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# Long-Term Outcomes of Endoscopic Treatment for Bile Duct Stones in Patients Aged ≥ 85 Years

**Nakamura H and Sugimoto S[1*]**

[1]Division of Gastroenterology, Ise Red Cross Hospital, 471-2, 1, Funae, Ise, Mie 516-8512, Japan

***Corresponding author:**

Shinya Sugimoto,
Division of Gastroenterology, Ise Red Cross Hospital, 471-2, 1, Funae, Ise, Mie 516-8512, Japan, Tel: +81-596-28-2171;
Fax: +81-596-28-2965,
E-mail: sh.sugimoto@ise.jrc.or.jp;
sh.sugimoto1013@gmail.com

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## 1. Abstract

**1.1. Aims:** There are limited data regarding the safety and efficacy of complete stone removal for the treatment of bile duct stones in elderly patients. Hence, this study evaluated the long-term outcomes of complete stone removal in elderly patients.

**1.2. Methods:** We retrospectively analyzed the clinical records of patients aged ≥ 85 years who underwent therapeutic endoscopic retrograde cholangiopancreatography for bile duct stones. Based on the extent of stone removal, patients were divided into two groups: complete stone removal (group C) and incomplete stone removal with plastic stent insertion (group I). Patient characteristics, outcomes of endoscopic procedures, adverse events, and long-term prognosis were compared between the groups.

**1.3. Results and Conclusion:** The median age of the 211 patients included in this study was 88 years (men, n = 70; women, n = 141). The proportion of patients with dementia was significantly higher in group I than in group C (48% vs. 24%; $p = 0.01$). The median diameter of the largest stone in groups C and I was 7 and 10 mm ($p = 0.028$), respectively, and the average procedural duration was 34 and 26 min ($p < 0.01$), respectively. Neither group had serious complications. The overall survival rate was significantly higher in group C than in group I ($p = 0.002$), while the disease-specific cumulative death rate was not significantly different between the groups ($p = 0.312$). Therapeutic endoscopic retrograde cholangiopancreatography can be safely performed in elderly patients. Therefore, advanced age should not be a reason to forgo complete stone removal.

## 2. Introduction

Endoscopic Retrograde Cholangiopancreatography (ERCP) is an established diagnostic and therapeutic approach for the treatment of bile duct stones. However, ERCP has an adverse event rate of 5–10% and a mortality rate of 0.3–0.5% [1-3]. Further, elderly patients who underwent ERCP had an increased risk of bleeding, cardiopulmonary events, and mortality [4]. As the life expectancy of elderly patients has dramatically increased worldwide [5], the proportion of elderly patients who may undergo therapeutic endoscopic interventions is likely to increase in the near future. Several studies have reported that complete stone removal for choledocholithiasis is safe [6] and may contribute to a good prognosis [7] even in elderly patients. Although biliary stent insertion may be a viable alternative to complete stone removal in high-risk patients, the long-term outcomes remain a concern [8-11]. To the best of our knowledge, few studies have assessed the need for complete stone removal in elderly patients with choledocholithiasis with respect to prognosis.

Therefore, this study aimed to evaluate the safety and efficacy of complete endoscopic stone removal in patients aged ≥ 85 years.

## 3. Materials and Methods

### 3.1. Study Population

This retrospective study initially enrolled 244 patients aged ≥ 85 years who were diagnosed with bile duct stones by computed tomography (CT) or magnetic resonance imaging. Patients underwent therapeutic ERCP at our institution between January 2012 and March 2019. We were unable to evaluate procedure times, adverse events, or long-term prognosis in 33 patients due to surgically altered anatomy (other than Billroth I) (12 patients) and various types of cancer (other than biliary tract) (21 patients). After excluding these cases, 211 patients (representing 354 ERCP procedures) were included in the analysis. The study design was approved by the Institutional Review Board of *[blinded information]* (approval number: 1-14). Research was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all patients before ERCP.

