Original Research Article

# Gallbladder function predicts subsequent biliary complications in patients with common bile duct stones after endoscopic treatment

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## Abstract

**Introduction:**There is no consensus regarding the ideal management of concurrent gallbladder and common bile duct (CBD) stones. Currently the treatment protocol involves most commonly a sequential approach consisting of endoscopic sphincterotomy followed by laparoscopic cholecystectomy or a single stage laparoscopic procedure, including cholecystectomy and exploration of the CBD.**Methods:** Patients with an intact gallbladder and CBDS after endoscopic clearance of bile duct were enrolled. Patients received a fatty meal sonography after liver function returned to normal. The fasting volume, residual volume, and gallbladder ejection fraction (GBEF) in FMS were measured. Relationships of patients' characteristics, gallbladder function and recurrent biliary complication were analyzed.**Results:** Gallbladder stones were identified in 58 patients by an abdominal sonogram or a CT before endoscopic treatment.19 patients were acute biliary pancreatitis. Thirteen patients had a juxtapapillary diverticulum. The mean common bile duct diameter was 1.3 ± 0.2 cm. Thirteen patients received endoscopic sphincterotomy (EST), while 90 patients received EPBD to enlarge the papillary orifice. In the patients who received EPBD, the mean diameter of the balloon was 1.0 ± 0.1 cm. Nine patients received mechanical lithotripsy to retrieve stones. The mean duration of the procedure was 53.2 ± 7.3 min. **Conclusions:** Gallbladder motility function was poorer in patients with a calculus gallbladder, but it cannot predict the recurrent biliary complication. Since spontaneous clearance of gallbladder stone may occur, wait and see policy of gallbladder management after endoscopic treatment of CBDS is appropriate, but regular follow- up in those patients with risk factors for recurrence is necessary.

**Keywords:** Laparoscopic cholecystectomy, Endoscopic sphinterotomy, CBD stones.



## Introduction

The incidence of gallstones is very common and varies from 6 % to 10 % in adult population. Their treatment involves surgeons, endoscopists and anesthesiologists depending on clinical presentation. The "gold standard" treatment for cholecystolithiasis is laparoscopic cholecystectomy (LC), whereas the "gold standard" treatment for isolated common bile duct (CBD) stones, especially in cholecystectomized patients, is endoscopic clearance [1]. On the contrary, when gallstones and CBD stones are present concurrently, the treatment is a challenge. A consensus on optimal management does not exist. Several approaches are used, all having their proponents, such as open surgery, laparoscopy, and laparoendoscopic treatments, either sequential or simultaneous. [2]From 10 % to 18 % of patients undergoing Laparoscopic Cholecystectomy (LC) for gallbladder stones have synchronous CBD stones [3]. These should be treated even if asymptomatic [4]. Prior to the development of minimally invasive surgery, when the surgical approach to CBD stones consisted of choledocholithotomy by open surgery, there was considerable morbidity (11–14 %) and even mortality (0.6–1 %) [4]. With the advent of endoscopic and laparoscopic techniques, CBD stones were removed preoperatively by endoscopy, which was followed by LC [5]. With refinements in laparoscopic techniques and experience many centers have started performing laparoscopic CBD exploration with acceptable results and complications [6]. Simultaneous or single-stage laparoscopic cholecystectomy and CBD exploration has not yet become standard management. There are only a few randomized trials available comparing the single stage with sequential management (ERCP followed by LC) of patients with concomitant gallstones and CBD stones [7-9]. Combined single stage laparoendoscopic approach to the management of choledocholithiasis has also been advocated by established centres with results comparable to sequential management and single stage total laparoscopic exploration.[10]The preoperative evaluation for CBD stones should include a careful history, biochemical tests and abdominal ultrasonography. It seems reasonable to avoid further diagnostic preoperative investigations and routine intraoperative cholangiography in patients with absence of jaundice, normal liver function tests, and ultrasonographic evidence of a normal biliary tree (CBD diameter <9 mm) even in the presence of a recent acute Cholecystitis [11]. Investigation of the group at risk is necessary. If there is any suspicion that preoperative choledocholithiasis is present magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP) is performed. ERCP should be performed only in patients who are expected to require an intervention; it is not recommended for use solely as a diagnostic test [12].It is desirable that all those and only those patients with choledocholithiasis should undergo CBD exploration at cholecystectomy. CBD should be imaged if there is intraoperative doubt about choledocholithiasis. This can be

