# Cholecystectomy for combined choledocholithiasis and cholelithiasis in elderly patients: do we need it?

Mohamed Abdel Fatah Selimah, Moustafa R. Abo Elsoud, Ayman Farouk

Department of Surgery, Medical Research Institute, Alexandria University, Alexandria, Egypt

Correspondence to Mohamed Abdel Fattah Selimah, MD, 165 El-Horrya Ave, Alexandria 21561, Egypt; Tel: +20 100 174 2123; fax: 002034208598; e-mail: mselima@gmail.com

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**Background**
After endoscopic common bile duct (CBD) stone removal, physicians always recommend prophylactic cholecystectomy even in the absence of gall bladder (GB) stones to prevent further complications such as acute cholecystitis, recurrent CBD stones, or cholangitis despite the fact that management of GB after endoscopic stone removal remains a matter of debate. The main options in managing concomitant CBD stones and the GB stones include selective preoperative endoscopic retrograde cholangiopancreatography (ERCP), postoperative ERCP, open explorations, and laparoscopic common bile duct exploration.

**Aim**
The aim of this study was to assess the need for cholecystectomy after endoscopic sphincterotomy for CBD stones in elderly patients aged more than or equal to 70 years with coexisting cholelithiasis.

**Patients and methods**
A total of 336 patients who underwent successful endoscopic CBD stone removal at the endoscopy unit of the Medical Research Institute Hospital, Alexandria University from January 2013 to December 2015, were analyzed retrospectively. Patients were divided into three groups: the in-situ group comprised 168 patients with an intact GB, the cholecystectomy group comprised 72 patients who had cholecystectomy performed after ERCP, and the third group comprised 36 patients who had cholecystectomy before ERCP.

**Results**
After endoscopic CBD stone removal, 72 (30%) patients underwent subsequent cholecystectomy and 168 (70%) patients did not. There was no significant difference as regards morbidity and mortality among the study groups. Age was not a contraindication for surgery; however, the presence of multiple comorbidities, mainly diabetes and cardiac diseases, was a significant contraindication for prophylactic cholecystectomy.

**Conclusion**
A wait-and-see policy may be recommended for elderly patients with comorbidities and GB *in situ* taking in consideration regular follow-up for early detection of acute biliary complications.

**Keywords:**
cholecystectomy, cholecystitis, choledocholithiasis, common bile duct, endoscopic retrograde cholangiopancreatography

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## Introduction

Over recent years, endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) is a widely accepted routine management for common bile duct (CBD) stones, with decreased morbidity and mortality since the introduction of new imaging techniques such as magnetic resonance cholangiopancreatography and endoscopic ultrasound with increasing accuracy of biliary system visualization without instrumentation [1–3], whereas laparoscopic cholecystectomy (LC) has largely replaced the open approach, with or without laparoscopic common bile duct exploration [4].

Subsequent cholecystectomy is usually advised to avoid serious complications such as acute cholecystitis or biliary pancreatitis [4,5], which might be fatal especially in old age with increased prevalence of comorbid conditions, such as cardiovascular disease, diabetes mellitus, and pulmonary diseases. However, these comorbidities may increase the operative risk and postoperative complications in elective surgery in elderly patients to about 21.2% compared with



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44.8% for emergency surgery [6–9], making post-ES cholecystectomy in the elderly a matter of debate [1,2,6,10].

The advancements of ERCP with ES markedly reduced their morbidity and mortality in elderly patients [11]. It has been shown that ES with or without an additional Cholecystectomy offers better protection than cholecystectomy alone in terms of reducing the number of recurrent biliary pancreatitis [12].

In elderly patients presenting with choledocholithiasis, it is important to clear the duct of stones, or at least establish an uninterrupted flow of bile. This can be effectively achieved by ES with stone extraction, mechanical lithotripsy, or simply by placing a plastic stent, which was proven to be quicker and cheaper, thereby very effective in the elderly population [13].

