

Safety and efficacy of extending a previous endoscopic sphincterotomy for the treatment of retained or recurrent common bile duct stones

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Abstract

Background The aim of the study was to evaluate the safety and efficacy of extending a previous endoscopic sphincterotomy (ES) in patients with retained or recurrent common bile duct (CBD) stones.

Methods Between 2001 and 2013, extension of a previous ES, for known or suspected CBD stones, was performed in 118 patients (m/f, 53/65) with a median age of 74 (range: 31-91) years (group A). During the same period, ES was performed in 1064 patients with suspected or known choledocholithiasis (group B). The efficacy and complications of the extension (group A) were analyzed and a comparison was made between groups regarding complications.

Results Bile duct cannulation was straightforward in all patients in group A, while it was considered difficult in 49% of patients in group B. Complete clearance was achieved in 76/97 patients (78%) with CBD stones, after a mean of 1.18 attempts per patient. Mechanical lithotripsy was required in 10% of patients. After extension, immediate bleeding occurred in 24 patients (20%), which stopped spontaneously in 9 (37%) and endoscopic hemostasis was required in the remainder. Complications were more frequent in group B (5.3% vs. 0.8%, $P=0.031$), but there was no significant difference for any individual complication. Immediate bleeding was more common in group B (29% vs. 20%, $P=0.035$), but there was no difference in clinical bleeding.

Conclusion Extension of a previous ES seems to be a simple, effective and safe technique, allowing stone clearance in nearly 80% of patients; it is thus recommended in patients with CBD stones after ES.

Keywords Endoscopic sphincterotomy, extension, choledocholithiasis, recurrent stones, balloon dilation, complications, sphincteroplasty, retained stones

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) has been established as a first-line treatment of choledocholithiasis. However, ES is associated with complications, such as bleeding, pancreatitis, and perforation, and long-term adverse events such as sphincter of Oddi dysfunction [1,2]. In an effort to avoid the adverse events of ES, endoscopic papillary balloon dilation has been introduced, but has not been established as a standard treatment because of the potential risk of severe pancreatitis [3].

Recurrent common bile duct (CBD) stone formation is not uncommon following ES, with an incidence ranging from 4-24% [4-7]. Repeat ERCP with extension of the previous ES is

often the treatment of choice for these patients [8]. Endoscopic papillary large balloon dilation (EPLBD) after a limited sphincterotomy has been recently established [9] with the intention of reducing complications and allowing the removal of large stones without the need for mechanical lithotripsy [10]. The aim of the present retrospective study was to assess the efficacy and safety of extending a previous ES for the treatment of recurrent or retained choledocholithiasis.

Patients and methods

A retrospective observational study was undertaken, extending over the years 2001-2013, based on data from a prospectively maintained database. This database includes 2520 ERCPs performed by a single operator (AV). Both demographic and clinical data are documented within this database.

In 118 cases with suspected or known choledocholithiasis, an extension of a previous ES was performed (group A). During the same period, ES was performed in 1064 patients with suspected or known choledocholithiasis (group B). Patients with malignancy were excluded. Antiplatelets (except aspirin) were discontinued for at least 5 days before the procedure. Acenocoumarol was discontinued for 2-3 days and perioperative bridging therapy with low molecular weight heparin was used.

Bile duct cannulation was defined as difficult when more than 5 attempts were required at cannulation, or when a needle-knife pre-cut was performed. Sphincterotomies were performed using an endo-cut mode. Complications were defined according to the previous literature [1,11]. Immediate bleeding after ES was documented separately from bleeding that was clinically evident after the examination. Clinically evident bleeding was designated as hematemesis or melena, with an associated decrease in hemoglobin of at least 2 g/dL or the need for blood transfusion [1,11].

A comparison was performed between groups regarding complications. The statistical analysis was conducted using the chi-square or Fisher's exact test for categorical variables and the Mann-Whitney test for non-parametric continuous variables. The study was reviewed by a biomedical biostatistician expert in medical data analysis. Minitab 16 Statistical Software was used for all calculations.

Results

Group A consisted of 53 male and 65 female patients with a median age of 74 (range: 31-91) years. The most common presenting symptom was acute cholangitis, encountered in 71% of the patients, whereas 22% were asymptomatic. Asymptomatic patients had a scheduled repeat ERCP for stent or stone removal. The median interval from the previous ES was 7 months (range: 4 days to 20 years). Patients in group A were older, more often asymptomatic and were more likely

to have undergone a previous biliary operation than those of group B, with cholecystectomy being the most common procedure (90%). There was no patient with acute pancreatitis as a presenting symptom in group A. Patient characteristics are shown in Table 1.

