

To assess the outcome of primary repair in common bile duct exploration for choledocholithiasis

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Abstract

The present study was planned in the Department of Surgery, Department of Surgery, U.P. University of Medical Sciences Saifai Etawah from July 2018 to August 2019. Total 42 patients of choledocholithiasis were included in present study. The patients were evaluated with routine investigations including full blood counts, liver function tests, ultrasonography upper abdomen, renal function tests, X-ray chest and ECG. When the location and cause of obstruction could not be diagnosed with ultrasonography then magnetic resonance cholangio-pancreatography was performed To rule out malignancy, contrast-enhanced computerized tomography was performed in selected cases. The criteria for choledochotomy were palpable CBD stones preoperative ultrasound or radiographic evidence of CBD stones or dilated CBD with or without jaundice. Patient with recurrent CBD stone, choledochal cyst CBD injury, stricture and previous CBD Surgery During routine investigations patients found with malignancy, renal failure, and other severe comorbidities were excluded from the study. All patients complications including bile leakage, biliary received prophylactic antibiotics in the form peritonitis, and postoperative jaundice were of Ceftriaxone 1 gram intravenous 30 minute. Primary closure following CBD exploration is a safe and effective measure for CBD stone associated with low complication rate and faster recovery. Primary closure of CBD is a safe and effective measure associated with low complication rates.

Keywords: Choledocholithiasis, CBD Surgery, Choledochotomy, Primary Repair, T-tube.

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Introduction

Choledocholithiasis is the common pathology that necessitates surgical intervention. Gallstone disease occurs in 3–20% of the population worldwide. It may occur in the gallbladder or in the common bile duct (CBD) or common hepatic or the right or the left hepatic duct. Choledocholithiasis is encountered in approximately 10%-15% of patients with symptomatic gallstones [1]. The incidence of choledocholithiasis is higher in elderly patients.

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It can cause biliary colic, obstructive jaundice cholangitis, or pancreatitis. It can be managed either by endoscopic sphincterotomy and stone removal or by surgical exploration of common bile duct i.e. choledochotomy[2]. Traditionally, the common bile duct (CBD) is closed over T-tube but potential morbidity and complication exist with this therapeutic modality[3]. These include cholangitis, dislodgement of tube, obstruction and/or fracture of tube[4]. Even leakage of bile may be encountered after removal of T-tube[5]. Patient may have to carry it for several weeks before removal [6]. All of these lead to prolong length of hospital stay[7]. Currently, primary closure of CBD with or without endobiliary stent has been described in literature to overcome these adverse consequences of T-tube.[2] But optimal techniques still

unclear. Insertion of a T-tube increases postoperative morbidity, psycho-logical trauma, prolonged hospital stay, and bed occupation irrespective of the surgical technique. Currently the use of T-tubes for biliary drainage has been controversial to this date.[8] Open biliary surgery, CBD exploration, and drainage with primary closure of the CBD can be safe in experienced hands and is specifically useful in a limited resource and set up[9].

Aims & Objectives:The aim and objectives of this study is to assess the Outcome of primary repair of CBD exploration for choledocholithiasis in terms of—

- safety & efficacy
- operating time
- duration of hospital stay
- postoperative complications.
- Total number of re-admission days for re-interventions/ associated morbidity
- To chart out any deficiencies/suggestions in current procedure.

Material & Methods

This prospective observational study was conducted in the Department of General Surgery, UPUMS, Saifai, Etawah, Uttar Pradesh, India from July 2018 to August 2019. A total of 42 patients of choledocholithiasis were included in this study. The patients were evaluated with routine investigations including full blood counts, liver function tests, ultrasonography upper abdomen, renal function tests, X-ray chest and ECG. When the location and cause of obstruction could not be diagnosed with ultrasonography then magnetic resonance cholangiopancreatography was performed.

To rule out malignancy, contrast-enhanced computerized tomography was performed in selected cases.

