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A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS

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ABSTRACT

Introduction: The selection of treatment for common bile duct stones (CBDS) is guided by multiple factors. Endoscopic retrograde cholangiopancreatography (ERCP) has emerged as the preferred alternative to open surgery. The failure rate of ERCP can be as high as 10% to 25%. Our study aims to identify the characteristics of CBD stones, which make them prone to failure by standardised ERCP extraction helping to prevent the morbidity associated with failed ERCPs and compare the different techniques of treatment with a special focus on the various surgical modalities.

Material and Method: In this prospective observational study 30 Patients who presented to Surgery OPD with choledocholithiasis not amenable to ERCP stone retrieval were included. Clinical presentation and examination findings, radiological investigation, stone characteristics, CBD characteristics, reasons for failed ERCP, surgical procedure undergone, postoperative complications, hospital stay, physical and mental score were analysed in detail.

Result: In our study reasons for failed ERCP includes multiple calculi seen in 40% of cases followed by large calculi in 23.3%, impacted stone in 13.3%, stricture in 10%, diverticulum in 2 cases and difficult cannulation in 1 case. Out of 30, 25 patients underwent open and 5 underwent laparoscopic CBD exploration. The mean length of hospital stay among open and laparoscopic surgery group was 6 & 5 days respectively. The average Physical status awell score in case of open CBD exploration was 43.57 and in laparoscopic was 49.46 and the average mental status awell score in case of open CBD exploration was 46.07 and in laparoscopic was 52.45.

Conclusion: There is no significant difference in the clinical outcomes between Open CBD Exploration with primary repair or T-tube or Choledochoenterostomy and Laparoscopic CBD Exploration, except for the Physical and mental status, which is higher in laparoscopic CBD exploration patients. The ideal management of choledocholithiasis remains controversial, but the treatment for choledocholithiasis must always be tailored to the needs of each patient.

Keywords: Choledocholithiasis, ERCP failure, laparoscopic CBD exploration, open CBD exploration.

INTRODUCTION

Choledocholithiasis is the presence of stone in common bile duct. It occurs in approximately 3% to 14.7% cases of cholelithiasis. Whereas cholelithiasis is found concurrently in 67% of cases of Choledocholithiasis [(1)].

Choledocholithiasis can be classified into Primary and Secondary stones. Primary CBD stones refer to stones that form directly within the bile duct itself as a denovo process. Primary common duct stones typically consist of brown pigment stones, which are formed from a mixture of precipitated bile pigments and cholesterol.

Secondary Choledocholithiasis are stones that originate in the gallbladder and then migrate into the CBD. These stones are typically composed of either cholesterol or black pigment.

Choledocholithiasis are generally asymptomatic. When symptoms do occur, they vary from biliary colic to obstructive jaundice, characterized by darkening of urine, scleral icterus and light-coloured stools. Painful jaundice in choledocholithiasis is more common due to the acute onset of bile duct obstruction, which leads to rapid distension of the duct and activation of pain receptors.

No single blood test can definitively diagnose the presence of common bile duct stones. Most common blood test used to diagnose CBD stone is Liver Function test. Serum bilirubin and alkaline phosphatase are usually the most frequently utilized laboratory values. Mild increases in AST and ALT can occur, but these levels become significantly abnormal in the context of cholangitis. However liver function panel abnormalities on their own are neither sensitive nor specific.

There are various approaches to diagnose common bile duct stones, each varying in their diagnostic accuracy. Even without symptoms of biliary colic, the presence of gallstones alongside a dilated bile duct suggests choledocholithiasis. Ultrasound is usually the initial diagnostic tool used, though its effectiveness relies on the operator's skill. MRCP is regarded as the most precise non-invasive diagnostic method. ERCP is considered Gold standard method because of its diagnostic as well as therapeutic role. It is an invasive procedure and is mostly used for therapeutic purposes nowadays rather than diagnostic purpose.

The selection of treatment for CBD stones is guided by factors such as patient preferences, the number and size of the stones, the complexity of the disease, and anatomical details like the characteristics of the cystic duct and CBD. The experience of the surgeon and the availability of appropriate tools are also key factors.

Endoscopic retrograde cholangiopancreatography (ERCP) has emerged as the preferred alternative to open surgery, particularly since laparoscopic cholecystectomy became the standard treatment for gallbladder stones [(2).] There are several advantages to using ERCP before laparoscopic surgery compared to open surgery. However, ERCP is not without risks, with complications occurring in up to 15% of cases. These complications may include pancreatitis, cholangitis, duodenal or bile duct perforation and bleeding, affecting 5%-8% of patients. The mortality rate associated with ERCP ranges from 0.2% to 0.5% [(3).]

Approximately 10% to 15% of patients may encounter difficulty in initially removing bile duct stones at first attempt due to challenging factors. The failure rate of ERCP can be as high as 10% to 25% [(4)] .The complexity of successful endoscopic treatment revolves around the precise cannulation of the ampulla of Vater and effective stone retrieval.

When ERCP fails to remove bile duct stones, CBD exploration becomes necessary. Previously, open CBD exploration was preferred alongside open cholecystectomy. However, with laparoscopic cholecystectomy now the preferred method for gallstone treatment, laparoscopic CBD exploration has become more favourable. It also offers benefits such as minimal invasiveness and cost-effectiveness. Nevertheless, performing this procedure requires advanced surgical skills.

AIMS AND OBJECTIVES

AIMS:

1) The study aims to revisit the pathophysiology and diagnosis of Choledocholithiasis and compare the different techniques of treatment with a special focus on the various surgical modalities.

2 To identify the characteristics of CBD stones, which make them prone to failure by standardised ERCP extraction helping to prevent the morbidity associated with failed ERCPs.

OBJECTIVES: The objective of the study is to know the difference in clinical outcomes between various surgical procedures used in failed ERCP choledocholithiasis.

MATERIAL AND METHODS

PLACE OF STUDY: Department of General Surgery, Gauhati Medical College & Hospital (GMCH)

DURATION OF STUDY: One year from 1st September, 2022 to 31st August, 2023.

STUDY TYPE: The present study is prospective, observational study.

STUDY POPULATION:

Patients with choledocholithiais not amenable to ERCP stone retival at Gauhati Medical College and Hospital, Guwahati who presented to Surgery OPD were included in the study, after considering the inclusion and exclusion criteria and taking prior informed consent.