Based on the extent of stone removal, patients were divided into two groups: complete stone removal (group C) and incomplete stone removal with plastic stent insertion (group I). Patients initially treated with biliary stent insertion and administered antibiotics for concurrent cholangitis who later underwent planned complete stone removal were assigned to group C. Group C also included 13 patients with difficult bile duct stones who were not scheduled for complete stone removal; however, these stones decreased in number or shrank in size sufficiently for complete stone removal to be performed during the follow-up period (Figure 1). The characteristics and long-term prognosis of the patients, as well as outcomes and adverse events of the endoscopic procedures, were compared between the groups.

### 3.2. Sedation Procedures

During ERCP, patient vitals were monitored continuously (every 5 min), and an electrocardiography was performed. Patients received oxygen at a rate of 2 L/min through a nasal cannula. Patients were intravenously administered midazolam (1–3 mg) or flunitrazepam (0.2–0.6 mg) for sedation and meperidine (5–10 mg) for analgesia before initiating the procedure. Additional doses of midazolam (1 mg), flunitrazepam (0.2 mg), and meperidine (5 mg) were administered intermittently, as needed, during the procedure.

There was no dedicated protocol for elderly patients; however, the dosage and frequency of each bolus were adjusted according to age and comorbidities. At our hospital, sedation was performed by an endoscopist.

### 3.3. Endoscopic Procedures

After patients were confirmed to be adequately sedated, ERCP was performed with a side-viewing endoscope (JF-260V and TJF-260V; Olympus Medical Systems, Co., Ltd., Tokyo, Japan). The common bile duct was selectively imaged, and the number and sizes of stones were confirmed. To access the stones, endoscopic sphincterotomy (EST), endoscopic papillary balloon dilation (EPBD), or endoscopic papillary large balloon dilation (EPLBD) was selected and performed at the operator's discretion. For bile duct stone removal, a retrieval balloon catheter or stone extraction basket was used. Mechanical lithotripsy was performed as needed. If complete stone removal could not be achieved, a plastic stent was inserted. A 7-Fr pigtail stent (Zimmon®; Cook Ireland Ltd., Limerick, Ireland) or a 7–8.5-Fr straight stent (Flexima™; Boston Scientific Japan, Tokyo, Japan) was placed in the bile duct.

The procedure time was defined as the time from endoscope insertion to its removal. Stone removal was considered successful if there was no evidence of radiolucent stones on contrast-enhanced imaging after removal. All ERCPs were supervised by four endoscopists who had performed over 1,000 ERCPs.

### 3.4. Definition of Adverse Events

Adverse events during endoscopy were defined as ERCP and/or sedation-related adverse events, such as hypoxemia (oxygen saturation < 90%), hypotension (systolic blood pressure < 90 mmHg), and bradycardia (heart rate < 50 beats/min). Pancreatitis was defined as abdominal pain with a threefold elevation in serum amylase levels. Bleeding was defined as a decrease in hemoglobin level of ≥ 2 g/dL (compared with the baseline) and clinical evidence of bleeding. Perforation was defined as retroperitoneal or bowel-wall perforation detected by any imaging modality.

### 3.5. Follow-Up

After ERCP, a protease inhibitor and an antimicrobial agent were administered to prevent pancreatitis and infection [12, 13]. All patients routinely underwent follow-up investigations with laboratory testing. For patients with abdominal pain, serum amylase levels were measured, and abdominal CT was performed, if symptoms persisted. After discharge, patients were either scheduled to visit our outpatient clinic or referred to their family doctor. Family doctors were asked to refer patients to our hospital if biliary tract infection (cholangitis, cholecystitis, or liver abscess) was suspected. In such cases, laboratory tests, abdominal CT, and ERCP, if necessary, were performed. The acceptance of stent exchange depends on the patients' environment (i.e., whether or not sufficient community support is available). Hence, although planned regular stent exchange is considered a good strategy, it was not used in this study.