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achieved by radiographic intraoperative cholangiography (IOC) via the transcystic approach or intracorporeal laparoscopic ultrasonography (LUS). In experienced hands, LUS seems to be as accurate as cholangiography for diagnosis of choledocholithiasis, but can be performed more rapidly. Li et al. in 2009 have shown that LUS is more sensitive than IOC for detecting stones but IOC is better for delineating the anatomy. Both these techniques should be viewed as complementary method to maximize the intraoperative detection of occult CBD stones [13].

**Material and Methods**

We enrolled 90 consecutive patients admitted to Tertiary care teaching Hospital over a period of 6 months with CBD stones, who received either ES or EBD and successful clearance of the bile duct stones. Patients with concomitant malignancies, prior Billroth II gastrectomy, incomplete clearance of bile duct and a follow-up period of <6 months were excluded. Consequently, a total of 90 patients were included in this study.

**Procedures**

Standard endoscopic treatment was performed using a side viewed endoscope. The stone number, stone size (the largest diameter), and the CBD size were measured by endoscopic retrograde cholangiography. For ES, sphincterotomy was done using a wire-guided sphincterotome. For EBD, a dilated balloon catheter (Olbert, 8 mm and 10 mm in diameter and 4 cm in length; CRE, 6e8 mm, 8e10 mm, 10e12 mm, 12e15 mm, 15e18 mm, 18e20 mm in diameter and 5.5 cm in length) was passed over the guide wire into the bile duct after guidewire insertion as ES. The size of the balloon was determined by the stone size and did not exceed the maximum diameter of the CBD. The balloon was gradually inflated with sterile saline at a pressure according to the manufacturer's instructions, and balloon inflation was halted whenever the patient experienced discomfort. The stones in the common bile duct were then removed using a Dormia basket after ES or EBD, with or without use of a mechanical lithotriptor. If the first treatment resulted in incomplete removal of all stones, a second stone extraction attempt was performed within 7 days. All patients were observed in the hospital for at least 24 hours following endoscopic treatment.

**Follow-up**

During endoscopic treatment, the general data and the endoscopic findings, including the presence of JPD, stone size, and stone numbers, were recorded. Stone removal was declared complete if the final cholangiogram showed no residual stones. After clearance of the bile duct and normalization of liver function, each patient was routinely advised to have regular follow-up evaluations that included an interview and transabdominal ultrasonography (US) every 3 to 6 months. Follow-up for patients with an intact gallbladder occurred every 3 months, and patients having previous cholecystectomy before endoscopic treatment or elective cholecystectomy after endoscopic treatment were followed up every 6 months. If any biliary symptoms developed between visits, the patient was advised to contact us immediately. Endoscopic retrograde cholangiography was performed if US demonstrated echogenic foci within the bile duct or significant dilatation of the common bile duct in comparison with previous US, or if abnormal liver function tests developed accompanied by typical biliary pain.All complicating biliary events that occurred during follow up were recorded, including acute cholecystitis, cholangitis, biliary colic, recurrent CBD stones, and acute pancreatitis.

**Statistical analysis**

All statistical analyses were performed with the SPSS program. The values were expressed as Mean±SD. Categorical variables were tested by the Chi-square test or Fisher's exact test. A p-value < 0.05 was considered significant.

**Results**

ERCP procedures were performed at tertiary care teaching Hospital. A total of 90 patients who were diagnosed as having CBDS based on their clinical symptoms, laboratory tests, and image studies, received endoscopic treatment to clear the bile duct. In our present study, a total of 90 patients were included out of which 41 (63.1%) were males and 24 (36.9%) were females (table-1).

**Table 1: Distribution of gender**

| Gender | No. of patients | Percentage |
|---|---|---|
| Male | 56 | 62.2 |
| Female | 34 | 37.7 |
| Total | 90 | 100 |

**Table 2: Distribution of different age groups of patients**

| Age | No. of patients | Percentage |
|---|---|---|
| <30 years | 9 | 10.0 |
| 31-50 years | 41 | 45.5 |
| 51-70 years | 33 | 36.6 |
| >71 years | 7 | 7.7 |
| Total | 90 | 100 |

In table 2, in our study, most of the patients were 31-50 years i.e., 41 out of 90 (45.5%), followed by 51-70 years, i.e., 33 out of 90 (36.6%).

