

## MANAGEMENT OF CHOLEDOCHOLITHIASIS IN KIMS HOSPITAL, BANGALORE: OUR EXPERIENCE

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**ABSTRACT: BACKGROUND:** Choledocholithiasis is a complication of gallbladder stones; only in a minority of the patients they arise de novo in the bile ducts. In the present study, we have attempted to enumerate the demographic characteristics, various modes of clinical presentation, diagnostic tests, management and complications of the patients with choledocholithiasis. **METHODS:** A prospective study was conducted from October 2009 to September 2011 (24 months including follow-up period) in patients diagnosed to have choledocholithiasis. Patients with intra-hepatic stones and biliary stricture were excluded from the study. Demographic characteristics, various modes of clinical presentation, investigations, management and complications of the patients with choledocholithiasis were studied. A total of 31 patients with a diagnosis of choledocholithiasis are included in this study. The patients were divided into two groups -Open Surgery (CBD exploration and cholecystectomy) and ERCP followed by Laparoscopic Cholecystectomy. **RESULTS:** Right hypochondrial pain was the most common clinical manifestation followed by jaundice and fever. Serum Bilirubin and Alkaline Phosphatase were in most cases. Ultrasonography was most important imaging modality failing which CT or MRI scans were indicated. ERCP with Endoscopic Sphincterotomy (ES) was done in 22 patients and was successful in 19 of them. 3 failures were due to impacted stones. 12 patients underwent open CBD exploration with cholecystectomy. Incidence of complications were significantly more and also the duration of Hospital stay was more in those who underwent open surgery. **CONCLUSION:** Ultrasonography has a sensitivity of 70.96% in detecting CBD calculi. Routine use of MRCP and CT is not required. ERCP with Endoscopic Sphincterotomy followed by laparoscopic cholecystectomy can be used for the treatment of CBD calculi. Complications are more in patients who undergo open surgery. There is a significant decreased mean hospital stay in patients who undergo endoscopic treatment.

**KEYWORDS:** Choledocholithiasis, ERCP, MRCP, Sphincterotomy, Cholecystectomy.

**INTRODUCTION:** Biliary obstruction, which is the interruption of bile flow from the liver to the small intestine, can occur at any level within the biliary system. Choledocholithiasis is most commonly a complication of gallbladder stones; only in a minority of the patients they arise de novo in the bile ducts. Langenbuch performed the first cholecystectomy in 1882. Soon enough, choledochotomy became the gold standard notwithstanding the fact that addition of the ductal exploration to cholecystectomy raises the morbidity and mortality significantly<sup>3, 4</sup>. The introduction of endoscopic sphincterotomy in 1974 opened the non-surgical options. Instantly it became popular. But many studies have proven that pre-operative endoscopic sphincterotomy and surgery offers no advantage over surgery alone<sup>5</sup>. However, endoscopy is a safe option in elderly patients and in those with medical risk factors. It relieves obstruction, improves the general condition in the settling of acute cholangitis with a much lower mortality. The advent of laparoscopy dramatically changed the

scenario. Management of choledocholithiasis has become even more controversial. Though some centers have specialized in laparoscopic common bile duct exploration, many resort to pre-operative sphincterotomy for ductal stones. In the study the demographic characteristics, various modes of clinical presentation, diagnostic tests, management and complications of the patients with choledocholithiasis were analysed.

**PATIENTS AND METHODS:** A prospective study was conducted from October 2009 to September 2011 (24 months including follow-up period) in patients diagnosed to have choledocholithiasis in KIMS Hospital and Research Centre, Bangalore. They were followed up for a period of 6 months. Patients with intra-hepatic stones and biliary stricture were excluded from the study. A total of 31 patients with a diagnosis of choledocholithiasis are included in this study. Detailed history was elicited including operative risk factors, previous biliary surgeries and a thorough physical examination was done. History regarding the age, jaundice, pain, fever, nausea/vomiting, pale stools, pruritis, cholangitis and pancreatitis was recorded. Medical risk factors such as diabetes, hypertension, ischemic heart disease etc were considered. Pain was considered biliary origin if it was located over the right upper abdomen with or without radiation to the lower right scapula. Patients who had previous biliary surgery and presented with CBD calculi were considered to be with Retained stones if the stone developed within 2 years from the date of previous surgery and Recurrent stones if it developed more than 2 years. Biochemical investigations including random blood sugar, urea, creatinine, liver function tests. Ultrasonography was performed in all patients with a clinical suspicion of CBD calculi. Dilatation of intra and extra hepatic biliary radicals was considered as an indirect evidence of CBD stones. Presence or absence of gall bladder stones or wall thickening was also noted. CT scan with MRCP was performed in patients in whom ultrasonography was not able to pick up stones in the CBD or detect dilatation of the biliary radicals. Stones were considered as primary stones if they were found only in the CBD and secondary if they also had gall bladder stones. ERCP was done in 22 patients. If stones were demonstrated, an endoscopic sphincterotomy was done in all patients and their retrieval was attempted. Stones were retrieved by either basketing or with balloon which was left to the discretion of the endoscopist. A 10 cm 10F CBD stent was inserted in all patients, which was to be removed after 6 weeks. ERCP was considered as a sole procedure in patients with only CBD stones and with a normal gall bladder. It was followed by cholecystectomy in patients with either gall bladder stones or cholecystitis. Laparoscopic cholecystectomy was attempted in all patients, failure of which entailed open cholecystectomy. The criteria for choosing patients for the endoscopic retrieval were - Old patients, Primary CBD stones, Patients with co-morbid conditions, Patients with acute cholangitis.

