

Digital cholangioscopy-guided laser versus mechanical lithotripsy for large bile duct stone removal after failed papillary large-balloon dilation: a randomized study

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Appendix 1s

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ABSTRACT

Background Endoscopic papillary large-balloon dilation (EPLBD) allows for the complete removal of large common bile duct (CBD) stones without fragmentation; however, a significant proportion of very large stones and stones floating above a tapering CBD require lithotripsy. Mechanical lithotripsy and cholangioscopy-guided laser lithotripsy are both effective for stone fragmentation. This study aimed to directly compare, for the first time, the efficacy of these two techniques in terms of stone clearance rate, procedure duration, patient radiation exposure, and safety.

Methods 32 patients with very large CBD stones or with stones floating above a tapering CBD, and in whom extraction after standard sphincterotomy and/or EPLBD had failed, were randomly assigned to mechanical lithotripsy or cholangioscopy-guided laser lithotripsy at two tertiary referral centers. Crossover was allowed as a rescue treatment if the assigned technique failed.

Results Patients' demographic data were not different between the two groups. Mechanical lithotripsy had a significantly lower stone clearance rate in the first session compared with laser lithotripsy (63% vs. 100%; $P < 0.01$). Laser lithotripsy rescued 60% of patients with failed mechanical lithotripsy by achieving complete stone clearance within the same session. Radiation exposure of patients was significantly higher in the mechanical lithotripsy group than in the laser lithotripsy group (40 745 vs. 20 989 mGycm²; $P = 0.04$). Adverse events (13% vs. 6%; $P = 0.76$) and length of hospital stay (1 vs. 1 day; $P = 0.27$) were not different.

Conclusions Although mechanical lithotripsy is the standard of care for a very large CBD stone after failed EPLBD, where available, cholangioscopy-guided laser lithotripsy is considered the better option for the treatment of this entity as it provides a higher success rate and lower radiation exposure.

Thai Clinical Trials Registry

TCTR20171121001

TRIAL REGISTRATION: Two-center, prospective, randomized study TCTR20171121001

at clinicaltrials.in.th

Introduction

The standard treatment for common bile duct (CBD) stones is endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and stone extraction [1, 2]. However, approximately 15% of CBD stones cannot be removed [3]. These difficult stones portend prolonged procedure times and multiple ERCP sessions, and may potentially increase complications [4–9]. Recently, endoscopic papillary large-balloon dilation (EPLBD) has been well accepted as the next step to tackle large CBD stones after failed standard stone extraction [10]. EPLBD has benefits over conventional ERCP in terms of a higher stone clearance rate, shorter procedure time, and lower cost, with comparable complications [11]. Furthermore, EPLBD reduced the need for lithotripsy by 51% [12]. However, a stone larger than the diameter of the balloon requires fragmentation [11, 13].

Mechanical lithotripsy was once the preferred method to facilitate stone fragmentation and extraction of large CBD stones [14]. However, in many experienced centers, mechanical lithotripsy is now falling behind EPLBD [15]. Digital cholangioscopy-guided laser lithotripsy or electrohydraulic lithotripsy have become more popular owing to the convenience in assembly [14, 16, 17]. High efficacy of laser lithotripsy for the treatment of difficult CBD stones has been reported, with bile duct clearance rates of up to 99% [18–20]. Unlike mechanical lithotripsy, cholangioscopy-guided laser lithotripsy and electrohydraulic lithotripsy do not require fluoroscopy during lithotripsy [14, 20]. To date, no study has compared the efficacy in terms of stone clearance rate, procedure duration, radiation exposure, safety, and length of hospital stay, between laser or electrohydraulic lithotripsy and mechanical lithotripsy. In our institution, only the laser system was available. Therefore, our study aimed to compare the efficacy of cholangioscopy-guided laser lithotripsy with that of mechanical lithotripsy in patients with large bile duct stones that were not amenable to EPLBD or were not successfully treated by EPLBD.