**Table 3: Distribution of Concomitant diseases**

| Concomitant disease | Number (%) |
|---|---|
| Chronic lung diseases | 9 (10%) |
| Cerebrovascular diseases | 1 (1.11%) |
| Cardiovascular diseases | 21 (23.3%) |
| Renal failure | 2 (2.2%) |
| Cancer diseases | 1 (1.1%) |
| Liver disease | 32 (35.5%) |
| Diabetes mellitus | 24 (26.6%) |

In table 3, concomitant diseases included chronic lung disease in seven patients, cerebrovascular disease in seven patients, cardiovascular disease in 21 patients, renal failure in two patients, a history of cancer disease after remission or curative treatment in 1 patient, chronic liver disease in 32 patients, and diabetes mellitus in 24 patients.

**Table 4: Distribution of complication of patients**

| **Parameters** | **Number (%)** |
|---|---|
| Juxtapapillary diverticulum | 13 (14.4%) |
| Gallbladder stones | 58 (64.4%) |
| Biliary pancreatitis | 19 (21.1%) |

In table 4, Gallbladder stones were identified in 58 patients by an abdominal sonogram or a CT before endoscopic treatment.19 patients were acute biliary pancreatitis. Thirteen patients had a juxtapapillary diverticulum.

**Table 5: Distribution of CBD characteristics among patients**

| Parameters | Number (%) |
|---|---|
| CBD diameter (mean±SD) | 1.3±0.2 cm |
| Number of CBD stones (no/single /multiple) | 7/52/31 |
| Largest CBD stones size (mean±SD)a | 0.8±0.1 cm |
| Endoscopic procedures (EST/EPBD) | 13/90 |
| Mean balloon diameter for EPBD (mean±SD) | 1.0±0.1 cm |
| Mechanical lithotripsy | 9 (10%) |
| Sessions for bile duct clearance (> 1 session) | 3 (3.3%) |
| Mean ERCP procedure time (mean±SD) | 53.2±7.3 |

In table 5, the mean common bile duct diameter was 1.3 ± 0.2 cm. Thirteen patients received endoscopic sphincterotomy (EST), while 90 patients received EPBD to enlarge the papillary orifice. In the patients who received EPBD, the mean diameter of the balloon was 1.0 ± 0.1 cm.
Nine patients received mechanical lithotripsy to retrieve stones. The mean duration of the procedure was 53.2 ± 7.3 min.

**Table 6: Complication among patients**

| Parameters | Number (%) |
|---|---|
| Postprocedural complications | 3 (3.3%) |
| Recurrent biliary complications | 11 (12.2%) |
| Spontaneous passage of gallstones | 7 (7.7%) |

In table 6, three patients developed complications, including mild acute pancreatitis in one patients and fever with bacteremia after endoscopic treatment in one, and all patients recovered after conservative treatment for those complications. Recurrent biliary complications occurred in 11 patients. Spontaneous passage of gallbladder of 7 patients was confirmed by a subsequent abdominal sonogram.

**Table 7: Multivariate analysis of the factors affecting recurrent biliary complications**

| Factors | Risk ratio (95% CI) | P |
|---|---|---|
| Gallstones (yes/no) | 9.32(1.03–67.23) | 0.041 |
| Renal failure (yes/no) | 1.43(0.38–5.58) | 0.524 |
| Sessions for bile duct clearance (1/> 1) | 0.31 (0.07–0.93) | 0.013 |

