD187.5; range, USD150–262.5), whereas in the T-tube drainage group it is much more, i.e. USD548.6 \pm 88.5 (median, USD600; range, USD300–712.5) (Table 3). 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 3).

Table 2. Postoperative complications

	Group (n=35)		p value
	Primary closure (n=16)	T-tube drain (n=19)	
Bile leakage	1 (6.3%)	2 (10.5%)	NS
Postoperative jaundice	0	1 (5.3%)	NS
Retained stone	0	0	-
Recurrence of CBD stones	0	0	-

Results are expressed as number and percentage. CBD = common bile duct; NS = not significant.

Discussion

Symptomatic gallstone disease is a very common indication for abdominal surgery.¹⁸ Before the laparoscopic era, cholecystectomy and CBD stones were removed in a single procedure. This approach has been effective with morbidity below 15% and mortality below 1% in a patient up to 65 years old.¹⁹ In the era of minimally invasive procedures, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries.

In this study, we performed open surgery for exploration of CBD and ensured the duct clearance by choledochoscopy following choledochotomy. After exploration of CBD for choledocholithiasis, intraductal drainage using a T-tube has been a standard practice.²⁰ The use of a T-tube is not without complications and there are many reports of complications with T-tube.^{8,10,21–24}

In our study, we had two cases of bile leakage in patients in whom the T-tube was used (10.5%), and one case among the 17 patients (6.2%) in whom primary closure of the CBD was done. Yamazaki et al⁵ 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} No such complication occurred in our patients and no deaths occurred in our study. The reason for this was probably that we used choledochoscopy and did not probe the lower end of the CBD. These measures reduced the risk of biliary leakage. There was a significant difference in postoperative

Table 3. Hospital stay, cost of treatment and follow up duration

	Group (n=35)						p value
	Primary closure (n=16)	Median	Range (Min–Max)	T-tube drain (n=19)	Median	Range (Min–Max)	
Hospital stay (d)	5.1 ± 1.1	5.0	4–7	13.6 ± 2.3	15.0	7–18	0.008
Cost of treatment (USD)	194.5 ± 41.5	187.5	150–262.5	548.6 ± 88.5	600	300–712.5	<0.001
Follow up duration (mo)	5.62 ± 0.7	6.0	4–6	5.7 ± 0.5	6.0	4–6	NS

Results are expressed as mean \pm standard deviation; median and range. The data was analysed in statistical program SPSS version 11.0. Fisher’s exact test of chi-squared was applied for categorical variables to calculate frequencies and percentage among the group. Student’s t test was used for continuous parameters to compare the means (2 tailed) with median and range between the groups. All the parameters were calculated on 95% confidence interval. A value of $p \leq 0.05$ was considered as statistically significant. NS = not significant.

hospital admission days and the total cost of treatment between our two groups. In a group where primary closure was performed, they remained in the hospital for a shorter period and were not burdened by a T-tube. In patients where the T-tube has been kept in place, there was the additional cost of postoperative cholangiography.

In a developing country like Pakistan, this difference in expenditure has a major impact on public health. Literature¹⁴ suggests that early discharge from hospital means an early return to work, which further has an indirect effect on the expenses of the patient.

Other authors reported similar results^{3,14} except in Japan where the number of hospital admission days was higher.⁵

Conclusion

In open choledochotomy, primary closure of the CBD is performed safely in selected patients with improved patient care. Choledochoscopy ensures clearance of the CBD and eliminates the need for a T-tube. The number of hospital admission days is less and average cost of treatment is much lower than in the patients with a T-tube.

From this study, we have concluded that after open surgery for CBD stones, primary closure of CBD is safe and effective with shorter hospital stays and lower costs.

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