

# Management of borderline common bile duct stones: Retrospective comparative study

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## Background

Borderline Size common bile duct stones (BLS-CBDS) are associated with hepatopancreato-biliary morbidity and complications. Its optimum management is still controversial till now.

## Aim

Is to compare conservative treatment versus endoscopic retrograde cholangiopancreatography (ERCP) for the treatment of BLS-CBDS.

## Material and methods

This retrospective study included patients with BLS-CBDS less than or equal to 10 mm who were treated conservatively or by ERCP endoscopic stone extraction followed by laparoscopic cholecystectomy (LC). The primary outcome was successful common bile duct (CBD) clearance, and the secondary outcomes were complications, impact on laparoscopic cholecystectomy, and hospital stay.

## Results

Out of 270 patients, 150 were treated by ERCP and 120 by the Conservative approach. There was complete clearance of CBDS in 75 (50%) patients out of 150 patients in the ERCP group and useless procedure in the remaining 75 (50%) patients. In the conservative group, there was complete clearance of CBDS in 99 (82.5%) cases, and useless in the remaining 21 (17.5%) patients. Post-ERCP pancreatitis occurred in 33 (22%) patients.

## Conclusion

BLS-CBDS increases the technical difficulty of ERCP and the risk of post-ERCP pancreatitis. Conservative management of CBDS is effective in clearing CBDS, it should be considered to avoid unnecessary ERCP and its complications.

## Keywords:

borderline size common bile duct stone, endoscopic retrograde cholangiopancreatography, GB stone, obstructive jaundice

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**Authors Contributions:** All authors participated in the concept and design of the study, selecting patients, performing the procedures and following up of the studied cases, and collection of data. A. performed the statistical analysis and wrote the primary draft of the study manuscript. T. refined, edited the manuscript to its final form, and is the corresponding author.

## Introduction

Gall Bladder stone disease is one of the most widespread digestive disorders in the world, it affects more women than men as they are twice as likely to develop this condition [1].

Cholelithiasis, or the presence of stones in the common bile duct, is one of the frequent consequences of gallstone disease and affects 3–15% of individuals with gallbladder stones who have cholecystectomy [2,3]. The stones may be clinically asymptomatic, only causing an increase in bilirubin and liver

enzymes, or they may cause biliary colic, jaundice, or more serious complications like acute pancreatitis, acute cholangitis, or liver abscesses, which can be life-threatening, and always happen suddenly [4].

Over the past few decades, management of symptomatic common bile duct stones (CBDS) has changed [5]. Laparotomy, CBD exploration, and T-tube insertion were the surgical procedures used to treat CBD stones prior to the development of laparoscopy and endoscopy. Laparoscopic CBD exploration, endoscopic sphincterotomy, and endoscopic retrograde cholangiopancreatography have all replaced the open surgical techniques in recent years [6].

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Endoscopic retrograde cholangiopancreatography (ERCP), which has 100% specificity [7] and is thought to be successful in 85–95% of all CBDS [8,9], is considered the gold standard method for the detection and treatment of CBD stones. However, cholangitis, retroperitoneal perforation, postsphincterotomy hemorrhage, post-ERCP pancreatitis, and anesthesia complications are all risks connected with ERCP [10]. Therefore, ERCP should only be done when clinically necessary.

Since magnetic resonance cholangiopancreatography (MRCP) detects up to 91% of CBDS, it has supplanted ERCP for the diagnosis of CBD stones [11]. However, only 71% of cases resulted in the detection of stones smaller than 5 mm. The following ERCP does not find any CBD stones in some individuals whose MRCP revealed they had CBD stones. These results imply that the CBD stones have already passed [12]. Numerous studies concluded that ERCP is occasionally a pointless procedure in around 40–60% of patients [13,14]. This is because stones may pass spontaneously before to the procedure, or the clearing of CBD may fail.

Given that ERCP may be technically challenging and that borderline size common bile duct stones (BLS-CBDS) have a greater chance of developing post-ERCP pancreatitis, there is debate about the best way to treat BLS-CBDS (6–10 mm) [15]. About 5–7% of ERCP cases results in post-ERCP pancreatitis, which is still the most dangerous and common complication [16,17]. In high-risk patients, particularly in BLS-CBDS, this number can rise to 20–40%. Moreover, according to a few studies, BLS-CBDS is best managed by conservative measures (spontaneous passing of the stone via the papilla) rather than by ERCP.

