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Conventional Surgical Management of Common Bile Duct Stones in the Endoscopic Era: Our Experiences in A Tertiary Care Hospital.

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Abstract:
Background:*Gallstone disease is prevalent in 10-14% of adult population of eastern world. Around 8−20% of patients undergoing cholecystectomy for cholelithiasis have been detected with common bile duct stones (CBDS).The role of conventional surgical management in the era of endoscopy for the treatment of choledocholithiasis have never declined to the baseline, rather it has always stood as an adjunct and saviour when failure of all other modalities is taken into account.Open surgical approach is based upon a number of factors like the diameter of the CBD, number of CBD stones, any impacted stone etc. and they in turn decide the type of biliary drainage after CBD exploration: internal (bilioenteric drainage) or external (T-tube drain).*
Aim: *To study the various modes of conventional surgical management for common bile duct stones in terms of their complications, hospital stay and operative time.*
Materials and methods:*This was a prospective hospital based observational study conducted in the Department of General Surgery of Assam Medical College and Hospital on 96 patients who were admitted in different units, with the diagnosis of choledocholithiasis and fulfilling the inclusion and exclusion criteria from June 2020 to May 2021.*
Results:*The mean age of occurrence of all cases of choledocholithiasis was 44.64 ± 14.23 years with maximum numbers of cases in the age group of 41-50 years.Female preponderance was seen with 69.79% of all cases of choledocholithiasis with Female: Male ratio to be 2.3:1.It was found that 64 cases of choledocholithiasis (66.66%) had underwent OCBDE with T-Tube Drainage while 32 cases (33.33%) underwent OCBDE with Choledochoduodenostomy.Out of 64 cases who underwent OCBDE with TTD, 25% had wound infection, 4.68% had cholangitis, 7.81% had biliary leak and 3.12% had haemorrhage post operatively. Out of 32 cases who underwent OCBDE with CDD, one had wound infection and only one had biliary leak. Mean Operating time in cases who underwent OCBDE with CDD was 2.24 ± 0.33 hours and it was significantly more when compared with that of OCBDE with TTD. Mean Hospital stay was 14.4 ± 1.1 days in cases who underwent OCBDE with TTD and it was found to be significantly more when compared with that of OCBDE with CDD.*
Conclusion: *In our study, open common bile duct exploration with T-tube drainage or choledochoduodenostomy were the main modes of management. Although T-tube drainage is a most commonly done procedure, choledochoduodenostomy is relatively safer with respect to complications as found in our study. No mortality was recorded in our study.*

Keywords: *CBDS, T-Tube drainage, choledochoduodenostomy, surgical management.*

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I. INTRODUCTION

Gallstone disease is prevalent in 10-14% of adult population of eastern world.[1]Around 8−20% of patients undergoing cholecystectomy for cholelithiasis have been detected with common bile duct stones (CBDS).[2]The incidence of CBDS in patients with symptomatic cholelithiasis varies widely in the literature between 5% and 33% according to age. CBDS are either primary (originating within the CBD) or secondary (originating in the gallbladder) and pass into the CBD.[3]Common bile duct stones are the most important cause of obstructive jaundice andcholangitis. Women are three times more likely affected with gallstone disease than men.[4]

Most of the time CBDS are clinically silent and is detected incidentally during cholangiography performed routinely during cholecystectomy.[2]In case of symptomatic CBDS, symptom complex varies from pain abdomen, jaundice with symptoms of cholestasis, cholangitis to biliary pancreatitis etc.[5]

Elevated serum bilirubin along with alkaline phosphatase may be found in the liver function test reports of patients with choledocholithiasis.[6]Ultrasonography is the most commonly done imaging modality in patients of gallstone disease with sensitivity of detecting biliary dilatation and choledocholithiasis as reported in various studies ranging from 55 to 91% and specificity upto 95%.[6] MRCP has sensitivity of more than 90% and specificity of almost 100% in diagnosis of CBDS.[5]