The Overall Survival (OS) and Disease-Specific Survival (DSS) rates were calculated to evaluate the necessity of complete stone removal in elderly patients with respect to prognosis. Survival time was calculated from the date of the initial ERCP to the date of the final survival confirmation. Disease-specific death was defined as death due to cholangitis, retrograde biliary infection, stent occlusion or shedding, stone recurrence, cholecystitis, or liver abscess.

Long-term follow-up data were collected by communicating with family doctors, reviewing outpatient notes, or calling patients' homes. The follow-up period was defined as the date of initial admission to the date of the last visit to the family doctor or outpatient clinic, or the date of confirmed survival by telephone.

### 3.6. Statistical Analyses

Continuous variables were presented as mean values, whereas categorical variables were reported as numbers and percentages. Continuous variables were compared using Student's t-tests or Mann–Whitney U tests, and categorical variables were compared using Fisher's exact tests, as appropriate. Kaplan–Meier estimates of survival curves and a fitted Cox proportional hazards model were used to assess OS. Gray's test was used to analyze DSS. Specifically, the cumulative deaths caused by biliary events versus non-biliary events were investigated with respect to the two groups. Statistical significance was set at $p < 0.05$. All statistical analyses were performed using PASW 18.0 (SPSS Inc., Chicago, IL, USA) and EZR (Easy R), a graphical user interface for R (The R Foundation for Statistical Programming, Vienna, Austria) [14].

## 4. Results

### 4.1. Patient Characteristics

A total of 211 patients were included in the study, which comprised 70 men (33%) and 141 women (67%). The median age at the time of the first ERCP was 88 (range, 85–104) years. In addition, 148 patients (70%) had complete stone removal (group C) and 63 patients (30%) had incomplete stone removal with plastic stent insertion (group I).

Sex, age, body mass index, performance status, most comorbidities, the use of antithrombotic drugs, and the presence of cholangitis were not significantly different between the two groups. However, the proportion of patients with dementia was significantly higher in group I than in group C (48% vs. 24%; $p = 0.01$) (Table 1).

**Table 1:** Patient characteristics

| | Complete stone removal (n=148) | Incomplete stone removal (n=63) | p value |
|---|---|---|---|
| Sex, male : female, % (n) | 34 (50) : 66 (98) | 32 (20) : 68 (43) | 0.873* |
| Age, years, median (range) | 89 (85–104) | 90 (85–96) | 0.057** |
| BMI, median (range) | 20 (14-31) | 20 (12–27) | 0.536** |
| Performance status(1), median (range) | 2 (0-4) | 2 (1–4) | 0.334** |
| Comorbidities, % (n) | | | |
| Coronary heart disease | 8 (12/148) | 16 (10/63) | 0.137* |
| Respiratory disease | 6 (9/148) | 6 (4/63) | 1.000* |
| Cerebrovascular disease | 22 (33/148) | 19 (12/63) | 0.714* |
| Renal failure(2) | 6 (9/148) | 0 (0/63) | 0.600* |
| Dementia | 24 (36/148) | 48 (30/63) | 0.010* |
| Use of antithrombotic drugs, % (n) | 30 (45/148) | 41 (26/63) | 0.152* |
| Cholangitis, % (n) | 63 (93/148) | 67 (42/63) | 0.635* |

(1) Eastern Cooperative Oncology Group. (2) Renal failure that needs hemodialysis.

*Fisher's exact test. **Mann–Whitney U test. BMI, body mass index

### 4.2. Results of the Endoscopic Procedure

The median number of procedures performed was 1 (range, 1–5) and 1 (range, 1–9) in groups C and I, respectively. The median procedure time was 34 min (range, 5–103) and 26 min (range, 6–125) in groups C and I, respectively, with a significantly longer procedure time in group C ($p < 0.01$).

The median number of stones was 2 (range, 0–23) and 1 (range, 0–12) in groups C and I, respectively. The median diameter of the largest stone was 7 mm (range, 0–32) and 10 mm (range, 0–50) in groups C and I, respectively, with a significantly smaller diameter in group C ($p = 0.028$).