With regard to CBDS clearing, overall complications, technical challenges, hospital stay and the impact on subsequent laparoscopic cholecystectomy, this research is intended to compare conservative therapy to ERCP endoscopic extraction in the management of patients with BLS-CBDS and concomitant gall bladder stones.

## Patients and methods

This is a multicenter cohort retrospective comparative study that included patients with BLS-CBDS (6–10 mm) in diameter with concomitant gallbladder stones who were treated either by conservative medical treatment or endoscopic stone extraction (ERCP)

followed by laparoscopic cholecystectomy (LC) from June 2020 to June 2023 in the general surgery department, Qena University Hospitals, South Valley University, and Suez University Hospitals, Suez University, Egypt.

## Ethical approval

The study was approved by the local Institutional Ethical Committee of Qena Faculty of Medicine, South Valley University (SVU-MEDSUR011-4-23-3-600).

## Inclusion criteria

Ages between 15 and 80 with a CBD diameter of less than or equal to 10 mm with one or two common bile duct stones and the size of the stones was 6–10 mm and Serum bilirubin level was less than 10 mg/dl and Serum glutamic-pyruvic transaminase (SGPT)/serum glutamic-oxalo-acetic transaminase (SGOT) ratio less than 500 IU/and concomitant gallbladder stones.

## Exclusion criteria

History of acute cholecystitis, pancreatitis, or cholangitis. CBD diameter greater than 10 mm or stones size greater than 10 mm or patients multiple CBD stones (>2 stones). History of ERCP or previous cholecystectomy, and pregnant women.

Patients were included in this study and divided into two groups:

Group (A): Conservative medical treatment.

Group (B): ERCP.

Patients who had CBDS and concomitant gallbladder stones underwent routine laboratory investigations, such as liver function tests and imaging, as well as clinical evaluation. Before enrolling a patient in this study, a MRCP was performed to confirm the presence of stones in the CBD if an abdominal ultrasonography examination revealed gallbladder stones and suspicion of CBD stones with a CBD diameter less than or equal to 10 mm.

## Methods

### Conservative treatment group (A)

Patients received medical treatment in the form of antibiotics Cefoperazone (cefobid) (third-generation cephalosporin) twice daily, oral Urso-deoxycholic acid 450 mg (livagoal) three times daily, analgesics, and antispasmodics three times daily (Buscopan), and Rowachol three times daily for 7 days. These patients

were followed-up for improvement of clinical symptoms and serum bilirubin level, and an abdominal ultrasound (US) was carried out to assess the CBDS. Successful conservative treatment was defined as the spontaneous passage of the stone to the duodenum, confirmed by the abdominal US, and decreased serum bilirubin within 7 days.

**ERCP group (B)**

An ERCP procedure was carried out using a duodenoscope with side viewing. (Olympus side-viewing endoscopes TJF- 160VR are employed). After cannulation with the sphincterotome assisted with a guide wire, a contrast agent was injected through the sphincterotome to confirm the presence of CBD stones. A retrieval balloon or a stone retrieval Dormia basket was employed to remove the stones. Each ERCP was followed by an occlusion cholangiography (balloon catheter cholangiogram) to make sure that no stones were missed.

*Follow-up*

Serum bilirubin and serum amylase were done on the fifth day.

LC was carried out under general anesthesia, utilizing the traditional 4 trocar approach and CO<sub>2</sub> insufflation.

**Data collection**

Data was collected retrospectively from patient’s files. Data included patient age, sex, clinical symptoms

(pain, jaundice), perioperative laboratory and radiological investigations. The diameter of the CBD and stones number and size were based on MRCP findings. Perioperative and follow-up findings and complications were collected and tabulated (pancreatitis, bleeding, and perforation, cholangitis, operative time, difficulty of the surgery, hospital stay. In patients scheduled for laparoscopic cholecystectomy, degree of adhesion, intraoperative bleeding, and conversion rate, difficulty of the surgery, operative time in minutes, hospital stay were recorded.