The criteria for choledochotomy were palpable CBD stones, preoperative ultrasound or radiographic evidence of CBD stones or dilated CBD with or without jaundice. Patient with recurrent CBD stone, choledochal cyst CBD injury, stricture and previous CBD surgery. During routine investigations patients found with malignancy, renal failure, and other severe comorbidities were excluded from the study. All patients received prophylactic antibiotics in the form of Ceftriaxone 1 gram intravenous 30 minute before incision.

Surgical technique:A Kocher's subcostal incision was used under general anaesthesia in supine position Hepatocystic triangle dissected and cholecystectomy done in standard manner A longitudinal supraduodenal choledochotomy about 1.5- 2cm was performed. Any obvious stones was then passed distally and generous

irrigation of the CBD was performed with normal saline. Use of this small tube allowed stones to float up along side to be extruded at the choledochotomy. It also facilitated passage of the tube through the ampulla (if no obstruction was present). Choledochotomy (Flow of irrigant with no return) was done to clear CBD. This was followed by dilating the sphincter of Oddi using Bake's dilator to 8- or 9-Fr caliber. If, however, a stone at the distal end could not be disimpacted, other options were carried out: a transduodenal sphincterotomy/ sphincteroplasty or choledochoduodenostomy was performed. As free drainage of the bile into the duodenum is ensured by any of these options, no T-tube or stents were used. However, a 20-Fr subhepatic drain was placed in situ for 48 h postoperatively. Cholangiogram is performed to see distal clearance of CBD.

When required choledochoscopy using flexible choledochoscope was done and stone removed.

Choledochotomy incision closed primarily with 3-0 vicryl in interrupted manner without placing any endobiliary stent or T-tube in situ. After saline irrigation and suction of surgical field hemostasis secured and 28-F ADK drain placed in subhepatic space, wound closed in layers. All patients received intravenous fluid, intravenous antibiotics and analgesics in post operative period as per requirement. ADK was removed when there was less than 20ml collection. All patients were given preoperative and postoperative antibiotics and follow-up was taken for the next 6 months. Patient's demographics (Like age and gender), operative time, duration of hospital stay, and postoperative complications including bile leakage, biliary peritonitis, and postoperative jaundice were recorded on a proforma. The data was compiled and the results tabulated using SPSS.

Observation & Results

A prospective & Observational clinical descriptive study consisting of 42 patients was taken. The mean age was 48.83 ± 11.714 years. . The highest incidence was noted in the 50 – 64 yrs age group followed by 35-49 yrs age group. Lowest incidence was in the <35 yrs age group. There were 07(16.70%) males and 35(83.30%) females. The male-to-female ratio was 1:5, the ages of the patients ranged from 20-70 years with mean 48.83 years Pain abdomen was invariably present in all the patients in my study (100%). Jaundice was present in 16 patients (38.09%). 5 patients (11.90%) had recurrent attacks of fever with chills and rigors, suggestive of cholangitis. 16 (38.09%) patients had clinical evidence of jaundice. All patients (42) had