SAMPLE SIZE: 30 cases of failed ERCP were included in the study

INCLUSION CRITERIA

1. ASA Class I & Il patients.
2. Age: 25-65 years.

EXCLUSION CRITERIA

1. Neonate
2. Pediatric age group
3. Pregnant
4. Ascites
5. Deranged coagulation profile
6. Decompensated cardiopulmonary status
7. ASA Class Ill and above
8. Patients who had previously undergone previous surgeries like gastrojejunostomy, Roex en y reconstruction surgeries etc.

ETHICAL CLEARANCE: Ethical clearance was taken before commencement of the study from the Institutional Ethics Committee (Human), Gauhati Medical College Hospital, Guwahati and written informed consent will be taken as per the consent form mentioned in Annexure iii B& C .

SOURCE OF DATA

Patients with choledocholithiais not amenable to ERCP stone retival at Gauhati Medical College and Hospital, Guwahati who presented to Surgery OPD department were included in the study, after considering the inclusion and exclusion criteria and taking prior informed consent .

Patients were thoroughly evaluated clinically and investigated comprehensively. All patients underwent the same pre-operative preparation and were subjected to various surgical procedures for the removal of choledocholithiasis. The imaging studies that was carried out included USG whole abdomen, MRCP with CEMRI, Chest X ray PA view.

Clinical presentation and examination findings, radiological investigation, stone characteristics, CBD characteristics, reasons for failed ERCP, surgical procedure undergone, post op complication, hospital stay, physical and mental score were analysed in detail.

A detailed clinical history and physical examination carried out and recorded as per the proforma given in Annexure iii D .

Patients were sorted, based on patient characteristics, stone characteristic, CBD diameter etc. Patient underwent various surgical management like Open cholecystectomy with common bile duct exploration with primary closure or T tube placement or bilio-enteric anastomosis (Choledochoduodenostomy / Hepatico-jejunostomy) or Laparoscopic cholecystectomy with laparoscopic common bile duct exploration'

FAILED ERCP

Patients with choledocholithiasis whose stones could not be cleared completely during ERCP procedure was defined as failed ERCP candidates

COMPLICATIONS:

Post-operative complications were observed and noted in the immediate post operative period till discharge of the patient and subsequent follow up.

DURATION OF HOSPITAL STAY

The total hospital days of patient from the date of admission to date of discharge were noted.

PHYSICAL AND MENTAL STATUS

Mental and physical status of the patient was assessed using SF 12 calculator using awell score.

STATISTICAL ANALYSIS.

The statistical software SPSS V 21.0 was used for the analysis of the data and Microsoft word and Excel have been used to generate tables and graphs.

RESULT AND ANALYSIS

AGE INCIDENCE

Patients of age group of 25 to 65 years of age group were included in the study.

Mean age was 49 ±11.02 years, mean age for males was 48.61 years and for females was 49.29 years.

Highest incidence is seen in 46-55 years age group.

Table 1: Age distribution with gender

Age group	Male	Female	Total	Percentage
25-35	2	2	4	13.3
36-45	3	2	5	16.6
46-55	3	9	12	40
56-65	5	4	9	30
Total	13	17	30	100
Mean	48.61	49.29	49 ±11.02	

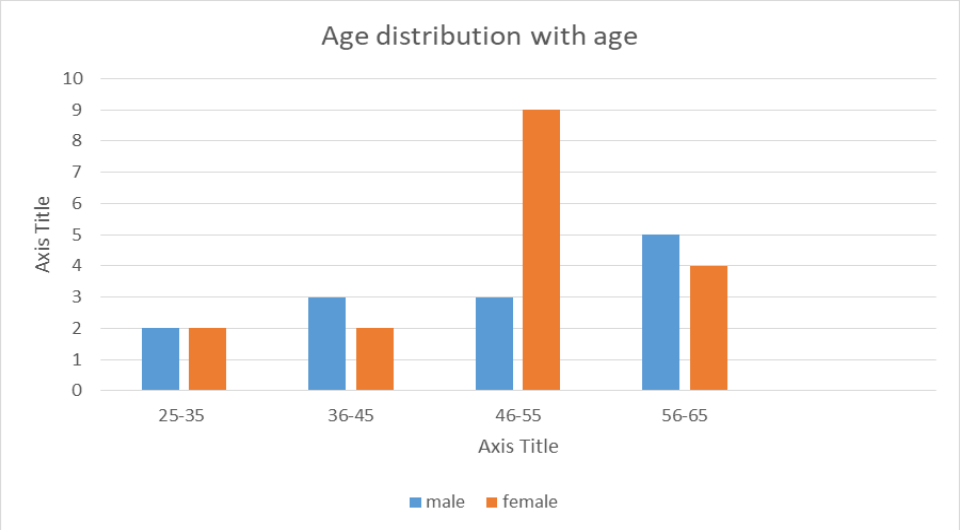


Figure 1: Age distribution with gender

SEX INCIDENCE

Out of 30 patients 17 (57%) were female and 13 were male (43%) male to female ratio 1:1.307

Table 2: Sex incidence in CBD stones

SEX	No of subject (N=30)	Percentage
MALE	13	43%
FEMALE	17	57%

Male: Female 1: 1.307

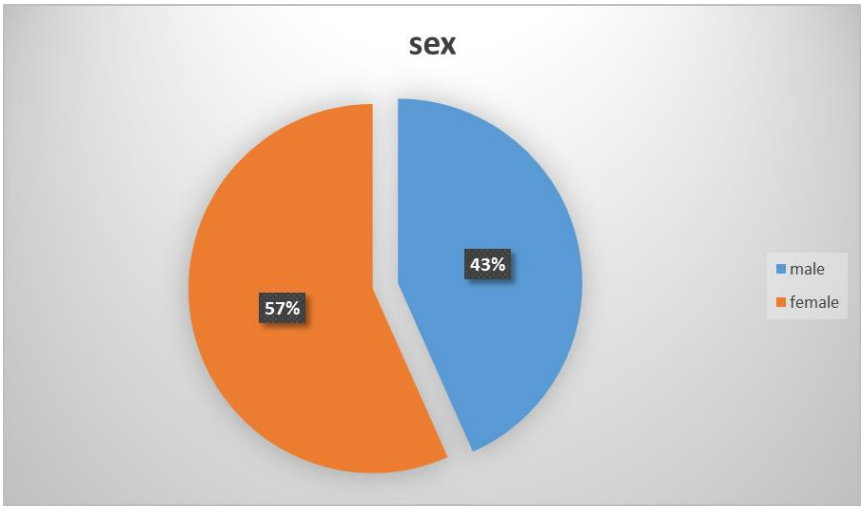


Figure 2: Sex incidence in CBD stones

CLINICAL EXAMINATION FINDINGS

The clinical factors assessed included the presenting and associated symptoms, the duration of symptoms, vital signs (Pulse rate, Blood pressure, Respiratory rate, and Temperature) and clinical signs, especially abdominal findings at time of presentation. The presence of pallor and jaundice was also recorded.