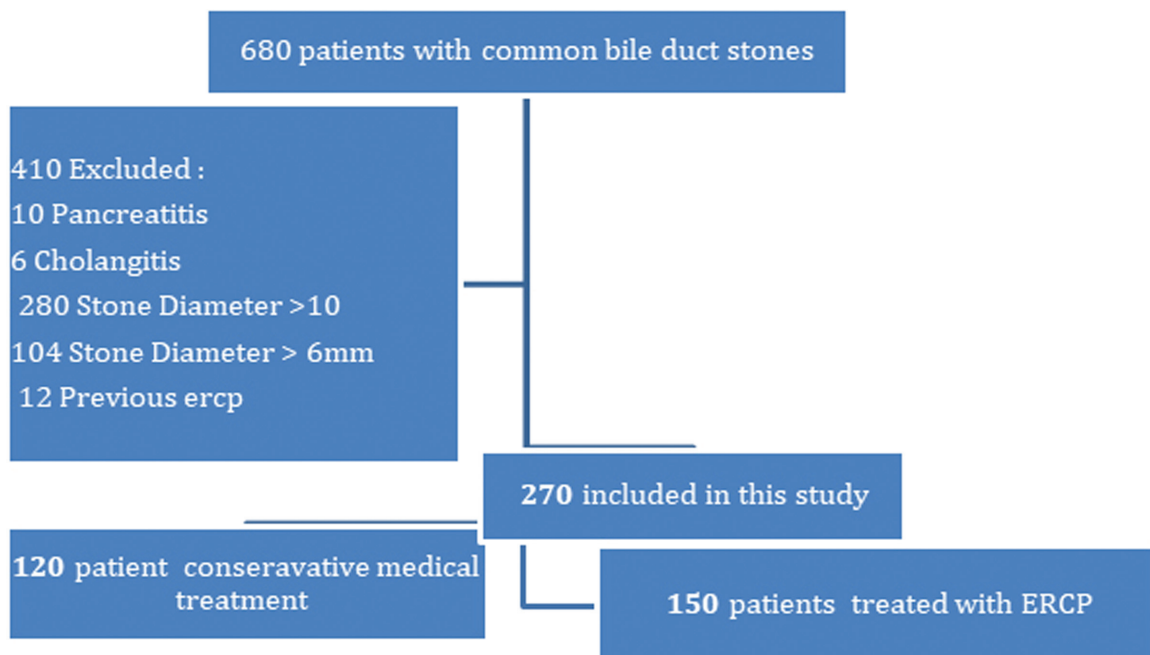
**Statistical analysis**

For statistical analysis, we utilized the SPSS program (Statistical Package for the Social Sciences ver. 26, SPSS Inc, Chicago, Illinois, USA). Statistical significance was defined as a probability value (*P*-value<0.05).

**Result**

During the study period from June 2020 to June 2023. 680 patients with CBD stones were presented to the general surgery department at Qena University hospitals, South Valley University, and Suez University. Of these 680 patients, 410 were excluded for several reasons, as given in the CONSORT diagram (Fig. 1), and 270 patients (198 patients in Qena University hospitals, and 72 patients in Suez gastroenterology hospital under protocol co-operation

**Figure 1**



Flowchart diagram show results of data collection.

between Suez University and Directorate of Health Affairs, Ministry of Health, Suez Governorate) were included in this study of whom 120 patients were treated using conservative medical treatment (Group A) and 150 patients were treated using ERCP and all patients were scheduled for LC within 3 weeks.

Their ages ranged from 19 years to 65 years, with a mean age of 42 years with a standard deviation of 23 in group (A), and ranged from 18 years to 67 years, with a mean age of 38 with a standard deviation of 20 in group (B). Female patients were 85 (70.8%) in group (A) and 107 (71.3%) in group B with male: female ratio was 1 : 2.4 in group (A) and 1 : 2.5 in group (B) as shown in Table 1.

Abdominal pain was in 107 (89.2%) patients in group (A) and in 129 (86%) patients in group (B). Jaundice was present in 103 (85.83%) patients in group (A) and in 125 (83.33%) patients in group (B). Total Bilirubin was slightly elevated in most of the 270 patients, the mean level of total bilirubin in the conservative group (group A) was 2.4 (0.3–9.8) mg/dl and it was 3.5 (0.3–9.9) mg/dl in the other group (group B). Alkaline phosphatase was 420.2±542.6 in group (A) and 404.6±424.6 in group (B). These results were summarized in Table 1.

