



A CLINICAL STUDY AND MANAGEMENT OF COMMON BILE DUCT STONES

General Surgery

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ABSTRACT

There are three goals for treating people with gallstone disease who may have stones in the common bile duct; to assess the probability of bile duct stones, to treat those stones if they are present & to remove the stone. As a result, the current study focuses on the various modes of presentation of CBD stones as well as the clinical outcomes of various choledocholithiasis treatment modalities such as pre-operative ERCP and LFT. The present study was a prospective clinical observational study carried out at Department of General Surgery, Smt. Kashibai Navale Medical College and General Hospital over a period of 24 months from 2020 to 2023. Total 50 patients were enrolled in this study. Age incidence varies between 35 and >65 years, and the mean age of incidence is 50 years. The most patients had CBD diameter either between 4.1 to 5 mm. 7 (14%) patients had clinical evidence of jaundice (icterus) because their total bilirubin values were near 1 mg%. Most of the patients had values between 0.4 to 0.7 mg%. Most common organism isolated was *E. Faecalis* 15 (30%) cases. 12 patients (24%) had no evidence of any growth despite of culturing for 48 hrs on both aerobic and anaerobic culture media. . MRCP was used in 50 cases with negative USG for CBD stones and had specificity of 100% in this study. Out of the 50, 24 showed the positive results. ERCP had success of clearing the CBD of all the stones in 25 % of the cases. 23 patients (46%) developed infection of surgical wound as a result of contamination from the biliary tract. Bile leak was seen in 26 patient (52%). From the study findings we conclude that, there can be no definite algorithm for the management of CBD stones as the patients' age, underlying general condition being the only standardizable factor with facilities for endoscopic management being variably available from institution to institution and hence, necessitating tailoring the management of CBD stones depending upon the Institution's resources.

KEYWORDS

CBD, ERCP, MRCP

INTRODUCTION

The presence of stones inside the common bile duct (CBD) is referred to as Choledocholithiasis and is also known as bile duct stones. The majority of CBD stones are made up of gallbladder-derived cholesterol stones.[1] Stones that are present in the common bile duct are the result of gallstones passing through the cystic duct into the common bile duct. Sometimes the common bile duct itself may be the origin of stones.[2] These are non-crumbling concretions having a diameter greater than 2 mm.[3] Common bile duct stones are classified as retained if they are found less than two years following cholecystectomy or recurrence if they are found more than two years later.[4]

There are two categories for common bile duct stones. Primary stones are made of calcium bilirubinate, with varying levels of cholesterol or fatty acids, and they developed directly in the bile duct.[5] Their etiology seems to be influenced by the presence of pathogenic infection and biliary stasis.[6,7] Generally, they are brown pigmented stone. Patients who do not have a congenital gallbladder and those who have had their CBD removed during previous gallbladder surgery are more likely to develop primary stones.[8] Secondary stones are considered to have gallbladder origin since they have the same composition as gallbladder stones, which is 80% cholesterol and 20% black pigment.[9] These compositional variations might influence how they react to therapy.[10] CBD stones that occur in the immediate postcholecystectomy period should be assumed to be secondary stones that are the result of an incompletely cleared CBD.[8]

Even though CBD stones may not cause any symptoms at first, they could become problematic if they do. Obstructive jaundice, ascending cholangitis, and acute pancreatitis are all conditions that can cause serious morbidity and occasionally even death and necessitate prompt medical intervention.[11] The abdominal discomfort is frequently intermittent, it can occasionally be chronic. The discomfort is typically felt as a mid-epigastric, deep visceral agony and is frequently accompanied by nausea and/or vomiting. Fever is a sign of cholangitis, although back pain, which may be the main symptom in 20% of patients, raises the chance of a related pancreatitis.[12] On rare occasions, a tiny stone might enter the bile duct and strike the ampulla,

resulting in discomfort and jaundice. The length of the obstruction determines the degree of the jaundice; however, when the stone moves on, the jaundice disappears on its own. A larger stone or stones are more frequently seen inside a dilated bile duct. The number of stones in the duct might occasionally significantly hinder bile flow. In some cases, a stone works as a "ball valve" and glides up and down within the duct, producing pain and jaundice when it hits but allowing the symptoms to go away on their own when the stone rises.[13] Choledocholithiasis may present clinically in a variety of ways since CBD stones might be asymptomatic in some cases (up to 50%). Asymptomatic CBD stones are probably one of the most difficult cases because patients face the danger of being "understudied" by inadequate diagnostic testing or "overstudied" by overly intrusive testing. Inappropriate procedures can also result in them receiving inadequate or excessive care. How to cost-effectively detect and, ultimately, treat CBDS, remain two major unresolved issues.[14,15] MRCP & ERCP are the diagnostic methods for CBD stone.

