

EFFICACY AND SAFETY OF PRIMARY CLOSURE OF COMMON BILE DUCT FOLLOWING LAPAROSCOPIC CHOLEDOCHOLITHOTOMY

Shalini

Department of General Surgery

Era's Lucknow Medical College and Hospital, Era University, Sarfarazganj Lucknow, U.P., India-226003.

Received on : 23-02-2023

Accepted on : 21-05-2023

ABSTRACT

Following surgical intervention for symptomatic cholelithiasis, approximately 10 to 15 percent of patients are diagnosed with choledocholithiasis, characterized by the presence of stones in CBD. Several surgeons perform open CBD exploration with primary duct closure. However, few surgeons perform duct closure laparoscopically due to technical difficulties and concerns about missed stones and post-operative complications. Thus, we evaluated the efficacy and safety of the primary closure of the common bile duct following laparoscopic choledocholithotomy. In this prospective observational study, 62 patients with CBD stones were confirmed pre-operatively by abdominal ultrasonography and/or magnetic resonance cholangiopancreatography (MRCP). CBD radiological findings and demographics were noted. Details on the intraoperative technique, overall operating time, and post-operative complications were observed. Patients were followed for one month, and post-operative data were collected and analysed. Most of the enrolled patients were female (69.35%), aged 41-50 (37.10%), and had abdominal pain (82.25%). 64.52% had multiple stones in the CBD of the calibre of 8–10 millimetres (40.32%). 94.52 ± 21.58 mins was the mean operative time. CBD clearance was noted in 96.77% of cases. In most cases, intraoperative bleeding was 51–100 ml. Laparoscopic primary closure was performed in 96.77% of patients. On days 3 and 7, 9.68% and 6.45% of patients had bile leakage, respectively. The removal of abdominal drains varied significantly between cases. During the follow-up, two patients with bile leaks and jaundice after surgery were found to have retained stones and underwent post-operative ERCP without additional complications. The primary closure after LCBDE is considered a safe and effective alternative to T-tube drainage with an acceptable short-term outcome.

Address for correspondence

Dr. Shalini

Department of General Surgery
Era's Lucknow Medical College &
Hospital, Era University, Lucknow-226003.
Email: shalinibvu1993@gmail.com
Contact no: +91-8407913622

KEYWORDS: Laparoscopic Common Bile Duct Exploration, Primary Closure, Cholelithiasis, T-Tube Drainage, Common Bile Duct, Ultrasonography.

INTRODUCTION

Approximately 10 to 15% of patients who undergo surgery for symptomatic cholelithiasis are found to have common bile duct (CBD) stones (1). Choledocholithiasis can be classified as primary or secondary, depending on the stone's origin. Primary stones are those that develop anew in CBD and are linked to bile stasis and infection. Most of the brown pigment stones (calcium bilirubin) that comprise the primary CBD stones come from the CBD. The most common are secondary stones that originate from the gallbladder and travel down via the cystic duct into the CBD. Chemically, these stones tend to be black pigment or cholesterol stones, seen mostly in case of biliary cirrhosis and hemolytic condition such as sickle cell disease, hereditary spherocytosis, (2). It is

crucial to address choledocholithiasis in order to prevent a wide range of health complications, from mild to severe illness and even death, due to the diverse complication exhibited, such as biliary colic, obstructive jaundice, ascending cholangitis and acute pancreatitis. Current treatment options include various strategies: laparoscopic CBD exploration (LCBDE) carried out in a single session; combined treatment of endoscopic retrograde cholangiopancreatography (ERCP) before, during, or after laparoscopic cholecystectomy; or an open approach (3). As laparoscopic surgery has become more advanced, LCBDE, has gained significant popularity and is now widely utilized in clinical practice (4). In the current situation, improved choledochoscopes are now accessible, enabling the comprehensive extraction of choledocholithiasis.