Although ERCP has been proven to be a safe and effective option for extracting CBD stones in most cases, it also has some devastating adverse effects, as it may induce various postoperative complications, including bleeding, perforation, or pancreatitis [14].

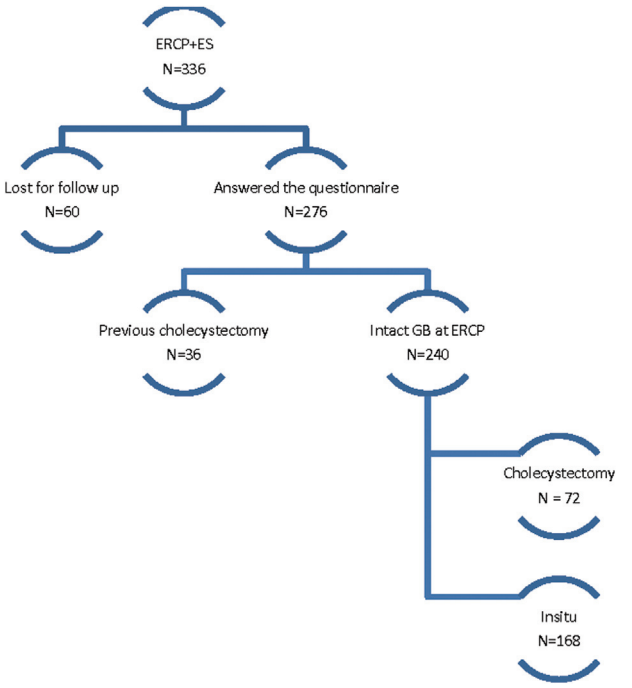
The aim of this study was to assess the need for cholecystectomy after ES for CBD stones in elderly patients aged more than or equal to 70 years with coexisting cholelithiasis.

## Patients and methods

A phone number and mail address database was made for patients aged 70 years or more at Endoscopy Unit of the Medical Research Institute Hospital, University of Alexandria, who underwent ERCP and ES for choledocholithiasis during the time interval from January 2013 to December 2015. A total of 336 records from were eligible for the study. The research protocol was approved by the ethical committee of the Medical Research Institute.

ERCP with ES was performed in all cases. All ERCP procedures were performed by an expert endoscopist with more than 300 procedures annually, using side-viewing endoscope Olympus TJF-145 (Olympus, Japan; Industriestrasse 20, CH-8117 Fallanden, Switzerland). Stones were extracted by using retrieval baskets and/or balloon catheters after ES in all patients. If stones were too large to be extracted, either mechanical lithotripsy is performed or a plastic stent was inserted in the CBD to ensure free flow of bile.

**Figure 1**




Studied groups of patients.

After successful biliary drainage, cholecystectomy was recommended to all patients with intact gall bladder (GB) with explanation of all the possible risks, leaving the final decision to the patient and their referring physician.

All eligible patients were phone-called at least 6 months after their discharge, and according to the answers of a questionnaire, patients were divided into four groups (Fig. 1).

Group A comprised 168 patients, in whom the GB was intact and will be referred to as the in-situ group. Group B comprised 72 patients, in whom GB is surgically removed, and will be referred to as the cholecystectomy) group. Group C comprised 60 patients who were lost to follow-up. Group D comprised 36 patients who already had cholecystectomy at least 6 months before ERCP; this will be referred to in text as the previous group.

### Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows (version 20.0, 2011; IBM Corp., Armonk, New York, USA). Qualitative data were described using number and percent and was compared using $\chi^2$-test, whereas normally quantitative data were expressed in mean±SD and

**Table 1 Demographic and endoscopic procedures for all groups**

| | Lost to follow-up (*n*=60) | Previous (*n*=36) | In-situ (*n*=168) | Cholecystectomy (*n*=72) | *P* |
|---|---|---|---|---|---|
| Age (years) | 74.7 (70–85) | 75.9 (70–85) | 76.5 (70–91) | 76 (70–86) | 0.131 |
| Sex | | | | | |
| Male | 29 (52) | 16 (44) | 79 (47 | 36 (50) | 0.929 |
| Female | 31 (48) | 20 (56) | 89 (53 | 36 (50 | |
| Follow-up period (days) | NA | 474.2 (219–760) | 515 (212–1103) | 488 (219–1039) | 0.347 |
| Endoscopic procedure | | | | | |
| Stent | 17 (28.3) | 13 (36.1) | 19 (11.3) | 17 (23.6) | <0.05 |
| CSE | 38 (63.3) | 20 (55.6) | 142 (84.5) | 54 (75) | <0.05 |
| Crushing | 5 (8.3) | 3(8.3) | 7 (4.2) | 1 (1.4) | <0.05 |

CSE, complete stone extraction; NA, not assessed. Qualitative data were described using number and percent and were compared using $\chi^2$-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Mann–Whitney test.

**Table 2 Showing relation between endoscopic interventions, demographics of in-situ and cholecystectomy groups and subsequent surgical procedures**

| | Endoscopic procedure | | |
|---|---|---|---|
| | Crushing (*n*=8) | CSE (*n*=190) | Stent (*n*=36) |
| Age (years) | 80.3 (72–86) | 77.1 (70–91) | 80.5 (72–91) |
| Sex | | | |
| Female | 2 (25) | 106 (54) | 17 (47) |
| Male | 6 (75) | 90 (46) | 19 (53) |
| Surgical procedure | | | |
| No | 7 (87.5) | 142 (72.4) | 19 (52.8) |
| Yes | 1 (12.5) | 54 (27.6) | 17 (47.2) |
| CBDE | 0 (0) | 0 (0) | 15 (41.7) |
| CD | 0 (0) | 0 (0) | 2 (5.6) |
| LC | 1 (12.5) | 28 (14.3) | 0 (0) |
| OC | 0 (0) | 26 (13.3) | 0 (0) |
| Recurrent symptoms | | | |
| Cholangitis | 0 (0) | 3 (1.5) | 15 (41.7) |
| Recurrent jaundice | 1 (12.5) | 16 (8.2) | 16 (44.4) |
| Death | 0 (0) | 10 (5.1) | 8 (22.2) |

Qualitative data were described using number and percent and were compared using $\chi^2$-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Kruskal–Wallis test or Mann–Whitney test. CBDE, common bile duct exploration; CD, choledochoduodenostomy; LC, laparoscopic cholecystectomy; OC, open cholecystectomy.

was compared using Student's *t*-test and was considered statistically significant at *P*-value less than or equal to 0.05.

## Results

As regards demographic characteristics of all patients, there was no statistical difference between the four groups as regards age or sex distribution (Table 1).

The 'previous group' has shown that 36 patients have presented to our unit after a mean of 29 months, ranging from 6 to 72 months, of cholecystectomy complaining of jaundice, for 12 of whom jaundice was associated with cholangitis and all patients responded to medical treatment ERCP with biliary clearance.

The American Society of Anesthesiologists grading of all patients and their duration of follow-up are summarized in Table 3, with a statistically significant association between the American Society of Anesthesiologists of the patient and the mode of treatment followed. A significant association between the presence of comorbidities and the mode of management was found as well, with higher significance when multiple comorbidities are present.

