

A Comparative Study between ERCP Stone Removal vs. Open CBD Exploration in Management of Choledocholithiasis

Anindita Bhar¹, Sagar Karmakar²

¹Associate Professor, Department of General Surgery, K.P.C. Medical College, Kolkata, West Bengal.

²Assistant Professor, Department of Ophthalmology, Burdwan Medical College, Burdwan, West Bengal.

ABSTRACT

BACKGROUND

Common bile duct stones (choledocholithiasis) generally lead to several health problems such as pain, jaundice, infection, acute pancreatitis etc. For which it needs surgical intervention. We conducted this study to compare success and complication rate between ERCP stone removal and open CBD exploration.

METHODS

A total of 50 patients were selected from those attending Department of Surgery of KPC Medical College and were divided in two groups randomly, with 25 patients in each group. Group I patients underwent ERCP stone removal while those in Group II were subjected to open CBD exploration. Both the groups were compared on the basis of their success and complication rate, time taken for the procedure, time taken to return to work, and duration of hospital stay.

RESULTS

A total of 50 patients were selected, with mean age being 37.5 ± 11.71 yrs., 62% were female and 38% male. In Group I success rate was 92% and in Group II it was 96%. Complication rate was significantly more ($p=.032504$) in Group II (45.83%) compared to that in Group I (13.04%). Time taken for the procedure in Group I (36.09 ± 6.39 mins) was much less than that in Group II (120.63 ± 11.92 mins). Mean duration of hospital stay in group I was 2.91 ± 1.08 days while in Group II it was 11.79 ± 1.58 days. 8.35 ± 1.61 days were taken to return to work in Group I compared to 20.53 ± 1.95 days in Group II.

CONCLUSIONS

This comparative study of CBD stone removal is a small endeavour on our part to assess the advantages of ERCP stone removal. With appropriate infrastructure ERCP stone removal carries a greater advantage compared to that by open surgery.

KEYWORDS

Common Bile Duct Stone, ERCP, Open Surgery

Corresponding Author:

*Dr. Sagar Karmakar,
Flat 4A, Basera Apartment,
224/3, N.S.C. Bose Road,
Kolkata-700047, West Bengal.
E-mail: sagarda123@gmail.com*

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BACKGROUND

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 preformed.¹ They are either primary or secondary stones. Primary stones form in CBD due to stenosis as a result of an ampullary stenosis or stricture of CBD or a hugely dilated CBD, secondary stones originate in the GB and then pass to CBD.² Common bile duct stones are the most common cause of obstructive jaundice, cholangitis and pancreatitis. Prolonged obstruction may lead to impairment of liver function which may progress to biliary cirrhosis. Most surgeons should come to the consensus that CBD stone once diagnosed should be removed. There are different approaches for removal. One has to choose the ideal approach depending on technical success, safety and cost effectiveness. 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 CBDS such as electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), dissolving solutions, and laser lithotripsy.³ Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) and basket or balloon extraction are well established therapeutic procedures for the management of CBD stones. It is estimated that nearly 85%-95% of all CBD stones can be managed effectively by these conventional endoscopic methods.⁴ Recent advances in the endoscopic removal of stones followed by cholecystectomy has greatly reduced the mortality and morbidity associated with the operation. Open CBD exploration has a long and successful history but it has its own drawbacks e.g. prolonged manoeuvre time, increased mortality, morbidity, invasiveness, prolonged hospital stay, and delayed return to work in contrast to ERCP stone removal.

In this observational study we are to find if there is any advantage of endoscopic removal of CBD stone over clearance of stone by open surgery in respect of operating time, duration of hospital stay, time to return to work and post-operative complications. We will also try to find that which procedure is more successful.

METHODS

This study was conducted in Department of Surgery of K.P.C. Medical College from 1st January 2014 to 31st December 2016. A total of 50 patients of choledocholithiasis admitted in department of surgery from 1st January 2014 to 31st December 2016 matching our criteria were selected for this study. Our criteria for selection were as follows:

Inclusion Criteria

- Age >18 yrs.

- Ability and willingness to give informed consent.
- Choledocholithiasis – suggested by USG or MRCP.