Consequently, numerous surgeons have chosen to perform open exploration of the CBD with primary closure, yielding a positive morbidity outcome within the reported range of 0 to 6.3 percentage (5). However, due to technical difficulties and concerns of overlooked stones and the potential consequences of post-operative bile leaks, only a relatively limited number of surgeons perform duct closure laparoscopically. Consequently, this study was conducted to determine the proportions of complications following laparoscopic primary CBD closure as well as the intra-operative and post-operative events that transpire within a month of surgical procedure.

AIM

To evaluate the efficacy and safety of primary closure of CBD following laparoscopic choledocholithotomy.

OBJECTIVES

To evaluate proportions of complications following primary closure of CBD and to assess intra-operative & post-operative events.

MATERIAL AND METHODS

From January 2021 to December 2022, a prospective observational study took place at the Department of General Surgery at ELMC&H, Lucknow. Sixty-two patients of either sex over the age of 18 who had been diagnosed with CBD stones and whose CBD diameter ranged from 8 to 25 mm were included after receiving approval from the institutional ethical committee and informed consent. At the same time, patients with intrahepatic choledocholithiasis, bile duct stricture, acute cholangitis, and biliary pancreatitis were excluded. The information sheet recorded demographic information about patients, including age, sex, symptom profile, and radiographic evidence of a common bile duct stone's presence, and provided measurements for the diameter of the CBD. Details on the intraoperative parameters, such as the number of stones, successful clearance of CBD, CBD clearance time, the method used to close the bile duct, bleeding, and total operative time, were observed in patients undergoing LCBDE. Patients were observed for up to one month, and the data was compiled and analysed. Both the surgical data and the follow-up data were gathered. Patients were monitored during their post-operative period in the wards, followed by 1, 3, 7, 14, and 30 days, respectively. During each follow-up session, patients underwent clinical examinations, and if they presented with abnormal liver function tests or clinical signs of jaundice, a whole abdomen ultrasonography and / MRCP were conducted to assess their condition.

Statistical Analysis

The data were entered into Microsoft Excel and analysed with SPSS version 26 (SPSS Inc., Chicago, IL, USA). Continuous variables were assessed using mean (standard deviation) or range values when necessary. The dichotomous variables, which were presented as numbers or frequencies, were analysed using the Chi-square test. A significant p-value of less than 0.05 or 0.001 was considered.

RESULTS

Most of the individuals involved in this research were between the ages of 41 and 50, comprising 23 cases, which accounted for 37.10% of the total. Out of the 62 patients, 43 were female and 19 were male. (Table 1). In 51 out of 62 patients, Common clinical presentations in decreasing order included abdominal pain, jaundice, abdominal pain accompanied by jaundice, and jaundice after cholecystectomy. (Figure 1). The majority of study participants (64.52%) had multiple stones with diameters of 8–10 mm (25, 40.32%), followed by 11–15 mm (23, 37.10%) (Figures 2 and 3). We performed the liver function test and recorded the mean values, such as total bilirubin (mg/dl) was 2.95 ± 2.10 , SGPT/ALT (u/l) was 86.18 ± 85.00 , SGOT/AST (u/l) was 72.16 ± 95.54 , and serum alkaline phosphatase (u/l) was 250.95 ± 270.86 (Table 2). The total operative time was 94.52 ± 21.58 minutes, and the CBD clearance time was 44 ± 15.16 minutes. Successful clearance of CBD, confirmed by a choledochoscope, was achieved in 60 cases (96.77%). Bleeding during the intraoperative period was within 51–100 ml in most cases 41 (66.13%). In 60 patients (96.77%), the primary closure of CBD following LCBDE was achieved. Two of the 62 cases underwent conversion from laparoscopic to open surgery (Table 3). Post-operative transient bile leakage was noted on post-operative days 3 and 7 in 6 and 4 patients, respectively, and it resolved on its own without requiring radiological or surgical intervention. No bile leakage during surgical follow-up was noted on days 14 and 30. On the third post-operative day, one case of wound infection was observed and treated with an upgraded antibiotic. On post-operative day 3, the abdominal drain was removed from 54 individuals with no complaints of bile leakage. Bile leakage was observed in the remaining 6 cases and in 2 cases with a T-tube in situ. After conservative treatment of temporary bile leakage on post-operative days 7 and 14, the drain was taken out in two and four cases, respectively. Drains were removed after the t-tube removal in the two cases with a t-tube in place. During the follow-up, retained stones were found in two people with bile leaks and jaundice after surgery. A successful post-operative ERCP was performed for those two patients with retained stones with no additional problems (Table 4).

