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**DILATION-ASSISTED STONE EXTRACTION  
(DASE) IS EFFICIENT AND SAFE FOR LARGE  
COMMON BILE DUCT STONES - AN  
EXPERIENCE WITH SHORT DILATION TIME  
FROM A FINNISH TERTIARY REFERRAL  
CENTER**

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# TIIVISTELMÄ

Samuli Kankare: DILATION ASSISTED STONE EXTRACTION -TOIMENPIDE (DASE) ON TURVALLINEN JA TEHOKAS VAIKEIDEN SAPPITIEKIVIEN POISTOSSA

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Alkuperäinen artikkeli: Dilation-assisted stone extraction (DASE) is efficient and safe for large common bile duct stones - An experience with short dilation time from a Finnish tertiary referral center.

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Dilation Assisted Stone Extraction -toimenpide (DASE) on sappi- ja haimatiehyn tähystystutkimuksen (ERCP) yhteydessä käytetty menetelmä, jota hyödynnetään erityisesti suurten sappitiekivien poistossa. Toimenpiteessä lyhyen sfinkterotomian jälkeen sappiteiden laskukohtaa dilatoidaan tyypillisesti 30–60 sekunnin ajan, jonka jälkeen suuret sappikivet on mahdollista poistaa. Tutkimusnäyttö DASE:n turvallisuudesta ja tehokkuudesta perustuu vähäisiin sekä osin pienen potilasaineiston tutkimuksiin. Tämän tutkimuksen tarkoituksena oli selvittää DASE-toimenpiteen tuloksia, kun dilataatioissa käytetään tavanomaista lyhyempää dilataatioaikaa.

Tähän prospektiiviseen rekisteritutkimukseen otettiin mukaan kaikki TAYS:ssa tehdyt ERCP-toimenpiteet vuosien 2011 ja 2020 väliltä. Vain ne potilaat, joille oli ERCP:n yhteydessä tehty DASE, otettiin lopulliseen aineistoon mukaan. Toimenpiteen jälkeisiä tapahtumia verrattiin iältä ja sukupuolelta vastaaviin verrokkipotilaisiin, joiden sappitiekiviä hoidettiin ERCP:n yhteydessä muilla endoskoppisilla menetelmillä. Jokaista tutkimuksen potilasta kohden valittiin satunnaistetusti kolme kontrollipotilasta.

Yhteensä 4338 potilaalle tehtiin ERCP, joista 1847:ssä indikaationa olivat sappitiekivet. ERCP:n yhteydessä DASE tehtiin 165 potilaalle (keski-ikä 75 [23–97] vuotta, 65 % naisia). Seuranta-aika toimenpiteen jälkeen oli 52 (2–110) kuukautta. Teknisesti kaikki toimenpiteet onnistuivat ja täydellinen kivien poisto saavutettiin 94 %:ssa toimenpiteistä. Kymmenelle potilaalle (6,1 %) tehtiin myöhemmin uusi elektiivinen ERCP. Vain kahdessa tapauksessa (1,2 %) vaadittiin ei-suunniteltu toimenpide DASE:n jälkeen. Komplikaatioita todettiin 11 (6,7 %) potilaalla, mikä oli vastaava verrattuna verrokkiryhmään (6,7 % vs. 7,5 %,  $p=0,729$ ). Aineistossa ei ollut toimenpiteeseen liittyviä kuolemia.

Lyhyen dilataatioajan DASE-toimenpide on turvallinen ja tehokas vaihtoehto suurten sappitiekivien hoitoon. DASE-toimenpiteen jälkeinen komplikaatoriski on vastaavaa tasoa kuin muissa sappitiekivien poistossa käytetyissä toimenpiteissä.

Avainsanat: DASE, ERCP, sappikivet, sappitiekivet, sappi- ja haimatiehyn tähystystutkimus

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# CONTENTS

1	ABSTRACT.....	1
1.1	Background and aims.....	1
1.2	Methods.....	1
1.3	Results.....	1
1.4	Conclusions.....	1
2	INTRODUCTION.....	2
3	MATERIALS AND METHODS.....	4
3.1	Endoscopic technique.....	4
3.2	Post-ERCP outcomes and complications.....	5
3.3	Statistical analyses .....	5
3.4	Ethical aspects .....	5
4	RESULTS .....	6
5	DISCUSSION .....	10
6	CONCLUSION .....	12
7	ABBREVIATIONS.....	12
	REFERENCES .....	13

# 1 ABSTRACT

## 1.1 Background and aims

While dilation-assisted stone extraction (DASE) is an accepted method for large common bile duct (CBD) stone removal, there is limited evidence of the safety and efficiency of the procedure. The purpose of this study was to report outcomes after DASE with short dilation time preceded by a sphincterotomy.