According to several studies, the prevalence of primary CBD stones ranges from 4% to 56%. Due to the prolonged duration of gallstones in older patients, the frequency of secondary CBD stones is age-sensitive and ranges from 11% to 18%. Initially detecting CBDS before, during, or after cholecystectomy is one of the key management considerations.[16] It can be challenging to choose the best management strategy for common bile duct stones.[17] Many researchers have tried to develop a paradigm to precisely anticipate the existence of common bile duct stones and thus suggest preoperative ERCP technique. It is the most widely used treatment method and includes duct cannulation and high clearance rates. [18] To avoid further difficulties, common bile duct treatment becomes extremely important. There are three goals for treating people with gallstone disease who may have stones in the common bile duct; To assess the probability of bile duct stones, to treat those stones if they are present & to remove the stone. As a result, the current study focuses on the various modes of presentation of CBD stones as well as the clinical outcomes of various choledocholithiasis treatment modalities such as pre-operative ERCP and LFT.

Methodology

The present study was a prospective clinical observational study carried out at Department of General Surgery, Smt. Kashibai Navale Medical College and General Hospital over a period of 24 months from 2020 to 2023. Ethical committee approval was taken. All the cases of Common bile duct stones with the patient's age >12 years, pre-op USG diagnosis of ductal dilation >8mm with or without CBD stones, multiple stones in gall bladder with dilated cystic duct & CBD stones complicating as obstructive jaundice, cholangitis, pancreatitis were enrolled in the study after taking written informed consent. Patient age ≤ 12 yrs & CBD <8 mm without stone on USG has very low predictive yield by even invasive imaging like per op cholangiogram were excluded. Total 50 cases were enrolled.

A detailed clinical history and examination were performed in all cases as per the proforma. Diagnostic investigations (ultrasonography abdomen, LFT) were done in all cases. MRCP was selectively used when USG was negative for CBD stones, but history and biochemical parameters were suggestive of CBD stones. Procedural investigations like Hb%, coagulation profile, TC, DC, RBS, blood urea, serum creatinine, chest X-ray, and ECG were performed in all cases. Bile cultures were obtained in all cases. Because of the extensive experience and adequate facilities in the institution, open CBD exploration and ERCP were chosen as treatment modalities. ERCP was done for – 1. Acute cholangitis 2. Visualized CBD stone on abdominal ultrasound, endoscopic ultrasound (EUS), computed tomography (CT), MRCP, or intraoperative cholangiogram 3. High suspicion of CBD stones: cholelithiasis, dilated CBD, and abnormal liver biochemical tests 4. Worsening gallstone pancreatitis 5. Recurrent CBD stones or gallstone pancreatitis, nonsurgical candidate for cholecystectomy Open CBD exploration was done for larger CBD stones or failed ERCP procedure.

Statistical analysis in the form of percentages, means, and confidence intervals, standard deviations, sensitivity, specificity, and positive predictive value were calculated to analyse the significance of the diagnostic investigations and the impact of the therapeutic procedures. The statistical software SPSS was used. For the following analysis of the data, Microsoft Word and Excel were used to generate graphs and tables.

RESULTS

Total 50 patients of CBD were enrolled in this study with mean age of 49.88 years (35-83 years). Majority of the patients aged between 35-44 years. About 52% male & 48% were female. About 38% had positive family history. (Table 1) Table 2 shows the mean serum value.

Pain in the abdomen was invariably present in almost half of the patients, i.e., 25 (50%). Severe pain abdomen Right upper quadrant pain was present in 19 patients (38%). Jaundice was present in 28 patients (56%). Pale stools were observed in 21 patients (42%). Thus, no patients were asymptomatic. (Fig 1)

Table 1: Distribution Of Patients According To Demographic Parameter

Parameter	Frequency	Percentage
Age Group	<35 years	16
	35-44	20
	45-54	1
	55-65	6
	>65	17
Gender	Male	26
	Female	24
Past History	Yes	19
	No	31