The introduction of endoscopic sphincterectomy (EST) by Demling et al in Erlangen in 1974 marked the outset of a new era in the nonsurgical treatment of common bile duct (CBD) stones.[7]More than 80% of all CBD stones can be effectively treated by endoscopic sphincterotomy and stone extraction using baskets or balloon catheters.[7]After ERCP and sphincterotomy, almost 50% of all patients will have recurrent symptoms of biliary tract disease if cholecystectomy is not done. 5% cases are converted to open surgery from ERCP. 8.8% cases of ERCP has complications like bleeding, acute pancreatitis etc.[8] Surgical management is more advantageous than endoscopic management of symptomatic cases of choledocholithiasis with cholelithiasis as cholecystectomy can be done in the same sitting and CBD visualised directly as well as palpated.[7]

Knowsley Thornton and Ludwig Courvoisier conducted the first open common bile duct explorations in London in 1889 and Basel in 1890, respectively.[9]Advent of first systematic use of biliary intubation started in 1897 by Kehr through exploration of the common bile duct with placement of a rubber tube (T-tube).[10]Choledochoduodenostomy (CDD) was first performed in1888 by Riedel but the first successful operation was performed in 1891 by Sprengel.[11]

Factors which are possibly associated with difficult or incomplete endoscopic stone extraction are large size stones, barrel shape, multiple stones, impacted stones, intrahepatic stones, severe acute cholangitis, low experience endoscopist, inadequate setting etc.[12]

The role of open surgical management in the era of endoscopy for the treatment of choledocholithiasis have never declined to the baseline, rather it has always stood as an adjunct and saviour when failure of all other modalities is taken into account. However open surgical approach is based upon a number of factors like the diameter of the CBD, number of CBD stones, any impacted stone etc. and they in turn decide the type of biliary drainage after CBD exploration: internal (bilioenteric drainage) or external (T-tube drain).

This study was being undertaken to share our experiences in conventional surgical management of common bile duct stones in a tertiary care centre.

II. AIM AND OBJECTIVES

1. To study the various modes of conventional surgical management for common bile duct stones.
2. To evaluate the various modes of surgical management in terms of their complications, hospital stay and operative time.

III. MATERIALS AND METHODS

This was a prospective hospital based observational study conducted in the Department of General Surgery of Assam Medical College and Hospital on all patients who were admitted in different units, with the diagnosis of choledocholithiasis, more than 12 years of age from June 2020 to May 2021. Before commencing the study, Ethical Clearance was obtained from the Institutional Ethics committee (Human), Assam Medical College & Hospital, Dibrugarh, Assam. Written and informed consent was taken from each and every participant of the study in their own understandable language.

Sample size calculation*:*Considering 95% confidence interval and with an absolute error of 10% and common bile duct stones among gallstone diseases to be 60%, (MJ, Ravi 2019,Clinical profile of patients with common bile duct stones attending tertiary care hospital[2])the sample size was calculated to be 96.

INCLUSION CRITERIA:-

All patients who are diagnosed with choledocholithiasis, more than 12 years of age, admitted in different units of Department of General Surgery, AMCH.

EXCLUSION CRITERIA:

1. Patients with severe co-morbid conditions.
2. All cases of choledocholithiasis associated with hepatobiliary malignancy.

IV. METHODOLOGY

After admission to the hospital, the clinical history and examination of patients were done and data was recorded. All patients underwent various biochemical tests like LFT, complete blood count, total leukocyte count, prothrombin time and INR, blood urea, serum creatinine, serum electrolytes etc. Transabdominal ultrasonography (TAUS) and MRCP were used for confirming diagnosis.If there was no evidence of choledocholithiasis on transabdominal USG, but clinical history, physical findings or changes in liver function test parameters was suggestive of choledocholithiasis, then MRCP was carried out to confirm the diagnosis. ERCP was not done due to unavailability in our institution.

Patients presenting with surgical jaundice due to choledocholithiasis, preoperative management constituted of hydration by oral and intravenous fluids, replacement of depleted glycogen stores by providing glucose by mouth or intravenous infusion of Dextrose Normal Saline, intramuscular administration of vit K for minimum of 3 days prior to surgery, fresh frozen plasma intravenously in cases with altered coagulation status not corrected with vitamin K alone, intravenous broad spectrum antibiotics prophylaxis, administration of mannitol in cases with systolic blood pressure more than 110mm Hg and high total serum bilirubin (>12mg/dL) and correction of other electrolyte imbalances along with oral or intravenous analgesics.

