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A Retrospective Study of Clinical Outcome of 30 Patients of Common Bile Duct Calculi

Dr. Dharmesh Vasavada[1], Dr. Hiral Parekh[2*], Dr. Rhythm Khanderia[3]

[1]Professor, Department of Surgery M P Shah Government Medical College Jamnagar, Gujarat, India
[2]Professor, Department of Radiodiagnosis M P Shah Government Medical College Jamnagar, Gujarat, India
[3]Resident Doctor in Surgery Department of Surgery M P Shah Government Medical College Jamnagar, Gujarat, India

***Corresponding author:** Dr. Hiral Parekh
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Abstract | **Original Research Article**

Common bile duct stone, also known as choledocholithiasis, is the presence of gallstones in the common bile duct (thus choledocho-+ lithiasis. Common bile duct stones are one of the medical conditions leading to surgical intervention. They may occur in 3%–14.7% of all patients for whom cholecystectomies are performed [1]. There are multiple approaches for diagnosing common bile duct stone with regard to diagnostic performance characteristics, technical success, safety, and cost effectiveness. One of the main factors in the management is initially the detection of common bile duct stone, before, during, or after cholecystectomy. The main options for treatment are pre- or postoperative ERCP with endoscopic biliary sphincterotomy (EST), laparoscopic or open surgical bile duct clearance. There are other options for the treatment of common bile duct stone such as electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), dissolving solutions, and laser lithotripsy. It is unlikely that one option will be appropriate for all clinical circumstances in all centers. Variables such as disease status, patient demographics, availability of endoscopic, radiological and surgical expertise, and healthcare economics will all have significant influence on practice.

Keywords: Bile duct stone, Cholidocholithiasis, ERCP.

INTRODUCTION

Common bile duct stone, also known as choledocholithiasis, is the presence of gallstones in the common bile duct (thus *choledocho-+ lithiasis*. Common bile duct stones are one of the medical conditions leading to surgical intervention. They may occur in 3%–14.7% of all patients for whom cholecystectomies are performed [1]. There are multiple approaches for diagnosing COMMON BILE DUCT STONE with regard to diagnostic performance characteristics, technical success, safety, and cost effectiveness. One of the main factors in the management is initially the detection of COMMON BILE DUCT STONE, before, during, or after cholecystectomy. The main options for treatment are pre- or postoperative ERCP with endoscopic biliary sphincterotomy (EST), laparoscopic or open surgical bile duct clearance. There are other options for the treatment of COMMON BILE DUCT STONE such as electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), dissolving solutions, and laser lithotripsy. It is unlikely that one option will be appropriate for all clinical circumstances in all centers. Variables such as disease status, patient demographics, availability of endoscopic, radiological and surgical expertise, and healthcare economics will all have significant influence on practice.

Gallstone disease is responsible for about 1.8 million ambulatory care visits and more than 700 000 cholecystectomies yearly [2]. Gallstone disease is the second most common reason for hospital admissions (with an estimated cost of US$5.8 billion annually), although only 15% of people with gallstones have related symptoms [3]. Choledocholithiasis (stones in common bile duct) is one of the complications of cholelithiasis (gallstones). Stones in the common bile duct most commonly result from the passage of gallstones through the cystic duct into the common bile duct [4]. Less frequently, they may originate in the common bile duct itself. More than 1 in 10 patients (10%–18%) undergoing cholecystectomy for gallstones have concomitant common bile duct stonesand up to 3.8% have symptoms related to common bile duct stones during the first year after cholecystectomy[5].
Complications of common bile duct stone include [6]

- Obstructive jaundice
- Acute cholecystitis

- Acute Pancreatitis
- *Gallstone Ileus*
- Primary Sclerosing Cholangitis
- Biliary cirrhosis

Thus, the management of common bile duct becomes very crucial to prevent further complications. The management of patients with gallstone disease suspected of having stones in the common bile duct has three aims[6].

- To evaluate the probability of stones in the common bile duct,
- To treat these stones when present, and
- To treat the stones in the gallbladder.

MATERIALS AND METHODS

Methodology

Materials

- Study Settings: Department of General Surgery in a large teaching public health hospital.
- Study period =: One year
- Sample Size : 30 Cases
- Study Type : Retrospective Study

Inclusion criteria

- Patient presenting with
- Right upper quadrant pain
- Complain of Nausea and vomiting after fatty meal
- Patients who give informed consent

Exclusion criteria

- As such there is no exclusion criteria but in patients
- Those who do not give consent
- Patients with uncorrected coagulopathies. Are excluded from the study.

Method

1. All the patients fulfilling the inclusion criteria were admitted. A detailed history of the symptoms like Right upper quadrant pain
2. Complain of

- Jaundice
- Fever

- Right upper quadrant painwill be resorted to Ultrasonography (B Mode) for detecting Bile duct stones and gallstones.
- Collection of blood for biochemical investigation was done for estimating: haemoglobin, total and differential counts, serum bilirubin,SGPT, Alkaline phosphatases, serum blood urea nitrogen, serum total proteins, serum creatinine, coagulation profile.
- X-Ray chest and abdomen, will be done in all cases and findings will be noted.
- Transabdominal ultrasonography will be done
- MRCP (Magnetic retrograde cholangio pancreatography)
- CECT Abdomen will be done to look for the common bile duct pathology.

A retrospective study was undertaken in 30 patients that have been detected with common bile duct calculi by USG or CECT abdomen, in which comparison of the outcome was done for those patients that have undergone pre-operative ERCP followed by Laparoscopic or Open cholecystectomy .These clinical outcomes were compared and conclusion was derived regarding the best treatment modality for common bile duct calculi.

Ultrasonography findings

Common bile duct stone identified while doing ultrasonography.

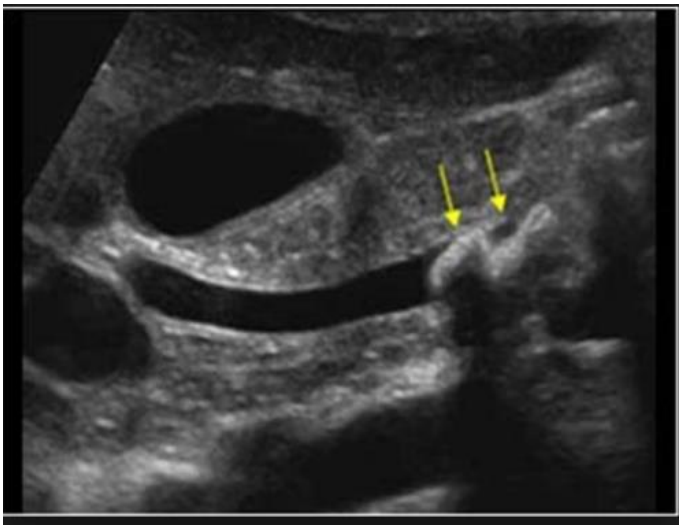


Fig-11: Two CBD stone identified in the common bile duct

Fig-12: Two Common Bile Duct stones identified

Fig-13: Multiple common bile duct stones identified

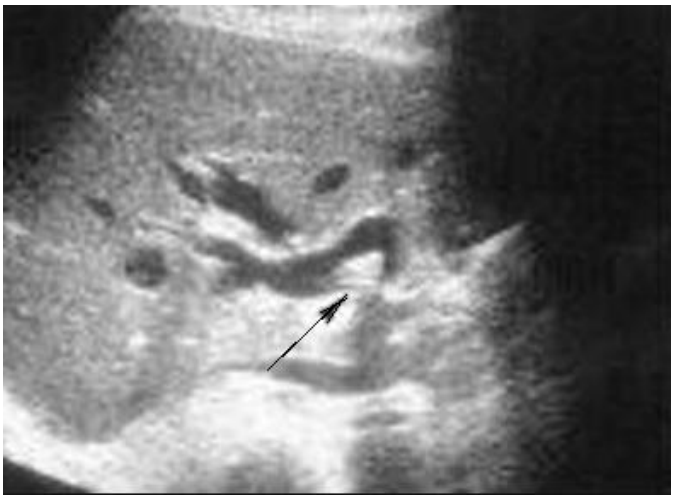


Fig-14: One common bile duct stone identified

ERCP-Equipment : ERCP was performed using Karl Storz Silver Scope-Duodenoscope [35] with albarran unit with 140 degree angled wide telescope.