Symptoms

The most common presenting symptom was abdominal pain (90%) followed by jaundice and vomiting found in 53.33%. Patients also complained of fever, dyspepsia and loss of weight

Table 3 : Presenting symptoms

SYMPTOMS	NUMBER OF PATIENTS	PERCENTAGE
Pain abdomen	27	90%
Jaundice	16	53.33%
Vomiting	16	53.33%
Fever	14	46.66%
Dyspepsia	12	40%
Loss of weight	2	6.66%

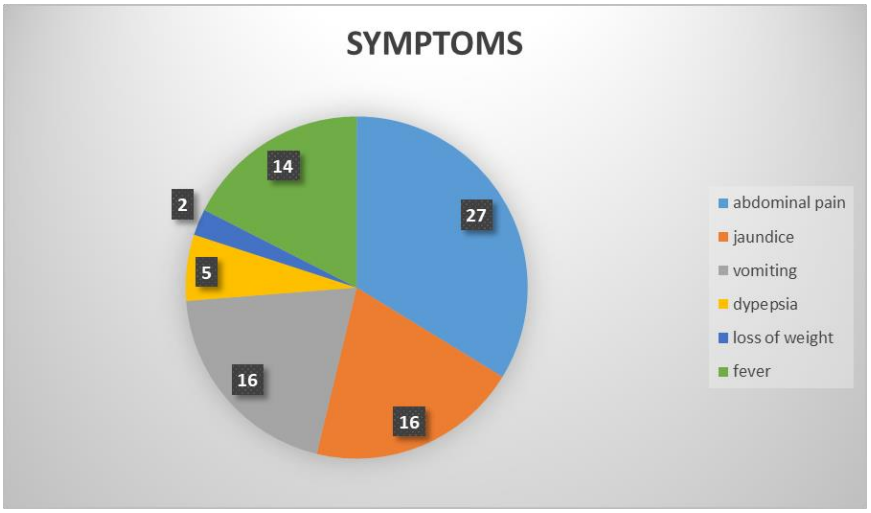


Figure 3: Presenting symptoms

PER ABDOMEN

Majority of patients presented with right hypochondrial tenderness (40%), while 33.3% had no abnormal per-abdominal findings.

Table 4: Per abdomen findings

Per abdomen findings	Number of patients	Percentage
Right hypochondrial tenderness	12	40%
Epigastric tenderness	5	16.6%
NAD	10	33.3%
Hepatomegaly	3	10%

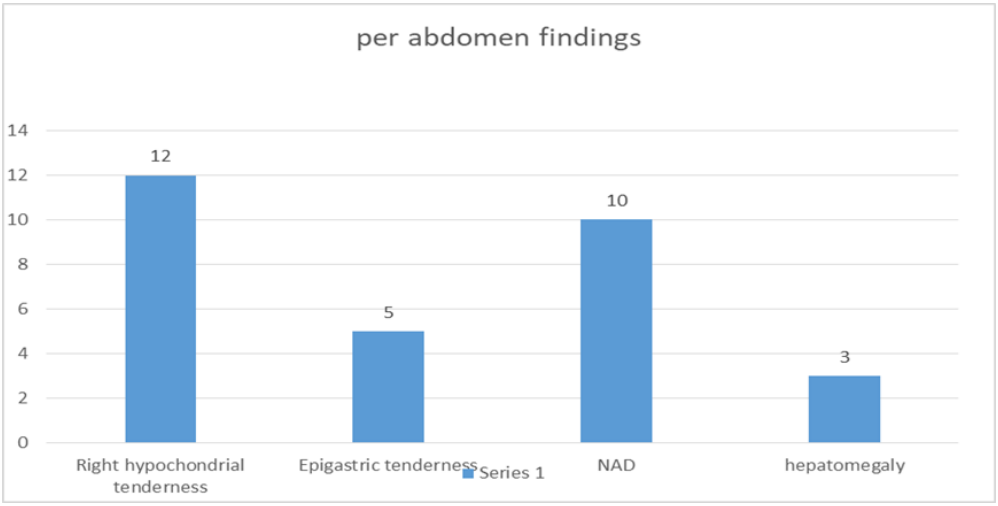


Figure 4: Per abdomen findings

INVESTIGATIONS

In our study, the mean hemoglobin level was 12.02 g/dL.

The average total bilirubin level was 4.774 mg/dL, with a median of 5.400 mg/dL and a standard deviation of 3.012.

The mean serum alkaline phosphatase (ALKP) was 248.56, with a median of 222.50 and a standard deviation of 144.80.

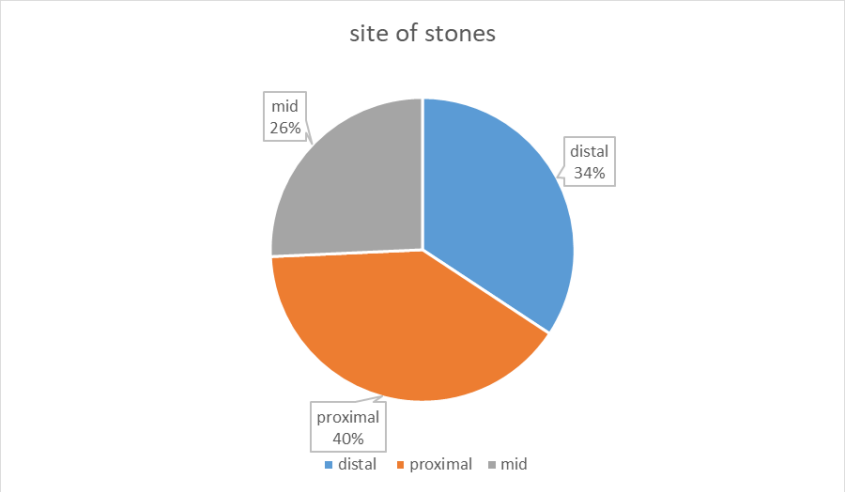
The mean levels of total protein and total albumin were within normal ranges, at 6.88 g/dL and 3.9 g/dL respectively.

