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Original Research Article

A retrospective analysis of outcome of endoscopic management in choledocholithiasis in a tertiary care centre

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ABSTRACT

Background: The role of endoscopic retrograde cholangiopancreatography (ERCP) as a therapeutic intervention for choledocholithiasis is long established. Endoscopic therapy involves stone extraction using conventional methods after performing endoscopic biliary sphincterotomy. The objective of this study was to determine the outcome of patients with choledocholithiasis being treated in our setup.
Methods: This retrospective observational study was conducted at T.N.M.C. and BYL Nair Hospital, Mumbai from January 2017 to October 2017. All patients with choledocholithiasis proven radiologically were admitted. All patients underwent elective endoscopic retrograde cholangiopancreatography. In patients in whom ERCP failed, open surgical clearance of the common bile duct was done.
Results: A total of 50 cases of choledocholithiasis were admitted during the study period. Age distribution in our study was from 27 years to 81 years of which, 46% were males and 54% were females. Successful clearance of CBD with balloon sweep, dormia basket, CBD stenting or sphincterotomy alone was done in 38 patients (76%). Nine patients (18%) required repeat ERCP/ more than one sitting for clearance of CBD. Most of the patients had stone size of >10 mm (8 out of 9 patients i.e. 88.89%). Three patients were referred for surgical intervention due to non-retrieval of calculus. All these patients had stone size >15 mm (100%).
Conclusions: In our study 94% patients eventually achieved successful clearance with ERCP. Also, the size of the stone was an independent risk factor that affected the outcome of ERCP.

Keywords: Choledocholithiasis, ERCP, CBD, Sphincterotomy

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was first introduced in 1968.[1] ERCP is commonly performed for the management of choledocholithiasis, diagnosis and management of biliary and pancreatic neoplasms, and postoperative management of biliary perioperative complications.[1] Bile duct stone management has changed dramatically in the last two decades when open surgery has been replaced by per-oral endoscopic procedures.[2,3] Nowadays, therapeutic endoscopic retrograde cholangiopancreatography is performed worldwide as the first approach in the management of extrahepatic bile duct stones and is superior to surgical or percutaneous approaches, although it can be challenging in some cases.[4-7] Endoscopic therapy involves stone extraction using conventional methods after performing endoscopic biliary sphincterotomy. The routine devices used for stone retrieval are balloon catheters, dormia baskets and mechanical lithotripters.[8] Alternatively, other therapeutic options such as intra or extracorporeal shock wave

lithotripsy may offer adjuvant therapy in selected patients or in particularly challenging cases.[9,10] Patients not achieving stone clearance post-ERCP require open or laparoscopic surgical choledocholithotomy.[11-13] ERCP carries an overall risk of adverse events of 7% or less and mortality rate not more than 0.1%.[14,15] Adverse events of ERCP include pancreatitis, bleeding, infection, perforation and sedation-related cardiopulmonary events.[16] Pancreatitis is the most common serious complication related to ERCP.[17] The incidence of post ERCP pancreatitis ranges from 1.6% to 15.7%, depending on patient selection. Hemorrhage is primarily a complication related to sphincterotomy. Hemorrhagic complications may be immediate or delayed, with recognition occurring up to 2 weeks after the procedure.[18] Perforation during ERCP may occur during sphincterotomy or may be induced by guidewire. Alternatively, luminal perforation may occur at a site remote from the papilla i.e. in the first part of duodenum.[19] Perforation rates with ERCP range from 0.1% to 0.6%. The rate of post-ERCP cholangitis is 1% or less.[20] The overall mortality rate after diagnostic ERCP is approximately 0.2%.[21,22] Death rates after therapeutic ERCP are twice as high (0.4%-0.5% in 2 large prospective studies). The aim of the present study was to evaluate the outcome of ERCP in choledocholithiasis in a tertiary care centre. The outcome of the patient with regards to the size, site and number of calculi in the common bile duct is not well analyzed before thoroughly which has been studied in our study.

METHODS

Study design, location, population and sample size

Current study was retrospective observational studies performed on surgical in-patients admitted to a tertiary care hospital; B. Y. L. Nair Hospital and T. N. M. C., Mumbai, Maharashtra. Number of cases studied were 50 from January 2017 to October 2017.

Method of data collection

After admission to the hospital, data was collected from the patient's records regarding the clinical features & investigations and based on the results they were diagnosed to have either surgical jaundice or medical jaundice. Those patients diagnosed to have surgical jaundice were assessed preoperatively and patients with choledocholithiasis on ultrasonography and/or contrast computed tomography of the abdomen and pelvis were subjected to ERCP procedure. Postoperatively patients' condition was assessed and complications were documented.