Fig 15: Duodenoscope for ERCP

Fig-16: Equipment cart for ERCP with Duodenoscope, Full HD monitor, Image Connect module, Link module, Video Endoscope adaptor, USB Adaptor, Cold Light fountain LED, Two pedal foot switch, Autocon power supply

Procedure

Duodenoscope is gently inserted to the upper esophageal sphincter. The esophagus is intubated blindly with gentle forward pressure and slight clockwise torque. If there was resistance then it was stopped, and changed to a forward viewing gastroscope to exclude anything which may cause difficulties with intubation (i.e. Zenker's diverticulum /stricture).Once the duodenoscope passes the gastroesophageal junction,a half turn clockwise was done and followed the lesser curve to the pylorus. As the duodenoscope is side viewing, the duodenum is entered by placing the pylorus in the 'setting sun' position, so that the upper half of the pylorus is visible at the 6 o'clock position. Check The shaft of the scope is at 12 o'clock position when intubating the pylorus as this ensures optimum positioning in front of the papilla.

The duodenoscope is then inserted into the second part of the duodenum. Two maneuvers are performed in succession: first turn the big wheel anticlockwise and the small wheel clockwise, thus deflecting the tip of the scope up and right, then withdraw the endoscope to 50–70 cm from the incisors

to reduce the gastric loop. The major papilla is now in the field of vision. The major papilla consists of a frenulum, a hood, infundibulum, and orifice. It is often a different color from the rest of the duodenum. The papilla should be inspected for evidence of stone passage (gaping or inflamed orifice), edema or papillary adenoma. The major papilla is then classified depending on its appearance. This is important when assessing how far a sphincterotomy may be extended. Now Cannulation of the major papilla is done. Flush the catheter or sphincterotome with dye prior to commencing the procedure to prevent any injection of air. Prior to attempting cannulation, optimize conditions and ensure there is an adequate view of the papilla by ensuring Duodenal hypotonia: give glucagon if necessary No bubbles or mucus: use antifoam solution (simethicone) Take time to optimally position the duodenoscope and ensure that the orifice is at the center of the image Wait a little for the orifice to open. To selectively cannulate the bile duct, the side-viewing duodenoscope should be placed below the major papilla. Place the catheter slightly below the papilla and direct the catheter vertically towards 11–12 o'clock in the right upper quadrant.The catheter should be placed on the right side of the papilla between 1 and 3 o'clock, with the catheter moving from left to right. If the os is difficult to catheterize, the catheter can initially be introduced a few millimeters, then directed towards the biliary or pancreatic orifice. The catheter is then introduced as far as possible into the chosen duct and required procedure is performed.

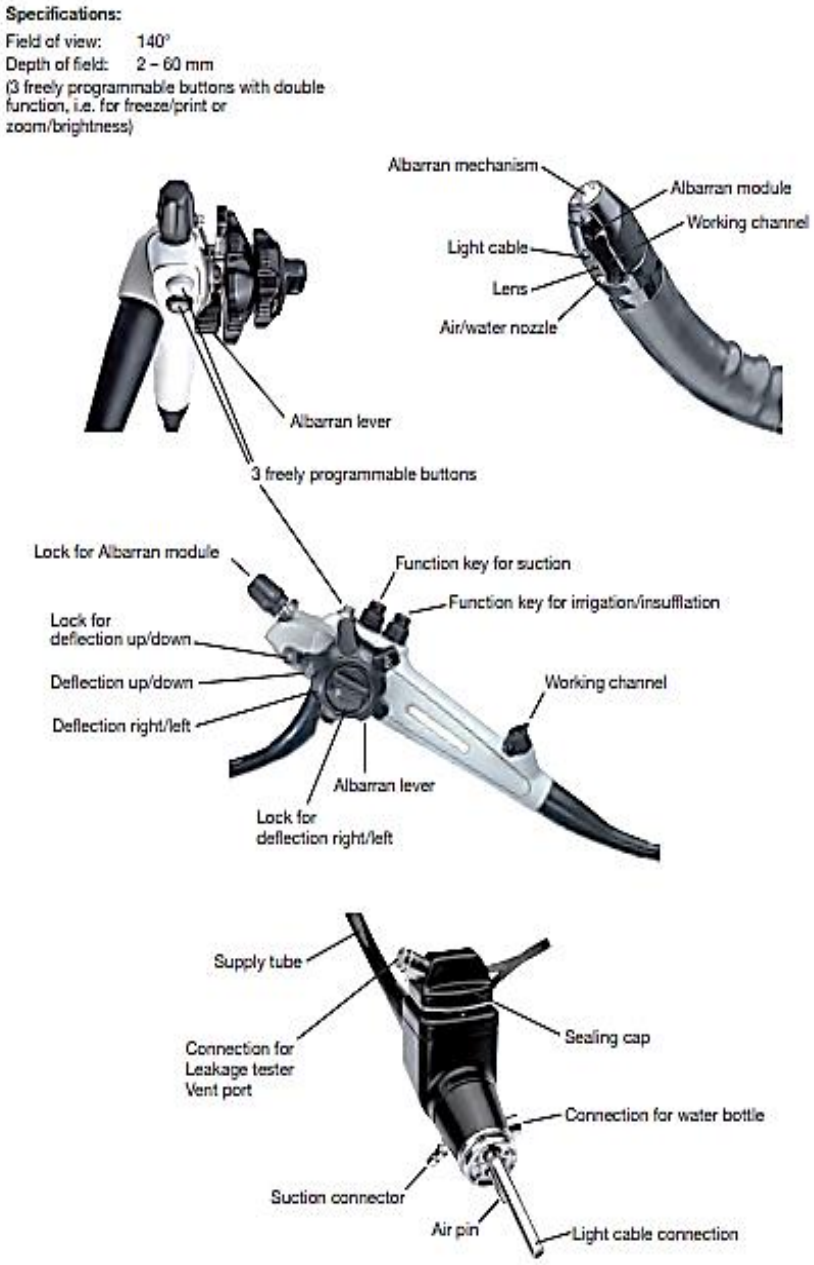


Fig-17: Parts of Duodenoscope [35]

Unique properties of the duodenoscopes

The unique modular construction of KARL STORZ duodenoscopes offers the user considerable benefits and sets new hygiene standards in flexible endoscopy.

- This new design feature enables previously inaccessible areas to be rinsed and cleaned, considerably reducing the risk of contamination to achieve excellent hygiene properties.
- Whereas the duodenoscope can be routinely disinfected in the cleaning machine, the deflectable bridge module can be cleaned in an ultrasound bath and subsequently sterilized in an autoclave to obtain 100% amicrobic conditions.
- In case of necessary repairs, the module can be removed and replaced by hospital staff without technical assistance. This saves considerable time and money.