Patients with stone size >1cm and patients in whom ERCP was a failure were subjected to open surgery. The procedures performed were - CBD exploration, CBD exploration with transduodenal sphincteroplasty, CBD exploration with choledocho-jejunostomy. Cholecystectomy was done in all patients who underwent surgery. Abdomen was opened with a right subcostal or right paramedian incision. Common duct was considered dilated if it was more than 0.9cm. Per-operative cholangiogram was used selectively, the indications being sonologically proven stones that could not be located per operatively or if the clearance of duct was doubtful after the retrieval of stones. Anastomosis was done in a single layer with interrupted absorbable sutures and a drain placed in the vicinity of the anastomotic site. Patients, after surgery were monitored for

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postoperative complications. Hospital stay was recorded in all cases including wound or chest infection. Patients were observed for abdominal complications including bile leaks from the drain site and intra-abdominal collections.

The patients were divided into two groups - Open Surgery (CBD Exploration and Cholecystectomy) and ERCP followed by Laparoscopic Cholecystectomy, for determining complication rates. The difference in the mean duration of hospital stay in each group was also checked for significance.

**STATISTICAL ANALYSIS:** The significance of differences was determined using the t-test and chi-square test. Confidence intervals within 95% were considered significant.

**RESULTS:** Thirty one patients were included in the study. Fifteen patients (48.4%) were females and 16 (51.6%) were males, thus the female to male ratio is 0.93:1. The age at presentation in the females ranged from 31 to 85 years, with a mean age of 56.80 years (SD 15.28). Similarly in males it ranged from 30 to 75 years with a mean age of 55.13 years (SD 13.42). Overall the mean age of presentation was 55.94 years (SD 14.14). Thus most of the females presented at a late age than males.

Age in years	ERCP+		Open Surgery		All patients	
	No	%	No	%	No	%
30-40	3	15.8	2	16.7	5	16.1
41-50	6	31.6	2	16.7	8	25.8
51-60	4	21.1	2	16.7	6	19.4
61-70	5	26.3	4	33.3	9	29
>70	1	5.3	2	16.7	3	9.7
Total	19	100	12	100	31	100
Mean ± SD	53.84±14.25		59.25±13.91		55.94±14.14	

**TABLE 1: AGE DISTRIBUTION OF THE PATIENTS STUDIED**

Jaundice was present in 17 of the 31 patients (54.83%). Pain was a complaint in 29 patients (93.54%). Twelve patients had fever (38.70%), of these 7 (22.58%) had the classical triad of cholangitis. Eighteen patients had nausea with or without vomiting (58.06%). Pale stools and pruritis was present in only 3 (9.67%) and 2 (6.45%) patients respectively. Serum bilirubin was raised in 25 patients (80.64%) with a maximum of 15.2 mg/dL and a mean of 4.02 mg/dL (SD 3.76). Twenty four (77.41%) patients had a raised serum alkaline phosphatase (>115IU/L) with a mean of 295.23 IU/L (SD 310.22).