Pallor was observed in 4 patients, while icterus was noted in 19 patients, or 63.3%.

CHARACTERISTICS OF CBD STONE FOUND IN CASES OF FAILED ERCP

Site of stone

In our study 40% of the stone was found in proximal followed by 34% in distal and 26% in mid CBD



Number of stones

- Most of the patients presented with multiple calculi.
- Single calculi is present in 23 % of the cases.
- 2 calculi was present in 20% of cases.
- 3 stones (27%) were noted in majority of cases.
- 20 % of the cases had 4 calculi and only 10% had 5 calculi.

Table 5: Number of stones and percentage of cases

Number of stones	Percentage of cases
1	23
2	20
3	27
4	20
5	10

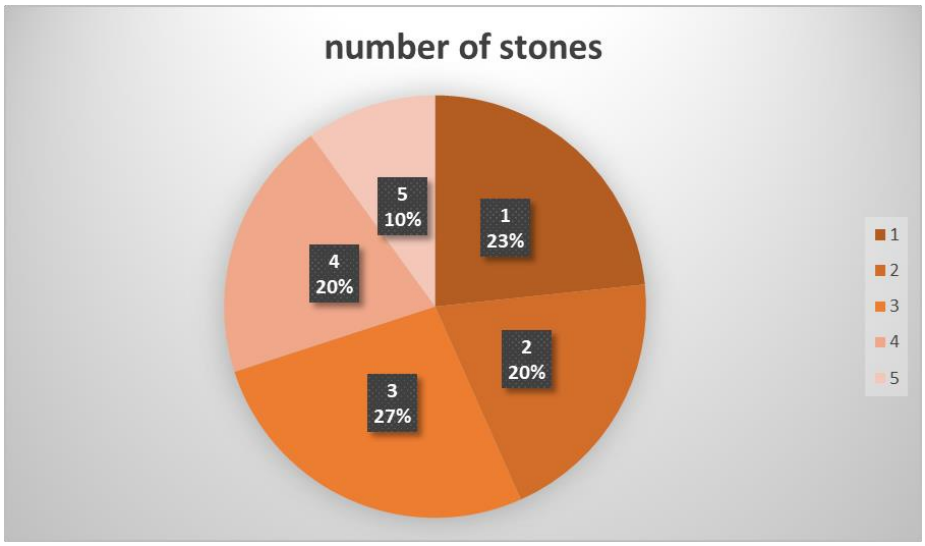


Figure 5: Number of stones and percentage of cases

Size of calculi

Size of calculi varied from 10 mm to 15 mm.

10mm stones was present in 2 cases , 11mm stone present in 8 patients ,12mm calculi was noted in majority of cases (11 cases) , 13mm stones was present in 7 cases 14mm and 15mm calculi was noted in 1 cases each.

Table 6: Size of calculi and number of cases (MRCP finding)

Size of calculi	Number of cases
10mm	2
11mm	8
12mm	11
13mm	7
14mm	1
15mm	1

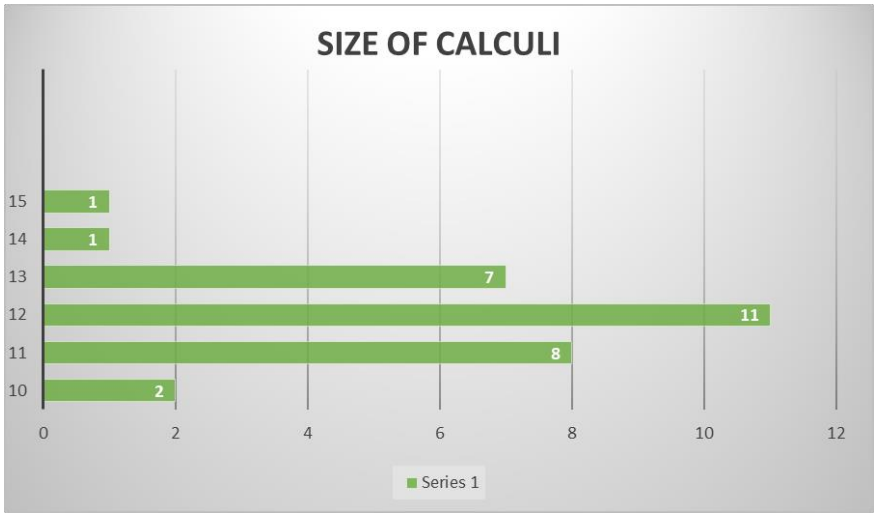


Figure 6: Size of calculi and number of cases (MRCP finding)

CBD diameter

Dilated CBD was noted in all the cases ranging from 10mm to 16mm

Majority of cases had 14 mm dilated CBD

Observation was as follows 10mm dilated in 1 case, 11mm in 4 case, 12mm in 4 case, 13mm in 3 case, 11 cases had 14mm whereas only 4 cases had 15mm and 3 cases had 16 mm

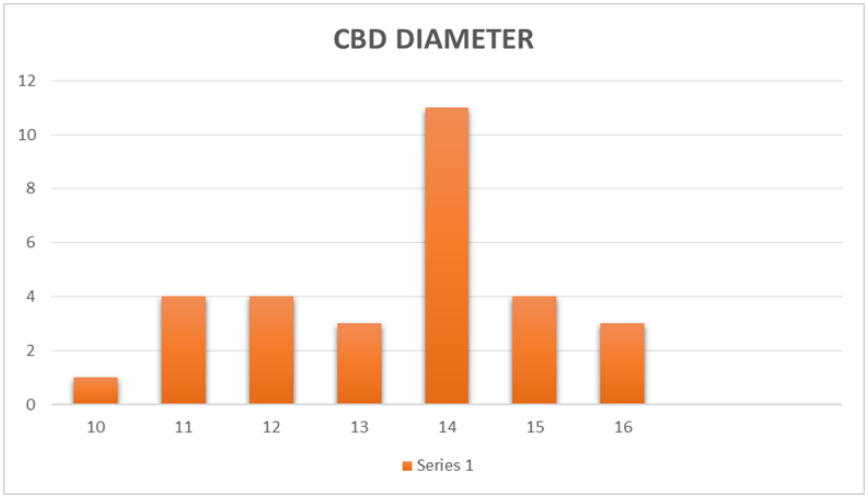


Figure 7 CBD diameter and number of cases

Number of ERCP attempt

The Average number of attempts made to remove CBD stones was 2 (Mean - 1.93; Median -2.0)