## 1.2 Methods

The data was collected from a prospectively managed, hospital-based registry containing all ERCP procedures and complications at a tertiary referral center. The study population consisted of patients undergoing DASE procedure during a nine-year study period from May 2011 to April 2020. Postoperative outcomes were compared to sex and age-matched control patients with CBD stones undergoing other endoscopic interventions. Three control patients were randomly assigned for each study patient.

## 1.3 Results

During the study period a total of 4,338 patients underwent ERCP, of whom 1,847 patients (43%) had CBD stones. A total of 165 patients (median age 75 [23-97] years, 65% female) underwent DASE. The median follow-up time after ERCP was 52 (2-110) months. Technical success was achieved in all cases. Ten patients (6.1%) underwent subsequent planned new ERCP. Only two patients (1.2%) required later unplanned endoscopic treatment for CBD stones. Eleven patients (6.7%) developed post-ERCP complications. Compared to CBD stones treated without DASE, (n=495), the overall risk of post-ERCP complications was similar (6.7% vs. 7.5%, p=0.729).

## 1.4 Conclusions

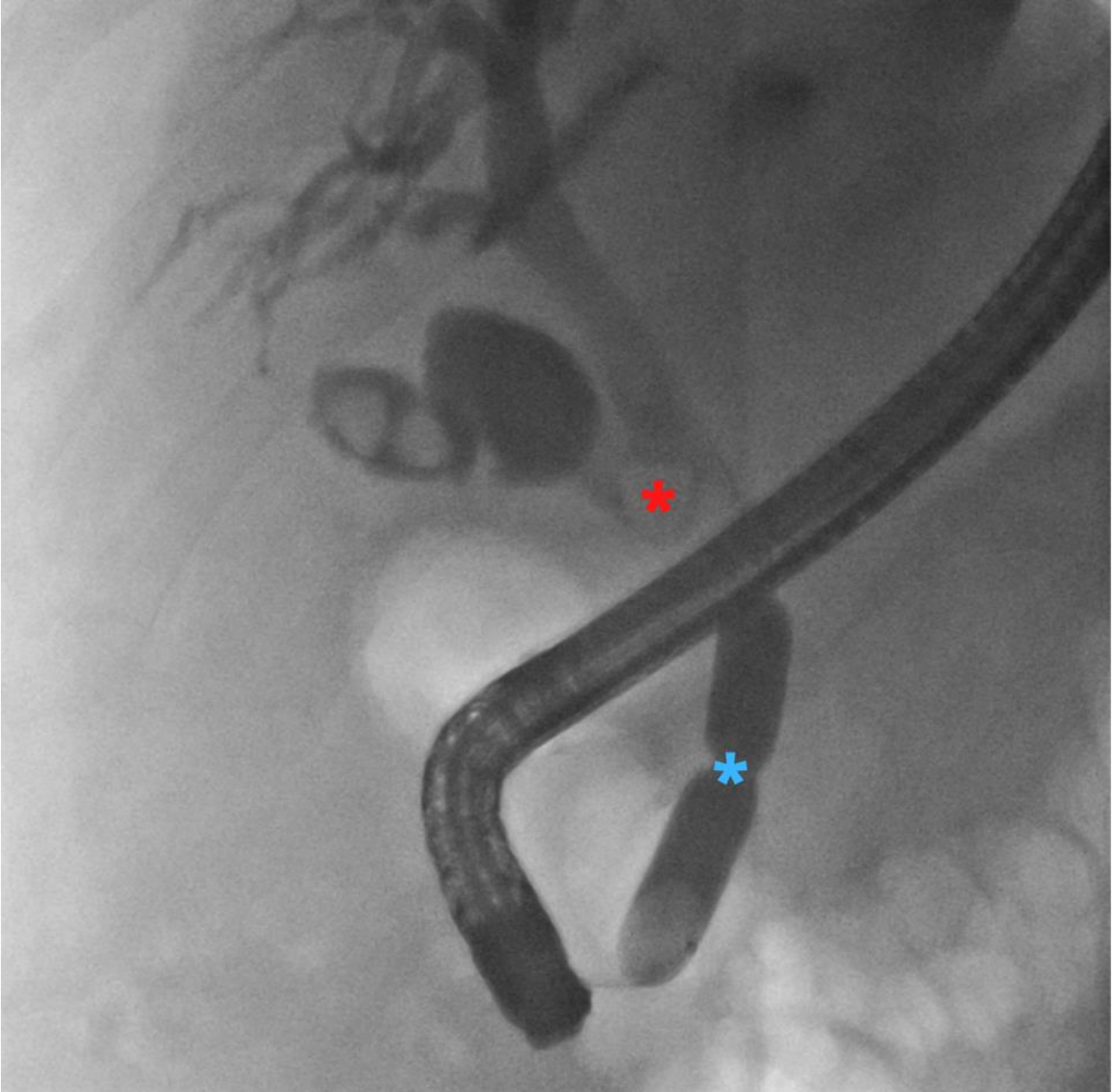
DASE with short dilation time is a safe and efficient technique in patients with large CBD stones. The risk of post-ERCP complications was similar to that in other interventions in the treatment of simple CBD stones.