Exclusion Criteria

- Clinical or sonographic evidence of suppurative or necrotising cholecystitis, gall bladder empyema or perforation.
- Clinical, radiological (USG or CT) and/or biochemical evidence of cirrhosis, portal vein thrombosis, intrahepatic gall bladder, liver mass or abscess and periampullary neoplasm.
- Pregnancy

The study population was then divided in two groups, group I and group II. Cases with stones (<12 mm) in lower end of CBD were subjected to ERCP (Group I) and those having more than 12 mm stone in upper end of common bile duct were selected for open CBD exploration (Group II). For ERCP removal patient was placed in left lateral position under anaesthesia. After insertion of endoscope the papilla was identified. Guide wire inserted through papilla, Inj. Buscopan given to relax the papilla. Position of guide wire in CBD was confirmed under fluoroscopic guidance and by aspiration of bile. Dye injected for confirmation of CBD pathology. Papillotomy done between 11 o'clock and 1 o'clock preferably at 12 o'clock. After that endoscopic balloon was inserted and inflated beyond the stone for removal of small stones and/or sludges. For bigger stones lithotripsy followed by removal of fragments (by the same procedure) and endoscopic stenting was done.

For open CBD exploration patient was given GA and placed in supine position. Abdomen opened, CBD identified. Stones were removed after vertical choledochotomy on anterior wall of CBD. In most of the cases after obtaining complete clearance of ductal system, CBD was closed (by 2-0 Vicryl) with T-tube (usually 14 Fr) in situ. After 7 days intermittent T tube clamping was done for 2 days followed by 24 hrs clamping, if patient had no symptoms like pain abdomen, bile leak, fever, jaundice etc., it was removed. If chance of recurrent stone suspected or stricture in lower CBD present than biliary enteric drainage (choledochoduodenostomy or choledochojejunostomy with jejunojejunostomy) done. In our study we have found two such cases, in one case there was multiple stones in CBD and in another case a benign stricture of lower CBD was suspected in MRCP.

Patients after discharge were followed up for one month. They were enquired about pain, dyspepsia and raised bilirubin.

Statistical Analysis

Data was presented as actual numbers and percentages, Epi Info and MedCalc software were used to find out statistical significance, $p < 0.05$ was considered as significant.

RESULTS

The mean age of study population was 37.5 ± 11.71 yrs. and ranged from 20 yrs. to 68 yrs. Out of them 32 patients (64%) were in 20 yrs. to 40 yrs. age group, 16 (32%) were in age group of 41- 60 yrs. and 2 patients were more than 60 yrs of age. In group I, 17 patients were in 20-40 yrs. group, 7 in 41 - 60 yrs. group. Only one patient was above 60 yrs. In group II, 15 patients were in the first age group i.e. 20-40 yrs., 9 of them in 41-60 yrs. group and one was above 60 yrs. In the study population 31 (62%) were female and remaining 19 patients (38%) were male. Out of them 17 patients of group I and 14 of group II were female and 8 patients of group I and 11 patients of group II were female. All 50 patients presented with abdominal pain, 45 of them had jaundice in addition, 20 had fever with chill and pruritus was present in 7 of them. Mean bilirubin level of the study population was 7.29 ± 5.07 mg/dl ranging from 1.2 to 24 mg/dl.

Table 1 shows that successful stone removal was more with open surgery i.e. group II (96%) compared to that by ERCP (group I), but this higher success rate is not statistically significant. In rest of the study the total number of patients in group I was taken as 23 as 2 patients had ERCP failure and in group II 24 as 1 patient has retained CBD stone. These failures were not calculated in both the groups. Table 2 shows that the mean time taken for the procedure/operation was more in group II (120.63 ± 11.92 mins) compared to that in group I (36.09 ± 6.39 mins), which was found to be statistically significant. In Table 3 we can see that the mean duration of hospital stay in group II (11.76 ± 1.56 days) was much higher than that in group I (2.91 ± 1.08 days) and which was found to be statistically significant.

	Type of Surgery	
	Gr I (n=25)	Gr II (n=25)
Success	23	24
%	92	96

Table 1. Distribution of Study Population on the Basis of Success Rate in Different Groups

χ^2 (Yates corrected) = 0.355 df=1, p = .5515, Non-Significant

Group	Mean \pm SD (mins)	Range (mins)	Median (mins)
I (n=23)	36.09 \pm 6.39	25-50	35
II (n=24)	120.63 \pm 11.92	105-150	120

Table 2. Distribution of Study Population on the Basis of Mean Time Taken for the Procedure in Different Groups

Difference = 84.540, Standard error = 2.808, 95% CI = 78.8850 to 90.1950, t-statistics = 30.110, DF = 45, p<0.0001 (Highly significant)