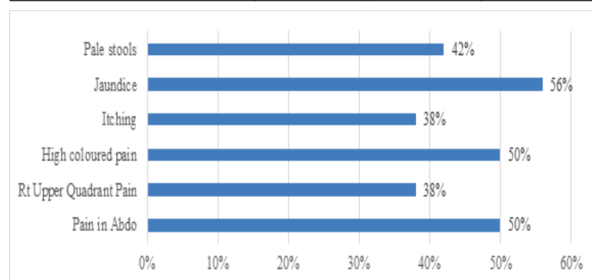


Fig 1: Presenting Complaints

Table 2 : Mean & S.D

Investigations	Mean	SD
Hb	12.76	2.72
PT	14.972	0.8
TC	7216.3	2030.8
Blood Urea	25.6	5.653
Sr. Creatinine	0.866	0.27
Total Bilirubin	0.54	0.228
Direct Bilirubin	0.31	0.26
Alkaline Phosphatase	35.04	12.52

Table 3: Distribution According To Clinico-diagnostic Findings

Investigation	Frequency	Percentage
Sr. Bilirubin	0.1-0.3	10
	0.4-0.7	33
	0.8-1	1
Alkaline Phosphatase	11-20	11
	21-30	8
	31-40	12
	41-50	13
	51-60	6
USG CBD Diameter	3.1-4	13
	4.1-5	19
	5.1-6	18
No. of stone	Multiple	12
	Single	22
	No stone	16
Wound infection	Yes	23
	No	27
Bile leak	Yes	26
	No	24
Laparoscopic CBDE	Dilated	27
	Normal	23
Stone Visualization by ERCP	Yes	25
	No	25
Stone Visualization by MRCP	Yes	24
	No	26
Bile culture organism	E. Coli	9
	E. Faecalis	15
	Klebsiella	14
	No growth	12

Most of the patients, i.e., 33, had total bilirubin values between 0.4 and 0.7 mg%, with the highest value obtained at 0.8 to 1 mg%. The mean alkaline phosphatase was 35.04 IU/L. Most patients had values between 41 and 50 IU/L. The CBD diameter of the majority of patients (38%) was between 4.1 and 5 mm. The highest recorded CBD diameter was between 5.1-6. 34 patients (68%) had sonological evidence of stones in the CBD. 16 (32% of the cases) had false negative sonology of the CBD for stones, which was confirmed with MRCP. The most common organism isolated was E. faecalis (30%) in 15 cases. 12 patients (24%) had no evidence of any growth despite culturing for 48 hours on both aerobic and anaerobic culture media. Klebsiella was found in 14 patients (28%). E. coli was found in nine patients (18%). Out of the 50 patients, 27 (54%) showed no wound infection, while 23 (46%) showed an infection. Over half of the patients, or 26, (52%), had bile leakage, while the other 24 did not. 23 cases (46%) had successful normal clearance of the laparoscopic CBD, while 27 cases had dilated laparoscopic exploration. In the ERCP, 25 cases showed a positive result for stone visualization, whereas only 24 cases showed a positive result in the MRCP. (Table 3)

DISCUSSION

Common bile duct stones are present in approximately 5% of patients undergoing elective cholecystectomy and 10% of patients with acute cholecystitis. The presence of a common bile duct stone cannot be determined by a single blood test or by a combination of blood tests.

CBD stones can be identified preoperatively with ultrasound, ERCP or magnetic resonance cholangiopancreatography but intraoperative cholangiography and choledochoscopy are required for a certain diagnosis. A variety of techniques can be used to diagnose choledocholithiasis before surgery. The patient's age and health, the existence of jaundice or cholangitis, the size of the duct and the stone, as well as other factors, define the best course of action.

The natural history of choledocholithiasis is unpredictable. Small

stones may pass spontaneously into the duodenum without causing symptoms, or they may obstruct the pancreatic duct temporarily, induce an episode of pancreatitis, and then pass into the duodenum, alleviating symptoms. Stones that do not pass into the duodenum may remain symptom-free in the bile duct for a long period of time, then suddenly precipitate an episode of jaundice or cholangitis.

The study was conducted in the Department of General Surgery, Smt. Kashibai Navale Medical College and General Hospital, Narhe, Pune. This study was aimed at studying and managing common bile duct stones. The study's primary goal was to investigate various modes of presentation of CBD stones as well as various treatment modalities for these stones.

The present study has been carried out on patients who were admitted with CBD stones to the Department of General Surgery from 2022–2033. During the study period, 50 patients who met the inclusion criteria were admitted and were a part of the investigation. In all cases, a detailed clinical history and examination were performed. The diagnosis of CBD stone was reached on the basis of abdominal ultrasonography and blood investigations. Selected cases were subjected to MRCP and ERCP.