Inclusion and exclusion criteria

Age more than 18 years, patient's investigations suggesting towards obstructive jaundice due to choledocholithiasis were included in the study. Age less than 18 years, medical jaundice and pregnant patients were excluded from the study.

Technique

Endoscopic retrograde cholangiopancreatography was performed and the stone size and number were recorded from the cholangiograms. CBD was cannulated selectively and sphincterotomy was performed using a diathermy unit with a cutting current and stones were extracted using a balloon catheter or a dormia basket. CBD stenting was done in all cases. One case with acute cholangitis underwent a naso-biliary drainage with double pigtail stenting.

Statistical analysis

Statistical analysis of the data was performed with Statistical Package for Social Sciences (SPSS) version 18 (SPSS Inc., Chicago, IL, United States) package software. Continuous variables were expressed as mean (±standard deviation), and median (interquartile range: 25-75 percentiles) when available, and categorical variables were expressed as number and percentage. Student's *t*-test was used to compare the groups with continuous variables while Pearson Chi-square test and Fischer exact Chi-square test were used to compare groups with categorical variables. Results with p values less than 0.05 were defined to be statistically significant.

RESULTS

The demographic distribution of our study was as shown in the (Figure 1). Age distribution in our study was from 27 years to 81 years of which, 46% were males and 54% were females. The most common age group was 31 to 70 years (90%). The peak age group was 31-40 years. The most common presenting symptom was pain in the abdomen (96%) followed by the presence of jaundice (80%). The most common clinical sign elicited was icterus, present in 80% patients followed by right hypochondriac tenderness which was present in 56% patients. >6 mg% bilirubin was found in 21 patients (42%) whereas three patients (14%) were found to have a normal serum bilirubin. Marginal elevation of direct bilirubin (upto 1 mg%) was found in 16% of patients. Elevation >1 mg% was found in the remaining patients (84%). Alkaline phosphatase was raised in all cases. Marginal elevation (upto150 IU/l) was found in 10% cases. Elevation >150 IU/l was found in 90% cases. CBD dilatation was found in 100% cases on USG and was confirmed on ERCP. Marginal duct dilatation (≤ 10 mm) was found in 30% cases. Rest of the patients (70%) were found to have CBD dilatation >10 mm.

Maximum numbers of stones were in the dimensions of 5-10 mm in diameter (50%). The most common site of CBD calculus was distal CBD i.e. 25 patients (50%). Obstructive jaundice due to a single calculus was found in most of the patients (72%) and 28% had multiple calculi. (Figure 2).

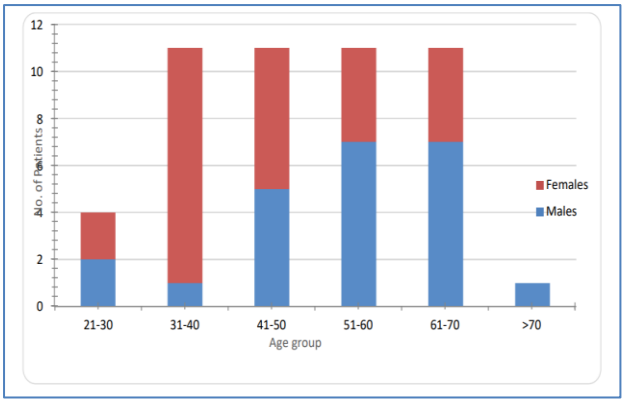

Figure 1: Age and sex distribution.

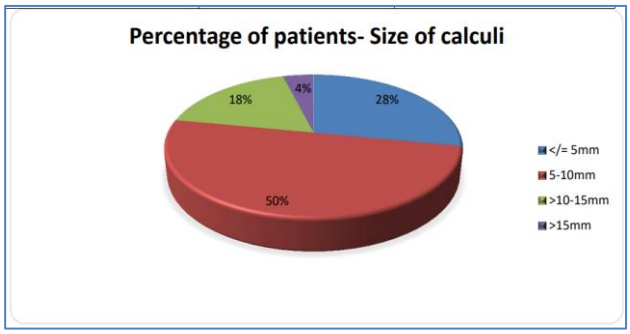

Figure 2: ERCP findings: size of the calculi.