As expected, bile duct cannulation was straightforward in all patients in group A, while it was considered difficult in almost half (49%) the patients in group B. The median CBD diameter in group A patients was 13 (range: 8-20) mm. The pancreatic duct was opacified in only 12 patients (10%), as cannulation of the pancreatic duct was not intended in patients of group A. CBD stones were found in 97 (82%) patients. The remaining 21 patients had dilated ducts with no visible stones and the extension was performed because of suspected stenosis of the previous ES. Thirty-three patients (34%) had CBD stones larger than 15 mm. Complete CBD clearance of stones was achieved at the first attempt in 76/97 patients (78%); a second attempt was required in 11 and a third in 3 patients. Mechanical lithotripsy was required in 10 patients (10%), whereas further extension of a previously extended ES was required in 7 patients, at the second or third attempt. Despite these therapeutic maneuvers, surgical CBD exploration in order to remove the stones was required in 15 patients (15%). Additionally, there were 27 patients with stones after ES, in whom an extension was not required to remove the stones; in 4 of them EPLBD was performed. These patients were excluded from our analysis. The outcome of patients with CBD stones is shown in Table 2.

Immediate bleeding, after extension, occurred in 24 patients (20%). Although it stopped spontaneously in 9 (37%), adrenaline injection or combination with other hemostatic techniques (argon plasma coagulation, application of diathermy, balloon tamponade) was required in 15/24 (62%) patients. Endoscopic hemostasis was achieved in all but one patient, who underwent a laparotomy for hemostasis. There was no difference regarding age, sex, time interval from previous ES, presence of CBD stones, duodenal diverticula or cholangitis, antiplatelet or acenocoumarol use, between patients who presented immediate bleeding in comparison with patients who did not have any bleeding complication (Table 3). An American Society of Anesthesiologists' (ASA) score ≥ 3 was the only factor associated with increased immediate bleeding after extension. There were no other complications in that group of patients. Two post-ERCP deaths occurred, but these were due to cardiovascular events, not directly related to the procedure. Complications are listed in Table 4. Complications were more frequent in group B (5.3% vs. 0.8%). There were 3 deaths in group B, but none was directly related to the procedure itself.

Discussion

CBD stones found 6 months or more after ERCP with ES are generally considered recurrent, as opposed to retained [5,6,12,13]. Risk factors for recurrent CBD stones are mainly periampullary diverticula and a dilated CBD. Other factors that have been identified include advanced age,

Table 1 Baseline characteristics of the patients

| Characteristic | Group A | Group B | P-value |
|----------------------------|------------|-------------|---------------|
| n | 118 | 1064 | |
| Sex (m/f) | 53/65 | 487/577 | NS (C-S) |
| Age (median, range) | 74 (31-91) | 73 (16-99) | 0.039 (M-W) |
| ASA score I, II / ≥III | 90/28 | 750/238 | NS (C-S) |
| Symptomatology | | | |
| Asymptomatic | 27 (22%) | 41 (4%) | <0.0005 (C-S) |
| Acute cholangitis | 84 (71%) | 785 (76%) | NS |
| Biliary colic | 7 (6%) | 55 (5.3%) | NS |
| Acute pancreatitis | 0 | 149 (14%) | <0.0005 (C-S) |
| Previous biliary operation | 86 (72%) | 363 (34%) | <0.0005 (C-S) |
| Antiplatelets | 12 (10%) | 93 (8.7%) | NS (C-S) |
| Acenocoumarol | 3 (2.5%) | 45 (4.2%) | NS (C-S) |
| Duodenal diverticula | 26 (22%) | 261 (24.5%) | NS (C-S) |

n, number of patients; m, male; f, female; ASA, American Society of Anesthesiologists' physical status classification; NS, non-significant; C-S, chi-square (or Fisher exact as appropriate); M-W, Mann-Whitney

Table 2 Outcomes of patients with recurrent or retained CBD stones

| Technique and outcome | No. of patients (n=124) |
|--|----------------------------|
| No extension | 23 |
| EPLBD | 4 |
| Extension ES | 97 |
| Stone size ≥15 mm | 33 (34%) |
| Complete CBD clearance after extension | 76 (78%) |
| Mechanical lithotripsy | 10 (10%) |
| Surgical CBD exploration | 15 (15%) |
| Lost to follow up | 2 |
| Laparotomy for bleeding | 1 |
| Death | 2 |
| Stents as definite treatment | 1 |

CBD, common bile duct; ES, endoscopic sphincterotomy; n, number of patients; EPLBD, endoscopic papillary large balloon dilation

previous biliary surgery and CBD angulation [14-17]. A dilated CBD may contribute to stone recurrence by bile stagnation and bacteriobilia, while periampullary diverticula promote stone formation by a combination of bacterial overgrowth and motility disturbance [18,19]. Our observations are in line with the literature, as our group A patients had high percentages of these risk factors: median CBD diameter was 13 mm, ranging from 8-20 mm, and the incidence of periampullary diverticula was 22%. On the other hand, in our cohort, the median interval from the previous ES was 7 months (ranging from 4 days to 20 years). Thus, a point of criticism could be that all stones in our cohort were not recurrent, as the interval was sometimes as short as 4 days. It is our policy to repeat the ERCP at 3 months

after placing pigtail stents for drainage when complete CBD clearance has not been achieved.