The following modes of surgery were used for definitive management in our study:

I. Open Common Bile Duct Exploration (OCBDE) with T-tube drainage with or without open cholecystectomy (depending on past cholecystectomy status).

II. Open Common Bile Duct Exploration (OCBDE) with choledochoduodenostomy with or without open cholecystectomy (depending on past cholecystectomy status).

Selection of mode of surgery was based on abnormal LFT and TAUS or MRCP findings preoperatively or sometimes decision was changed on table on the day of surgery based on intraoperative findings after exploration of CBD.

Indications for OCBDE with CDD in our study were:

a) Multiple CBD calculi.
b) Papillary stenosis with impacted calculi.
c) Symptomatic residual stones.
d) Marked CBD dilatation (> 1.5 cm).
e) Distal duct stricture with stones.
f) Intrahepatic stones.
g) Primary CBD stones.

After preoperative preparation, surgery was performed in all cases under General Anaesthesia with Endotracheal Intubation using inducing agents like Propofol and Succinylcholine and maintenance agents like Oxygen and Nitrous gaseous mixture, Sevoflurane and Atracurium most commonly.

V. **SURGICAL PROCEDURE**:

Incision and Exploration:- All patients were explored through right sub costal incision after antiseptic draping with 10% Betadine and proper haemostasis was achieved. Gallbladder (GB), CBD and calots triangle was carefully examined after proper dissection. Cholecystectomywas done according to past surgical status.

Choledochotomy and Choledocholithotomy:Cholecystectomy was followed by identification of CBD by needle aspiration with syringe, two stay sutures using 3-0 atraumatic chromic catgut, were inserted and a longitudinal incision in CBD (choledochotomy) was performed at the supraduodenal part of the CBD. CBD stones are cleared (choledocholithotomy) with the help of Desjardin's forcep and probing of CBD by dilator 4-6 mm and irrigation with normal saline by multiple flushing with the help of 6F or 8F infant feeding tube proximally first then distally to avoid contamination from gut was done. If any stone in distal CBD could not be accessed, then kocherization of the duodenum was tried for extraction.

On table decisionfor type of drainage was made based on the intraoperative findings for CBD stones, CBD diameter etc. as described earlier.

T-tube drainage*:* A Kehr's T-tube size 12-14 F and made of polyvinyl chloride with a radio opaque line throughout the tube, was inserted using Desjardin's forcep. A slit is made in the short arm and a rim of tube is cut away along the slit made before insertion according to the diameter of CBD. Interrupted sutures of polyglactin (vicryl) 3-0 round body was used to repair CBD over the T- tube. A corrugated drain made of polyvinyl chloride was inserted in the right sub hepatic space. After achieving proper haemostasis, abdomen was closed in layers with polydioxanone suture (PDS-II) no.1 and both T-tube and drain was fixed to the skin using mersilk 2-0 reverse cutting suture. Skin was closed with ethilon 2-0 suture.

Choledochoduodenostomy:Initial steps upto CBD exploration and choledocholithotomy was same in this procedure also. Mobilization of the 1st part of duodenum was done by dividing the hepatoduodenal ligament. A horizontal incision was made in the anterior wall of the duodenum along its axis and a single layer side to side anastomosis was done between CBD and duodenum using 3-0 polyglactin (vicryl) round body atraumatic sutures. A corrugated polyvinylchloride (PVC) drain was placed in the right subhepatic space. After achieving proper haemostasis, abdomen was closed in layers with polydioxanone suture (PDS-II) no.1 and drain was fixed to skin using mersilk 2-0 reverse cutting sutures. Skin was closed with ethilon 2-0 suture. Specimen of GB was routinely sent in all cases to pathology for histopathological examination after preserving in 10% formalin, within 24 hours after surgery.

Operative time was noted in both types of surgery.

