Assessment and Treatment of Choledocholithiasis when Endoscopic Sphincterotomy is not Successful

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Abstract
Background: Choledocholithiasis exists in approximately 15% of patients with gallstones and is present in 3%-10% of those undergoing cholecystectomy.

Methods: In this study, we retrospectively analyzed the outcome patients with choledocholithiasis that were managed by open common bile duct (CBD) exploration according to our center’s protocol. Endoscopic retrograde cholangiopancreatography (ERCP) was performed for CBD stone clearance. If ERCP and sphincterotomy were not successful, open surgical exploration of CBD was performed with T-tube insertion without routine intraoperative cholangiography (IOC).

Results: We studied 1462 patients with choledocholithiasis. ERCP was successful in 82 (44.1%) patients and choledochojejunostomy was performed in 20 (10.8%). Retained stones were found only in 4 cases which were treated by ERCP.

Conclusion: ERCP is successful in most cases with choledocholithiasis. If ERCP fails, open exploration of CBD and T-tube insertion, or biliary-enteric anastomosis are acceptable ways for CBD drainage. The rate of retained stone is more than expected, thus elective IOC is more acceptable than routine IOC. Routine IOC is time-consuming and particularly difficult in elderly patients and emergency conditions.

Keywords: Choledochoduodenostomy, Choledochojejunostomy, Choledocholithiasis, ERCP

Introduction

Choledocholithiasis is a medical condition that mandates surgical intervention. It may occur in 3% – 10% of patients with cholecystectomy,¹ and as high as 14.2% in some series.² Generally, the prevalence of asymptomatic bile duct stones is reported between 5.2% and 12%.³

There are several diagnostic approaches for common bile duct (CBD) stones. These include: laboratory analysis, ultrasonography (US), computed tomography scans (CT scan), magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasonography (EUS), and endoscopic retrograde cholangiopancreatography (ERCP). Intraoperative cholangiography (IOC) during cholecystectomy can be performed routinely or selectively to diagnose choledocholithiasis.⁴ Nowadays, 2 groups of interventions have a significant role in the management of patients with gallstone and CBD stones: pre- or post-cholecystectomy ERCP with endoscopic sphincterotomy (ES), which is a two-stage procedure, and surgical bile duct clearance and cholecystectomy by single open or laparoscopic surgery (one-stage procedure). Several randomized controlled trials have shown comparable effectiveness of these modalities.⁵ ⁶ Other methods include electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), laser lithotripsy and dissolving solutions that are advocated for special conditions.⁷ ⁸ ⁹

Although, ERCP and laparoscopic CBD exploration are preferred methods in most centers, open CBD exploration should never be abandoned. Some studies have proposed choledochotomy with primary laparoscopic closure of the CBD which eliminates the need for a T-tube, thus reducing surgical time and postoperative morbidity.¹⁰ However, open CBD exploration with T-tube insertion remains the standard procedure for most patients.

In this study, we review the results of surgical management in 186 out of 1462 patients with choledocholithiasis. We present our protocol for the management and treatment of choledocholithiasis, particularly in cases of unsuccessful ERCP and sphincterotomy.

Materials and Methods

From June 2007 to March 2010, 1462 patients with choledocholithiasis referred to Shariati Hospital, Tehran University of Medical Sciences. After primary evaluation with laboratory tests and US, patients’ diagnoses were confirmed by EUS or MRCP.

We performed ERCP and ES in confirmed cases to extract CBD stones. When ERCP was not successful the patient underwent surgery. We administered antibiotic therapy (ceftriaxone 1 gr/IV/BD and metronidazole 500 mg/IV/TDS) to patients with cholangitis and/or cholecystitis. This therapy continued for 5 – 7 days in patients with acute cholangitis and for 48 hours after elective surgeries in those without cholangitis. Surgical procedures included...
CBD exploration and T-tube insertion or biliary enteric anastomosis (choledochoduodenostomy and choledochojejunostomy). Figure 1 shows the algorithmic approach to patients with choledocho lithiasis at Shariati Hospital.