As regards the mean diameter of CBD, it was almost the same in both groups as it was 8.3 (5–10) in group (A) and 8.6 (5–10) in group (B) and the mean size of

the stone was 4.2 (3–10) in group (A) and was 4.5 (3–10 mm) in group (B) which were not statistically different between the two groups and most of patients have single stones (Table 1).

Both groups were well matched in terms of demographic profile and the presenting clinical features. Abdominal pain was the predominant presenting feature in most of the patients (86–90%), and 83–86% of the patients presented with jaundice (Table 1).

The liver function tests were deranged in the majority of the patients so baseline characteristics to be compared included age, sex, and proportion of preoperative abnormal liver function tests. All baseline characteristics were not statistically different between the two groups (Table 1).

ERCP was performed in 150 cases with operative time between 25–96 min with mean of 36±30 min and successful cannulation was done in 138 (92%) patients and failed in 12 (8%) patients. In seven (4.66%) patients, precut papillotomy was required to perform biliary cannulation. Twelve (8%) patients had cannulation failure, with three cases being related to tiny papillae, two being due to juxta-diverticulum papillae, and seven being due to stones impacted in papillae. In 81 (54%) of the patients, CBDS, were entirely removed by balloon or Dormia basket, while stones passed naturally, and the CBD was free from

**Table 1 Demographic data**

Data	Group (A) conservative (n=120)	Group (B) ERCP (n=150)	P value
Age			
Range (years)	19-65	18-67	0.45
Mean±SD	42±23	38±20	0.74
Sex			
Male	35 (29.2)	43 (28.7)	0.78
Female	85 (70.8%)	107 (71.3)	0.67
M : F	1 : 2.4	1 : 2.5	
Clinically			
Jaundice	103 (85.83%)	125 (83.33%)	0.34
Pain in abdomen	107 (89.2%)	129 (86%)	0.67
Laboratory Investigations			
Serum bilirubin (mg/dl)	2.4(0.3–9.8)	3.5(0.3-9.9)	0.85
WBC cells/mm <sup>3</sup>	7.2 (4–12.4)	81 (3.4-16.4)	0.23
SGPT (IU/l)	75 (40-235)	55 (40-300)	0.78
SGOT (IU/l)	70 (40-190)	65 (40-259)	0.64
Alkaline phosphatase (IU/dl)	420.2±542.6	404.6±424.6	0.86
MRCP Findings			
CBD Diameter in mm	8.3 (5–10)	8.6 (5–10)	0.88
Stone size in mm	4.2 (3-10)	4.5 (3-10)	0.74
Single Stone	113	124	0.43
Two Stones	7	26	0.53

**Table 2 Endoscopic retrograde cholangiopancreatography group (group B)**

Parameter	Number of patients <i>n</i> =150 patients
Operative time	
Mean±SD	36±30
(Range)	25–96
Cannulation	
Successful cannulation	138/150 (92%)
Failed cannulation	12 (8%)
Number of patients with CBD stones during ERCP	75 (50%)
Number of patients passing stones naturally (Free CBD)	63 (42%)
Useless procedure (Passed stone + Failure of cannulation)	75/150 (50%)
Method of stone extraction	
Dormia basket extraction	85/138 (56.7%)
Balloon extraction	53/138 (43/33%)
CBD cannulation	
Standard	131/150 (87.33%)
Precut	7/150 (4.66%)
ERCP stent placement	11/150 (7.33%)
Complications	
Cholangitis (mild)	2 (1.3%)
Perforation (retroperitoneal minor)	1 (0.22%)
During ERCP Bleeding (minor to mild)	2 (1, 33%)
Post ERCP pancreatitis	33 (22%)
Mild pancreatitis	23 (15.33%)
Moderate pancreatitis	9 (6%)
Sever pancreatitis	1 (0.67%)

stone while doing ERCP in 63 (42%) of the patients. Biliary stents was inserted in 11 (7.33%) patients. In 75 (50%) cases, ERCP is a worthless operation, either due to natural passage of the stone in 63 (42%) patients or due to failed cannulation in 12 (42%) patients. Successful clearance of CBD was 82.5% in the group (A) and 54% in the group (B) (Table 2).