Postoperatively*,* the patients were managed by giving intravenous antibiotics, adequate fluid and nutrition and analgesics.Pulse rate, temperature, respiratory rate, systolic blood pressure, oxygen saturation,

urine output, T-tube drain output, PVC drain soakage were noted.Nasogastric decompression through Ryle's tube was carried out hourly for upto 48 hours postoperatively or longer than that in case of biliary enteric anastomosis. Bile output in T-tube as well as in Ryle's tube was properly noted. Ambulation and oral feeding were started gradually according to the appearance of bowel sounds.

Gradual intermittent Clamping of T-tube was started from 10-12 days postoperatively at an interval of 2 hours, 4 hours, 8 hours etc. followed by continuous clamping for 24 hours to 48 hours and a T-tube cholangiogram was done on 13th/14th postoperative day or later depending upon the condition of the patient and output of T-tube. T-tube was removed with gradual traction and counter traction with proper clamping after confirmation of absence of any residual stones depicted in T-tube cholangiogram.

Other drains were removed in proper time based on their output and oral intake of the patient and passage of stool. Stitches were removed after 10th postoperative day or longer than that based on the wound healing.

Complication like haemorrhage, bile leak, wound infection or any other complications were noted and recorded and treated accordingly.

Follow up of the patients were done at 2 weeks, 6 weeks, and 12 weeks only (on the basis of OPD check-up, readmission to hospital or telephonic conversation) due to the limitation of the study period. In each visit, patients were evaluated for any recurrence of symptoms like pain abdomen, recurrence of jaundice, wound site or drain site infections, any residual stones, bladder and bowel habits etc. Investigations advised in follow up were LFT and TAUS as and where necessary.

STATISTICAL ANALYSIS

The categorical variables were summarized as frequencies and percentages. The continuous data were presented as mean ± Standard Deviation. Statistical significance were assessed by using Chi Square / Fisher's exact test for categorical variables and using t- test for continuous variables. A p-value of <0.05 was considered as statistically significant. All the analysis were performed using SPSS (Statistical Product and Service Solutions) version 16.0 software.

VI. RESULTS

Table 1: Age distribution

AGE GROUP (IN YEARS)	NUMBER OF CASES (N=96)	PERCENTAGE
12-20	1	1.04
21-30	14	14.58
31-40	19	19.79
41-50	27	28.12
51-60	22	22.91
61-70	11	11.45
>70	2	2.08
Mean ± SD	44.64 ± 14.23 years.	

In the present study, the mean age of occurrence of all cases of choledocholithiasis was 44.64 ± 14.23 years. The maximum numbers of cases (27) were found in the age group of 41-50 years, followed by 51-60 years. The range of age of the cases was from 18-75 years.

Table 2: Sex distribution:

SEX	NUMBER OF CASES (N=96)	PERCENTAGE
Male	29	30.20
Female	67	69.79
Ratio of Female: Male	2.3:1	

Female preponderance was seen with 69.79% of all cases of choledocholithiasis with Female: Male ratio to be 2.3:1.

Table 3: Modes of surgical management.

SURGICAL PROCEDURE	NUMBER OF CASES(N=96)	PERCENTAGE
OCBDE+ T-Tube Drainage	64	66.66
OCBDE+ Choledochoduodenostomy	32	33.33

64 out of 96 cases of choledocholithiasis (66.66%) had underwent OCBDE with T-Tube Drainage while 32 cases (33.33%) underwent OCBDE with Choledochoduodenostomy.

Table 4: Post Operative complications of all cases of Choledocholithiasis.

COMPLICATIONS	OCBDE & TTD (N=64)	OCBDE & CDD (N=32)	p- VALUE*
Wound infection	16 (25)	1 (3.12)	0.01 #
Cholangitis	3 (4.68)	0 (0)	0.54
Biliary leak	5 (7.81)	1 (3.12)	0.66
Residual stone	0 (0)	0 (0)	
Haemorrhage	1 (3.12)	0 (0)	1
Sump syndrome	0 (0)	0 (0)	
Septicaemia	0 (0)	0 (0)	
Biliary Peritonitis	0 (0)	0 (0)	

Figures in bracket denotes percentage.
* p-value is calculated using Fisher's Exact test.
# Significant at 5% level of Significance.