Fig. 1: Distal tip

Fig. 2: Open Albarran module

Fig. 3:
① Albarran module
② Albarran cable control guide
③ Duodenoscope with removed Albarran

Fig. 4: Activated Albarran lever

Fig-18: Albarran module for ERCP[35]

Fig-19: Parts of side viewing scope for ERCP [35]

SILVER SCOPE®	Order No. PAL	Order No. NTSC	Sheath Outer Diameter	Working Channel Diameter	Working Length	Deflection up/down	Deflection left/right	Field of View	Depth of Field
Duodenoscope	13885 PKS	13885 NKS	12.6 mm	4.2 mm	1260 mm			140°	2–60 mm

Accessories included in the delivery of 13885 PKS/NKS:

110282-01* **Biopsy Forceps,** with oval jaws, coated, working length 180 cm, for single use, sterile, for use with flexible endoscopes with working channels as of diameter 2.8 mm

110910-01* **Cleaning Brush,** with double-sided brush, length 220 cm, brush diameter 5 mm, for single use, unsterile, for use with flexible endoscopes with working channel diameters 2.8 – 4.2 mm

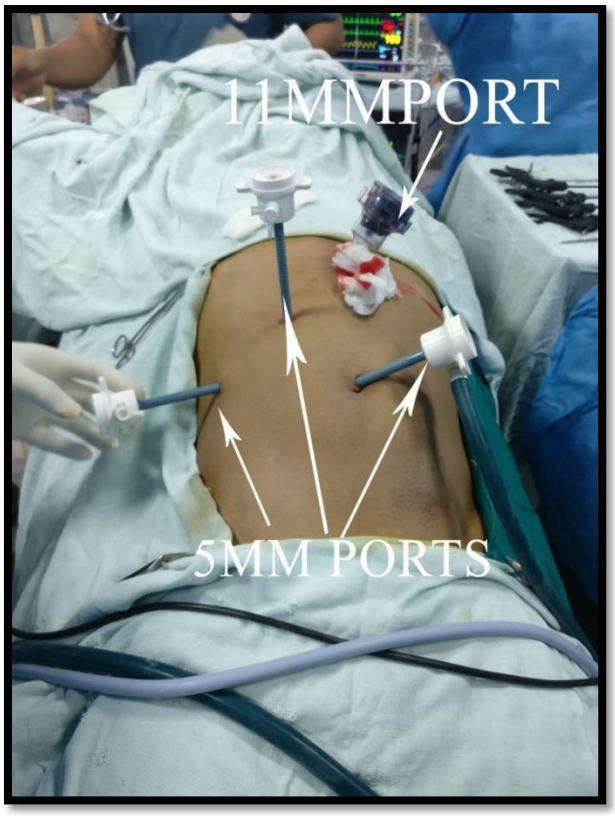
27651 F **Cleaning Brush,** flexible, outer diameter 2.5 mm, for working channel diameter 1.4 – 2.3 mm, length 180 cm

Fig-20: Duodenoscope maneuvourability for ERCP [35]

Laparoscopic cholecystectomy

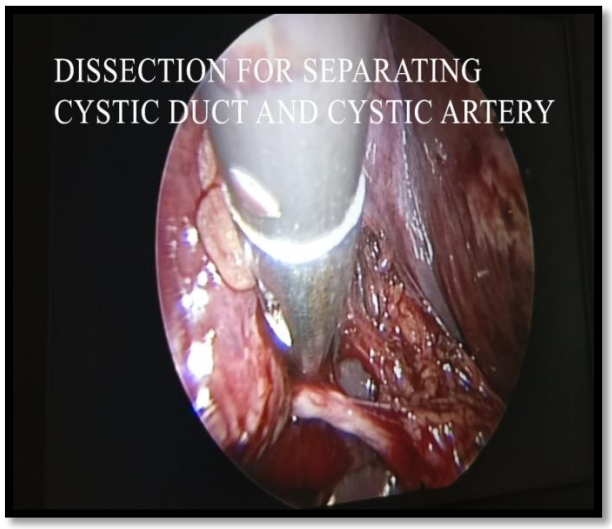
The surgeon is standing to the left of the patient with the camera person on his right towards the patient's left shoulder. The laparoscopic trolley with monitor and other equipment is set up in front of the surgeon to the patient's right at the level of the umbilicus.

The procedure starts with the patient in the supine position andboth hands tucked by the side. The pressure areas are protected and the patient is secured to the table. Later, the table may have to be tilted in a Trendelenburg and right side-up position to let the abdominal viscera gravitate away from the right upper quadrant. Four ports are used: optical (11mm), one 5mm and one 11mm operating, and one 5.0mm assisting port. The optical port is at or near the umbilicus and routinely a 30 degree laparoscope is used. Some surgeon who has started laparoscopy earlier they are more comfortable with 0 degree telescope.A diagnostic laparoscopy of the entire abdomen is performed including assessment of the degree of contamination with purulent fluid, if present.



First view of gallbladder after insertion of telescope

Once all the four ports are in position the fundus of the gallbladder is grasped by the assistant and flipped upwards and over the superior edge of the right lobe of liver.



Pledget dissection of Cystic pedicle

The dissection of the cystic pedicle can be carried out with two handed technique. The dissection should be started with antero-medial traction by left hand grasper placed on the anterior edge of Hartmann's pouch; theantero-medial traction by left hand will expose the posterior peritoneum. The peritoneum of the posterior leaf of the cystic pedicle is divided superficially as far back as the liver.

Separation of Cystic artery from Cystic duct

The separation of the cystic duct anteriorly from the cystic artery behind can be performed by a Maryland's grasper by gently opening the jaw of Maryland between the duct and artery.

Clipping of cystic artery

The cystic artery is clipped and then divided by hook scissors. Two clips are placed proximally on the cystic artery and one clip is applied distally. The

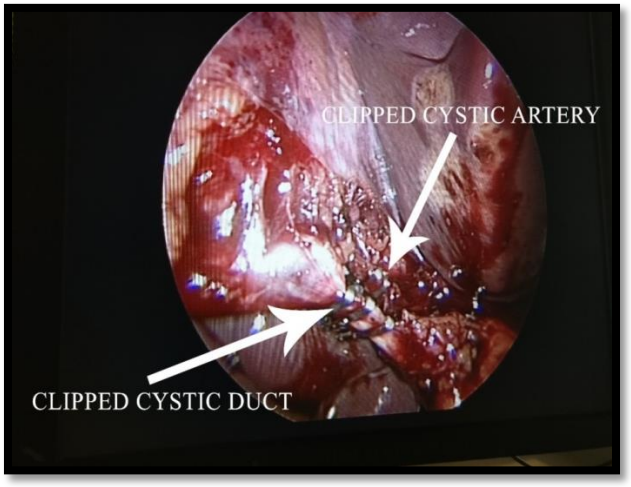
artery is then grasped with a grasper on the gallbladder wall and then divided between second and third clip.

Ligation of Cystic Duct

Although the majority of surgeons opt for clipping the cystic duct, before dividing it, this technique though quick is intrinsically unsound as internalisation of the metal clip inside the common bile duct over the ensuing months is well documented.

Extraction of Gallbladder

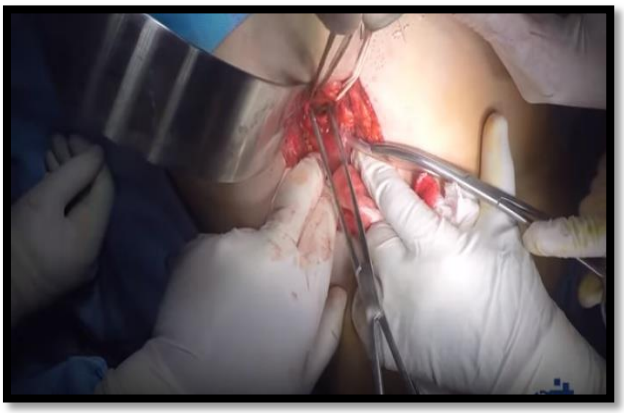
The gallbladder is extracted through the 11 mm epigastric operating port with the help of gallbladder extractor. Many surgeons use umbilical port for withdrawal of gallbladder. First the neck of the gallbladder should be engaged in the cannula and then cannula will withdraw together with neck of gallbladder held within the jaw of gallbladder extractor.



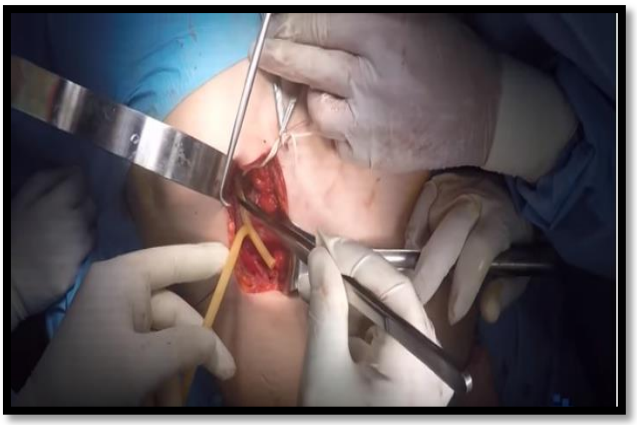
The Instrument and then ports are removed. Telescopic is removed leaving gas valve of umbilical port open to let out all the gas. At the time of removing umbilical port telescope is again inserted and umbilical port removed over the telescope to prevent any entrapment of omentum. The wound is closed with Suture. Vicryl is used for rectus and Un-absorbable intra-dermal or Stapler for skin. Sterile dressing over the wound is applied.