## 2 INTRODUCTION

Common bile duct (CBD) stones occur in up to 15% of patients with gallstones [1]. Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (EST) is the current standard care for CBD stones [2,3], and dilation-assisted stone extraction (DASE) is considered to be an effective method in removal of large CBD stones [4, 5].

DASE is performed with a balloon dilation of the sphincter of Oddi and distal CBD, preceded by limited size sub-maximal biliary sphincterotomy. The main advantage of DASE is removal of large stones by extraction balloon or basket, with no need for mechanical lithotripsy or surgery, even in a single ERCP session [4]. It can be performed in combination with e.g. SpyGlass (Boston Scientific, MA, USA) guided electrohydraulic lithotripsy, where DASE facilitates extraction of large stone fragments [6]. The evidence on safety and efficacy in the management of large CBD stones is based on a limited number of studies and patients [7,8]. Additionally, earlier studies vary in the technical aspects of DASE, e.g. with sub-maximal or no biliary sphincterotomy and often report procedures with continuous dilation times of 30-60 s [4].

There is limited evidence of the safety and efficiency of DASE [7,8]. Our aim was therefore to study the outcomes of standardized DASE technique with a short dilation time only until the disappearance of the balloon waist when a stone was unextractable in preceding sphincterotomy. Cholangiography images from ERCP are presented in Figure 1.



**Figure 1.** Cholangiography images from ERCP with a large cubic stone in the common hepatic duct. DASE balloon dilatation catheter (blue), CBD stone (red)

### 3 MATERIALS AND METHODS

The study was conducted in a single tertiary care center in Finland. A prospectively managed, hospital-based registry containing all ERCP procedures and complications in Tampere University Hospital, Finland was used to form the study population. The study included all patients with CBD stones treated endoscopically in a catchment area of over 500,000 inhabitants as well as some patients referred from elsewhere in Finland. Each consecutive patient. All consecutive patients undergoing the procedure between May 2011 to April 2020 were included.

The following information was prospectively collected and registered: indication for ERCP, all procedures performed, outcome of the procedure, post-ERCP complications, other adverse events. Patients' medical records were retrieved and reviewed for comorbidities. CBD stones were diagnosed in one or more abdominal imaging studies (ultrasonography, computed tomography or magnetic resonance imaging). Cannulation was considered difficult if it either took more than five min, if there were more than five cannulation attempts on the papilla, or if the pancreatic duct was cannulated more than twice, according to established criteria [9].