Endoscopic sphincterotomy with balloon sweeps was the most common procedure performed. (72% patients). Sphincterotomy with dormia basket retrieval was done in 4% of the patients for the patients with fragmented stent and for one with impacted stone. CBD stenting alone without calculus extraction was done in 11 patients (22%). Out of these patients, 8 patients were referred for repeat ERCP and 3 were referred for surgery. In one patient of acute cholangitis with CBD calculus, a naso-biliary drain and a double pigtail stent was placed initially and the patient was subsequently subjected to repeat ERCP and stone was retrieved. (Figure 3). All the patients underwent stenting. All the CBD stents inserted were temporary. Out of the 50 patients, two patients (4%) developed cholangitis following the procedure. This was treated with intravenous antibiotics. Two patients (4%) developed bleeding at the time of ERCP which was treated with heat coagulation probe and adrenaline injection. Five patients (10%) developed pancreatitis post-operatively, all of which were mild and self-limiting confirmed by rise in the levels of serum amylase. There was no biliary leak, bile duct perforation or retro-duodenal perforation reported during the study. One patient (2%) developed severe cholangitis leading to sepsis and death (Table 1). Successful clearance of CBD with balloon sweep, dormia basket, CBD stenting or sphincterotomy alone was done 38 patients (76%). Nine patients (18%) required repeat ERCP/ more than one sitting for clearance of CBD. Most of the patients had stone size of >10 mm (8 out of 9 patients i.e. 88.89%). Three patients were referred for surgical intervention due to non-retrieval of calculus. All these patients had stone size >15 mm (100%). Out of the 50 cases, only one died because of severe cholangitis and sepsis due to repeat ERCP.

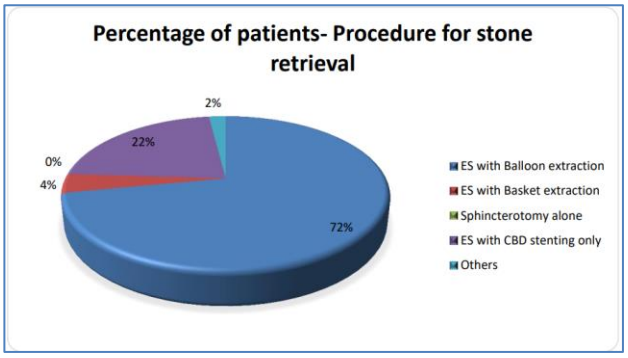

Figure 3: ERCP procedure done.

Table 1: Complications of ERCP.

Complications	Number of patients	Percentage of patients
Pancreatitis	5	10
Cholangitis	2	4
Bleeding	2	4
Bile duct injury	0	0
Sepsis	1	2
Retroduodenal perforation	0	0
Others	1	2

Table 2: Outcome of patient post-ERCP compared to size of calculus.

Size of calculus		Successful clearance	Repeat ERCP	Surgery	Total
≤5	N	14	0	0	14
	%	100	0	0	100
>5-10	N	24	1	0	25
	%	96	4	0	100
>10-15	N	0	8	1	9
	%	0	88.89	11.11	100
>15	N	0	0	2	2
	%	0	0	100	100
Total	N	38	9	3	50
	%	76	18	6	100

Continued.

Size of calculus	Successful clearance	Repeat ERCP	Surgery	Total
Chi-square test applied	**Value**	**P value**	**Difference is**	
Pearson Chi-square test	39.64	<0.00001	Significant	

None of the patients with stone size >10 mm had successful CBD clearance and 8 out of the 11 (72.72%) were referred to repeat ERCP and 3 were referred for surgery. Patients with stone size of >15 mm were referred for surgery (open CBD exploration; 2 of 2 patients). Thus, the outcome was significant with respect to the size of calculus (Table 2). The outcome was not significant with respect to the size of the CBD, the site of the stone, the number of stones.

DISCUSSION

Surgical jaundice is a common condition of biliary tract disorders and the evaluation and management of the jaundiced patient is a common problem facing the general surgeon. All patients of jaundice admitted in a tertiary care hospital were subjected to detailed clinical history and a complete physical examination. Based on the above findings, patients with jaundice underwent a battery of biochemical and serological investigations; USG of the abdomen and CECT scan of the abdomen. Those patients diagnosed with choledocholithiasis were included in our study. Choledocholithiasis is the commonest cause of obstructive jaundice.[25,26] In our study, we have analyzed the cases of choledocholithiasis causing surgical jaundice, their presentations and these patients were subjected to ERCP and various stone retrieval procedures. The total number of cases in our study were 50 patients. In our study, the peak incidence of surgical jaundice was seen in age group of 31 to 70 years with M:F ratio=1:1.17. This is in concordance with the findings of Sutton et al who reported the commonest age presentation of 65.7 years with a M:F ratio of 1:3.[16]

Benjaminov et al in their study also reported a M:F ratio of 1:1.06 with a peak incidence in the age group of 51-70 years.[23] In our study, the most common presenting symptom was pain in abdomen (96% patients) followed by jaundice (80%).