**Discussion**

Reduced gallbladder motility is widely recognized as an important factor in the formation of cholesterol stones [14], but the role of the gallbladder function in the formation of pigment stones is controversial [15]. Brown stones form secondary to stasis and anaerobic bacterial infection in any part of the biliary tree including the gallbladder [16, 17]. A higher percentage of our patients with calculus gallbladder than that of the acalculous gallbladder, had suboptimal gallbladder motility (53.3% vs. 25.9%), so gallbladder motility should be considered as a factor in the formation of gallbladder stone.Following the endoscopic treatment of CBDS, recurrent biliary complication occurred in 3 21% of patients after EST and in 5–25% of patients after EPBD [18]. Calculus gallbladder was identified as one of the factors that is responsible for such complications [19]. EPLBD, using balloon ≥12 mm, is a safe and effective method in facilitating the removal of CBDS as seen, but is not a sphincter-preserving procedure [20]. Sphincter-preserving methods such as EPBD, using the conventional 8 mm balloon should be suitable for patients with secondary CBDS that migrates from the gallbladder. EPLBD and a full EST can facilitate the biliary drainage of the bile duct and are suitable procedures for patients with primary CBDS or a prior cholecystectomy[21].

Although gallbladder motility improved only temporarily after endoscopic papillary dilation using a conventional 8 mm balloon [22], improvement of gallbladder emptying and facilitation of the spontaneous passage of gallbladder stones after EST have been reported [23]. In this study, even gallbladder ejection in patients with a calculus gallbladder was inferior to that in patients with an acalculous gallbladder, and 46.7% of the former maintained optimal gallbladder ejection. The presence of gallbladder stones rather than the gallbladder EF was the factor affected the late biliary complications in this study.Non-filling of the gallbladder may be an indication for cholecystectomy [24, 25]. Non-filling of the gallbladder may lead to failure of gallbladder contraction. However, bile stasis with subsequent sepsis and carcinoma is questionable, and no strong evidence supports the beneficial effect of cholecystectomy in patients with non-filling gallbladder [26, 27]. Although 8.4% (10/118) of patients developed acute cholecystitis (including one with gallbladder rupture) after endoscopic treatment for CBDS, all patients recovered completely after their operation.In addition, fifteen patients (12.7%) were found to have been spontaneously passed their gallbladder stones in the follow-up period. Endoscopic treatment of the biliary sphincter by either EST or endoscopic sphincterotomy plus large balloon dilation (ESLBD) may increase the gallbladder motility, facilitating the spontaneous passing of gallstones and increasing the risk of recurrent biliary complications, particularly gallbladder complications[28].Except in cases of gallbladder-related complic-ations,elective cholecystectomy does not help to prevent recurrent CBDS or cholangitis [29].Other studies have shown that prior cholecystectomy may be a factor in causing the recurrent CBDS [30]. These contradictory results raise a question regarding who will benefit from elective cholecystectomy following endoscopic treatment for CBDS. Some studies claimed that prophylactic cholecystectomy is not required in patients with acalculous gallbladder following endoscopic clearance of the bile duct [31], but elective cholecystectomy in patients with calculus gallbladder following endoscopic treatment is recommended owing to the risk of subsequent recurrent biliary complications [32]. However, most relevant studies that strongly recommend routine cholecystectomy neglect the evidence of the spontaneous clearance of the gallbladder following endoscopic treatment. Although a calculus gallbladder is identified as a significant risk factor for recurrent biliary complications in this study, the rate of acute cholecystitis as a late complication was 8.4% (10/118), whereas the rate of asymptomatic spontaneous clearance of gallbladder stones was 12.7% (15/118). All patients in the current study were regularly followed at our clinic and were alert for recurrent symptoms. As a result, the possible recurrent complications can be detected early and managed properly [33]. Therefore, the wait-and-see policy for the patients with simple gallbladder stones may also be applicable for the patients with concurrent gallbladder stones and CBDS following endoscopic treatment. Surgical intervention should be conducted only on patients with recurrent gallbladder related complications to prevent an unnecessary cholecystectomy,

particularly for the aged patients and patients with a high likelihood of the spontaneous emptying of gallbladder stones, including those with small stones, a wide cystic duct, low or a small angle of cystic duct insertion with CBD [33]. This study has some limitations. The follow-up time was not long enough to observe the rate of re-recurrent biliary complications in patients who had undergone a cholecystectomy. Most of the stones in our patients were mixed black and brown, so differentiating between secondary and primary bile duct stones was difficult. Our patients were acutely ill before endoscopic treatment, so no FMS was performed before endoscopic treatment for baseline reference. Owing to blockage by gas or stone, FMS was not successfully performed in all patients. A further long-term study is required to evaluate the clinical significance of gallbladder function and the effect of cholecystectomy in these patients.

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