#### 3.1 Endoscopic technique

All ERCPs were performed by six endoscopists, including trainees. Before ERCP patients received either deep or conscious sedation (Midazolam in combination with an opioid analgesic for conscious sedation or propofol for deep sedation administered by an anesthetist). All ERCPs were performed in an outpatient setting except for acute cases admitted for severe acute cholangitis. ERCPs were performed by using air or carbon dioxide insufflation and standard duodenoscopes (Olympus Europe, Hamburg, Germany) with conventional guide wires and sphincterotomes. After biliary cannulation and EST, DASE was performed using a balloon catheter (CRE RX biliary balloon dilation\*\* catheter, 55mm in length 10-16mm diameter, \*\*\*Boston Scientific, MA, USA) passed over the guidewire. The balloon was gradually pressurized with diluted contrast medium for fluoroscopic visibility until straightening of the balloon and disappearance of the "waist" in the papillary region, according to manufacturer's instructions. The final dilation diameter of the balloon was recorded. CBD stones were extracted with a retrieval balloon catheter or Dormia basket according to the decision of the endoscopist in question. Occasionally SpyGlass DS Single-operator Direct Visualization System Boston Scientific, MA, USA) guided electrohydraulic lithotripsy (EHL) (Autolith Touch, Northgate Technologies, IL, USA) was used in the same

procedure for stone fragmentation. If the stones could not be removed a plastic stent was inserted and subsequent ERCP was planned

### **3.2 Post-ERCP outcomes and complications**

Post-ERCP outcomes were compared to the control group with randomly selected age and gender-matched patients with CBD stones treated with endoscopic methods other than DASE. Three control patients were selected for each study patient.

The main outcome measures were clinical success rate (defined as need for later endoscopic or surgical interventions for residual or recurring CBD stones), postoperative morbidity, mortality (<30 day). Complications and adverse events were defined and categorized as mild, moderate, or severe according to the Cotton classification [10]. Clavien-Dindo classification [11] was used to define and grade other complications. Causes of death were registered. The follow-up data was available on all patients.

### **3.3 Statistical analysis**

All statistical analyses were performed using SPSS Statistics version 22 for Windows (IBM Corp, Armonk, NY).  $\chi^2$  test or Fisher's exact test (when expected cell value was 5 or lower) tests were performed to compare categorical variables and Student's t test for continuous variables. All tests used were two-tailed. Statistical significance was set at a value of  $p < 0.05$ .

### **3.4 Ethical aspects**

The study was performed according to the terms of the Helsinki Declaration, and institutional review board approval was obtained.



## 4 RESULTS

During the study period a total of 4,338 patients underwent ERCP, of whom 1,847 (43%) had CBD stones. A total of 165 patients (8.9% of all patients with CBD stones, median age 75 [23-97] years, 65% female) underwent DASE for removal of CBD stones. The median follow-up time after DASE was 52 (2-110) months. Patient-, disease- and procedure-related characteristics are presented in Table 1.

In 65% cases the operation was planned elective, while the rest underwent emergency procedures (35%) due to acute and severe presentation. Sixty-three patients (38%) had undergone earlier ERCP with EST. Cannulation was considered to be difficult in 36 patients (22%), double guidewire technique was used in 24 patients (15%) and rendezvous ERCP technique in six (3.6%). Twenty-three patients underwent Spyglass ERCP, and 12 of them Spyglass EHL stone extraction. Median DASE dilation was 12 (12-18) mm.

Post-ERCP outcomes are presented in Table 2. Technical success was achieved in all cases. DASE success rate was estimated to be 99% (163/165) with only two patients requiring subsequent unplanned ERCP for CBD stones after DASE (delay from the index operation to new ERCP 9 and 46 months). Endoscopic treatment was sufficient in all cases, no patients required surgery. Thirty-three patients (21%) underwent cholecystectomy after DASE, and ten patients underwent planned second operations as not all CBD stones could be completely removed in the index procedure. In these cases stents were inserted as bridges for the second procedure.

After DASE 11 patients (6.7%) suffered from post-ERCP adverse events. Four patients (2.4%) had ERCP-related perforation, three (1.8%) of them having severe presentation. One patient required surgery, while the remainder were resolved with conservative management. Three patients (1.8%) had postoperative pancreatitis. There were no anesthesia-associated complications. All complications occurred among those with EST, but none reached statistical significance (8.4% vs. 0.0%,  $p=0.080$ ). Higher age was not associated with morbidity - median age among those with post-ERCP-related complications was 77 (60-88) years and 75 (23-97) years among those without complications ( $p=0.640$ ). Two patients (1.2%) died within a month of the operation, but there was no procedure-associated mortality. Postoperative morbidity and mortality are presented in Table 3. When patients with DASE were compared to sex and age-matched and randomly selected control patients, the rates of post-ERCP complications were similar, as shown in Table 4.