In majority of cases only a single attempt was tried, followed by 2 attempts in 9 cases, 3 attempts in 8 cases and upto 4 attempts in a single case

Table 7: Number of ERCP attempt and number of cases

Number of ERCP attempt	Number of cases
1	12
2	9
3	8
4	1

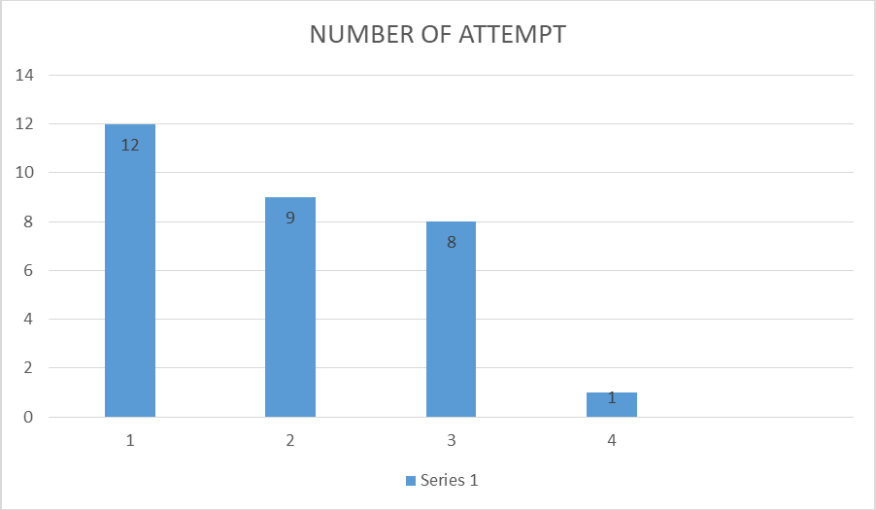


Figure 8: Number of ERCP attempt and number of cases

ERCP FAILURE CAUSES

In our study reasons for failed ERCP includes Multiple calculi seen in 40 % of cases followed by large calculi in 23.3%, impacted stone in 13.3 %, stricture in 10%, presence of diverticulum in 2 cases and difficult cannulation in a case

Table 8: Causes of failed ERCP

Causes of Failed ERCP	Frequency	Percentage
Diverticulum	2	6.66%
Difficult cannulation	1	3.33%
Multiple	12	40%
Stricture	3	10%
Impacted stone	4	13.3%
Large	7	23.3%
Hilar calculi	1	3.33%

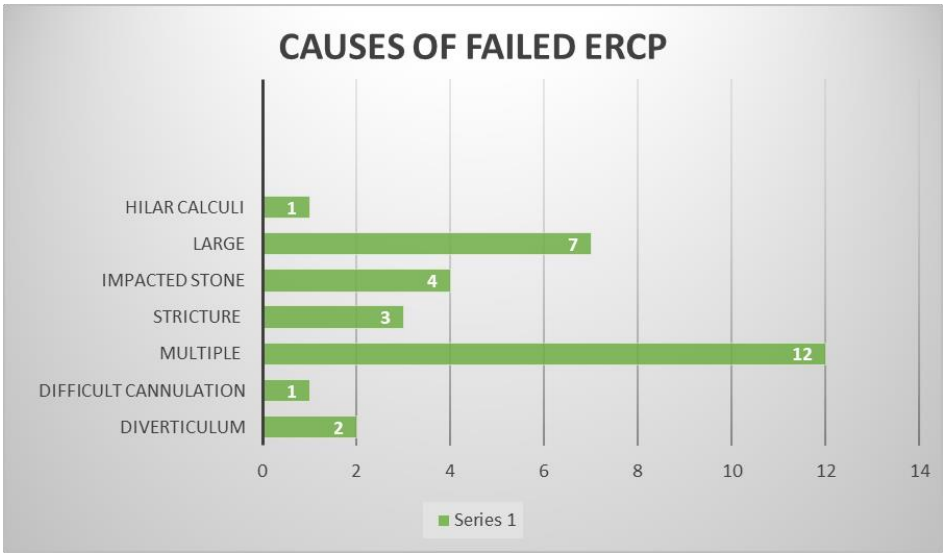


Figure 9 : Causes of failed ERCP

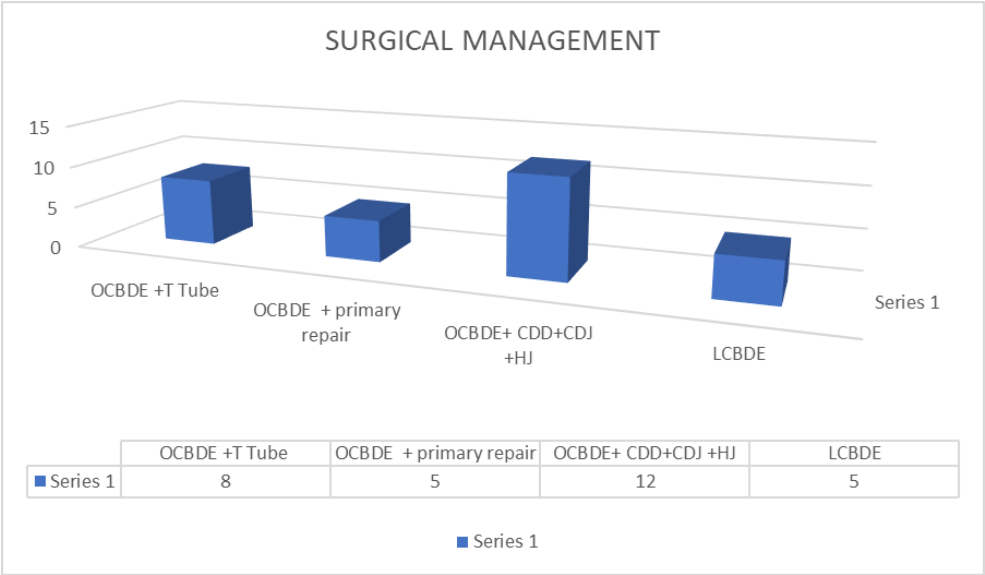
SURGERY OUTCOME

Out of 30 patients ,5 underwent Open CBD Exploration (OCBDE) + Primary repair, Open CBD Exploration + T tube was done for 8, 12 out of 30 underwent Open CBD Exploration with Choledochoduodenostomy/ Hepaticojejunostomy.