As age is considered a risk factor for the recurrence of stones, it should be pointed out that patients in group A were marginally older (74 vs. 73 years); however, we consider this statistical difference to be secondary to the inequality of the patients included in our cohort rather than a true clinical difference. In addition, the majority of them had a previous cholecystectomy, as the primary ES is usually followed by cholecystectomy. No patient in group A presented with acute pancreatitis, because after ES the pancreatic orifice is away from the biliary opening and stones can pass to the duodenum without causing pancreatitis [20].

Although extension of ES may appear straightforward, it cannot always be extended, because the anatomical landmarks for guiding the incision are sometimes obscure. When the previous ES is already large enough or inside a diverticulum, it can be considered that there is no space for extension. In 27 of our patients with stones after ES, no extension was performed because either the ES was considered of sufficient length and the stones were removed with standard techniques (23 patients), or EPLBD was performed (4 patients). During the study period, EPLBD had just started to be implemented in our department, thus precluding a comparison of ES extension and EPLBD, which might otherwise have been interesting. Thus, the aforementioned 27 patients were excluded from our analysis. Finally, complete CBD clearance was achieved in 78% of patients after several attempts (mean 1.18 per patient) and the use of mechanical lithotripsy in 10%.

Following ES, the size of the incision shrinks over time [21,22]. In addition, the formation of scar tissue may cause difficulties during extension or make it uncontrollable. This in turn, could increase the incidence of bleeding or perforation. Extension of a previous ES has been reported as a risk factor

Table 3 Comparisons between patients who presented immediate bleeding or not after extension of previous ES (group A)

| Variable | Immediate bleeding | | P-value |
|---|--------------------|-------------|-------------|
| | Yes n=24 | No n=94 | |
| Age (median, range) | 73.5 (41-89) | 74 (31-82) | NS (M-W) |
| Sex (m/f) | 11/13 | 42/52 | NS (C-S) |
| ASA score ≥III | 1 (4%) | 25 (26%) | 0.018 (C-S) |
| Interval from previous ES (months: median, range) | 20 (0.5-80) | 6 (0.1-244) | NS (M-W) |
| Antiplatelets | 2(8%) | 10 (10%) | NS (C-S) |
| Acenocoumarol | 0 | 3 (3%) | NS (C-S) |
| CBD stones | 21 (87%) | 76 (80%) | NS (C-S) |
| DD | 4 (16%) | 22 (23%) | NS (C-S) |
| Cholangitis | 15 (62%) | 69 (73%) | NS (C-S) |

ES, endoscopic sphincterotomy; NS, non-significant; M-W, Mann-Whitney; C-S, chi-square; CBD, common bile duct; DD, duodenal diverticula; ASA, American Society of Anesthesiologists

Table 4 Comparison of complication rate between groups

| Complication | Group A (n=118) | Group B (n=1064) | P-value (C-S) |
|-------------------------------|--------------------|---------------------|------------------|
| Acute pancreatitis | 0 | 22 (2%) | NS |
| Immediate bleeding | 24 (20%) | 315 (29%) | 0.035 |
| Endoscopic hemostasis | 15 (62%) | 228 (72%) | NS |
| Clinical bleeding | 1 (0.8%) | 16 (1.5%) | NS |
| Laparotomy | 1 (0.8%) | 0 | NS |
| Acute cholangitis | 0 | 3 | NS |
| Acute cholecystitis | 0 | 3 | NS |
| Perforation | 0 | 13 (1.2%) | NS |
| ERCP-related death | 0 | 0 | NS |
| Total clinical complications* | 1 (0.8%) | 57 (5.3%) | 0.031 |

ERCP, endoscopic retrograde cholangiopancreatography; NS, non significant; C-S, Chi-square or Fisher's exact test as appropriate

(*Total clinical complications do not include "immediate bleeding" and "endoscopic hemostasis").

for bleeding [23,24], the reason being the increased chance of cutting the larger blood vessels around the distal bile duct and the increased vascularization at the previous ES site. It has also been suggested that the incidence of bleeding increases when the extension is performed early after the primary ES [25]. In contrast, extension was not identified as a risk factor for bleeding by Freeman *et al* [1]. In our study, immediate bleeding was less frequent after extension rather than primary ES (20% vs. 29%) and there were also fewer episodes of clinical bleeding (0.8% vs. 1.5%), although this difference did not achieve statistical significance (Table 4). The lower incidence of immediate bleeding may be associated with the shorter incision performed in patients with previous ES (group A) and to an edematous papilla after the previous cannulation attempts in primary ES patients (group B). The incidence of required endoscopic hemostasis in patients with immediate

bleeding was statistically similar between the two groups (62% vs. 72%) (Table 4). In our study, bleeding after extension was not associated with the time interval from the previous ES. The only factor associated with increased immediate bleeding was an ASA score ≥3. It seems that patients with associated severe comorbidities tend to bleed easily.