Group	Mean \pm SD (days)	Range (days)	Median (days)
I (n=23)	2.91 \pm 1.08	1-5	3
II (n=24)	11.79 \pm 1.58	10 - 16	11

Table 3. Distribution of Study Population on the Basis of Mean Duration of Hospital Stay in Different Groups

Difference = 8.880, Standard error = 0.396, 95% CI = 8.0815 to 9.6785, t-statistics = 22.397, DF = 45, p<0.0001 (Highly significant)

Group	Mean \pm SD (days)	Range (days)	Median (days)
I (n=23)	8.35 \pm 1.61	7-12	8
II (n=24)	20.63 \pm 1.95	18 - 26	20

Table 4. Distribution of Study Population on the Basis of Mean Time Taken to Return to Work after Operation in Different Groups

Difference = 12.280, Standard error = 0.523, 95% CI = 11.2269 to 13.3331, t-statistics = 23.486, DF = 45, p<0.0001 (Highly significant)

Table 4 shows the mean time taken to return to work after operation was more in group II (20.63 ± 1.95 days) than group I (8.35 ± 1.61 days) and which was found to be statically significant.

Study Population	Group I (n= 23)	Group II (n=24)	Total
Complicated	3 (13.04%)	11 (45.83)	14
Non- complicated	20 (86.96%)	13 (54.17)	33
Total	23 (100%)	24 (100%)	47

Table 5. Distribution of Study Population According to Complication Rate in Different Groups

χ^2 (Yates corrected) = 4.5717, df=1, p= .032504, significant

In table 5 we can see that post-operative complications was more in group II (45.83%) compared to group I (13.04%) and this higher rate of complication in group II was found to be statistically significant.

DISCUSSION

There is no consensus on the better therapeutic approach (endoscopic vs surgical) to choledocholithiasis. In past i.e., in era of open surgery and even in early endoscopic era open bile duct surgery seemed superior to ERCP in achieving common bile duct stone clearance based on the evidence available but with advent of endoscopic surgery it is becoming one of the most popular procedure for removal of CBD stones.⁵ The impact of endoscopic surgery on the management of stones in the CBD was studied in 2005 by I G Martin, P Curley, M J McMohan. Their experience suggested that open exploration of CBD will become increasingly infrequent and may be replaced by endoscopic surgery in the majority of patients.⁶

In a study in Kyorin university school of Medicine by Sugiyama et al it was revealed that Endoscopic sphincterotomy is a reasonable method of treating CBD stones even in young patients.⁷ A review was done on surgical versus endoscopic treatment of bile duct stones in 2006 by D J Martin, D R Vernon, J Toouli to systemically review the management of CBD stones by different approaches. They concluded that in the era of open cholecystectomy open bile duct surgery was superior to ERCP in achieving CBD stones clearance. In the laparoscopic era data are close to excluding a significant difference between laparoscopic and ERCP clearance of CBD stones. Similar conclusion was also drawn by Martin DJ et al.^{8,9} In spite of such findings we should not regress and consider open exploration of CBD as first and only approach, it should however be considered as a reliable and highly effective technique not to be forgotten and one that surgeons dealing with the biliary tree should be proficient equipped to apply when circumstances dictate.¹⁰

The mean age of study population was 37.5 ± 11.71 yrs. and ranged from 20 yrs. to 68 yrs. In a study by Helmy MZ et al, a total of 120 patients were randomized to the treatment of CBD stones. The ages of patients ranged from 20 to 80 (mean = 40) years,¹¹ The mean age of our study is more or less in agreement with this study of Helmy MZ. In a study by Ghazal AH et al it was seen that mean age was

45.07+ 11.3 yrs.¹² In many other studies we found that mean age is in close proximity of 55 yrs. with a range between 35 to 55 yrs.^{13,14,15}

In our study population 31 (62%) were female and remaining 19 patients (38%) were male, out of them 17 patients of group I and 14 of group II were female and 8 patients of group I and 11 patients of group II were male, thus we found a female preponderance with female:male proportion being 1.63:1. Similarly in study by Helmy MZ et al, female: male ratio was 1.6:1. (female/male = 74/46). In other studies, by K. K. Tamrakar, Way et al it was seen that the ratio was 3:1 to 2:1.^{16,17} Our study revealed all 50 patients presented with abdominal pain, similarly in the study by Kishore Kumar et al, all patients presented with right upper quadrant pain. Of the 50 patients in our study 45 had jaundice in addition, 20 had fever with chill and pruritus was present in 7 of them. Mean bilirubin level of the study population was 7.29 ± 5.07 mg/dl ranging from 1.2 to 24 mg/dl.