In group C, EST was performed in 65% (160/245) of the procedures, EPBD in 3% (7/245), and EPLBD in 11% (28/245). In contrast, in group I, EST was performed in 20% (22/109) of the procedures, EPBD in 1% (1/109), and EPLBD in 5% (5/109). The number of ESTs and EPLBDs performed was significantly higher in group C than in group I ($p < 0.01$ and 0.047, respectively) (Table 2).

**Table 2:** Results of endoscopic procedures

| | Complete stoneremoval (n=148) | Incomplete stone removal (n=63) | p value |
|---|---|---|---|
| Total number of procedures, n | 245 times | 109 times | |
| Number of procedures, median (range) | 1 (1–5) | 1 (1–9) | 0.156** |
| Procedure time, median, min (range) | 34 (5–103) | 26 (6–125) | <0.01** |
| Number of stones, n (range) | 2 (0(3)- –23) | 1 (0–12) | 0.112** |
| Diameter of the largest stone, median, mm (range) | 7 (0(3) –32) | 10 (0–50) | 0.028** |
| Endoscopic procedure, % (n) | | | |
| EST | 65 (160/245) | 20 (22/109) | <0.01* |
| EPBD | 3 (7/245) | 1 (1/109) | 0.443* |
| EPLBD | 11 (28/245) | 5 (5/109) | 0.047* |

(3) Debris counted as 0 and 0 mm.

*Fisher's exact test. **Mann–Whitney U test

EST, endoscopic sphincterotomy; EPBD, endoscopic papillary balloon dilation; EPLBD, endoscopic papillary large balloon dilation; ERCP, endoscopic retrograde cholangiopancreatography.

### 4.3. Adverse Events

The frequency of adverse events (hypoxemia, hypotension, and bradycardia during ERCP, and pancreatitis, bleeding, and perforation after ERCP) that occurred in groups C and I are presented in (Table 3). The incidence of bradycardia was significantly higher in group C than in group I ($p < 0.01$). The proportion of patients who developed pancreatitis was not significantly different between groups C and I (0% and 2%, respectively; $p = 0.238$). No bleeding occurred in either group. Only one patient in group C had perforation during EPLBD. All patients who developed adverse events post-ERCP recovered with conservative treatment (Table 3).

**Table 3:** Adverse events

| | Complete stone removal (n=148) | Incomplete stone removal (n=63) | p value |
|---|---|---|---|
| During ERCP | | | |
| Hypoxemia, % (n) | 3 (8/245) | 6 (6/109) | 0.377* |
| Hypotension, % (n) | 15 (37/245) | 20 (22/109) | 0.279* |
| Bradycardia, % (n) | 9 (23/245) | 0 (0/109) | <0.01* |
| Post ERCP | | | |
| Pancreatitis, % (n) | 0 (1/245) | 2 (2/109) | 0.225* |
| Bleeding, % (n) | 0 (0/245) | 0 (0/109) | NA |
| Perforation, % (n) | 0 (1/245) | 0 (0/109) | NA |

*Fisher's exact test

ERCP, endoscopic retrograde cholangiopancreatography

### 4.4. Long-Term Prognosis

The causes of death during a median follow-up period of 549 days (range, 6–2512) (group C) and 549 days (range, 2–2118) (group I) are presented in (Table 4). The mortality rate was significantly higher in group I than in group C (43% vs. 21%; $p = 0.001$). In groups C and I, 3 and 3 patients died of biliary tract infection, and 28 and 24 patients died of other diseases, respectively.

Kaplan–Meier survival curves showed that the OS rate of group C was significantly higher than that of group I (log-rank $p = 0.002$). This was confirmed by the Cox proportional hazards model (hazard ratio, 0.44; 95% confidence interval: 0.26–0.74; $p = 0.002$) (Figure 2).