In our center, laparoscopic cholecystectomy is the surgery of choice. However, due to insufficient experience in laparoscopic exploration of CBD and previous open cholecystectomy in some patients who had subsequent adhesions, we performed open surgery in these cases through a right subcostal or upper abdominal midline incision. We inserted a T-tube in the CBD when its diameter was less than 12 mm and in patients with cholangitis. In other patients that underwent elective surgery with CBD diameter more than 12 mm, we performed biliary-enteric anastomosis (choledochoduodenostomy or choledo chojejunostomy).

Routine IOC after T-tube insertion can determine retained stones. However, because IOC is time-consuming we did not perform this procedure if we could pass appropriate biliary dilators through the sphincter of Oddi after stone extraction and certainty of CBD clearance. This timesaving approach was particularly important in older or critically ill patients. Then, after irrigation of the CBD with normal saline, we inserted a 14 or 16 Fr T-tube in the CBD and closed the choledochotomy with absorbable (Vicryl 3-0) separate sutures. Seven to eight days after surgery, T-tube cholangiography was performed. In cases without retained stones the T-tube was extracted 14 to 21 days after surgery.

**Statistical analysis**

Statistical analysis was performed using SPSS for Windows version 16.0 (SPSS Inc., Chicago, IL). For quantitative data, mean and ranges were calculated. Quantitative data were reported as relative frequencies and percentages. In this study, the significant variables analysis was entered into both the chi-square and t-tests. *P* values < 0.05 were considered statistically significant.

**Results**

There were 186 out of 1462 patients with choledocholithiasis who underwent surgery. Of these, 82 (44%) were women and 104 (56%) were men. Patients' mean age was 58.6 ± 15 years (range: 21 – 78 years). The main presentations and comorbid diseases are shown in Table 1. Comorbidities of hypertension, diabetes mellitus, ischemic heart disease, and chronic obstructive pulmonary disease were present in 65 (34.9%) patients.

Sixty-six (35.5%) patients had leukocytosis (wbc > 11,000/mm³). Jaundice was present in 38 (20.4%) patients and the mean total bilirubin was 2.7 ± 1.7 mg/dl. Alkaline phosphatase was greater than 300 U/dl in 96 (51.6%) patients. US showed a mean CBD diameter of 14.4 ± 6.4 mm; the mean stone size was 13.3 ± 4.8 mm. There was a history of previous cholecystectomy in 45 (24.2%) patients.

ERCP was successful in 1276 of 1462 (87.3%) patients and 186 (12.7%) underwent open surgical CBD exploration. Main reasons for ERCP failure were multiple stones, large stones (≥ 1.5 cm) and impacted stone in the distal portion of the CBD, among others. Existence of periamppullary diverticulum (3 cases), bulbar deformity of the duodenum (1 case), and ampullary polyp (1 case) also prevented ERCP.

In 84 (45.2%) out of 186 patients CBD exploration and T-tube insertion were performed. Of these, 40 (47.6%) had acute cholangitis, 33 (39.3%) had cholecystitis, and 11 (13.1%) had pancreatitis. There were 4 cases with retained stones after T-tube insertion according to postoperative T-tube cholangiography. Endoscopic sphincterotomy and stone extraction were successfully performed to extract the retained stones.

We performed biliary-enteric anastomoses in 102 (54.8%) patients whose surgical conditions were not urgent and had CBD diameters of 12 mm or more. Included in this group were patients with cholangitis who were responsive to antibiotic therapy. For 82 (44.1%) patients, choledochoduodenostomy was performed and 20 (10.7%) underwent choledochojejunostomy. The latter was performed when adhesions or deformity of the duodenum and difficulty in its mobilization were present.

Mean surgery time was 128 ± 23 minutes. The length of hospitalization was 6.8 ± 3.8 days, which was less in patients who had T-tube insertions when compared with biliary-enteric anastomosis (6.4 ± 3.4 days vs. 8.5 ± 4 days, *p* = 0.02). The age of patients with T-tube insertion was less than those with biliary-enteric anastomosis (54.4 ± 14.4 vs. 63.7 ± 16.5 years, *p* = 0.01).