Open Common bile duct exploration

Open CBD exploration was done by putting right subcostal incision and after dissecting subcutaneous tissue and muscles, gall bladder was identified. Calot's triangle was dissected, cytic duct and cystic artey was tied and cholecystectomy was done. After the gallbladder has been removed, Second part of duodenum was mobilised by Kocher's manovour. Next, peritoneum is opened to expose the CBD above the first part of the duodenum. Two stay sutures are placed at the level of the mid-portion of the CBD. Using a pointed scalpel CBD is opened vertically and incision is extended for about 2 cm using scissors. Bile stones are removed through the opening using forceps. And T tube was cut and placed in common bile duct and its patency checked. After ensuring hemostasis closure was done.



Removal of CBD stone during CBD exploration



T-Tube placement

The following format was used to collect data about the participants of the study.

Proforma
1. Personal details:
A.name
B. Age
C. Sex
D. Residence
E. Occupation
F. Indoor no
G. Date of admission
H. Date of discharge
2. Chief complains:
A) right upper quadrant pain:
Mode of onset
Site
Character
Duration
Radiation
Shift
Aggravating factors
Relieving factors
B) nausea
C) vomiting
Onset
Frequency
Content
Colour

D) other complains if any and their characteristics
3. Past history

Similar complains in past
Tuberculosis
Diabetes mellitus
Hypertension
Jaundice
Gall stone
Surgery

Family history
Personal history

Diet a) vegetarian
B) non vegetarian
C) mixed

Sleep
A) adequate
B) inadequate

Apetite
A) normal
B) decreased

Bowel habits
A) regular
B) altered

Bladder habits
Addiction
6. Obstretic history
7. Menstrual history
Last menstrual period date
Menstrual complains

Examination findings
A) general examination
Consciousness and orientation
Nourishment
Temperature
Pulse
Blood pressure
Respiratory rate
Pallor +/-
Oedema +/-
Lymphadenopathy +/-
Icterus +/-
Cyanosis +/-
Clubbing +/-
Bone/joint/spine
B) systemic examination
A) per abdominal examination-
1) inspection-
Contour and shape
Bilateral symmetry
Umbilicus

Veins/arteries
Peristalsis
Respiratory movements
Any visible fullness or swelling
2) palpation-
Temperature
Tenderness
Rigidity/guarding
Organomegaly- liver/spleen/kidney
Ascitis
Hernial sites
External genitalia
Any other significant findings
3) percussion
4) auscultation
B) rectal examination per rectal examination
Proctoscopy examination
C) cardiovascular system
D) respiratory system
E) central nervous system

Investigations

A) blood investigations-
HB
TC
DC
ESR
RBS
S. Creatinine
Blood urea
Rvd testing
HBSAG
Liver function test-

S. Bilirubin-total - increased/decreased
Direct - increased/decreased
Indirect - increased/decreased
S.G.P.T. - increased/decreased
S. Alkaline phosphatase – increased/

Decreased

Coagulation profile-
PT
INR
APTT
11. S. Lipase
12. S. Amylase
13 stool investigations

B) radiological investigation
1. X-ray
Chest
Abdomen
Standing
Lying

2. USG
Table-1: Age distribution

Abdomen

CECT abdomen
MRCP

Complications
A. Local
Acute fluid collection
Sterile pancreatic necrosis
Infected pancreatic necrosis
Pancreatic abscess
Pseudocyst
Pancreatic ascites
Pleural effusion
Portal/splenic vein thrombosis
Pseudoaneurysm

B. Systemic
1. Cardiovascular
A) shock
B) arrhythmia

2. Pulmonary

A) ARDS
3. Renal failure
4. Hematological
A) DIC

5. Metabolic
A) hypocalcemia
B) hyperglycemia
C) hyperlipidemia

6. Gastrointestinal
A) ileus

7. Neurological
A) visual disturbances
B) confusion, irritability
C) encephalopathy

8. Miscellaneous
A) subcutaneous fat necrosis
B) arthralgia

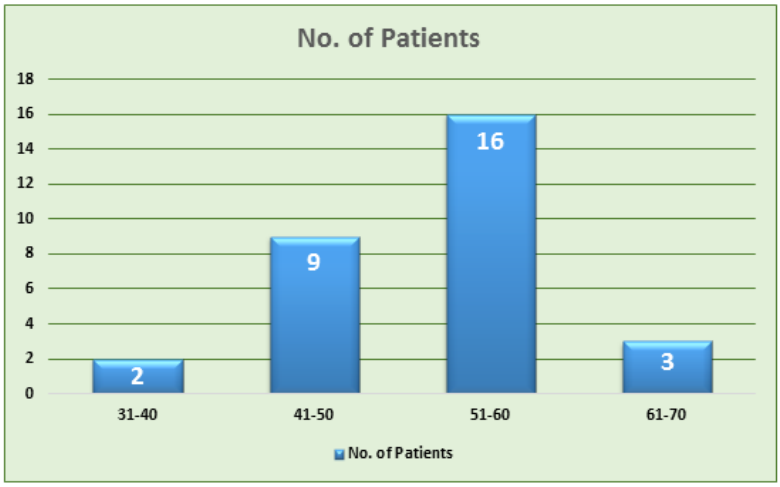
Treatment
ERCP followed by laparoscopic cholecystectomy
Or
RE-ERCP with successful CBD clearance
Or
Open CBD exploration followed by cholecystectomy
(in case of residual stones in CBD)

Post-operative complications

Observations
In this study 30patients had been selected and following observations were made

Age(Years)	No. of Patients
31-40	2
41-50	9
51-60	16
61-70	3
Total	30

In this study, out of 30 patients highest number of patients (16) was from age group of 51 to 60 years. While there were 2 patients from 31-40 years group, 9 from 41-50 years and 3 from age group 61-70 years.

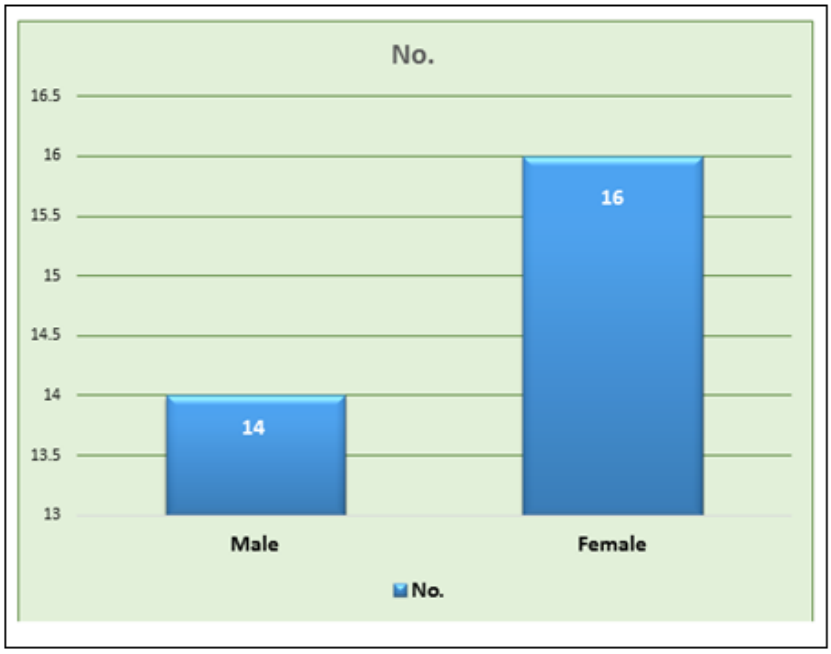


Graph-1: Age Distribution

Table-2: Sex Distribution

Sex	No.	Percentage
Male	14	46.6%
Female	16	53.4%

Out of 30 patients 14 were male and 16 were females.