The described numbers of deaths were used as competing risk events in the DSS analysis. Gray's test showed that the probability of an incident (death) was significantly higher in group I than in group C in case of "other diseases death" (statistic = 8.056; $p = 0.005$). In contrast, Gray's test showed that the probability of an incident (death) was not significantly different between the two groups in case of "biliary tract infection death" (statistic = 1.023; $p = 0.312$) (Figure 3).

**Table 4:** Cause of deaths during the follow-up period

| | complete stone removal (n=148) | Incomplete stone removal (n=63) | p value |
|---|---|---|---|
| Follow-up period, median, days (range) | 549 (6-2512) | 549 (2-2118) | 0.584** |
| Deaths during follow-up period, % (n) | 20 (31/148) | 43 (27/63) | 0.001* |
| Cause of deaths | | | |
| Senility, n | 10 | 9 | 0.112* |
| Infection except cholangitis, n | 5 | 9 | 0.006* |
| Heart/cerebrovascular disease, n | 6 | 3 | 1.000* |
| Renal/hepatic failure, n | 5 | 0 | 0.325* |
| Cholangitis, n | 3 | 3 | 0.366* |
| Cancer, n | 1 | 0 | 1.000* |
| Unknown, n | 1 | 3 | 0.081* |

*Fisher's exact test. **Mann–Whitney U test

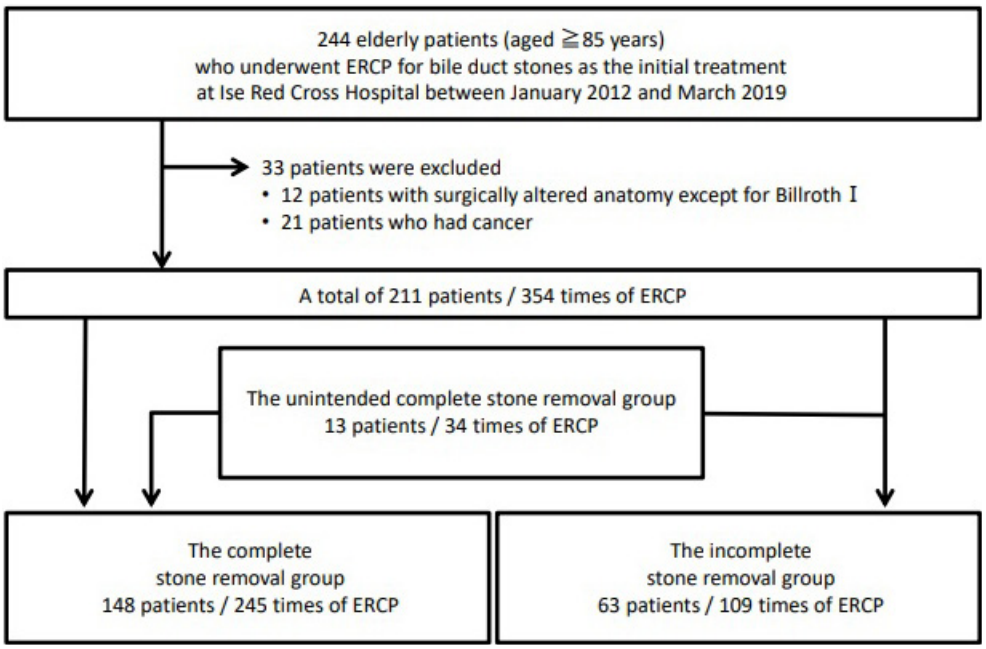