DEMOGRAPHIC PARAMETERS		NUMBER	PERCENTAGE	P-VALUE
AGE (YRS)	18-30	7	11.29%	X=14.96 p=0.0048*
	31-40	16	25.81%	
	41-50	23	37.10%	
	51-60	15	24.19%	
	61-70	1	1.61%	
GENDER	Female	43	69.35%	X=4.826 p=0.0280*
	Male	19	30.65%	

Table 1: Demographic Parameters of Enrolled Patients (n=62)

LIVER FUNCTION TEST	MEAN±SD
Total Bilirubin (mg/dl)	2.95±2.10
SGPT/ALT (u/l)	86.18±85.00
SGOT/AST(u/l)	72.16±95.54
Sr. Alkaline Phosphatase (u/l)	250.95±270.86

Table 2: Liver Function Test of Enrolled Patients (n=62)

INTRAOPERATIVE PARAMETERS		NUMBER	PERCENTAGE	P-VALUE
SUCCESSFUL CLEARANCE OF DUCT	No	2	3.23%	X=34.73 p<0.0001*
	Yes	60	96.77%	
BLEEDING (ml)	<50	17	27.42%	--
	51-100	41	66.13%	
	>101	4	6.45%	
MODE OF CLOSURE	Laparoscopic primary closure	60	96.77%	X=34.73 p<0.0001*
	T-Tube Closure	2	3.23%	
CONVERSION TO OPEN SURGERY	No	60	96.77%	--
	Yes	2	3.23%	

Table 3: Intraoperative Parameters of Enrolled Patients (n=62)

POST-OPERATIVE PARAMETERS		PRESENT		ABSENT		P-VALUE
BILE LEAKAGE		N	%	N	%	
	P.O.D. 1	0	0.00%	62	100.00%	---
	P.O.D. 3	6	9.68%	56	90.32%	X=24.08 P<0.0001*
	P.O.D. 7	4	6.45%	58	93.55%	X=29.02 P<0.0001*
	P.O.D. 14	0	0.00%	62	100.00%	---
	P.O.D. 30	0	0.00%	62	100.00%	---
WOUND INFECTION	P.O.D. 1	0	0.00%	62	100.00%	---
	P.O.D. 3	1	1.61%	61	98.39%	X=37.91 P<0.0001*

Table 4: Post-operative Parameters of Enrolled Patients (n=62)

	P.O.D. 7	0	0.00%	62	100.00%	----
	P.O.D. 14	0	0.00%	62	100.00%	---
	P.O.D. 30	0	0.00%	62	100.00%	----
ABDOMINAL DRAIN REMOVAL	P.O.D 1	0	0.00%	X=34.73 p<0.0001*		
	P.O.D 3	54	87.10%			
	P.O.D 7	2	3.23%			
	P.O.D 14	6	9.67%			
	P.O.D 30	0	0.00%			
RETAINED STONE	No	60	96.77%	X=34.73 p<0.0001*		
	Yes	2	3.23%			
POST-OPERATIVE INTERVENTION	No	60	96.77%	X=34.73 p<0.0001*		
	ERCP	2	3.23%			

Cont. Table 4: Post-operative Parameters of Enrolled Patients (n=62)