Methods

Patients

Patients diagnosed with CBD stones at the King Chulalongkorn Memorial Hospital, Bangkok, and the Thabo Crown Prince Hospital, Nong Khai, Thailand, were screened. Inclusion criteria were patients aged >18 years with bile duct stones that were not cleared by endoscopic sphincterotomy and EPLBD or were not amenable to EPLBD because of a tapering CBD. Exclusion criteria were pregnancy, uncorrected coagulopathy (platelet count <50,000/mL or international normalized ratio >1.5), unstable vital signs, and surgically altered anatomy (Billroth II or Roux-en-Y).

The study protocol was approved by the Institutional Review Board (IRB number 397/60) and was registered at the National Clinical Registry (TCTR identification number 20171121001). The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT), as shown in **Appendix 1s** in the online-only Supplementary material. Informed consent for

ERCP and/or lithotripsy was obtained from all patients prior to randomization.

Interventions

ERCP was performed with the patient in the prone position and under conscious sedation. The therapeutic side-viewing duodenoscope (TJF-Q180V; Olympus, Tokyo, Japan) was used. Selective biliary cannulation was performed with standard wire-guided technique. If difficult cannulation was experienced [21], other advanced techniques (e.g. double guidewire or precut) were applied. After a cholangiogram had been obtained, the stone size and bile duct diameters (at the widest point and at the distal CBD) were measured by using Synapse radiographic program (Fujifilm USA, Valhalla, New York, USA). Tapered CBD was defined as the width of the distal CBD at 1.5 cm proximal to the ampulla being less than one-third of the widest CBD diameter. Initial stone extraction was attempted after sphincterotomy by extraction balloon or basket. In the event of failure, a dilation balloon catheter (CRE; Boston Scientific, Marlborough, Massachusetts, USA) with a diameter range of 12–18 mm was used for papillary dilation. The size of the CRE balloon was selected based on the diameter of the distal CBD. The balloon was gradually inflated to the desired diameter and maintained for 60 seconds [10]; then stone extraction was repeated.

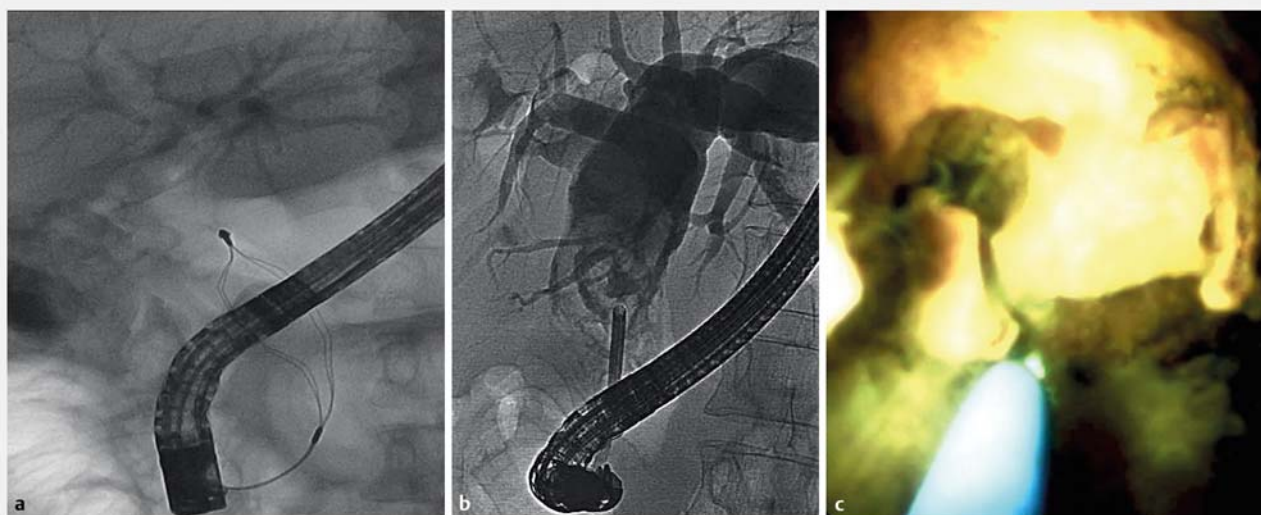
If stone removal failed, an envelope containing a computer-generated randomization code, in blocks of four and a 1:1 ratio, was disclosed for the lithotripsy method. In the case of a tapering CBD, EPLBD was not performed and the randomization process was started directly after a complete biliary sphincterotomy. In order to prevent stone impaction at the distal CBD, the stone was pushed upward by the balloon before lithotripsy.