**Figure 1:** Flowchart of patient enrollment. ERCP, endoscopic retrograde cholangiopancreatography.

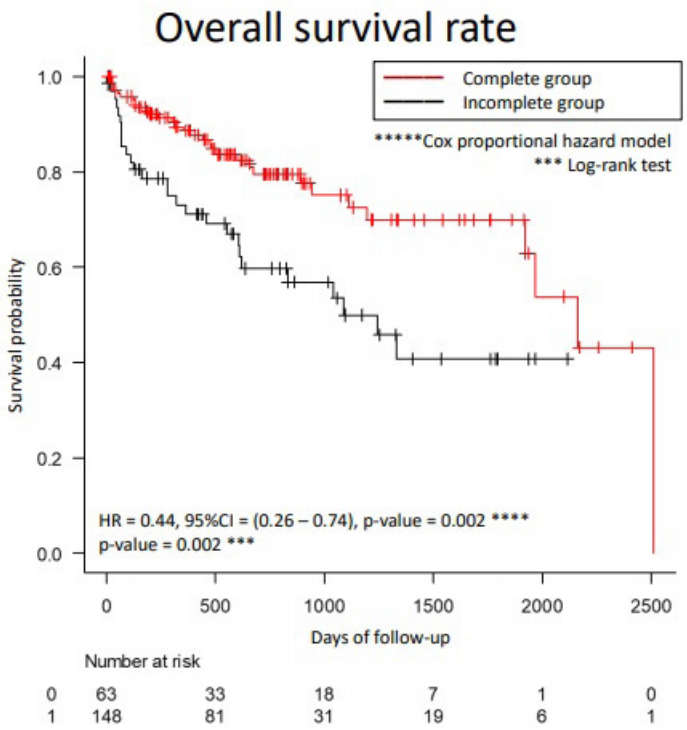


**Figure 2:** Kaplan–Meier curves showing that the overall survival rate of group C was significantly higher than that of group I. CI, confidence interval; HR, hazard ratio

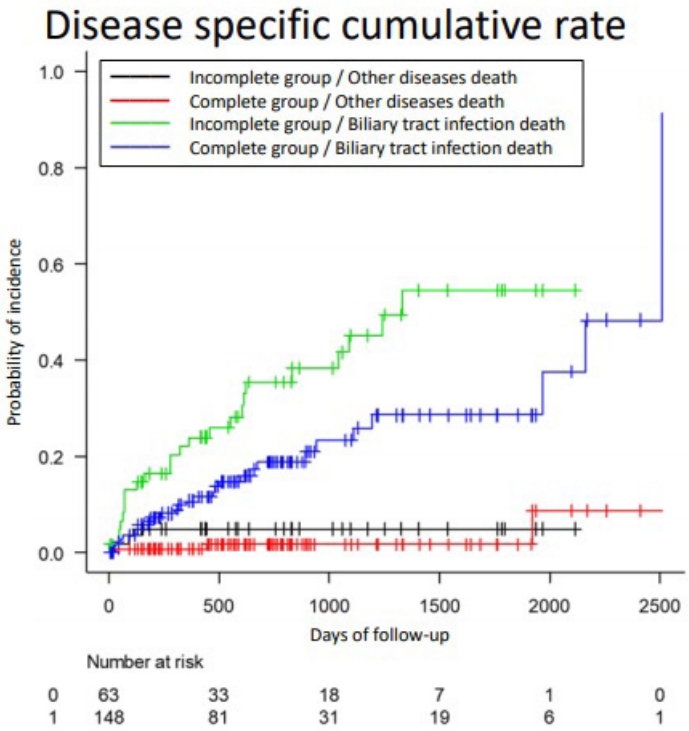


**Figure 3:** Gray's test showing that the probability of an incident (death) was not significantly different between the two groups in case of "biliary tract infection death".

## 5. Discussion

This study showed that the DSS rate was not significantly different between patients who underwent complete stone removal (group C) and patients who underwent incomplete stone removal with plastic stent insertion (group I). Many causes of death in these patients were unrelated to biliary tract infection. Therefore, biliary stenting may be an acceptable option for patients in whom it is difficult to achieve complete stone removal. No adverse events were fatal and, hence, complete stone removal may be a safe procedure in patients aged ≥ 85 years. These results suggest that advanced age per se may not be a reason to forgo complete stone removal.