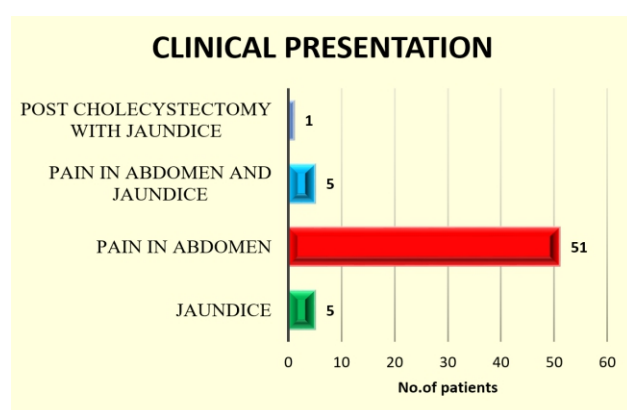


Fig. 1: Clinical presentation of the Enrolled Patients

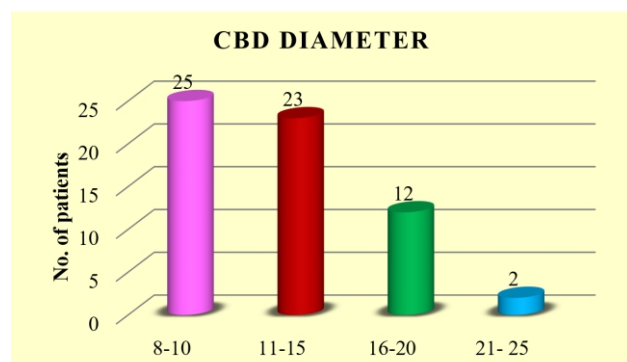


Fig. 2: CBD stone Diameter of the Enrolled Patients

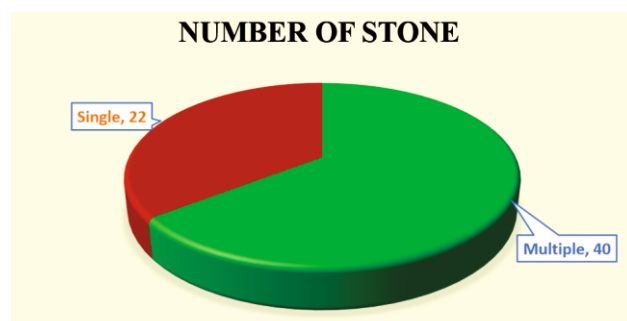


Fig. 3: Number of stones in the Enrolled Patients

DISCUSSION

The age group with the highest number of cases in this study was between 41 and 50 years old, accounting for 27.10% of the total cases. Subsequently, there were 16 cases recorded within the age range of 31 to 40 years, representing 25.81% of the cases. In terms of gender distribution, there were 43 female cases, accounting for 69.35% of the total cases. The findings of this study are in line with those of a study done by Pimpale R. et al (6). with a mean age of presentation of choledocholithiasis of 45.03 ± 13 years. Our study found that 51 patients (82.25%) presented with abdominal pain. Currently, MRCP (magnetic resonance cholangiopancreatography) is widely acknowledged as the most precise non-invasive investigation for identifying CBD stones, boasting a sensitivity range of 85 to 92 percent and a specificity range of 93 to 97 percent. (7-9). Nevertheless, the sensitivity and specificity values mentioned above tend to decrease when dealing with small stones measuring less than 5 millimetres in size. In this particular study, the presence of CBD stones was confirmed through a radiological assessment involving techniques such as ultrasound whole abdomen and/or MRCP. The results showed that in most cases, 40 (64.52%) had more than one stone, and an assessment of CBD diameter showed that in most cases, 25 (40.32%) fell within the 8-10 mm range. Currently, a flexible choledochoscope is widely recognised as a key instrument in the management of choledocholithiasis. The use of choledochoscope provides an advantage by allowing direct visualisation of the stone within the biliary channel, thereby facilitating its removal. Moreover, it allows for examination of the distal CBD to identify any additional factors that may be causing obstruction, specifically regarding the anatomy of S.O.D (Sphincter of Oddi). Cai H. et al. (10) attained a