Laparoscopic CBD exploration (LCBDE) was done in 5 patients.

Table 9: Type of surgery and number of patients

Surgery	Number of patients
OCBDE + primary repair	5
OCBDE + T tube	8
OCBDE + CDD+HJ	12
LCBDE	5



It was found that factors like Bilirubin levels, Serum alkaline phosphatase, Stone characteristics like number, largest size, site, CBD diameter showed no statistical differences in open and Laparoscopic group .

LIKERT SCALE

Likert scale was used in assessing the quality of life post surgery, grading was done from 0 to 10. 0 was the worst score and 10 was the best score.

The average value among open group was 6 (Median- 6, SD- 1.003) and laparoscopic group was 7 (median – 7, SD- 0.5477).

The LCBDE group had higher Likert scale scores compared to the Open CBDE group, reflecting greater patient satisfaction and a more favourable perception of their results in the LCBDE group.

HOSPITAL STAY

The mean length of hospital stay is 6 days.

The mean length of hospital stay for open procedure was 6 days and laparoscopic was 5 days.

The minimum day of stay was 5 days and maximum day of stay was 14 days.

POST OPERATIVE COMPLICATIONS

Among our 30 postoperative cases, 5 patients experienced complications: specifically, there was one incidence of bile leak (OC+OCBDE+CDD), one case of wound dehiscence (OC+OCBDE+Primary closure) and three cases of mild surgical site infection (SSI) (1 case of OC + OCBDE + CDD, 2 cases of OC+OCBDE+ T-Tube). All were noted in post open procedure

Table 10: post op complications and number of cases.

Complications	Number of cases	Type of surgery
Bile leak	1	OC+ OCBDE+CDD
Wound dehiscence	1	OC+ OCBDE +Primary closure
Surgical site infection	3	1 case of OC + OCBDE + CDD,
		2 cases of OC+OCBDE+ T-Tube

PHYSICAL STATUS AND MENTAL STATUS

The physical and mental status score was calculated using 12-Item Short Form Survey (SF12) using Awell score.

The average Physical status score in case of open CBD exploration was 43.57 (SD-3.831) and in laparoscopic was 49.46 (SD- 2.221).

The average Mental status score in case of open CBD exploration was 46.07 (SD-2.75) and in laparoscopic was 52.45 (SD- 4.22).

There was statistically significant result in $P < 0.05$ with physical and mental status highest in laparoscopic group compared to open group.

DISCUSSION

AGE INCIDENCE.

In our study, patients aged between 25 and 65 years were included, with a mean age of 49 ± 11.02 years.

The average age was 49.29 years in females and 48.61 years in males. The majority of patients fell within the age range of 46 to 55 years.

Rai MK et al (2017) reported that among 23 patients with Choledocholithiasis, the predominant age group was 40 to 49 years ([5]).

In a study by Kaufman et al. (1989), the average age of patients with Choledocholithiasis was reported as 55 ± 7 years ([6]).

Barkun et al. (1994) found an average age of 57.5 ± 16.8 years in their study of 74 patients with Choledocholithiasis ([7]).

According to Vidagany N et al. (2016), the mean age was 63 years (ranging from 24 to 91 years) in a study involving 160 patients ([8]).
Saudi J et al. reported a mean age of 46.3 years among 426 patients who underwent ERCP for choledocholithiasis. Older patients were more common in the group where the initial ERCP did not clear the biliary system ([9]).

Study	**Mean age**	**Total patients**
Our study	49 ± 11.02 years.	30
Kaufman et al.	55 ± 7 years	65
Barkun et al.	57.5 ± 16.8	74
Vidagany N et al	63 years	160

SEX INCIDENCE
In our study involving 30 patients, 17 (57%) were female and 13 (43%) were male, resulting in a female-to-male ratio of 1.3:1. The prevalence of CBD stones was higher among females in our study.
Barkun et al. (1994) reported a ratio of 87 females to 40 males out of 127 patients with CBD stones, equating to 1:2.1 ([7]).
Vidagany N et al. (2016) reported a ratio of 1:1.75 between males and females among 160 patients with Choledocholithiasis ([8]).
Rai MK et al. (2017) documented a ratio of 1:1.97 between males and females in their study of 23 patients, with 6 males and 17 females ([5]).
Saudi J et al. reported that among 426 patients undergoing ERCP for choledocholithiasis, 41.7% were males and 58.3% were females, resulting in a male-to-female ratio of 0.7:1([9]).
Ko et al. (2013) observed 57 males and 158 females among 215 patients with Choledocholithiasis, yielding a ratio of 1:2.7 ([10]).
Tozatti et al. (2015) found a male-to-female ratio of 1:1.61 in their study of 47 patients with choledocholithiasis ([11]).
Tazuma et al. (2006) reported a female-to-male ratio of 0.89:1 among patients with CBD stones ([12]).
However, Yang et al. found no significant gender predominance in patients with choledocholithiasis, with a male-to-female ratio of 1.07:1.37 ([13]).

Study	female	male	M:F
Our study	17	13	1.3:1
Barkun et al	87	40	1:2.1
Ko et al	158	57	1:2.7
Rai et al	17	6	1:1.97

PRESENTING SYMPTOMS
In our study of 30 patients, the majority presented with abdominal pain (27 patients, 90 %), while vomiting and jaundice were noted in 16 patients each (53.33%). Fever was observed in 14 patients (46.66 %), and a few patients also reported weight loss and dyspepsia.
Tozatti et al. (2015) found that among 47 patients, 95.7% experienced abdominal pain, 14 had jaundice, and 30% had fever ([11]).
Prat et al. (1999) documented that out of 880 patients with Choledocholithiasis, 664 patients presented with abdominal pain (75.5%), while 23.1% had jaundice and 15.8% had fever ([14]).

Manimaran et al. (2016) reported that among 115 patients with Choledocholithiasis, abdominal pain was the primary symptom in 70 patients (60.86%), followed by jaundice in 44 patients (38.26%) and fever in 42 patients (36.52%) ([15]).