Acute pancreatitis occurred in 2% of patients in group B, while there was no such complication after extension. This is probably due to the ease of cannulation through the previous ES and to the separation of the biliary opening and pancreatic orifice, so that the cutting would be away from the pancreatic sphincter. Despite the fear of uncontrolled incision with no clear landmarks, there was no perforation in group A patients. The incidence of perforation in group B patients seems high (1.2%), but half of them were guidewire perforations due to cannulation attempts, with no clinical significance. The low

overall incidence of complications (0.8%) makes extension even safer than the initial sphincterotomy, in agreement with previous reports [25].

Two patients died after extension, one from myocardial infarction in the recovery room and the other from pneumonic embolism 7 days after the procedure. Three patients died in group B. Two of them (critically ill patients, already in the Intensive Care Unit), underwent ERCP-ES for severe pancreatitis with biliary obstruction and died as a consequence of the pancreatitis. The third one died of cardiac failure, two days after the procedure. Hence, it is evident that none of the mortality events in our study was directly related to the procedure itself.

Overall complications were more frequent in group B (5.3% vs. 0.8%). However, we believe that this appears to be a cumulative effect, as we failed to identify any specific complication which was significantly more prominent in either group. A possible exception to this might be the occurrence of endoscopically diagnosed bleeding, which was more common among patients in group B; however, this difference did not correlate with the occurrence of clinically evident bleeding.

EPLBD is an alternative technique to ES extension that involves dilation of the biliary sphincter with a large-diameter (≥ 12 mm) balloon [9,26]. EPLBD in combination with ES versus ES alone have similar outcomes in terms of stone clearance, with less use of mechanical lithotripsy and a lower risk of overall adverse events [10,27,28].

In patients with stones after a previous ES, treatment is controversial. In some of them (19% in our study) the stones can be removed using only standard balloon or basket techniques. In the remaining cases, a widening of the biliary orifice is required to achieve stone clearance, because of either stone size or ES shrinkage. To the best of our knowledge, there are no randomized studies comparing ES extension with EPLBD in these patients. The only existing evidence comes from case series and retrospective studies [29-32]. In these studies, patients with stones that were difficult to extract underwent EPLBD. However, these studies were inhomogeneous in various aspects, including the definition of difficulty and the size of difficult stones, which ranged from ≥ 10 to ≥ 12 mm or even larger. Complete clearance was achieved in nearly all patients with minor complications, but lithotripsy (mechanical, laser, electrohydraulic) was required in 30% [32]. In our study, complete clearance was achieved in 78% of cases after extension, with a need for mechanical lithotripsy in 10%. The high incidence of surgical exploration (15%) in our study was attributed to the lack of electrohydraulic or laser lithotripsy in our department and to the referring surgeon's preference. Laparoscopic or open CBD exploration remains an alternative to repeated ERCPs in surgically fit patients [33]. Naturally, offering this alternative to a patient warrants sound clinical judgment. In our series, all patients who underwent surgical exploration had stones larger than 15 mm.

The limitations of our study include its retrospective design, as well as the inequality of the sample size between the two groups. However, performing a study with equal numbers of patients in the two groups, given the difference in occurrence of *de novo* choledocholithiasis (which is more common) and

Summary Box

What is already known:

- Endoscopic retrograde cholangiopancreatography with endoscopic sphincterotomy (ES) is the first-line treatment of choledocholithiasis
- ES is associated with complications, including bleeding, pancreatitis and perforation; to avoid such adverse events, endoscopic papillary balloon dilation is being extensively used, but also carries the risk of pancreatitis
- Recurrent or remnant common bile duct stones are not uncommon; their treatment can be facilitated either by balloon dilation or by extension of a previous ES

What the new findings are:

- Extension of a previous ES is even safer than primary ES, with fewer overall complications
- Extension of a previous ES allows common bile duct stone clearance in nearly 80% of patients

recurrent CBD stones would have to include some degree of selection bias. Another limitation that we must acknowledge is the inability to distinguish complications related to cannulation attempts or ES in group B, in order to make a better comparison to group A complications.

In conclusion, extension of a previous ES, in experienced hands, seems to be a simple, effective and safe technique allowing stone clearance in nearly 80% of patients. Therefore, patients with stones after ES, either recurrent or retained, which cannot be extracted with standard techniques should be considered for ES extension. Further studies, including randomized controlled trials, will be required to define the role of EPLBD in these patients.

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