



Original Research

Expectant management of gallbladder stones after endoscopic removal of common bile duct stones



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HIGHLIGHTS

- Wait-and-see policy after endoscopic sphincterotomy can not be recommended as a standard treatment.
- Biliary-related events occur throughout the follow-up time.
- Short-term mortality after endoscopic sphincterotomy is mainly due to cholangitis.
- Long-term mortality is mostly non-biliary related.

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ABSTRACT

Background: Wait-and-see policy after endoscopic sphincterotomy (ES) for common bile duct (CBD) stones in patients with concomitant gallbladder stones may lead to recurrent biliary complications. The aim of this study was to assess the short and long-term results of wait-and-see policy in patients with intact gallbladder after endoscopic clearance of CBD stones.

Materials and methods: From January 1999 to December 2014 a total of 181 consecutive patients with intact gallbladder underwent ES for CBD stones. The main measures of outcome were long-term biliary complications, biliary related mortality, CBD stone recurrence and need for surgical interventions. Secondary outcomes were 30-day mortality and 30-day morbidity. Clinical data were retrospectively collected from hospital records and from the National Registry of Death.

Results: During the median follow-up of 3.9 years (IQR 1.6–6.6) late biliary complications were observed in 24 (13.8%) patients. Cumulative biliary related morbidity at 3 and 5 years was 7.6% and 10.8%, respectively. CBD stone recurrence was observed in 9 (5.2%) patients. On-demand cholecystectomy was performed in 6 (3.3%) patients. 30-day mortality was 3.9% and 30-day morbidity 9.4%. Overall cumulative mortality rate at 3 and 5 years after ES was 31.4% and 49.7%, respectively. Long-term biliary related mortality was 1.7%. No significant difference in long term complications or biliary mortality was observed between patients < 75 or ≥ 75 years of age.

Conclusion: Prophylactic cholecystectomy after ES has been shown to reduce mortality even in high-risk patients. In our series late biliary related mortality and morbidity were relatively low, because a considerable number of patients died from non-biliary related causes. However, most biliary-related events seem to occur evenly during the follow-up after ES. A prompt risk assessment and consideration of surgical treatment during index admission may prevent late biliary –related complications.

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1. Introduction

Modern alternatives for CBD stone removal in patients with gallbladder stones include laparoscopic CBD exploration and stone

removal at the time of surgery, or pre-, intra or postoperative ERCP together with LC [1]. Even in high-risk patients laparoscopic CBD clearance can be achieved efficiently, without an increase in complications and with fewer procedures per patient. However, some patients are thought to be high-risk candidates for surgery or refuse cholecystectomy. Therefore a wait-and-see policy, e.g. leaving the gallbladder in situ after endoscopic sphincterotomy (ES) for bile duct stones, is increasingly used in poor surgical candidates [2].

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Patients with expectant management after endoscopic clearance of CBD, however, are prone to adverse complications such as biliary pain, acute cholecystitis, cholangitis and pancreatitis. Randomized studies have shown that cholecystectomy after ES reduces biliary events from 21–47% to 2–7% when compared to wait-and-see policy [3–6]. Nearly half of the patients managed with wait-and-see policy have to undergo a subsequent cholecystectomy or an additional ERCP due to frequent episodes of biliary pain, cholecystitis or recurrent bile duct stones. Moreover, conversion rate to open surgery may be higher in those patients needing emergency cholecystectomy after expectant management [5]. Despite the fact that retrospective studies have been shown controversial results with high incidence of late biliary complications, in the elderly and high-risk surgical patients the expectant management has been seen as a safe option [7–11].

Elective cholecystectomy after a finding of choledocholithiasis is supported by many, and has been common strategy in our institution. From existing studies, the decision to perform cholecystectomy after endoscopic sphincterotomy in high-risk elderly patients appears to be somewhat subjective. We therefore set out to determine the fate and long-term outcome of patients having cholecystectomy deferral after endoscopic removal of common bile duct stones.

1.1. Patients and methods

From January 1999 to December 2014 181 patients with gallbladder stones and known CBD stones underwent ES and stone extraction without subsequent cholecystectomy in our institution which is the only hospital offering advanced endoscopic services for 276 000 inhabitants in the Central Finland Health Care District. The diagnosis of CBD stones was done by MRCP or ERCP. All 181 patients underwent endoscopic sphincterotomy and clearance of CBD with balloon or Dormia basket and mechanical lithotripsy, when appropriate. In case of unsuccessful CBD stone clearance during the first ERCP a subsequent ERCP was scheduled, often after placement of a biliary stent. Wait-and-see policy was selected if the patient refused the forthcoming cholecystectomy or was evaluated to be a high-risk patient for surgery. This decision was made by the consultant internist and operating surgeon and was based on physical and mental performance status, age and significant comorbidities. Patients with biliary tract or pancreatic malignancies were excluded.