**Table 1.** Patient-, disease- and operation-specific characteristics of patients undergoing DASE (n=165)

Variable	
Age, median (min-max)	75 (23-97) years
Sex, female	107 (65%)
Comorbidities	
Diabetes	32 (19%)
Coronary artery disease	25 (15%)
Congestive heart failure	9 (5.5%)
Connective tissue disease	9 (5.5%)
Chronic kidney disease	8 (4.8%)
Earlier cerebrovascular incidents	6 (3.6%)
Chronic liver disease	5 (3.0%)
Chronic obstructive pulmonary disease	3 (1.8%)
Peripheral vascular disease	3 (1.8%)
Dementia	13 (7.9%)
Charlson Comorbidity Index, median (min-max)	4 (0-10)
Preoperative radiological studies	
Ultrasonography	109 (66%)
Computed tomography	53 (32%)
Magnetic resonance imaging	73 (44%)
Endoscopic ultrasonography	3 (1.8%)
Serum bilirubin, umol/l, median (min-max)	15 (2-545)
Elective procedure	113 (69%)
Emergency procedure (<72h from admission)	52 (31%)
Sphincterotomy	131 (79%)
Difficult cannulation	36 (22%)
Prophylactic pancreatic stent	11 (6.7%)
DASE dilatation, mm (min-max)	12 (6-18)

**Table 2.** Post-ERCP outcomes (n=165)

Variable	
Technical success	165 (100%)
Complete removal of stones in the index procedure	155 (94%)
One new planned ERCP with bridging stent	8 (4.8%)
Two new planned ERCPS with bridging stent	2 (1.2%)
Stone recurrence	2 (1.2%)
Median period of stone recurrence	28 (9-46) months

**Table 3.** Postoperative morbidity and mortality (n=165 patients)

Variable	
Morbidity, total	11 (6.7%)
Mild / Moderate / Severe	3 (1.8 %) / 3 (1.8%) / 4 (2.4%)
Pancreatitis	3 (1.8%)
Mild / Moderate / Severe <sup>1</sup>	0 (0.0%) / 2 (1.2%) / 1 (0.6%)
Perforation	4 (2.4%)
Mild / Moderate / Severe <sup>1</sup>	1 (0.6%) / 0 (0.0%) / 3 (1.8%)
Bleeding	3 (1.8%)
Mild / Moderate / Severe <sup>1</sup>	2 (1.2%) / 1 (0.6%) / 0 (0.0%)
Other complications	3 (1.8%)
Clavien-Dindo I-II <sup>2</sup>	1 (0.6%)
Clavien-Dindo III-IV <sup>2</sup>	2 (1.2%)
Morbidity, early learning curve ( $\leq 60$ operations)	4 (6.7%) (p=1.000)
Morbidity, late phase (>60 operations)	7 (6.7%)
Morbidity, difficult cannulation	4 (11%) (p=0.227)
Morbidity, normal cannulation	7 (5.4%)
Morbidity, age <80 years	6 (5.9%) (p=0.607)
Morbidity, age $\geq 80$ years	5 (7.9%)
30-day mortality	2 (1.2%)
Procedure-related	0 (0.0%)
90-day mortality	2 (1.2%)

<sup>1</sup> Definition and classification according to Cotton classification [10]

<sup>2</sup> Any deviation from the normal postoperative course graded as: I = no need for pharmacological treatment or invasive interventions, II = pharmacological treatment required, III = invasive interventions required, IV = life-threatening complications, V = death of a patient [11]

**Table 4.** Post-ERCP complications among patients undergoing DASE and simple stone extraction by balloon or basket with sphincterotomy without DASE required

	<b>DASE</b> n=165	<b>Other interventions</b> n=495 <sup>1</sup>	<b>p-value</b>
Morbidity	11 (6.7%)	37 (7.5%)	0.729
Pancreatitis	3 (1.8%)	16 (3.2%)	0.347
Perforation	4 (2.4%)	4 (0.8%)	0.100
Bleeding	3 (1.8%)	6 (1.2%)	0.561
Other	3 (1.8%)	5 (1.0%)	0.411

<sup>1</sup> Randomly assigned sex and gender matched control patients

## 5 DISCUSSION

Evidence of the safety and efficiency of DASE has been limited. Here we have shown that standardized DASE with short dilation time is an efficient and safe procedure for the treatment of large CBD stones. Overall success rate with endoscopic treatment alone was 100%, with 6% of patients having a planned ERCP for definitive stone clearance. Only two patients required later unplanned treatment for CBD stones, and less than seven percent developed adverse events after ERCP and DASE.