In the present study, it was observed that out of 64 out of 96 cases who underwent OCBDE with TTD, 25% had wound infection, 4.68% had cholangitis, 7.81% had biliary leak and 3.12% had hemorrhage post operatively. Out of 32 cases who undergone OCBDE with CDD, one had wound infection and only one had biliary leak. Wound infection was found to be significantly more in cases who underwent OCBDE with TTD as compared to those who underwent CDD. All complications encountered in our study were managed conservatively.

Table 5: Comparison of Mean Operating time and Mean Hospital stay in all cases of Choledocholithiasis who underwent OCBDE with TTD and OCBDE with CDD.

	OCBDE +TTD	OCBDE + CDD	p -VALUE*
Operating Time (in hours) (mean ± SD)	1.90 ± 0.48	2.24 ± 0.33	0.0041#
Hospital stay (in days) (mean ± SD)	14.4 ± 1.1	10.4 ± 1.3	< 0.0001#

* p-value is calculated using t-test.
# Significant at 5% level of Significance.
In the present study, it was found that Mean Operating time in cases who underwent OCBDE with CDD was 2.24 ± 0.33 hours and it was significantly more when compared with that of OCBDE with TTD. Mean Hospital stay was 14.4 ± 1.1 days in cases who underwent OCBDE with TTD and it was found to be significantly more when compared with that of OCBDE with CDD.

VII. DISCUSSION

1. ***Age and sex distribution:***In the present study, the mean age of occurrence of all cases of choledocholithiasis was 44.64 ± 14.23 years. The maximum numbers of cases (27) were found in the age group of 41-50 years.Female preponderance was seen with 69.79% of all cases of choledocholithiasis with Female: Male ratio to be 2.3:1. **Kumar N, 2020** in his study found comparable resultsi.e, out of the 38 patients, 14 (37.14%) were male and 24 (62.85%) were female. The mean age for male was 50.92 years and for female, it was 51.74 yrs.[13]

2. Modes of surgical management:

In the present study it was found that 64 cases of choledocholithiasis (66.66%) had underwent OCBDE with T-Tube Drainage while 32 cases (33.33%) underwent OCBDE with Choledochoduodenostomy.**Al-Araji**, **Karim,2010**, in his study to compare the two surgical treatments of patients with choledocholithiasis, 83 out of 154 patients (53.8%) underwent OCBDE with TTD and 71 out of 154 patients (46.1%) underwent OCBDE with CDD.[14]

3. ***Post operative complications of all cases of Choledocholithiasis:***In the present study, it was observed that out of 64 cases who underwent OCBDE with TTD, 25% had wound infection, 4.68% had cholangitis, 7.81% had biliary leak and 3.12% had haemorrhage post operatively. Out of 32 cases who undergone OCBDE with CDD, one had wound infection and only one had biliary leak. Wound infection was found to be significantly more in cases who underwent OCBDE with TTD as compared to those who underwent CDD.

Table 6:Post operative complications of OCBDE with TTD are compared with various other studies.

COMPLICATIONS	PRESENT STUDY ,2021	Maneesh, Sharmaetal., 2016[15]	M, Asaduzzamanetal., 2017[16]	Ambreen, M et al.2009[17]	Haider J et al., 2009[18]	Gupta A et al., 2021[19]
Wound infection	25%	5%	13.3%	-	-	8%
Dislodgement of t-tube.	-	-	-	-	-	8%
Cholangitis	4.68 %	2.5%		-	-	
Biliary peritonitis/ bile leak	7.81%	2.5%	13.3 %	10.5%	7.98%	8%
Subphrenic collection	-	-	-	-	2.63%	-
Post operative jaundice	-	-	-	5.3%	-	8%
Residual stone	0	-	-	-	-	8%
Haemorrhage	3.12 %	-	-	-	-	-
Sump syndrome	0	-	-	-	-	0
Septicemia	0	-	-	-	-	-
Pain abdomen	-	10%	-	-	-	-
Vomiting	-	5.0%	-	-	-	-