A total of 33 (17.7%) patients were transferred to the intensive care unit (ICU) after surgery, mainly due to older age and comorbid diseases. The mean time in the ICU was 2.7 days (range: 1 – 5 days).

Postoperative complications were seen in 14 (7.5%) patients and included wound infection (8), pneumonia (3) and pancreatitis after surgery (3). Mortality occurred in 3 (1.6%) female patients, who were all over 50 years of age, as a result of sepsis (2) and myocardial infarction (1).

Patients were followed at two weeks, one, three, and six months, and one year after surgery. Follow-up evaluations included physi-
cal examination, laboratory tests, and US. There were no cases of recurrent choledocholithiasis or any long-term complications.

**Discussion**

The management of choledocholithiasis has always been challenging. Nowadays, ERCP has essentially replaced open surgery for safe and effective CBD stone extraction. Open CBD exploration is an important surgical procedure when ERCP fails and expertise for laparoscopic CBD exploration is not available.

The optimal method for performing open CBD exploration is unclear. The routine use of IOC during laparoscopic cholecystectomy remains controversial. Stuart et al. have performed IOC in 348 patients, of which it was abnormal in 17 (5%) cases. However, documented retained stones that existed in 5 patients were removed by CBD exploration or ERCP in that study. Mir et al. did not perform IOC, and reported reductions in costs and hospital stay. We did not perform IOC in order to reduce the surgical time. In our study, there were cases of 4 retained stones in patients with T-tube insertion that were successfully extracted by ERCP. Generally, ERCP is more feasible in this subgroup since postoperative T-tube cholangiography shows the anatomy of the biliary tree and large or impacted stones that have been extracted during surgery. The rate of retained CBD stones in our study was not greater than other studies. For this reason, we have proposed that routine IOC is not necessary after surgical CBD exploration and clearance.

In our center, the appropriate surgical method was chosen based on the patient’s condition. In patients with sepsis due to cholangitis and accompanying diseases, it was necessary to shorten the time of surgery. In addition, biliary-enteric anastomosis increased the risk of complications. In such cases, the T-tube was inserted following CBD exploration. In cases with CBD diameters less than 12 mm, the T-tube was used because of the high risk for anastomotic stricture and subsequent complications. Most authors have preferred insertion of T-tube for CBD drainage, but some centers have utilized transcystic tubes (C-tube) or antegrade stenting with choledochocholangiography for CBD drainage. In patients with residual distal stone, ductal imaging in the postoperative period and provision of an access route for removal of residual CBD stones has been performed.

The most commonly used choledochoenterostomy is side-to-side choledochojejunostomy, usually in the setting of a dilated CBD. In cases where duodenal anastomosis was impossible, choledochojejunostomy was performed.
Currently, many centers use laparoscopy for CBD surgeries. Expert surgical teams have reported a CBD clearance rate of about 97%. The morbidity rate has been reported to be 9.5% and retained stone rate of 2.7% for exploratory laparoscopic CBD. Nevertheless, in comparison to open surgery, laparoscopic surgery is more time consuming, yet has shorter postoperative hospitalization. Open surgery is still straightforward for management of choledocholithiasis and has a higher stone clearance rate.

**Conclusion**

Choledocholithiasis remains a challenging problem for clinicians. Currently, ERCP is used mainly for extraction of CBD stones, but surgery is the method of choice when ERCP fails. Performing an IOC assists in the detection of CBD stones but routine use of IOC remains controversial. Although ERCP and then laparoscopic CBD exploration are selective methods in most centers, open CBD surgery is the method of choice when ERCP fails. Performing laparoscopic cholecystectomy is more time consuming, yet has shorter postoperative hospitalization. Nevertheless, in comparison to open surgery, laparoscopic surgery is more time consuming, yet has shorter postoperative hospitalization. Open surgery is still straightforward for management of choledocholithiasis and has a higher stone clearance rate.

**References**