Our main finding was that with DASE, large and difficult stones can be safely managed with a low readmission rate. Large balloon dilation of the papilla Vateri carries a potential risk of perforation and uncontrollable bleeding, as well as a risk of post-ERCP pancreatitis. A systematic review of 32 endoscopic papillary large balloon dilation studies analyzed a total of 2,511 patients undergoing the procedure with EST and a total of 413 patients undergoing the procedure without EST procedures [12]. The study also examined procedure-related deaths from the 32 studies and only 3/32 (9.4%) studies reported any deaths, which is consistent with the results of the present study of no procedure-related deaths. A recently published DASE review also reported similarly excellent rates of CBD clearance and complications [4]. Overall, all CBD stones were removed with endoscopic treatment alone; no patients required surgery. Only two patients required later treatment for CBD stones, and endoscopic treatment was successful in all these cases. Median follow-up in the present study was 52 months, which is suggested to be sufficient to report long-term stone recurrence rates [13]. Overall morbidity and mortality were similar those reported earlier in the literature [12].

However, possibly due to only short-duration, careful dilation and preceding sphincterotomy, the complications were mostly non-severe; only seven percent of patients suffered from any adverse event, predominantly non-severe. The perforations were mostly mild extravasation of contrast and gas and could be managed conservatively. After DASE, none of the episodes of hemorrhage was classified as severe. Further supporting the safety of DASE, PEP rate did not differ from that of standard ERCP performed for simple small stones.

The safety of the procedure is especially important in frail elderly patients, who typically present with large CBD stones. Similar to standard ERCP with low morbidity in the elderly [14], using DASE for the removal of large stones did not increase risk in the elderly. Successful single-session stone clearance by DASE seems to effectively prevent readmissions, stone recurrence, and episodes of acute cholangitis, even without scheduled cholecystectomy, issues especially beneficial to frail elderly patients. In safe DASE usage, care must be taken not to over-inflate the dilation balloon wider than the diameter of the common bile duct (above)??, use only short dilation times, use a contrast-filled dilation balloon to indicate the disappearance of the balloon waist and careful positioning of the balloon to avoid stone impaction. In frail patients with large thin-walled peri-papillary duodenal diverticulum or a distal biliary stricture, other stone management options may be safer, such as SpyGlass guided lithotripsy for difficult CBD stones [6].

Whether DASE should be preceded by EST is still a matter of debate according to a recent study [15]. In our unit stone extraction in ERCP was performed in a pragmatic, step-wise manner: the procedure was initiated with wide enough sphincterotomy and continued with DASE when necessary for large stone extraction when stones were too large to be extracted via sphincterotomy opening only.

The strength of the study is the inclusion of all ERCPs and DASE procedures as well as subsequent readmissions over a period of nine years in the catchment area of the second largest tertiary referral center in Finland. The data were collected in a single high-volume tertiary care center with experienced endoscopists and trainees performing all the operations. The data was prospectively retrieved and supplemented from digital comprehensive hospital records. Follow-up data was available on all patients. During the study years, the core instrumentation used and management strategy of difficult CBD stones remained constant between endoscopists. Contrary to the original DASE technique and earlier studies, we only used very short duration of dilation, only until disappearance of the balloon waist instead of a pre-determined time. The rather small number of patients must be considered a limitation in this study.

## 6 CONCLUSION

Since the low rate of ERCP-related complications observed in a real-life clinical practice setting, DASE with short dilation time is considered to be a safe and efficient rescue method for the removal of large CBD stones when standard ERCP is insufficient.

## 7 ABBREVIATIONS

DASE	Dilation-assisted stone extraction
ERCP	Endoscopic retrograde cholangiopancreatography
CBD	Common bile duct
EHL	electrohydraulic lithotripsy
EST	endoscopic sphincterotomy

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