In his study, Saluja et al also reported that 42 out of 58 cases (72%) presented with pain in the abdomen as the most common symptom.[24] Total Sr.bilirubin was found normal in 14% of the patients despite obstruction which can be attributed either to a partial or intermittent obstruction. This favors Giannini et al who stated that biliary obstruction can cause varying degrees of hyperbilirubinemia, the severity depending on degree and duration of obstruction and functional reserve of liver.

Sr.direct bilirubin levels were raised in almost all of the patients suggesting that high levels of direct bilirubin as an indicator of obstructive jaundice. This is in concordance with a study carried out by Beckingham et al who reported rise in the levels of conjugated fraction of bilirubin in all cases of obstructive jaundice.[23]

Sr. Alkaline phosphatase was raised in all cases of our study. This is also in accordance with Thornton et al who concluded that Sr. ALP is good indicator of biliary tract obstruction.[25] Notash et al reported 72.1% specificity of ALP in diagnosing choledocholithiasis. Also, Giannini et al had explained that levels of ALP remain elevated long time even after resolution of obstruction.[4] USG abdomen was carried out in all patients in this study as a standard first line investigation and as a screening test, as was concluded by Deitch et al. It was successful as the cheapest non-invasive technique of detecting site and level of obstruction in most of the cases. CBD dilation was picked up very effectively on USG and was found in all cases. This is in accordance with the conclusion of Singh A et al who found USG to be good non-invasive and cheaper tool with 88% accuracy to diagnose biliary tract obstruction.[26] Thornton et al found USG to be 90% sensitive and 95% specific for diagnosing choledocholithiasis.[25,26] CT scan was used to confirm the USG findings. In our study, ERCP was successful in diagnosing all cases of CBD stones. Cannulation was successful in 100% of the cases. This favors a study by Sahoo et al with 90.2% successful cannulation rate and a study by Swan et al with 100% cannulation.[27,28]

Endoscopic sphincterotomy was performed in 100% cases which is comparable to a study by Lauri et al who reported 85% cases (in a series of 100 cases) undergoing endoscopic sphincterotomy (ES).[29] Endoscopic Sphincterotomy with stone retrieval with balloon tip catheter was the most common procedure carried out for stone extraction in our study (36 patients). Successful complete clearance of CBD with ES and balloon/ basket retrieval with or without stenting was achieved in 76%, in comparison to Liu et al with stone extraction rate of 88% and Benjaminov et al with 83.4% success rate in their series of 80 patients.[30] CBD clearance was not achieved in the first sitting in 24% (12 cases). They were subjected to repeat ERCP. Of these, 9 cases were subjected to repeat ERCP and 3 were referred for surgery. This is comparable to incomplete clearance in meta-analysis made by Anthony et al who found 12% referral to surgery.[31] The failure rate in large study of 10,000 cases by Bilbao et al is around 30%, and that of Sahoo et al for ERCP for stone clearance is 29%.[27] This is also in accordance with a study by Benjaminov et al who required more than one sitting in 3 out of 80 cases (3.7%) for CBD clearance. Most of these patients with incomplete CBD clearance (88.89%) had CBD stone of size >10 mm. This follows a large meta-analysis by Anthony et al who found stone size >10 mm affecting the success of ERCP.[31] Lauri et al in 100 ERCP cases,

cleared only 12% CBDs having stones >15 mm.[29] None of the patients with calculus size >15 mm had clearance of CBD. In our study, the outcome of ERCP was not dependent on the number or site of the calculus or the diameter of CBD. The procedure related complication rate in our study was 20% cases. This is comparable with complication rates in a study of 2000 patients carried out by Katsinellos et al which was 16%.[32] The complication of pancreatitis was seen in 10% cases, bleeding was seen in 4% cases, cholangitis was seen in 4% cases and retroduodenal perforations was seen in none of the cases. This is comparable to a study by Katsinellos et al with complication rates being 4.9% for pancreatitis, 4.5% for bleeding, 2.3% for cholangitis and 0.11% for retroduodenal perforations.[32] Benjaminov et al in his study of 80 patients also reported a total complication rate of 5% with 2.5% rate of pancreatitis, 1.2% rate of bleeding and 1.2% rate of retroduodenal perforations.

Limitations

Current study has the limitation of small sample size. The study is also limited by the advanced stone extraction methods which are not available at our institute.

CONCLUSION

ERCP is a highly effective method in the treatment of CBD stones. In current study 94% of the patients eventually achieved successful clearance after ERCP. Also, the size of the stone was an independent risk factor that affected the success of ERCP.

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