sonological evidence of stones in the CBD. The mean CBD diameter was 9.90 ± 1.462 mm with most patients having CBD diameter either between 9 to 10 mm (66.66%). The highest recorded CBD diameter was 16 mm. 23 patients (54.80%) having multiple stone, 16 patients (38.10%) having single stone and 3 patients (7.10%) having sludge. Most of the patient having stone of size 11-14 mm (69.047%). The highest recorded CBD stone was 16 mm. 15 patients (35.7%) having stone at distal CBD & 27 patients (64.3%) having stone at junction of cystic duct. 34 Patients (81.4%) having no intra operative adhesion & 8 patients (18.6%) having adhesion. All patients having normal liver status, no patient having duodenal injury and significant intraoperative bleeding. Operative time ranged from 50 minutes to 100 minutes with 26 patients (61.90%) operated in 50-70 minutes. Mean operating time 71.1705 ± 12.53335 minutes. 33 patients (78.60%) stayed in the hospital after operation for a duration ranging from 5 to 7 days. 5 patients (12%) stay up to 8 days. Whereas only 4 patients (9.5%) had a stay up to 10 days. No patient was discharged prior to 5 days of operation. Mean post operative hospital stay was 6.61 ± 1.6 days. Only 8 patients (19.05%) having bile leak and 34 patients (80.95%) having no bile leak. On Pod 1, 4 patients (50%) having 150 ml bilious content in subhepatic drain and 4 patients (50%) having 100 ml. On Pod 3, most of the patients (50%) having 100 ml bilious content in subhepatic drain, 2 patients (25%) having 50ml, 1 patient (12.5%) having 75ml and 1 (12.5%) patients having 150 ml (highest). On Pod 5 most of the patients (50%) having 50 ml bilious content in subhepatic drain and other 4 patients having 30ml, 25ml, 20ml and 10ml bilious content respectively. On POD 10 only 4 patients having 5ml bile leak. Drain was removed most commonly between POD 5 and 7. 1 patient (2.38%) developed infection of surgical wound as a result of contamination from the biliary tract, 2 patients (4.76%) developed Lower Respiratory Tract Infection (LRTI). None of the patients developed post operative abdominal collection, biliary peritonitis, cholangitis, ascites, renal failure, hepatic failure, jaundice and none of the patient required readmission or Re-intervention. There was no mortality in our study. At the same time if you will compare primary closure and T-Tube drain. Here we have taken 21 with primary closure of CBD after stone removal and 21 patients in T-tube drain for the explanation one can refer Table 1. 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 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 INR 33065 ± 7055 (median, INR 31875; range, INR 25500–44625), whereas in the T-tube drainage group it is much more, i.e. INR 93262 ± 15045 (median, INR 102000; range, INR 51000–121125) (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 1: Demographic characteristics of patients

| | Primary Closure (n=21) | Median | Range | T-tube drain (n=21) | Median | Range | p value |
|-----------------------------|------------------------|---------|---------|---------------------|--------|---------|---------|
| Age(years) | 48.83 ± 11.714 | 48.50 | 20-72 | 41.9 ± 13.9 | 40.0 | 23–75 | NS |
| Gender | | | | | | | |
| Male | 4 (19.04%) | - | - | 4(19.04%) | - | | NS |
| Female | 17(82.0%) | - | - | 17(82.0%) | | | |
| Symptoms | | | | | | | |
| Biliary colic | 10(47.61%) | - | - | 15(71.42%) | - | | NS |
| Acute cholecystitis | 5 (23.80%) | - | - | 5 (23.80%) | | | |
| Jaundice | 8(38.09%) | - | - | 8(38.09%) | | | |
| Co-morbidities | 5 (23.80%) | -- | - | 4(19.04%) | - | | NS |
| Concomitant gallstones | 14(66.67%) | | | 13((61.9%) | - | | 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 | 99-1050 | 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 ± standard deviation; median and range. CBD = common bile duct; NS = not significant.

Table 2: Postoperative complications

| | Group (n=42) | | |
|--------------------------|------------------------|--------------------|---------|
| | Primary Closure (n=21) | T-tube drain(n=21) | P value |
| Bile leakage | 1(4.8%) | 2(9.52%) | NS |
| Postoperative Jaundice | 0 | 1(4.8%) | 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

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

| | Primary Closure(n=21) | Median | Range | T-tube drain(n=21) | Median | Range | P value |
|-------------------------|-----------------------|--------|-------------|--------------------|--------|--------------|---------|
| Hospital stay(days) | 5.1 ± 1.1 | 5.0 | 4-7 | 13.6 ± 2.3 | 15.0 | 7-18 | 0.008 |
| Cost of treatment (INR) | 33065 ± 7055 | 31875 | 25500-44625 | 93262 ± 15045 | 102000 | 51000-121125 | < 0.001 |
| Follow up duration | 5.62 ± 0.7 | 6.0 | 4-6 | 5.7 ± 0.5 | 6.0 | 4-6 | NS |

Results are expressed as mean ± 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.