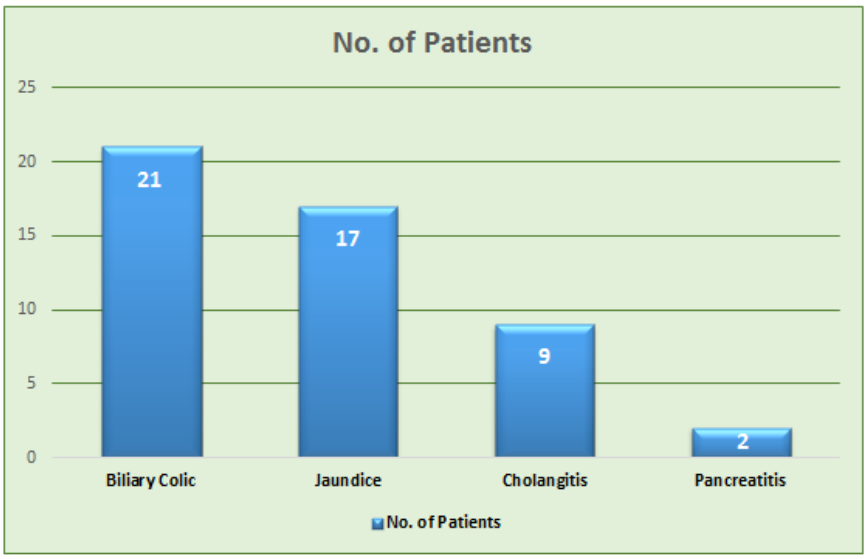


Graph-2: Sex Distribution

Table-3: Presentation of patient with common bile duct calculi

Clinical features	No. of Patients
Biliary Colic	21
Jaundice	17
Cholangitis	9
Pancreatitis	2

Out of 30 patients, 21 patients presented with biliary colic that includes pain in right hypochondrium. 17 patients had jaundice which was associated with increased total bilirubin while 9 patients had associated cholangitis. 2 patients presented with features of pancreatitis.



Graph-3: Presentation of patient with common bile duct calculi

Table-4: Liver function tests in patients of symptomatic Common bile duct calculi

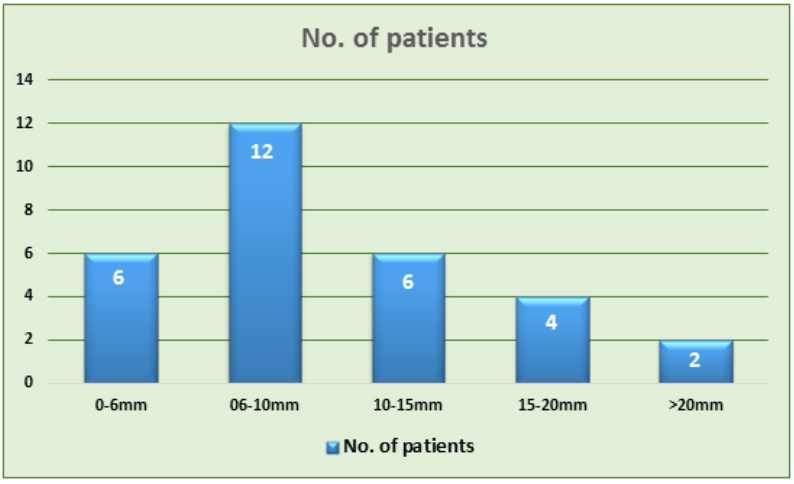
Liver function tests	Serum levels
Total bilirubin (mg/dL)	Increased in 28 patients
Direct bilirubin	Increased in 28 patients
Indirect bilirubin	Increased in 13 patients
Alkaline phosphatase (IU/L	Increased in 26 patients
Serum Amylase levels	Increased only in 2 patients

Out of 30 patients, 28 patients had increased total bilirubin ranging from 4.2 to 18.3 mg/dl. Direct bilirubin also increased in 28 patients ranging from 3.8 to 16.9 mg / dl. While alkaline phosphatise increased in 26 patients ranging from 408 IU/L to 836 IU/L. Serum amylase levels increased in only 2 patients with maximum rise of 800 IU/L

Table-5: Ultrasonographic findings regarding size of CBD Stone

CBD Stone size (mm)	No. of patients
0-6	4
6-10	12
10-15	6
15-20	4
>20	2

Out of 30 patients, 4 patients had CBD stone less than 6 mm size, 12 patients had CBD stone between 6 to 10 mm, 6 patients had between 10-15 mm, 4 patients between 15-20 mm and 2 patients had > 2 cm size CBD stone. 2 patients could not be detected by sonography and CT scan was done for the confirmation. So the sensitivity of USG in detecting CBD stone comes out to be 93.33 and specificity about 100 %.

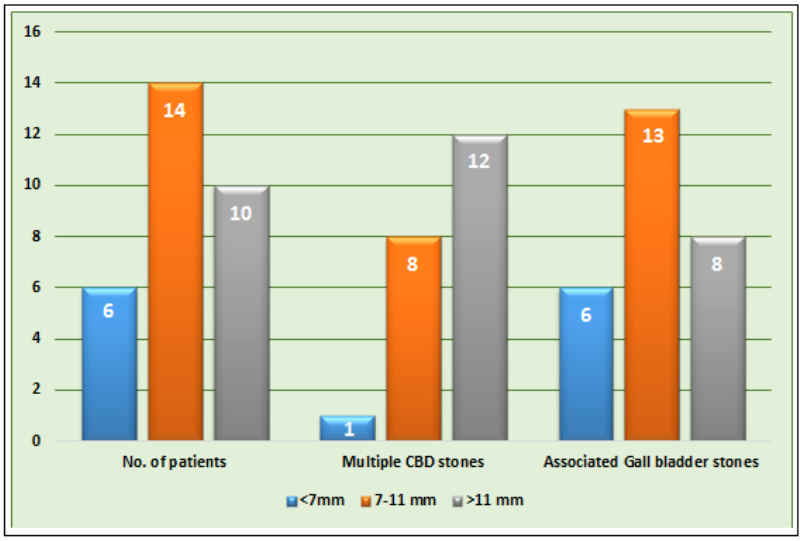


Graph-4: Ultrasonographic findings regarding size of CBD Stone

Table-6: USG findings regarding Common bile duct diameter

Common bile duct diameter	No. of patients	Multiple CBD stones	Associated Gall bladder stones
<7mm	6	1	6
7-11 mm	14	8	13
>11 mm	10	12	8

Among the 30 patients, 1 patient with CBD diameter between 7-11 mm and 2 patients with CBD diameter > 11 mm did not have associated gall bladder stones, which arises the possibility of spontaneous passage of GB stone through the dilated Common bile duct.



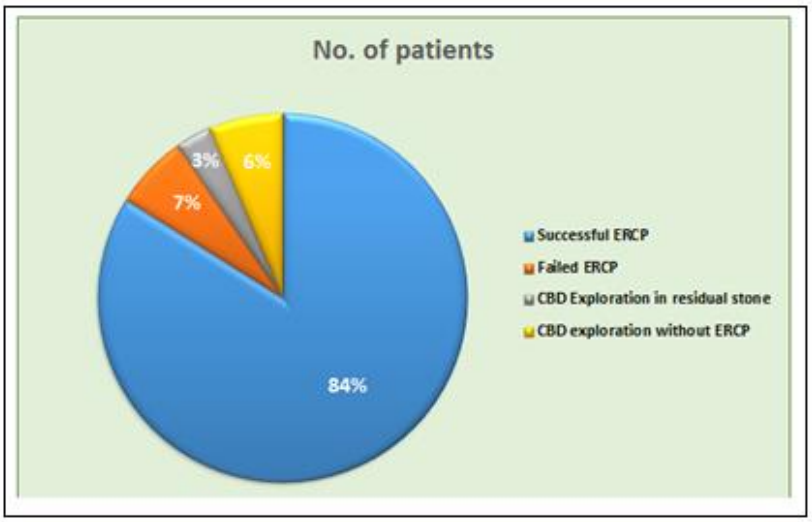
Graph-5: USG findings regarding Common bile duct diameter

Table-7: Management of CBD stone

Intervention	No. of patients
ERCP with successful CBD clearance f/b Laparascopic cholecystectomy	26
ERCP with failed clearance undergoing second time successful ERCP(Residual stones) followed by Laparascopic cholecystectomy	2
CBD Exploration in patients with failed Re - ERCP	1
CBD exploration without ERCP	2

Out of 30 patients, 26 had successful clearance of CBD which were followed by Laparoscopic cholecystectomy. 2 patients had failed ERCP clearance, out of which 1 patient had undergone re-ERCP with

successful clearance of the stone. The other 1 patient had to undergo Open CBD exploration followed by cholecystectomy. 2 patients with CBD stone greater than 2 cm had to undergo direct CBD exploration without undergoing ERCP.