ERCP is the intervention of choice for the treatment of bile duct stones. Ukkonen et al. [15] reported a 96.6% success rate of complete stone removal in 279 elderly patients who underwent ERCP, with only 3.4% of patients experiencing complications. Therefore, we performed endoscopic treatment to achieve complete stone removal in elderly patients with bile duct stones.

Elderly patients occasionally have serious comorbidities and multiple and/or large stones that are difficult to remove. Hence, the longer procedure time and many treatments required to remove the stones may be too physically demanding for these patients. In elderly patients, the complication rate associated with ERCP is higher, and the rate of complete duct clearance is lower than of those in younger patients. Obana et al. [16] reported a significantly lower rate of complete stone clearance in elderly patients than in younger patients (92.4% vs. 99.0%; $p < 0.01$).

With regard to safety, EST and EPLBD were significantly more commonly performed, and the procedure time was significantly longer in group C than in group I. These procedures were more physically demanding in these patients, and bradycardia was significantly more common in group C than in group I. Regarding adverse events, the proportion of pancreatitis was 0% in group C and 2% in group I. No bleeding occurred in either group. One patient in group C had perforation during EPLBD. None of the adverse events were fatal. Therefore, we consider endoscopic stone removal to be safe in patients aged ≥ 85 years.

Biliary stenting is an effective and safe strategy for treating bile duct stones. It has a shorter procedure time, is less invasive than complete stone removal, and can be performed at any facility [17]. It also achieves remarkable improvements in the symptoms of acute cholangitis by preventing incarceration of bile duct stones. However, the incidence of acute cholangitis is higher after biliary stenting than after complete stone removal, with reported recurrence rates of 20.0–63.2% [10, 18-20] and 11.3–13.2% [21, 22], respectively. This supports the strategy of aiming to remove bile duct stones completely, if possible, to prevent cholangitis recurrence.

To the best of our knowledge, few reports have evaluated the long-term prognosis of elderly patients with common bile duct stones after endoscopic treatment. In addition, these were relatively small reviews from a single facility.

An advantage of our study compared with previous reports is that we evaluated efficacy. In this study, the OS rate was significantly high-

er in group C than in group I. In contrast, the DSS rate was comparable between the groups. However, Gray's test is very sensitive; thus, owing to the small number of deaths from biliary tract infection (n = 6), we could not definitively draw the conclusion that complete stone removal leads to a good prognosis in elderly patients.

The median number of procedures was 1, and no difference was found between the two groups. In terms of long-term prognosis, biliary stenting had effects similar to complete stone removal. In group I, the cause of death in many patients was unrelated to bile duct stones before cholangitis recurrence. One reason is the retrospective evaluation; hence, in patients with a relatively severe condition (and high risk of death), clinicians tend to choose biliary stenting. In this study, no significant differences in sex, age, body mass index, performance status, and most comorbidities were found between the groups; only the proportion of patients with dementia was significantly higher in group I. Although dementia does not cause death, patients with dementia were unable to report their symptoms adequately, resulting in symptoms only being detected once the disease became critical. In addition, other factors that we did not consider might have also affected the patients' condition. Thus, good prognostic predictors of health status may be useful in deciding appropriate treatments for bile duct stones in elderly patients.

This study has some limitations. First, this was a retrospective investigation. Information on the cases excluded from endoscopic surgery was not available. Although elderly patients with severe comorbidities are probably at a greater risk of developing complications, patients who should have been excluded from endoscopic surgery could not be determined. Second, the treatment strategy for bile duct stones was not randomized. Although individual factors such as age, underlying disease, and patient preference may have affected treatment decisions, performing a randomized trial was not possible for ethical reasons.

## 6. Conclusion

This study could not definitively draw the conclusion that achieving complete stone removal necessarily leads to a good prognosis. However, therapeutic ERCP can be performed safely in elderly patients. Therefore, advanced age should not be a reason to forgo complete stone removal.

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