clearance rate of 100 percentage using choledochoscopy. During this research, we achieved total ductal clearance in 60 out of 62 patients (96.77%). This was accomplished with the assistance of a choledochoscope. In the two remaining patients, laparoscopic surgery was switched to open surgery since the clearance of CBD could not be confirmed after numerous attempts using choledochoscopy, and T-tubes were utilised to close the CBD. However, these two patients underwent a T-tube cholangiogram after surgery, and it did not disclose any signs of obstruction. With a p value <0.0001 , using a choledochoscope to confirm ductal clearance followed by primary closure of CBD is a significant finding. In the present study, post-operative bile leakage was noted on post-operative days 3 and 7 in 6 and 4 patients, respectively, which was transient and did not require any intervention to control it. No instances of biliary peritonitis, a dreaded complication following common bile duct exploration, were observed among the patients included in this study. The primary closure of the CBD was followed by no recorded cases of biliary peritonitis, according to a meta-analysis done by Podda M. et al (11). However, when T-tube drainage was used, 12 instances were recorded. Another study by Noble H. et al (12) observed a bile leak rate of 15.6%. The higher intracholedochal pressure resulting from sphincter spasm after instrumentation can contribute to bile leakage, but this can be mitigated by intraoperative glucagon and post-operative hyoscine butyl bromide. Additionally, bile leaks can occur from needle bites, which typically resolve on their own. The use of finer suture material (4-0 vicryl) for closure significantly reduces the occurrence of transient bile leaks. Achieving effective clearance of the duct is crucial in order to avoid any biliary leaks. When encountering a post-operative bile leak, it is essential to prioritize prompt evaluation and intervention using urgent imaging techniques, such as magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP), to identify and remove any retained stones (13). Bile leakage can occur from the gallbladder fossa from the cystohepatic duct. Thus, the trend of no bile leakage during surgical follow-up in the present study was statistically significant, as indicated by the p-value of <0.0001 . During the third day of post-operative care, a single patient was identified to have a wound infection, which was promptly addressed by administering a higher grade of antibiotic. The p-value of <0.001 shows that the lack of wound infection is statistically important. In this study, in

most of the cases on Post-operative day 3 (POD), the abdominal drain was removed from 54 individuals with no complaints of bile leakage. After conservative treatment of temporary bile leakage on POD 7, the drain was removed in two cases. On POD 14, the remaining 6 cases of drain were removed (4 due to control of transient bile leakage), and 2 cases where t-tube closure was done in view of inconclusive clearance had their abdominal drain removed after the removal of the t-tube. p-value <0.001 is statistically significant, indicating drain removal in most cases on POD 3. Retained stones are one of the most serious problems that might arise after primary duct closure. Lauter and Froines (14) observed that after LCBDE, out of 71 patients who underwent the surgery, 11 individuals (15.5%) had residual stones. A recent study (15) found that following LCBDE 4 out of 115 participants (3.4%) had residual stones. However, the incidence of residual stones in the present study was found to be 3.23%, with only 2 out of 62 patients experiencing this complication. This rate is considerably lower compared to findings from previous studies. The implementation of a choledochoscope during the procedure, along with the repeated verification of ductal clearance before duct closure, likely contributed to this favorable outcome. A p-value of 0.0001 further demonstrates a statistically significant trend indicating the absence of retained stones when employing a choledochoscope during the procedure.. These two cases of retained stones were clinically apparent in post-operative follow-up with the development of icterus and a deranged liver function test. They were managed with endoscopic retrograde cholangiopancreatography (ERCP).

CONCLUSION

LCBDE with primary CBD closure with the aid of a choledochoscope yielded satisfactory results in achieving comprehensive stone clearance. Based on short-term follow-up data, employing primary closure following laparoscopic common bile duct exploration (LCBDE) showed a minimal occurrence of bile leakage, retained stones, and wound infection. Therefore, laparoscopic CBD exploration followed by its primary closure is regarded as safe and effective, resulting in a favourable short-term outcome. Nevertheless, as the follow-up period of this study was limited in duration, it is not possible to draw definitive conclusions regarding the recurrence of stones or the occurrence of common bile duct strictures. To comprehensively address these concerns, it is imperative to conduct an extended follow-up period to gather data with increase in sample size.

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**Orcid ID:**

Shalini - <https://orcid.org/0009-0005-8686-6941>

How to cite this article:

Shalini. Efficacy And Safety Of Primary Closure Of Common Bile Duct Following Laparoscopic Choledocholithotomy. *Era J. Med. Res.* 2023; 10(1): 37-42.

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