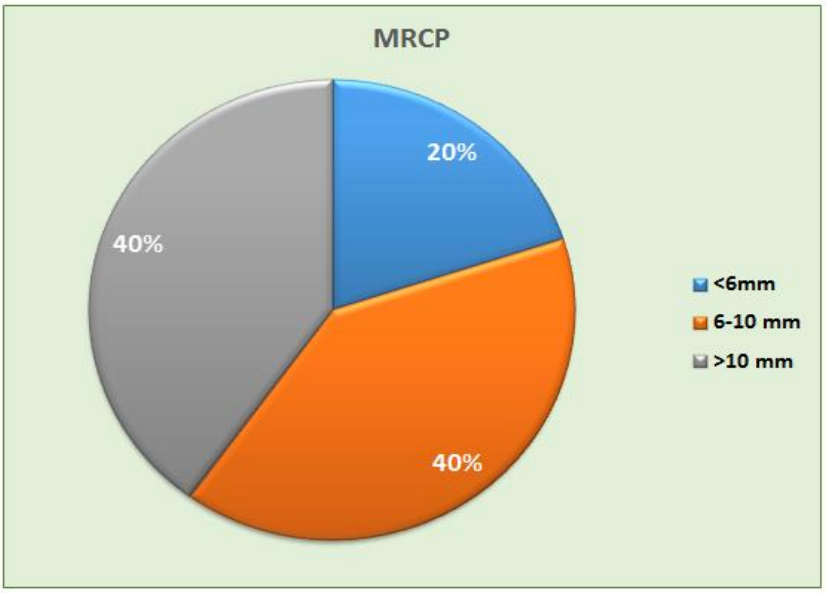


Graph-6: Management of CBD stone

Table-8: Magnetic Resonance CholangioPancreatography (MRCP)

Investigation	<6mm	6-10 mm	>10 mm	Single stone	Multiple stone
MRCP	6	12	12	5	25

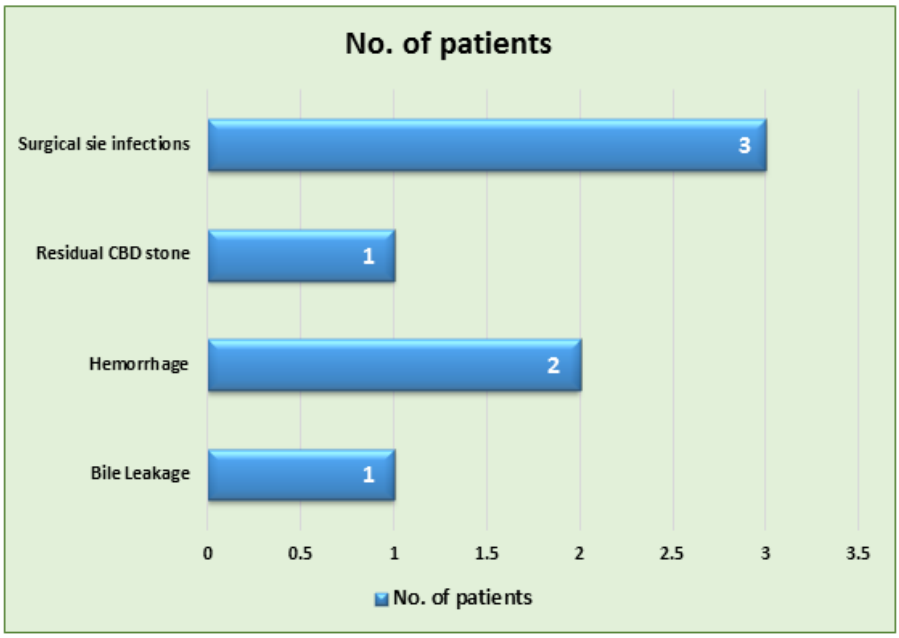
While doing MRCP, 6 patients had stone size less than 6 mm, while 12 patients were between 6-10 mm and 12 patients with CBD stone size greater than 10 mm.25 patients had multiple CBD stone while 5 had single stone in common bile duct.



Graph-7: Magnetic Resonance CholangioPancreatography (MRCP)

Table-9: Complications following surgery on follow up for 6 months

Complications	No. of patients	%
Bile Leakage	1	3.33%
Hemorrhage	2	6.66%
Residual CBD stone	1	3.33%
Surgical sie infections	3	10%



Graph-8: Complications following surgery on follow up for 6 months

Out of 30 patients included in the study, 3 patients operated by Open CBD exploration had surgical site infection with seroma formation and were treated conservatively. 2 patients had hemorrage following laparoscopic cholecystectomy probably from cystic artery which were undergone re-Laparoscopy and hemostasis achieved. 1 patient had bile leakage probably from the clip applied to cystic duct and undergone re-Laparoscopy and closed successfully. 1 patient had residual CBD stone that was identified on re-ERCP and removed succefully by ERCP.

DISCUSSION

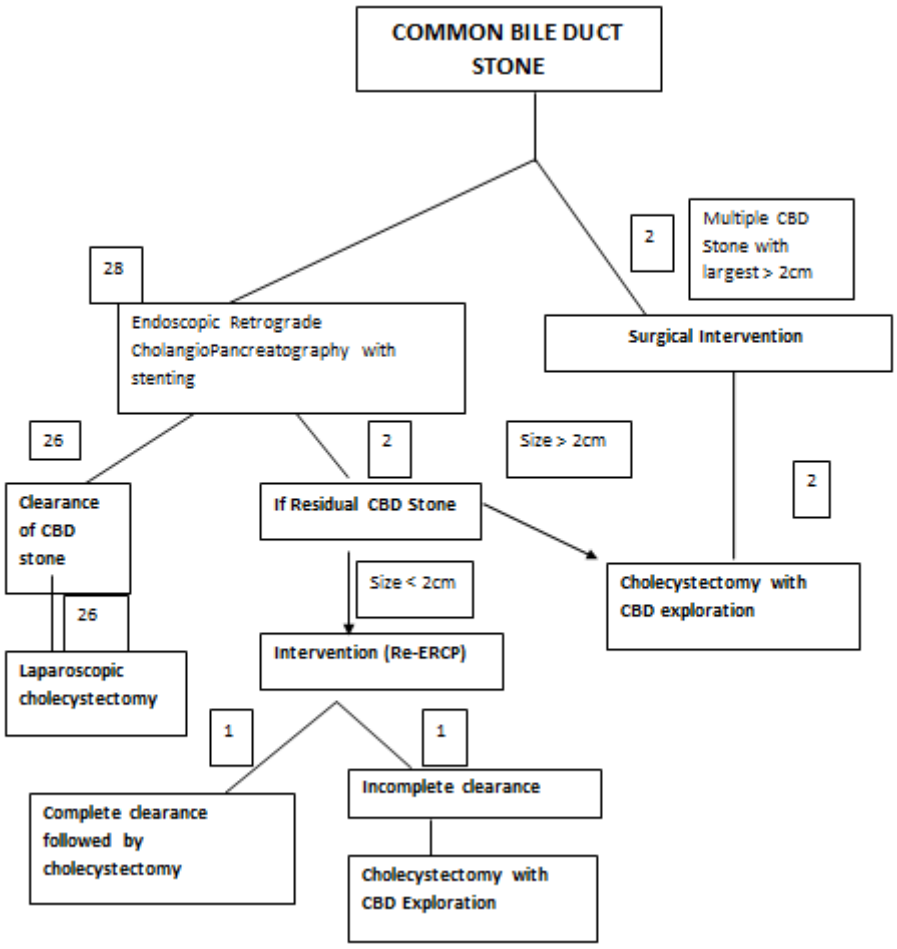
The primary goal of treatment in choledocholithiasis is to achieve common bile ductal clearance with the fewest number of interventions, lowest cost and least morbidity. Bile duct stones are found in 7–20% of patients with symptomatic gallstones [15]. Treatment is essential because the presence of stones in the bile duct is related to severe complications (jaundice, acute pancreatitis or acute cholangitis). Traditional surgical treatment comprises intra-operative cholangiography to detect the presence of bile duct calculi followed by choledocholithotomy and T-tube placement. For many years this procedure offered effective therapy and was associated with a morbidity rate of 10–15%, a mortality rate of <1% (in patients under 65 years) and a retained stone rate below 6% [15].