According to Rai MK et al. (2017) among 23 patients with Choledocholithiasis, all patients presented with epigastric or right hypochondrial pain (100%) and nausea/vomiting (100%). Scleral icterus and dark urine were present in 17 patients each (74%), wh ile pruritus was noted in 3 patients (13%) and steatorrhea in 12 patients (52%). Tenderness in the epigastric or right hypochondrial area and jaundice were universal findings (100%) ([5]).

Vidagany N et al. (2016) noted that out of 160 patients, the highest number presented with abdominal pain. Specifically, 83 patients had abdominal pain as their primary symptom, and 27 patients presented with jaundice ([8]).

Study	Pain abdomen	Jaundice
Our study	90%	53.33%
Tozatti et al	95.7%	29.7%
Prat et al	75.5%	23.1%
Manimaran et al	60.86%	38.26%
Vidagany N et al	51.8%	16.8%

INVESTIGATION :

In our study, the mean total bilirubin level was 4.774 mg/dL (Median 5.400 mg/dL; SD = 3.012), and the mean serum alkaline phosphatase was 248.56 (Median 222.50; SD = 144.80). The mean total protein and total albumin levels were 6.88 g/dL and 3.9 g/dL, respectively.

Costi et al. identified total bilirubin as a primary laboratory marker and a strong predictor of common bile duct stones ([16]).

Prat et al. noted that liver enzyme levels are within normal limits in up to 54.7% of patients with Choledocholithiasis, with a sensitivity of 74% ([14]).

Freitas et al reported that elevated bilirubin levels indicate the presence of CBD stones but lack sensitivity and specificity ([17]).

Saltzein et al concluded that alkaline phosphatase may be a more reliable indicator of common duct stones compared to bilirubin, but neither marker alone is statistically significant ([18]).

Yang et al. reported that alkaline phosphatase had higher sensitivity than total bilirubin, which in turn exhibited the highest specificity (87.5%). Both markers were identified as independent predictors of CBD stones ([13]).

In the study by Pereira Lima et al., alkaline phosphatase demonstrated a sensitivity of 74.7%, while total bilirubin had a sensitivity of 73.6%. Aspartate aminotransferase (AST) was the least sensitive biochemical parameter ([19]).

Carlsen et al found no significant link between CBD stones and either serum bilirubin or alkaline phosphatase levels ([20]).

Anciaux et al noted that increased levels of GGT and ALKP were frequently observed in patients with symptomatic CBD stones ([21]).

CHARACTERISTICS OF CBD STONES FOUND IN CASES OF FAILED ERCP

Our study mainly relied on MRCP findings to define radiological characteristics of choledocholithiasis, particularly focusing on factors affecting ERCP outcomes.

We found that stones located proximally were observed in 40% of cases. Our analysis revealed that stones larger than 12mm (mean 12.77; median 12.50) and numbering more than 3 (mean 2.83; median 3.00) were prone to

failure during ERCP. Furthermore, our study found that the mean CBD diameter was greater than 14mm (mean 13.43; median 14mm).
Sharma et al suggested defining a stone as large if its size exceeded the CBD diameter by more than 2mm (stone size / CBD diameter ratio > 1) ([22]).
In a study by J. Szejnfeld and colleagues assessing the diagnostic accuracy of MRCP versus ERCP, MRCP succeeded in 44 out of 45 patients (98%), while ERCP had a 93% success rate, failing in three cases. MRCP provided an accurate diagnosis in 44 patients (98%), with an overall diagnostic accuracy of 92% ([23]).

FAILED ERCP

In our study, failed ERCPs were attributed to multiple stones in 40% of cases, large stones in 23.3%, impacted stones in 13.3%, strictures in 10%, presence of diverticulum in 2 cases, and difficult cannulation in 1 case.
In our study, we observed that having more than three stones (mean 2.83; median 3.00) was associated with a higher likelihood of ERCP failure.
The study by Saudi J et al found that a higher average number of filling defects (1.8 compared to 2.6 stones, $p < 0.01$) was associated with lower odds of successfully clearing the biliary system ([9]).
Lynn AP et al noted a significant correlation between increased stone size and number and decreased success rates ([24]).
Han JY et al reported a clearance rate of only 62.5% for stones smaller than 1 cm during the initial procedure, with a procedure-related adverse event rate of 14.7% ([25]).

DIVERTICULA

Regarding diverticula, our study identified diverticula in 2 out of 30 cases where ERCP failed.
Chen et al reported that patients with periampullary diverticula had lower success rates for stone removal compared to those without diverticula (83.53% vs. 94.31%, $p = 0.005$) ([26]).
Sfarti et al. highlighted that periampullary diverticula can contribute to increased difficulty or failure rates during cannulation in ERCP procedures ([27]).
Lobo et al. noted that the occurrence of periampullary diverticula rises significantly in patients over the age of 75. They also observed a substantial decrease in cannulation success rates due to the presence of these diverticula, which become more common with advancing age ([28]).
In contrast, Christoforidis et al. in a large-scale study, found no significant impact of periampullary diverticula on the success of stone extraction accor analysis ([29]).

IMPACTED STONE

In our study, we identified 4 cases of impacted stones among 30 cases of failed ERCP ding to their multivariate.
Saudi J et al. observed a significantly higher failure rate in clearing the biliary system when impacted stones were present (17.2% vs. 6.3%, $P < 0.01$; OR 3.09; 95% CI, 1.52–6.18), though this association lost significance in multivariate analysis (OR 1.34; 95% CI, 0.47–3.61). Additionally, Saudi J et al. found a higher failure rate for clearing CBD stones larger than 15 mm during initial ERCP (72.0% vs. 52.0%, $P < 0.01$), which was significant in univariate analysis (OR 2.38; 95% CI, 1.46–3.99) ([9]).

FAILED CANNULATION

Among the patients in our study cannulation failure was cause of failed ERCP in 1 case.
Successful ERCP involves cannulating the biliary tract and acquiring a cholangiogram, as cannulation is essential for both diagnostic and therapeutic interventions ([30]).
Colton JB et al reported that failed cannulation is a common cause of unsuccessful ERCP. Biliary cannulation success rates range from 84% to 94%([31]).
Hang et al. achieved an 83.2% success rate in cannulating patients with an ectopic papilla of vater, citing difficulties due to the challenging visibility of the ectopic opening([25]).

Li et al reported success rates of 84.1% for accessing the duodenal ampulla and 92.1% for selective biliary cannulation in patients with Billroth II anatomy([32]).