All patients achieved biliary drainage with normalization of bilirubin level after ERCP. A total of 198 (82.5%) patients had CBD stone clearance, of whom eight (3.3%) patients required mechanical lithotripsy. In all, 42 (17.5%) patients achieved biliary drainage through placement of plastic stents. Seven patients reported post-ERCP complications; five reported mild pancreatitis with persistent vomiting associated with epigastric pain and elevated levels of amylase and lipase, and they responded well to conservative

**Table 3 Mortality, morbidity, and comorbidities in the in-situ and cholecystectomy groups**

| | In-situ (*n*=168) | Cholecystectomy (*n*=72) | *P* |
|---|---|---|---|
| ASA | | | |
| I+II | 138 (82.1) | 50 (69.4) | 0.029* |
| III | 10 (6) | 19 (26.4) | <0.001* |
| IV | 20 (11.9) | 3 (4.2) | 0.062 |
| Comorbidity | 133 (79.2) | 65 (90.3) | 0.042* |
| Number of comorbidities | | | |
| 0 | 35 (20.8) | 7 (9.7) | |
| 1 | 54 (32.1) | 41 (56.9) | |
| 2 | 48 (28.6) | 23 (31.9) | <0.001* |
| 3 | 18 (10.7) | 0 (0) | |
| 4 | 5 (3) | 0 (0) | |
| Diabetes | 56 (33.3) | 36 (50) | 0.015* |
| Hypertension | 57 (33.9) | 36 (50) | 0.02* |
| Cardiac | 39 (23.2) | 6 (8.3) | 0.007* |
| Bronchial asthma | 9 (5.4) | 4 (5.6) | 1.000 |
| Cirrhosis | 16 (9.5) | 1 (1.4) | 0.024* |
| Renal | 24 | 0 (0) | <0.001 |
| Hypercoagulability and thrombotic complications | 11 (6.5) | 0 (0) | 0.037* |
| Others | 12 (7.1) | 4 (5.6) | 0.783 |
| Recurrent symptoms | | | |
| Cholangitis | 12 (7.1) | 3 (4.2) | 0.563 |
| Recurrent jaundice | 27 (16.1) | 16 (22.2) | 0.255 |
| Death | 11 (6.5) | 7 (9.7) | 0.392 |

Qualitative data were described using number and percent and were compared using $\chi^2$-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Mann–Whitney test. ASA, American Society of Anesthesiologists. *Mortality, morbidity, and comorbidities in the in-situ and cholecystectomy groups.

measures and completely resolved; and two patients complained of symptoms of upper gastrointestinal bleeding in the form of melena, and Oesophagodudenoscope (EGD) was performed and it revealed bleeding esophageal varices in one patient and bleeding from sphincterotomy site in the other one, which required hemostasis using monopolar cautery.

The relation between endoscopic interventions and demographics of all patients is summarized in Table 2.

The cholecystectomy group had 72 patients who underwent a post-ERCP cholecystectomy either alone or as a part of other operative procedures with a time interval between ERCP and cholecystectomy ranging between 1 and 300 days with an average of 55 days. In all, 29 patients had LC, 26 patients had open cholecystectomy, 15 had common bile duct exploration (CBDE) and stone extraction without insertion of T-tube, and two patients had choledochoduodenostomy. Six patients had postoperative complications; the first two had wound sepsis and responded to conservative measures and were discharged from the hospital 5 and 30 days postoperatively. The third one with uncontrolled diabetes also developed wound sepsis in association with diabetic keto acidosis (DKA), and septicemia; unluckily the patient died in the ICU on the 40th postoperative day. The fourth patient had bile duct injury with bile leak, and a choledochojujenostomy was performed after several trials for percutaneous drainage, and unfortunately the patient developed multiorgan failure and died on the 45th day postoperatively. The fifth patient developed duodenal fistula after choledochoduodenostomy with burst abdomen and died after 6 weeks. The last one developed ventricular arrhythmia intraoperatively with cardiac arrest, and cardiopulmonary resuscitation (CPR) was performed with return to sinus rhythm, the CBDE was completed, and the patient was transferred to ICU; however, he developed ventricular arrhythmia with subsequent cardiac arrest not responding to CPR measures. The other 63 patients had uneventful postoperative course, and the remaining three patients died for causes unrelated to operation (Table 3).