This diagnostic and therapeutic approach to bile duct stones has been substantially modified over the last 25 years, along with technological advances in diagnostic imaging and in minimally invasive therapy: endoscopic retrograde cholangiopancreatography (ERCP), endoscopic sphincterotomy (ES), laparoscopic cholecystectomy (LC) and magnetic resonance cholangiography (MRCP).The most common treatment modality for CBD stone is ERCP, with duct cannulation and clearance rates reaching 98% in expert hands. The Surgical options have been limited mainly to larger CBD stones with occasional transcystic or transductal stone removal. The surgical removal of common bile duct stones, whether open or laparoscopic is usually reserved for patients in whom ERCP has failed.

In this study, evaluation was done based on the treatment protocol followed in our institution with the available facilities and along with certain limitations like lack of Cholangiography facilty, Endoscopic shockwave lithotripsy and Endoscopic ultrasonography and expertise for the laparoscopic CBD Exploration.

Age Distribution

In this study, out of 30 patients highest number of patients (16) were from age group of 51 to 60 years. While there were 2 patients from 31-40 years group, 9 from 41-50 years and 3 from age group 61-70 years. These findings are consistent with the study done by Ye Rim Chang *et al*. [37] in 2013 and Do Hoo *et al.* [36] in 2016 which suggested that majority of patients with CBD stone were from the age group of 50 to 70 years. The probable reason being sited is that in older patients CBD stone are usually due to migration of primary gall bladder stone at later age.



Treatment Protocol for patient with common bile duct stone

Table-1: Age Distribution

Study	Findings
Ye Rim Chang *et al.* [36] in 2013	Average age between 51 to 60 years
Do Hoo *et al*. [37] in 2016	Average age between 51 to 70 years
Our study	Average age between 51 to 60 years

Sex Distribution

Out of 30 patients 14 were male and 16 were females. The number of female patients are higher which is consistent with the study done by Dr Ankit Chhoda in 2017[38] and Henry Volzke *et al*. [39] in 2005 which states thata significantly higher proportion of females compared to males were in the intermediate probability group for CBD stone and suggests that better sex stratification can help improve the positive and negative predictive values of (American Society for Gastrointestinal Endoscopy) ASGE risk stratification criteria and improve patient outcomes and reduce associated healthcare cost.

Table-2: Sex Distribution

Study	Findings (% of Females)
Henry Volzke *et al*. [39] in 2005	62%
Dr Ankit Chhoda in 2017 [38]	58.5%
Our study	53.33 %

Presentation of patient with common bile duct calculi

Out of 30 patients, 21 patients presented with biliary colic that includes pain in right hypochondrium. 17 patients had jaundice which was associated with increased total bilirubin while 9 patients had associated cholangitis. 2 patients presented with features of pancreatitis. These findings are similar to study done by Majid A. Almadi *et al*. [40] in 2012 and Joana Tozatti *et al*. [41] in 2015 which suggested that the best

predictors of common bile duct stones in patients before cholecystectomy were features of cholangitis(right hypochondriac pain, jaundice and fever) and ultrasound evidence of stones in the common bile duct.

Table-3: Presentation of patient with common bile duct calculi

Study	Biliary colic	Jaundice	Cholangitis	Pancreatitis
Majid A. Almadi *et al*. [40]	76.5%	60.2%	40.5%	8.9%
Joana Tozatti *et al*. [41] in 2015	82%	59%	38.5%	9.2%
Our study	70%	56.6%	30%	6.67%

Liver function tests

Out of 30 patients, 28 patients had increased total bilirubin ranging from 4.2 to 18.3 mg/dl. Direct bilirubin increased in 28 patients ranging from 3.8 to 16.9 mg / dl. While alkaline phosphatase increased in 26 patients ranging from 408 IU/L to 836 IU/L. Serum amylase levels increased in only 2 patients with maximum rise of 800 IU/L. These findings are consistent with study by Majid A. Almadi *et al.* [40] in 2012 and Joana Tozatti [41] in 2015 who suggested that elevated alkaline phosphatase level and hyperamylasemia are modest predictors of CBD stone.

Table-4: Liver function tests in patients of symptomatic Common bile duct calculi:

Study	Total Bilirubin Increased	Direct Bilirubin Increased	Serum Alkaline Phosphatase Increased	Serum Amylase Increased
Majid A. Almadi *et al.* [40]	96%	95.3%	88.6%	9.8%
Joana Tozatti *et al*. [41]	95.5%	92.2%	80.8%	5.4%
Our study	93.3%	93.3%	86.6%	6.6%

Ultrasonography

Out of 30 patients, on ultrasound 6 patients had CBD stone less than 6 mm size, 12 patients had CBD stone between 6 to 10 mm, 6 patients had between 10-15 mm, 4 patients between 15-20 mm and 2 patients had > 2 cm size CBD stone. 2 patients could not be detected by sonography and CT scan was done for the confirmation. In our study the sensitivity of USG in detecting CBD stone comes out to be 93.33% and specificity about 100 %.According to study by Kurinchi Selvan Gurusamy *et al*. [42] in 2015 and Barkun *et al*. in 2004[42], ultrasound had average sensitivity of 73% and specificity of 91% for Common bile duct stone.These results conflict with the present study. This discrepancy can be attributed by being the exam operator dependent and that technical difficulty may vary according to the patient body type.

Table-5: Ultrasonographic findings regarding size of CBD Stone

Study	CBD stone size < 6mm	6-10 mm	>10 mm	Sensitivity	Specificity
Kurinchi Selvan Gurusamy *et al*. [42] in 2015	22%	41.5%	36.5%	73%	91%
Taha Ahmed M. Alkarboly *et al*. [43] 2016	21.5%	38.5%	40%	80%	87.5%
Barkun *et al*. in 2004[42]	23.5	30.2	46.3%	72%	90%
Our study	20%	40%	40%	93.3%	100%

Among the 30 patients, 1 patient with CBD diameter between 7-11 mm and 2 patients with CBD diameter > 11 mm did not have associated gall bladder stones, which arises the possibility of spontaneous passage of GB stone through the dilated Common bile duct. This shows sensitivity and specificity of about 93.3% and 100% respectively. According to Taha Ahmed M. Alkarboly *et al*.[43] 2016, the sensitivity and specificity of detecting CBD stone while considering CBD diameter was 80% and 87.5 % respectively which is consistent with the present study.