In our study, in group I, two patients had failure of ERCP stone removal. One of them had a large impacted stone above narrow segment, other one had an anatomical abnormality of periampullary duodenal diverticula and both of them were managed later by open surgery. In group II, one patient had failure who had a retained stone. For rest of the study these failures were not calculated thus total number of patients in group I was taken as 23 and that in group II as 24. So our study revealed that patients undergoing ERCP stone removal had a success rate of 92% compared to that of 96% in patients treated by open surgery. In a study done by Dr. P. V. Durga et al success rate in ERCP/ES was 86.36%.¹⁸ In another study by Lambert et al sphincterotomy was accomplished in 91.5 per cent & bile ducts were demonstrated to be completely cleared of stones in 81.6 per cent.¹⁹ In another study by Bose et al success rate was 74%.²⁰ These data more or less conforms with our study.

In a study by Alaa A Redwan et al they found a median operative time of 30 (20-45)mins in patients undergoing endoscopic stone removal with a hospital stay of 1 (1-2) days while time taken in patients undergoing open surgery was 90 (60-180)mins with a median hospital stay of 8 (5-12) days.²¹ These data are very close to our study which revealed that the median operative time taken in ERCP group was 35 (25-50) mins and 120 (105-150)mins for open surgery group with a hospital stay of 3 (1-5) days and 11 (10-16)days in either group respectively. Thus in our study mean operative time in group I (36.09 ± 6.39)mins is much less than group II (120.63 ± 11.92)mins and was found to be statistically significant while mean hospital stay was also prolonged for group II (11.76 ± 1.56) days compared to group I (2.91 ± 1.08)days and this was also statistically significant.

In our study we have found a mean hospital stay of 11.76 ± 1.56 days in group II i.e. those treated by open surgery while it was 2.91 ± 1.08 days in ERCP group (Group I). Median hospital stay in ERCP group being 3 days and that

in open surgery group was 11 days. Thus it can be seen that hospital stay in open surgery group is more than ERCP group. In our study we have found this association to be statistically significant. Similar findings were seen in many studies e.g. studies by Stain SC e alt, Suc B, they all found a prolonged hospital stay for open surgery group.^{22,23}

In the study by Alaa A. Redwan et al they found that the time taken to return to work was 3 (2-5) days in endoscopically treated patients while it was 14 (12-20) days in patients treated by open choledocholithotomy and T-tube insertion. Similarly, in our study we found a significantly shorter time needed to return to work in patients subjected to ERCP stone removal compared to that in open surgery. Study by Lein Ray Mo et al revealed immediate post-operative complications in 8 patients out of 141 patients i.e. 5.67%, in whom ERCP stone removal was successful. 3 patients had post ERCP pancreatitis and 3 had post ERCP cholangitis.²⁴ In another study by Melvin WS et al it was seen that in open CBD exploration there was bile leak in 2-6% of cases and surgical site infection in 10% cases.²⁵ In a study by Xiao-Dong Zhou et al bile leak found in 2.3% in open CBD exploration.²⁶

In our study we have found complication in 3 patients out of 23 patients (13.04%) in group I out of which 2 patients had cholangitis and 1 was suffering from pancreatitis, all of them were treated conservatively. In group II 11 patients out of 24 (45.83%) developed complications, of them 8 (33.33%) had superficial wound infection, which was also managed conservatively, 3 (12.5%) had bile leak through drain (two of them had spontaneous stoppage of leak, one managed with endoscopic stenting). Thus we can see that complication is higher in group II compared to that in group I and which was found to be statistically significant ($p = .032504$).

At one month follow up in group I three patients had mild pain, two had dyspepsia and one had mild raised bilirubin while in group II five patients had pain abdomen, five had dyspepsia, one had mildly raised bilirubin. In subsequent follow up these patients became symptom free by conservative management.

CONCLUSIONS

Current means of endoscopic sphincterotomy and removal of CBD stones is associated with definite advantage in terms of duration of procedure, duration of hospital stay, time to return to work and early and late complications. However this procedure carries comparatively increased chance of failure due to difficult anatomy, stone size, stone impaction and endoscopic expertise. These can be overcome by improved techniques and constant training. Although this procedure may be a first line of treatment for the patients with CBD stones irrespective of age of patients, still open CBD exploration has got its place in our health set up till we can reduce the failure rate of endoscopic removal of stone.

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