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Clinical symptoms	ERCP+ (n=19)	Open Surgery (n=12)	All patients (n=31)	P value
Icterus	10(52.6%)	7(58.3%)	17(54.8%)	0.756
Pain	18(94.7%)	11(91.7%)	29(93.5%)	1
Fever	9(47.4%)	3(25%)	12(38.7%)	0.213
Pancreatitis	2(10.5%)	0(0%)	2(6.5%)	0.51
Pale stools	1(5.3%)	2(16.7%)	3(9.7%)	0.543
Pruritis	1(5.3%)	1(8.3%)	2(6.5%)	1
Chills	5(26.3%)	3(25%)	8(25.8%)	1
Nausea/Vomiting	14(73.7%)	4(33.3%)	18(58.1%)	0.027*
H/O Jaundice	10(52.6%)	2(16.7%)	12(38.7%)	0.065+

**TABLE 2: CLINICAL SYMPTOMS OF PATIENTS STUDIED**

Except for the 4 patients who had undergone prior cholecystectomy, gall bladder was visualised in all the 27 patients. Of these, 20 patients had gall bladder stones (74.07%) and gall bladder thickening was present in 14(51.85%). Ductal dilatation was seen in 28 of the 31 patients (90.32%) and ultrasound was able to pick up stones in 22 patients (70.96%). Nine patients, in whom ultrasonography did not show signs of stone, underwent a CT scan of the abdomen with MRCP. CT and MRCP picked up stones in the common bile duct in all (100%) patients.

ERCP with ES was used primarily as a therapeutic modality. Of the 22 patients in whom endoscopic retrieval of stones was attempted it was successful in 19 patients (86.36%). In 3 (13.63%) patients there was failure due to impacted stones. All 3 patients underwent formal CBD exploration and cholecystectomy. In 10 (52.63%) patients ERCP with ES was the sole procedure performed as these patients neither had gall bladder stones nor thickened gall bladder. Nine (47.36%) patients further underwent cholecystectomy, 6 (66.67%) by laparoscopic method and 3 (33.33%) by open method. Among the 7 patients with cholangitis, 3 (42.85%) patients had a prior history of cholecystectomy. These 3 patients, in addition to 2 other patients underwent ERCP with ES as the sole procedure. The other two patients underwent CBD exploration and cholecystectomy.

Twelve (38.70%) patients underwent open surgical procedures. Included in this 12 are the 3 failed ERCP cases. Ten (83.33%) patients underwent open CBD exploration with cholecystectomy. Nine (90%) of these patients had a T-tube inserted into the CBD. One (8.33%) patient who was cholecystectomized underwent choledocho-jejunostomy with jejunostomy for a massively dilated proximal CBD (3.5cm) with a narrowed distal CBD which had multiple impacted stones. One (8.33%) patient underwent CBD exploration with transduodenal sphincteroplasty. This was done for an impacted stone at the ampulla of Vater. Four patients (33.33%) in whom there were doubtful clearance of CBD calculi underwent an intra-operative cholangiogram. Stones were palpable intra-operatively in 10 (83.33%) patients. Macroscopic evaluation revealed that there was a high incidence of pigment and mixed stones.

Culture and sensitivity of the aspirated bile was done in the patients who underwent open surgery. Positive cultures were obtained only in four patients. *Escherichia coli*, and *Klebsiella* spp were the most common organisms isolated from the bile cultures.

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Two patients who underwent CBD exploration developed wound infection and 1 developed pneumonia. Persistent bile leak was present in 1 patient which necessitated re-exploration and closure of the leaking CBD rent. In patients who underwent ERCP with ES, 1 patient developed acute renal failure requiring dialysis and 1 developed pneumonia.

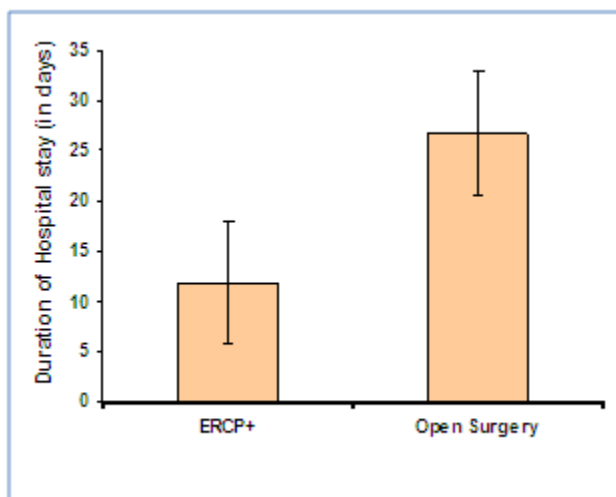
Complications	ERCP+ (n=19)	Open Surgery (n=12)	All patients (n=31)
Nil	17(89.5%)	7(58.3%)	24(77.4%)
Yes	2(10.5%)	5(41.7%)	7(22.6%)
Inference	Incidence of complications are significantly associated with open surgery with p=0.078+		

**TABLE 3: COMPLICATIONS OF THE PROCEDURES**

In patients who underwent ERCP alone, the mean hospital stay was 8.7 days (SD 4.08), ranging from 4 to 18 days. The patients who underwent cholecystectomy following ERCP had a mean hospital stay of 15.33 days (SD 6.042) ranging from 3 to 24 days. Overall, the patients in the ERCP group had a mean hospital stay of 11.84 days (SD 6.01). Patients who underwent open surgery had more prolonged hospital stay with a mean of 26.67 days (SD 6.17) ranging from 18 to 42 days. Comparing the endoscopy group and the open surgery group, the difference is significant p<0.001.