Regarding complications, pancreatitis was encountered in three (2.5%) patients in the conservative group

versus 33 (22%) patients in ERCP group. Most of cases (25 patients (9.25%)) were mild and were treated successfully by conservative management. Moderate pancreatitis was encountered in 10 (3.6%) patients which were admitted to ward and successfully managed conservatively. Severe pancreatitis was encountered in only in one (0.36%) post-ERCP case. The patient was admitted to intensive care unit for 7 days till improved, then shifted to ward and discharged home in day 12 (Table 3).

**Table 3 Outcomes of both groups**

Parameter	Group (A) conservative ( <i>n</i> =120)	Group (B) ERCP ( <i>n</i> =150)	<i>P</i> value
CBD clearance			
Successful	99 (82.5%)	75 (50%)	0.02
Useless	21 (17.5%)	75 (50%)	0.03
Serum amylase	48 (24–123)	78 (38–1230)	0.0013
Number of patients developing pancreatitis	3 (2.5%)	33 (22%)	0.0027
Mild pancreatitis	2 (1.67%)	23 (15.33%)	0.0024
Moderate pancreatitis	1 (0.833)	9 (6%)	0.0032
Sever pancreatitis	0	1 (0.67%)	0.23
Number of patients undergoing early LC	117 (97.5)	115 (76.67)	0.236
Number of patients undergoing delayed LC	3 (2.5%)	35 (32.33)	0.324
Conversion rate	1 (0.83%)	5 (3.33)	0.042
Adhesions	15 (12.5%)	78 (52%)	0.023
Hospital stay (days)	2 (0-5)	5 (1-8)	0.043
Follow-up			
Recurrent CBDS	0	1 (0.67%)	0.213
Recurrent cholangitis	0	5 (3.33%)	0.076
Recurrent pancreatitis	0	1 (0.67%)	0.235

Other low incidence complications was encountered in ERCP group, mild Cholangitis in two (1.3%) patients, retroperitoneal minor perforation in one (0.22%) patients and minor to mild bleeding in two (1, 33%) patients.

As regards the mean length of hospital stay, it was 2 (1–5) days in group (A) versus 4 (1–8) days in group (B) (Table 3).

Regarding conversion rate in laparoscopic cholecystectomy, it was significantly reduced in conservative group, one (0.83%) patient in group A versus 5 (3.33%) patients in ERCP group.

As regards the mean length of hospital stays, please add and to was 4 (1–8) days in group (B).

Interestingly, in patients' follow-up, recurrent CBD stones, recurrent cholangitis and recurrent pancreatitis were encountered only in ERCP group (Table 3).

## Discussion

Gallstone disease is a commonly encountered disease worldwide and its incidence increases with age and more commonly in females as compared with male patients [1]. Choledocholithiasis complicates 10–15% of gallstone disease [18]. Treatment of common bile duct stones is a surgical challenge as there are many options for treatments such as preoperative ERCP followed by LC either in the same session or in two separate sessions, CBD exploration either open or laparoscopy, and postoperative ERCP. CBD clearance using the laparoscopic technique is a popular minimally invasive method but requires laparoscopic skills that may not be readily available [19].

Spontaneous passage of CBD stones is a commonly observed clinical phenomenon that eliminates the need for invasive and expensive ERCP. Spontaneous CBD stone passage has been reported by many studies. A recent study by Lefemine *et al.* [20], reported that more than half of patients with obstructive jaundice had spontaneous passage of the gallstones from the CBD [20] and in another study, Spontaneous stone migration out of the CBD may occur in as many as 20% of choledocholithiasis cases [12].

There are many studies about the parameters suggesting spontaneous passage of stones from common bile ducts. In a study by Tawfik Khoury and colleagues patients with small stone size, distal

stones, and absence of intrahepatic dilatation tend to pass their stones spontaneously and improvement in GGT, alkaline phosphatase, and bilirubin level predicted spontaneous CBD stone passage. Also in this study, they revealed that advanced age and male gender were associated with failure of spontaneous passage of CBD stones [21,22].