Swan et al. found that referring cases with cannulation failures to experienced, high-volume tertiary centers led to a high success rate and improved patient outcomes. In their study, 47 patients were referred from other hospitals after their initial ERCP failed and 46 of these patients were successfully cannulated on their second attempt at our center([33]).

ATTEMPT OF ERCP

In our study, the average number of attempts to remove CBD stones was 2 (Mean - 1.93; Median - 2.0)

Brown NG et al observed that some cases necessitate multiple procedures, with an average of up to 2.5 ERCPs. They reported that the success rate for duct clearance during the initial ERCP varied between 72.5% and 79.1%. ([34]).

Uskudar O et al reported on 102 patients who underwent surgery for choledocholithiasis following repeated failed ERCP attempts. All patients had at least 2 unsuccessful procedures (mean = 3.2 ± 1.7), and 25 (23.5%) experienced major ERCP-related complications ([35]).

Ramirez et al demonstrated that having the same person perform a second ERCP following an initial failed attempt improves the success rate from 87.5% to 95% ([36]).

SURGICAL MANAGEMENT

Out of 30 patients ,5 underwent Open CBD Exploration + Primary repair, Open CBD Exploration + T tube was done for 8, 12 out of 30 underwent Open CBD Exploration with Choledochoduodenostomy / Hepaticojejunostomy.

Laproscopic CBD exploration was done in 5 patients.

Zhu et al found evidence of superiority of surgery over ERCP, since there was greater bile duct clearance and shorter hospital stay in the surgical group, with no evidence of difference regarding mortality and total postoperative morbidity ([37]).

HOSPITAL STAY:

Our study found that the average hospital stay for all cases was 6 days. Specifically, patients who underwent open procedures stayed for an average of 6 days, while those who had laparoscopic procedures stayed for 5 days. The shortest stay observed was 5 days, and the longest was 14 days.

Ujiki M et al observed that patients undergoing open Common Bile Duct (CBD) exploration and primary repair had an average hospital stay of 7.25 days ([38]).

LCBDE was as effective as ERCP in clearing CBD stones. There was a trend towards shorter operating theatre times with LCBDE and significantly shorter hospital stays compared to ERCP([39]).

For uncomplicated transcystic duct stone extraction, hospitalization duration was comparable to that of laparoscopic cholecystectomy alone, averaging approximately 1-2 days. The transcystic approach avoids the need for choledochotomy, which is its main advantage ([40]).

Liberman et al reported significantly lower total hospital charges and costs for the LCBDE group, along with a shorter hospitalization period compared to single operative procedures([41]).

MENTAL AND PHYSICAL STATUS:

In our study, the Physical Score averaged 43.57 (SD 3.831) for patients who underwent open CBD exploration and 49.46 (SD 2.221) for those who underwent laparoscopic procedures and regarding the Mental Score, patients in the open CBD exploration group averaged 46.07 (SD 2.75), whereas those in the laparoscopic group averaged 52.45 (SD 4.22).

Statistical analysis indicated a significant difference ($P < 0.05$), showing that both physical and mental statuses were higher in the laparoscopic group compared to the open CBD exploration group.

Koc et al (2013) reported that laparoscopic CBD exploration offers a less morbid alternative treatment approach that is cost-effective. It enables quicker recovery and reduces the duration of short-term disability ([42]).
Abolfazl Shojaiefard reported that the outcomes of the transcystic method align well with the goals of laparoscopic surgery: minimal morbidity, avoidance of T-tube and drain placement, and rapid return to normal activities for most patients ([1]).
Hungness ES et al reported higher patient satisfaction with OCBDE primary closure methods. While some research suggests that 'laparoscopic choledochotomy with primary closure of the common bile duct (CBD) is safe, eliminates the need for T-tube placement, and reduces both operative time and postoperative morbidity' ([40]).

COMPLICATIONS:

Among our 30 postoperative cases, 5 patients experienced complications: specifically, there was one incidence of bile leak (OC+OCBDE+CDD), one case of wound dehiscence (OC+OCBDE+Primary closure) and three cases of mild surgical site infection (SSI)(1 case of OC + OCBDE + CDD, 2 cases of OC+OCBDE+ T-Tube). All were noted post open procedures.
Ujiki M et al observed that out of 416 patients in his study complications occurred in only 4 patients, accounting for 16.66% of cases. These included wound infection in 2 patients (8.33%), intra abdominal pus collection in 1 patient (4.16%), and bile leak in 1 patient (4.16%). One patient was lost to follow-up. None of the patients developed retained CBD stones or strictures ([38]).
Petelin JB et al in their study, reported that primary closure in open biliary tract surgery does not lead to higher incidences of bile leakage or peritonitis ([43]).
Guan G et al stated that despite LCBDE showing advantages such as reduced costs and shorter hospital stays, its adoption is hindered by concerns over insufficient training and a higher incidence of biliary leakage ([44]).
Vargas Avila et al observed that out of 78 cases Post-surgical complications derived from the laparoscopic surgical procedure occurred in 7 cases (9%) with two cases converting to open surgery (3%), three cases with bile leakage that required postoperative ERCP (4%), and two cases of bile leakage that resolved with conservative management (3%) ([45]).
Dasari et al. found that the open surgery group showed superior bile duct clearance compared to ERCP, with no significant differences in mortality or complications ([46]).

CONCLUSION

In conclusion, the study identifies the following key features of choledocholithiasis associated with ERCP failure:

- The presence of multiple stones (≥2).
- Stones located predominantly in the proximal third of the CBD.
- Stones averaging 12 mm in size.
- CBD diameter exceeding 14 mm.

While there is no significant difference in clinical outcomes between Open CBD exploration (primary repair or T-tube or choledochoenterostomy) and Laparoscopic CBD exploration, patients undergoing laparoscopic procedures reported superior physical and mental well-being ($p < 0.05$). This suggests that laparoscopic CBD exploration may offer better patient-reported outcomes compared to traditional open approaches.
The optimal management of choledocholithiasis is still debated, but treatment should always be customized to meet the individual needs of each patient. Nowadays, Surgery for complex choledocholithiasis following unsuccessful ERCP is considered a safe and effective long term solution.

LIMITATION

The current study has several limitations, including:

- A relatively small patient cohort from a single center.
- Limited access to a consistent surgical team proficient in advanced laparoscopic techniques and equipment, resulting in a bias towards open CBD exploration data.
- Short-term follow-up of patients, preventing assessment of CBD stone recurrence.

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