Table-6: USG findings regarding Common bile duct diameter

Study	CBD diameter <7 mm	Between 7-11 mm	>11 mm
Taha Ahmed M. Alkarboly *et al.* [43] 2016	24.6%	51.2%	28.8%
Kurinchi Selvan Gurusamy *et al.* [42] in 2015	30.2%	50.5%	30.2%
Barkun *et al*. in 2004[40]	21.2%	46.5%	27.5%
Our study	20%	46.6%	33.33%

MRCP: Magnetic resonance cholangio pancreatography

While doing MRCP, 6 patients had stone size less than 6 mm, while 12 patients were between 6-10 mm and 12 patients with CBD stone size greater than 10 mm.25 patients had multiple CBD stone while 5 had single stone in common bile duct. The sensitivity of MRCP in detecting CBD stone came out to be 100 % and specificity also 100%. According to study by Norero *et al*.[44] in 2008 andI Petrescu *et al*. in 2015[43], the sensitivity and specificity of MRCP came out to be 100 % and 99% respectivelywhich is consistent with the present study., MRCP precisely depicts the size of the CBD stone upto 1 mm size[43].

Table-7: MRCP Sensitivity and Specificity

Study	Sensitivity	Specificity
Norero *et al*. in 2008[44]	99.5%	98%
I Petrescu *et al*. in 2015[43]	100%	99%
Our study	100%	100%

1) Management of CBD stones

Out of 30 patients, 26 had successful clearance of CBD which were followed by Laparoscopic cholecystectomy. 2 patients had failed ERCP clearance, out of which 1 patient had undergone re-ERCP with successful clearance of the stone. The other 1 patient had to undergo Open CBD exploration followed by cholecystectomy. 2 patients with CBD stone greater than 2 cm had to undergo direct CBD exploration without undergoing ERCP. According to Xiaohong Wang *et al*. [45] 2017, clearance rate of ERCP was 97.7 %.

According to AP Lynn *et al*. [46] 2014, ERCP can do successful clearance of CBD stone in 93% of the cases. While it becomes 100% on subsequent ERCP. This is consistent with our study, in which there is successful clearance rate about 92.85% which increases to about 96.4% on second ERCP.

Also according to Wan XJ *et al*. [47] 2011, the clearance rate of CBD stone of size > 2cm is only 58.3 %, which is very less and so such patients must be resorted to Common bile Duct exploration which was followed in the present study.

Table-8: Management of CBD stone

Study	First ERCP and complete clearance of CBD	Re-ERCP in patients of residual stone	CBD Exploration (Failed clearance)
Xiaohong Wang *et al*. [45] 2017	97.7%	6.2%	8%
AP Lynn *et al*. [46] 2014	93%	4.4%	4%
Wan XJ *et al*. [47] 2011	92.7%	8.2%	6.2%
Our study	86.6%	7.14%	10%

2) **Mirrizi syndrome**

Out of 30 cases, 5 cases had impacted gall bladder stone causing external compression of common hepatic duct- (Mirrizi syndrome). According to Acquafresca P *et al*. [48] in 2014, the incidence of Mirrizi syndrome ranges from 0.05 to 4 % in patients of hepatobiliary diseases. This is comparatively less as compared with our study having incidence of about 16 %.The reason could be due to the Selection bias and the small sample size of the present study.

Table-9: Mirrizi syndrome

Study	Mirrizi syndrome (Prevalence)
Acquafresca P *et al*. [89] in 2014	4%
M.A. Beltran 2014	7.2%
Our study	16%

3) Complications following surgery

Out of 30 patients included in the study, 3 patients oprated by Open CBD exploration had surgical site infection with seroma formation and were treated conservatively. 2 patients had hemorrhage following laparoscopic cholecystectomy probably from cystic artery which were undergone re-Laparoscopy and hemostasis achieved. 1 patient had bile leakage probably from the clip applied to cystic duct and undergone re-Laparoscopy and bile leakage stopped successfully. 1 patient had residual CBD stone that was identified on re-ERCP and removed succefully by ERCP. This complication rate is similar to study by David K. Warren *et al*.[49] in 2017 which showed average rate of wound infection of about 4.93% and study by S Duca *et al*. [50] in 2003 which indicates rate of hemorrhage about 2.3%, bile leakeage in 0.5% and residual stone about 0.1% patients.

Table-10: Complications following surgery on follow up for 6 months

Study	Hemorrhage	Bile leakage	Residual CBD stone	Wound infection
David K. Warren *et al.* [90] in 2017	5.8%	2.4%	2.2%	4.9%
S Duca *et al.* [91] in 2003	2.3%	0.5%	0.1%	5.4%
Our study	6.6%	3.3%	3.3%	10%

From above discussion, it becomes clear that for the management of CBD stone, first of all one has to undergo complete evaluation of bile duct anatomy, size of the CBD stone, diameter of common bile duct along with the evaluation of co-morbidities like Pancreatitis and Cholangitis. This involves undergoing laboratory investigations, Ultrasonography CT scan, and MRCP For removal of the stone, one has to undergo ERCP followed by cholecystectomy. But there are multiple scenarios at this point. If the CBD stone is less than 2 cm size, one can undergo ERCP with complete clearance of CBD, followed by cholecystectomy. If there remains a residual CBD stone after ERCP, then another time ERCP is done for clearance of the stone. If there is still incomplete clearance of CBD stone, then one has to proceed for CBD exploration followed by Cholecystectomy. Another scenario is, if the CBD stone size is> 2 cm then one has to undergo CBD exploration directly without undergoing ERCP; followed by cholecystectomy.

There were multiple limitations of the present study including small sample size and selection bias. Also there were limitations in availability of some facilities like lack of Cholangiography facilty, Endoscopic shockwave lithotripsy and Endoscopic ultrasonography and expertise for the laparoscopic CBD Exploration

Open exploration remains a safe approach and is the "gold standard" if ERCP fails. Similarly Laparoscopic clearance of stones from the common bile duct was found to be as effective as preoperative and postoperative ERCP .Another approach is the intra-operative ERCP during laparoscopic cholecystectomy. This was less costly than preoperative ERCP and resulted in decreased morbidity. But, may be logistically challenging and prolongs operative times.

Failure rates with conventional ERCP for the removal of large stones in the common bile duct can reach upto 20%, requiring supplementary specialized techniques like Endoscopic papillary balloon dilation of the ampullary orifice or targeted percutaneous lithotripsyor need for Open CBD exploration as a last resort. In patients who are poor candidates for surgery, long-term biliary stenting by insertion of an endoprosthesis is a safe and effective alternative to duct clearance.

Summary

This retrospective study was done in 30 cases of Common bile duct stone in Dept. Of General Surgery in Shri Guru Govindsingh hospital Jamnagar from Sep 2017 to Sep 2018.

- CBD stone is common hepatobiliary disease and its diagnosis is essential at an early stage to prevent its complications.
- All 30 patients included in the study were appropriately investigated by laboratory investigations, USG, CT scan and MRCP.
- Out of 30 patients included in the study, 26 had undergone successful ERCP and had successful clearance of CBD which were followed by Laparoscopic cholecystectomy.
- 2 patients had failed ERCP clearance, out of which 1 patient had undergone re-ERCP with successful clearance of the stone.
- The other 1 patient had to undergo Open CBD exploration followed by cholecystectomy. 2 patients with CBD stone greater than 2 cm had to undergo direct CBD exploration without undergoing ERCP
- From above study it can be said that proper preoperative investigation (USG, CT scan, MRCP) of the patient with appropriate laboratory test is must before deciding the treatment protocol.
- Appropriate identification of CBD stone size, location, number and CBD diameter associated with features of cholangitis, jaundice and pancreatitis is essential
- The gold standard for the removal of CBD stone is ERCP followed by laparoscopic cholecystectomy.
- Common bile duct exploration is considered in patients with failed clearance of CBD following ERCP OR CBD stone size > 2cm.

CONCLUSIONS

It can be concluded from this study that management of Common bile duct stone is a complicated procedure requiring a step-wise strategic approach.

- For successful management of CBD stone patients, after appropriate investigations gold standard treatment is ERCP followed by laparoscopic cholecystectomy.
- While in patients with incomplete clearance of CBD stone after ERCP, Common bile duct exploration either laparoscopic ally or by open

approach (as per the expertise available in the institution) should be preferred.

- While in patients with CBD stone >2 cm size, direct CBD exploration is the preferred option.
- An integrated health care team including surgeons, gastroenterologists and radiologists can decrease patient morbidity, enhance cost-effectiveness and optimize patients' quality of life.

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