In the in-situ group, we had 11 mortalities, 10 of whom due to unrelated causes, and one due to severe sepsis owing to perforated GB after acute gangrenous cholecystitis, in whom the general condition was unfavorable to have cholecystectomy, and percutaneous cholecystostomy did not relieve the condition. In all, 13 patients complained at least once having signs and symptoms of biliary cholangitis relieved by antibiotics; 16 patients had

recurrent jaundice and required repeated ERCP and CBD clearance.

A logistic regression was performed to ascertain the effects of age, sex, complete stone extraction, and presence of comorbidities on the likelihood that patients have cholecystectomy. The logistic regression model was statistically significant, with *P*-value less than 0.0005. The model explained 36.1% (Nagelkerke's $R^2$) of the variance in cholecystectomy and correctly classified 78.3% of cases. Incomplete biliary clearance (stenting) is 9.7 times more likely to cause cholecystectomy, but the presence of more than one comorbidities, especially cardiac disease and history of thromboembolic complication or liver cirrhosis, was associated with a reduction in the likelihood of having cholecystectomy.

## Discussion

ES and stone extraction has been recommended by many authors for the management of CBD stones, and if the CBD cannot be cleared a temporary plastic stent can be used to achieve biliary drainage until a surgical clearance with prophylactic cholecystectomy can be performed [5].

ES with a mortality of less than 2% has obvious advantages for managing CBD calculi in elderly patients if cholecystectomy is avoided [15,16], compared with 9.5% mortality in CBDE [17].

Despite marked improvement of endoscopic and laparoscopic techniques in the past decades, still the very conservative wait-and-see policy has a place for the management of many diseases especially in the elderly who must be individually assessed preoperatively in terms of the intended surgery, predicted morbidity and mortality, versus perceived benefit, as well as the influence of other coexistent medical conditions.

Post-ERCP prophylactic cholecystectomy is always recommend, in our department, for patients with combined cholelithiasis and choledocholithiasis. However, social and environmental factors usually influence the patient's decision, especially in the elderly patient. In our study, an overall of 28.3% of patients underwent prophylactic cholecystectomy after CBD drainage, 27% in complete CBD clearance, which rose to 47.2% in incomplete CBD clearance associated with insertion of plastic stent. The rate of cholecystectomy after ES and CBD stone extraction was in the range of 4.8–22% in various studies [2,18].

It is not clear whether cholecystectomy can prevent the development of secondary CBD stones. Lai *et al.* [19] conducted a study on 140 patients with a mean age of 69 years complaining of CBD stones with intact GB, who underwent ES for clearance of stones in the bile duct. Of the 140 patients, 32.8% underwent elective LC soon after ES and 67.2% did not. There was no statistically significant difference as regards recurrent complications between the two groups, concluding that elective cholecystectomy did not prevent recurrent biliary complications. Similar conclusions were drawn by Boytchev *et al.* [20].

The incidence of recurrent biliary symptoms after ES was shown to be about 10% in many retrospective and nonrandomized studies [21–23] with a recurrence rate of CBD stones after ES reported to be in the range of 6.5–17.4% in patients with GB *in situ* [1,24–27]. The recurrent biliary symptoms in our research were seen in 27 (16%) patients of the in-situ group and six (8.3%) patients in the cholecystectomy group; this was controlled by repeated ERCP and biliary clearance in case of recurrent stones, or systemic antibiotics, anticholinergic drugs, and other supportive measures in cholangitis and fatty dyspepsia.

The presence of comorbidity was significantly associated with patient's decision – the more comorbidities are found the more the likelihood that the patient will be in the in-situ group; on the other hand, age had no significant influence on decision-making. Similar reports have confirmed our results, showing that age alone should not be a contraindication to cholecystectomy in the elderly patient [18,28].

In summary, GB *in situ* was not associated with increased morbidity or mortality even in the presence of GB stones. A wait-and-see policy may be recommended for elderly patients with comorbidities and GB *in situ*, taking in consideration regular follow-up for early detection of acute biliary complications.

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#### Conflicts of interest

There are no conflicts of interest.

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