The main measures of outcome were biliary complications, mortality, CBD stone recurrence and subsequent surgical interventions in the long-term, with 30-day mortality and morbidity as secondary outcome measures. The study was approved by hospital administration. Data were collected retrospectively from hospital records. The interval between the first ERCP and recurrent biliary symptoms, additional ERCPs, hospital readmission, complications, surgical interventions and causes of death were recorded. Biliary pain episodes not needing hospital readmission were not documented. Comorbid illnesses were calculated using Charlson Comorbidity Index and ASA score. Retained CBD stones and long-term complications were defined when biliary event occurred after 30 days from primary ERCP + ES.

Ethics approval was not sought as retrospective data were collected from hospital records and National Registry of Death. This study was reviewed according to guidelines from the Strengthening the Reporting of Observational Studies in Epidemiology [12].

1.2. Statistical analysis

The data are presented as means with standard deviations (SD), medians with interquartile range. (IQR) or counts with percentages. Pearson's χ^2 or Fisher's exact

tests were used to compare frequencies, and Student's *t* and Mann-Whitney *U* tests were used for continuous variables.

The Kaplan-Meier method was used to calculate the cumulative long-term mortality and complication rate, and the differences between groups were compared with the log-rank test. Survival times were calculated from the date of ES until the time of death, long-term complication or the end of follow-up. $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS statistical software.

2. Results

A total of 181 patients with a mean age of 79.6 ± 9.2 years underwent ERCP + ES for the treatment of CBD stones. Baseline characteristics are shown in Table 1. All patients had also gallbladder stones or sludge verified by ultrasound (US). Charlson Comorbidity Index (CCI) in patients <75 years was significantly lower [mean 3.9 (SD 2.8)] than in patients ≥ 75 years [mean 5.8 (SD 2.6)], $p < 0.001$. At the index admission all patients had biliary pain, 93 (51.4%) had jaundice or elevated liver enzymes, 34 (18.8%) biliary pancreatitis, 29 (16.0%) acute cholecystitis and 25 (13.8%) acute cholangitis. Diagnosis of CBD stones was performed with MRCP in 97 patients (53.6%), CT in 16 (8.8%) and US in 10 patients (5.5%). The remaining CBD stone detection was made during ERCP procedure. Endoscopic clearance was successful in 168 (92.8%) patients at first attempt and 13 (7.2%) patients had ≥ 2 ERCP procedures during 30-day time.

Table 1
Baseline demographic characteristics, $n = 181$.

| | |
|---------------------------------------|------------|
| Age, mean (SD) years | 79.6 (9.2) |
| Gender male, n (%) | 91 (50.3) |
| ASA I, n (%) | 1 (0.6) |
| ASA II, n (%) | 21 (11.6) |
| ASA III, n (%) | 103 (56.9) |
| ASA IV, n (%) | 56 (30.9) |
| Charlson Comorbidity Index, mean (SD) | 5.4 (2.8) |
| Comorbidity, n (%) ^a | 168 (92.8) |
| Cardiovascular | 121 (66.9) |
| Neurologic | 68 (37.6) |
| Hypertension | 64 (35.4) |
| Pulmonary | 34 (18.8) |
| Diabetes | 30 (16.6) |
| Renal | 10 (5.5) |
| Liver | 6 (3.3) |
| Other | 59 (32.6) |

^a Figures in the columns are not additive because some patients had more than one symptom.

Table 2
30-day mortality and morbidity after endoscopic sphincterotomy, $n = 181$.

| | |
|------------------------------------|-----------|
| 30-d mortality, n (%) | 7 (3.87) |
| Cholangitis and sepsis | 4 (2.21) |
| Myocardial infarction | 2 (1.10) |
| Post ERCP bleeding | 1 (0.55) |
| 30-d morbidity, n (%) | 17 (9.4) |
| Residual CBD stones, n (%) | 10 (5.5) |
| Pancreatitis, n (%) | 3 (1.66) |
| Post ERCP bleeding, n (%) | 3 (1.66) |
| Retroperitoneal perforation, n (%) | 1 (0.55) |
| Clavien-Dindo complications, n (%) | 24 (13.3) |
| Gr I | 1 (0.55) |
| Gr II | 3 (1.66) |
| Gr IIIa | 12 (6.6) |
| Gr IIIb | 1 (0.55) |
| Gr IVa | 0 (0) |
| Gr IVb | 0 (0) |
| Gr V | 7 (3.87) |

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