Patients underwent relevant blood investigations (haemoglobin, TC, DC, RBS, blood urea, serum creatinine, liver function test. Patients with abnormal bleeding and clotting times, were evaluated further using the PT. Bile culture and sensitivity testing were done for all cases. The protocol was followed, patients were monitored, and complications were investigated.

Age & Sex Incidence:

The patients' ages ranged from 35 to over 65. In men, the average age was 50.23, and in women, the average age was 49.5. The combined average was 49.88. The age group of >65 years old had the most patients (17 cases), followed by the age group of 35 years old (16 cases). In the study conducted by Girard RM et al. (2000) [19], the maximum incidence was seen in the age group between 50 and 59 years (20.1%). Thus, the cases presented to us were older. The female to male ratio was 1.5. According to Gerard RM (2000)[19], the female to male ratio was 1.72.

Presenting Symptoms:

Pain was the most common symptom. 25 (50 %) of patients complained about it. It varied from right upper quadrant pain to high coloured pain associated with itching in 19 cases (38%). Jaundice was present in 28 cases (56%). According to Wani NA et al.[20] 94% had pain in the right upper abdomen. According to Acosta JM et al (1974),[21] gall stones are responsible for 50% of all cases of pancreatitis. Conversely, 4 – 8% of patients with gall stones develop pancreatitis. According to Abboud66 (1996) et al.'s [22] meta-analysis, clinical jaundice was present in 29 patients (58%) with a positive predictive value of 64%, indicating that jaundice has a positive predictive value of 39% for choledocholithiasis.

USG CBD Diameter:

Out of 50 patients, on ultrasound 13 patients had CBD stone less than 4 mm size, 19 patients had CBD stone between 4.1 to 5 mm, 18 patients had between 5.1-6 size CBD stone. In our study the specificity of USG in detecting CBD stone comes out to be about 100%. According to study by K Gurusamy et al [23] in 2015 and Barkun et al [24] in 2004, ultrasound had average sensitivity of 73% and specificity of 91% for Common bile duct stone. These results conflict with the present study.

Analysis Of Lab Investigations

Mean total Bilirubin was 0.54 and 66% confidence interval 0.4 – 0.7. The sensitivity of elevated bilirubin in predicting CBD stones in our study was 88.2%. In the study done by Abboud et al (1996) of 69% sensitivity probably due to advanced presentation of cases with prolonged and significant cholestasis.

Many studies have been performed to seek predictive tools for the presence of CBD stones in patients with gallbladder stones awaiting cholecystectomy, showing that preoperative laboratory findings and US evaluation of choledochal diameter were individually significant predictive factors and the likelihood of CBD stones increases up to 99% when all the predictors were positive.[25]

ALP is usually associated with symptomatic CBD stones 68 and has the

highest sensitivity in the diagnosis of choledocholithiasis among the biochemical parameters.[26]

Videhult et al. showed that almost half (48%) of the patients with CBD stones had normal ALP and bilirubin values. Thus, by using only findings of normal ALP and bilirubin as indicators of the absence of CBD stones would imply that half of CBD stones would remain undetected. [27]

ERCP was accepted as the 'gold standard' for bile duct imaging, with the advantage of permitting the bile duct to be cleared of stones. However, it is an invasive technique, with a reported mortality rate of 0.1–3%. [25] Ideally, its use should be restricted to therapeutic procedures alone and not recommended as a routine examination.

MRCP is a non-invasive imaging technique that does not require the use of X-rays or contrast media. The most important drawbacks of MRCP are its inability to offer therapeutic interventions and its high cost. The criteria for a positive MRCP were signal defects within the CBD, defined variably as foci or rounded and oval in some studies.[28] In 2003, Romagnuolo et al. reported an authoritative meta-analysis of 67 published controlled trials, showing that MRCP has an excellent overall sensitivity of 95% and a specificity of 97% for demonstrating CBD stones. Our results, with sensitivity and specificity of 100% for demonstrating CBD stones, are, therefore, in line with those previously reported.[29]

CONCLUSION

From the study findings we conclude that, there can be no definite algorithm for the management of CBD stones as the patients' age, underlying general condition being the only standardizable factor with facilities for endoscopic management being variably available from institution to institution and hence, necessitating tailoring the management of CBD stones depending upon the Institution's resources.

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