Table 7:Post operative complications of OCBDE with CDD are listed and compared to other studies:

COMPLICATIONS	PRESENT STUDY, 2021	Gupta A et al., 2021[19]	Al-araji, Karim, 2010[14]	Zafar et al., 2011[20] BILIARY ENTERIC ANATOMISIS (INCLUDED CDD)
Wound infection	3.12 %	4%	2.81%	22.8
Cholangitis	0	-	2.81%	8.9 %
Biliary leak	3.12 %	12%	-	10%
Residual stone	0	0	0	-
Biliary obstruction	-	-	1.40%	-
Jaundice	-	0	-	8.9 %
Heamorrhage	0	-	-	2.5%
Sump Syndrome	0	4%	-	-
Septicemia	0	-	-	-
Biliary peritonitis	0	-	-	-
Delayed Gastric emptying	-	-	-	8.9%
Pancreatitis	-	-	-	1.3%

4. ***Mean hospital stay and Mean operative time****:* In the present study, it was found that Mean Operating time in cases who underwent OCBDE with CDD was 2.24 ± 0.33 hours and it was significantly more when compared with that of OCBDE with TTD. Mean Hospital stay was 14.4 ± 1.1 days in cases who underwent OCBDE with TTD and it was found to be significantly more when compared with that of OCBDE with CDD.

Table 8:Comparison of Mean operating time (hours).

STUDY SERIES	OCBDE +TTD	OCBDE + CDD
Present study, 2021	1.90 ± 0.48	2.24 ± 0.33
Okamoto H et al., 2017[11]	-	2.03 ± 0.12
Khan AZ et al., 2017[21]	1.95 ± 0.13	-

Table 9:Mean hospital Stay for OCBDE with TTB.

STUDY SERIES	MEAN HOSPITAL STAY (DAYS)
Present Study,2021	14.4 ± 1.1
Akram M et al., 2020[22]	9.5 ± 2.3
Sinha S et al., 2017[23]	6 ± 3.1

Table 10: Mean hospital Stay for OCBDE with CDD.

STUDY SERIES	MEAN HOSPITAL STAY (DAYS)
Present study,2021	10.4 ± 1.3
Gupta A et al., 2021[19]	8.4+.30
Hans, Saptal et al., 2020[24]	7 ± 1.1

Freund H et al.,1977[25]	14.7 ± 0.2

It is interpreted after discussing the various modes of surgical management, their complications, operative time and hospital stay that OCBDE with T- tube drainage is the most commonly done procedure for choledocholithiasis cases. However, the complicationsare more in TTD than CDD. Wound infection rate is significantly high in TTD as compared to CDD. Mean operative time is significantly more in OCBDE with CDD as compared to TTD and mean hospital stay is significantly more in cases undergoing OCBDE with TTB as compared to CDD.

VIII. CONCLUSION

Gallstone disease including choledocholithiasis is the most commonly encountered disease in a resident surgeon's life but due to its myriad presentations it is also subjected to the emerging diagnostic as well as minimally invasive procedures. Inspite of this, the position of open surgical intervention is irreplaceable and has a good outcome and always stands as the last resort in complicated cases.In our study, open common bile duct exploration with T-tube drainage or choledochoduodenostomy were the main modes of management. No surgical procedure is devoid of complications and our study was not an exception to this, and we encountered some complications with each procedure. Although T-tube drainage is a most commonly done procedure, choledochoduodenostomy is relatively safer with respect to complications as found in our study. No mortality was recorded in our study. It is evident that open surgical procedure under an experienced surgeon is also a good treatment modality which is quite acceptable in this endoscopic era.

Limitation of this study:

- It is a single institution based study.
- It is a study of very short duration (1 year).
- It has very limited number of cases due to Covid-19 outbreak.
- Facilities for all the ideal procedures like ERCP and investigations intraoperative cholangiography are not available in the place of study.
- Lack of expertise in the field of advanced management options.

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DR. DEEPSHIKHA KAR, et. al. "Conventional Surgical Management of Common Bile Duct Stones in the Endoscopic Era: Our Experiences in A Tertiary Care Hospital." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 21(03), 2022, pp. 51-58.