Duration of Hospital stay (in days)	ERCP + (n=19)	Open Surgery (n=12)	All patients (n=31)
Min-Max	24-Mar	18-42	Mar-42
Mean ± SD	11.84±6.01	26.67±6.17	17.58±9.46
Inference	Mean duration of hospital stay is significantly more associated with Open surgery with p<0.001**		

**TABLE 4: DURATION OF STAY IN THE HOSPITAL**



**CHART.1 DURATION OF STAY**

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**DISCUSSION:** The study included 31 patients with almost equal gender distribution. Most of the females presented at a later age than males. Pain in right hypochondrium, Jaundice and fever were the most common symptoms at the time of presentation. Serum bilirubin and Alkaline phosphatase were raised in most cases. Ultrasonography was the most important investigative modality to diagnose CBD stones, GB wall thickness as well as GB stones. ERCP with Sphincterotomy was used primarily as a therapeutic modality followed by laparoscopic cholecystectomy if gall stones were present. Failing which Open CBD exploration and cholecystectomy was done. The complications following surgery included Wound infection, Pneumonia, Haemorrhage and Bile leak. The duration of hospital stay was significantly more in those who underwent Surgery.

**CONCLUSION:** Ultrasonography has a high sensitivity of 70.96% in detecting CBD calculi and 90.32% in detecting ductal dilatation, an indirect evidence of CBD calculi. Pain abdomen, jaundice and fever are the most common presenting symptoms. Serum Bilirubin and Alkaline phosphatase are the most common parameters in liver function tests which are altered. Although MRCP and CT have sensitivity of almost 100%, their routine use is not required and useful only in patients with strong clinical suspicion and in whom ultrasonography fails to show the calculi. Choledocholithiasis is associated with cholecystolithiasis in nearly two thirds of the cases. ERCP can be used as the only intervention for treatment of only CBD calculi with normal gall bladder. Laparoscopic Cholecystectomy is needed following ERCP in those cholecystolithiasis and cholecystitis. Open CBD exploration is suitable for patients with large CBD stones and in whom endoscopic retrieval is a failure. Macroscopic evaluation revealed a higher incidence of pigment and mixed stones. E. coli and Klebsiella species are the most common organisms causing infection of bile in patients with CBD calculi. Complications are more in patients who undergo open surgery. There is a significant decreased mean hospital stay in patients who undergo endoscopic treatment for bile duct calculi.

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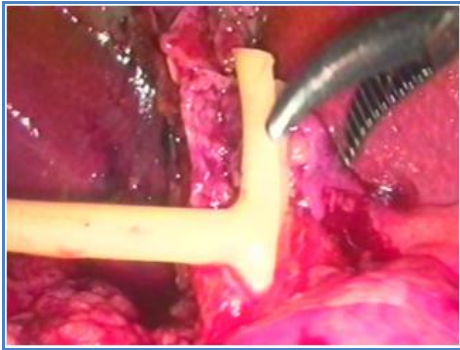


FIG.1 OPEN CBD

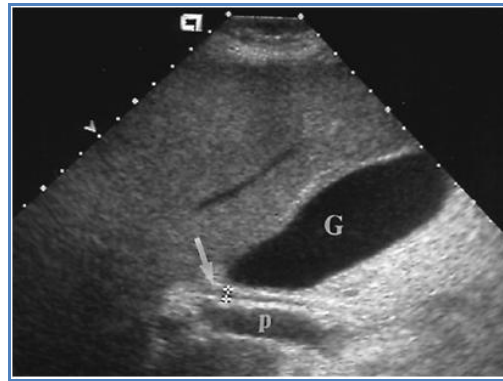


FIG.2 ULTRASOUND IMAGE OF CHOLEDOCHOLITHIASIS.



FIG.3 ERCP SHOWING CBD CALCULUS WITH STENT IN SITU



FIG.4 ERCP SHOWING CBD CALCULI

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