Discussion

Choledocholithiasis have been managed traditionally with T-tube closure or more recently with minimally invasive procedure like laparoscopic CBD exploration or with help of ERCP. T-tube drainage of the common bile duct is performed for the following reasons (Williams 1994)

- (a) Post-operative decompression of the common bile duct (If outflow obstruction occurs)
- (b) Post-operative visualization of common bile duct
- (c) Availability of a T-tube to extract common bile duct stones with a Burhenne steerable catheter (Burhenne 1973). [10,11]

However, the use of T-tube is not without complications. It is associated with peritubal leakage, excess bile drainage, electrolyte imbalance, peritubal cellulitis, sepsis, necrotizing fasciitis, post T-tube removal bile leakage etc. [12,13]

Moreover, removal of biliary endoprosthesis requires second-stage endoscopic extraction.

A third option for choledochotomy closure is primary closure without the use of T-tube or biliary endoprosthesis. Favorable short-term and long-term results have been published with this technique. This option avoids the morbidities related to the use of T-tube or biliary stents. In this study, no postoperative mortality occurred. The postoperative hospital stay and the operation time were shorter. However, our results do not match with those of some authors. A study noted higher complication and bile leakage rates after primary closure than those reported by this study, and an experimental study addressed the issue of stenosis following primary closure without some form of

drainage. We need studies with longer follow-up period for the evaluation of ductal stenosis. At the end, according to the results of this early experience, primary closure did not increase the risk for bile leakage after the operation. Postoperative hospital stay and operation time were shorter, and the hospital expenses were lower. In addition, with primary closure, we could definitely avoid T-tube-related complications. This study showed no major morbidity associated with primary repair of bile duct after supraduodenal choledochotomy for choledocholithiasis. Moreover, this technique carried shorter operating time and duration of hospital stay. Zhang et al noticed 28.6% of complications rate associated with T-tube in contrast to 11.1% in whom primary repair was performed [14] Biliary complications are considered to be the major consequence after primary repair of CBD; however, their overall frequencies are much less than that of T-tube closure. Ahmad and Colleagues observed 22% and 8.9% of these complications in T-tube and primary closure groups respectively. [15] Ambreen et al. noticed one (6.3%) patient of bile leakage that subsided conservatively, which is comparable to this study. None of the patients in this study experienced postoperative jaundice and biliary peritonitis. This is comparable to the study conducted by Ambreen and associates. [16] However, Perez et al. reported biliary peritonitis after removal of T-tube. [17] As a result of postoperative complications and long placement of T-tube till removal, duration of hospital stay gets prolonged. This forced surgeons to move towards primary repair technique that have been advised in literature. In this study, mean duration of hospital stay was 6.61 days, which is nearly comparable to the study conducted by Decker et al. The hospital stay was significantly longer in the T-tube group in three trials (Payne 1986; Williams 1994; Marwah 2004). [18] group compared to the T-tube group (Mean 87.8 versus 116.7 minutes, $P < 0.001$). [20] 8 case (19.05%) developed bile leak in which no further action was required and the leak closed spontaneously. Most of the patients (approx. 80%) had drain tube in situ for 3-6 days. Regarding the post-operative bile leak, it was 19.05% in the primary suture patients. Sikic reported like the current study

less leak in the primary suture patients (1.6%) than T-tube patients (7%).[21]

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. The use of a T-tube is not without complications and there are many reports of complications with T-tube. 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. There were no major complications noted in any of our patients. There have been reports of intraperitoneal leakage with subsequent biliary peritonitis. 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 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. Literature 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 except in Japan where the number of hospital admission days was higher.

Conclusion

Primary closure following CBD exploration is a safe and effective measure for CBD stone associated with low complication rate and faster recovery. Primary closure of CBD is a safe and effective measure associated with low complication rates. It can be done in most of the cases of choledocholithiasis even in the setting of a very limited resource. Primary closure of CBD has significantly shorter operating time and lesser duration of stay at hospital. It is concluded that primary suture is a significantly less expensive procedure,

requiring less medication, I.V fluids, x-ray and laboratory tests.

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