There is a controversy about the best option for the treatment of BLS-CBDS in which CBD diameter is smaller than 10 mm as the percentage of passage of stone from papilla is high and may reach 10–90% of Cases [13,15]. Also, it was noticed that in BLS-CBDS, ERCP is technically difficult and the risk of post-ERCP pancreatitis was high and shown that CBD stones less than 6 mm in size were more likely to spontaneously pass without the need for further ERCP [23]. Therefore, 40–60% of the time, ERCP is not necessary since residual stones, unsuccessful CBDS removal, and spontaneous stone passage can all occur [24]. By treating BLS-CBDS with a conservative medical approach, we can avoid unnecessary, expensive, and complicated ERCP. According to a study by Moller and colleagues conservative treatment for the management of CBDS was associated with a poor outcome in 25.3% of cases, which was significantly higher than other methods of clearing CBD [13].

In this study, in the ERCP group, clearance of CBDS was achieved in 81 (54%) patients who were extracted completely by ERCP, and in 63 (42%) patients stones were passed spontaneously. On the other hand, in the conservative group, complete clearance of CBD was achieved in 99 (82.5%) cases, while 21 (17.5%) cases failed to pass the stone spontaneously and ERCP was useless in about 75 patients out of 150 (50%) patients. In another study by Elnakeeb *et al.* [25], in which they found that the ERCP procedure in BLS-CBDS was useless in about 24 patients out of 50 (48%) patients, and the number of patients with passed stone was 19 (38%) patients [25]. So, this conservative management has many advantages as it avoids inherent ERCP risks and unnecessary ERCP.

As regards pancreatitis, only three (2.5%) patients in the conservative group (A) and 33 (22%) patients in the ERCP group (B), and most of the cases are mild (in the current study, pancreatitis was noted significantly more in the ERCP group than it was in the conservative group). In all cases, in our study, pancreatitis was self-limiting and treated conservatively, and, when these results were compared with the study conducted by Elnakeeb *et al.* [25], in which they reported that

pancreatitis occurred in 2 (4%) patients in a conservative group and 8 (16%) patients [25]. Despite recent advances in ERCP accessories and techniques, the rate of post-ERCP morbidities has remained unchanged over recent years [1,16,26].

Multivariate analysis revealed that young patients aged less than 35 years old, a CBD diameter greater than 10 mm, and the number of pancreatic cannulations were independent risk factors for the development of post-ERCP pancreatitis [26,27].

We used Urso-deoxycholic acid (UDCA) in our study to promote cholesterol stone dissolving gradually and improving cholestasis and also can be used to reduce the saturation of cholesterol in bile by inhibiting the intestinal re-absorption of cholesterol and reducing the secretion of cholesterol into the bile, improve the excretion of bile by increasing the flow rate and volume of bile, and thus it may be effective on prevention the recurrence of CBDS [26,28].

In this present study, the baseline differences in age, sex, abnormal liver function test, bilirubin level, and alkaline phosphatase between the two groups were not statistically significant.

As regard length of hospitalization, in our study, there was a difference in hospital stay between the two groups and more reduced in the conservative group (A) mean 2 (0–5 days) than ERCP group (B) 5 (1–8) days and this differences noted in many studies [24,25,27], and most of patients in conservative group does not need to be admitted to hospital although in group (B), there were some patients needed hospital admission in between two procedure.

Also, our results showed that conversion rate was significantly reduced in conservative group (A) as it was one (0.83%) patient in group A and five (3.33%) patients in ERCP group (B) and this differs from study reported by Elnakeeb *et al.* [25], in which they found that conversion rate was occurred in two (8%) patients out of 25 patients in conservative group and one (4%) patients out of 25 patients [25]. The conversion rate in our study was due to inflammatory adhesions and bleeding during dissection and this was consistent with other studies [11,15,25,27].

## Conclusion

BLS-CBDS increases the technical difficulty of ERCP and the risk of post-ERCP pancreatitis. Conservative management of CBDS is effective in clearing CBDS, it

should be considered to avoid unnecessary ERCP and its complications.

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## Conflicts of interest

There are no conflicts of interest.

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