Mechanical lithotripsy was performed by a 30-mm basket mechanical lithotripter (LithoCrush V, BML-V242QR-30; Olympus) (► **Fig. 1a**). The stone capture by basket was attempted under fluoroscopy guidance. Once the stone had been captured, the basket was enclosed within the Teflon sheath followed by the metal sheath. Additional mechanical lithotripsy could be repeated if the fragmented stone could not be extracted or if more stones were found.

Cholangioscopy-guided laser lithotripsy was performed by digital cholangioscope (SpyGlass DS; Boston Scientific). The cholangioscope was inserted through the accessory channel of the duodenoscope (► **Fig. 1b**) and advanced through the ampulla. The cholangioscope was inserted until it reached the most distal CBD stone and the higher positioned stones were later targeted sequentially. Laser lithotripsy was performed by insertion of a 365 µm holmium laser probe (Dornier Medilas H Solvo; Dornier MedTech, Wessling, Germany) through the biopsy channel of the cholangioscope (► **Fig. 1c**). Laser energy settings were 2 J energy and 10 Hz frequency (20 W).

Both lithotripsy procedures aimed to fragment the stone into pieces small enough to be removed by either extraction balloon and/or basket. Occlusion cholangiogram was used to confirm the stone clearance.

The experienced endoscopists (R.R., W.R., and P.A.) who performed these procedures had performed over 500 standard ERCPs, 100 mechanical lithotripsy procedures, 100 cholangios-



► **Fig. 1** Lithotripsy methods. **a** Fluoroscopy image of mechanical lithotripsy. **b** Fluoroscopy image of cholangioscopy-guided laser lithotripsy. **c** Cholangioscopy image of laser lithotripsy.

copies, and 30 cholangioscopy-guided laser lithotripsy procedures prior to participating in the study.

End points

The primary outcome of the study was stone clearance rate within the first session of the randomized method. However, if the randomized method could not be initiated within 20 minutes by the selected technique (e.g. the basket could not be fully opened or adequately capture the stone, or the cholangioscope could not be positioned to target the stone), it was defined as disintegration failure and then the crossover method was performed.

Secondary outcomes were procedure time, stone clearance time, radiation exposure, procedure-related adverse events, and length of hospital stay of the first ERCP session. The procedure time was defined as the time from duodenoscope insertion until its withdrawal. The stone clearance time was defined as the time between initiation of randomized lithotripsy to scope withdrawal. According to a previous multicenter study, the maximum time required for lithotripsy in difficult biliary stones was 137 minutes [19]; we therefore set 120 minutes as the maximum allowable procedure time for stone clearance. If more time was required, it was considered as failure and a plastic stent was placed and repeat ERCP was scheduled in the next 4–8 weeks. The method of lithotripsy at the repeated ERCP session and the number of repeated ERCPs before referring patients to surgery were at the discretion of the endoscopist. Radiation exposure of the patient was measured as dose area product (DAP).

Follow-up

After the procedure, the patient was admitted for a 24-hour observation period to check for any post-ERCP complications, which were recorded and graded according to the American So-

ciety for Gastrointestinal Endoscopy lexicon [22]. The total length of hospital stay was recorded.

All patients were followed up at the outpatient department at 1 and 4 weeks and at 6 months. Baseline characteristics of patients, size of CBD and bile duct stones, and number and shape of bile duct stones were recorded. Stone types (cholesterol, black pigment, or brown pigment stone) were determined during stone extraction.

Statistical analysis and sample size calculation

The qualitative variables were presented as frequency (percentage). Quantitative variables were presented as mean (standard deviation [SD]) or median (interquartile range [IQR]), where appropriate. The comparison of qualitative variables between two groups were made by chi-squared or Fisher's exact test. The comparison of quantitative variables between the two groups were made by unpaired Student's *t* test or Mann-Whitney *U* test, where appropriate. A *P* value of less than 0.05 was considered statistically significant. IBM SPSS statistics for Windows, version 23.0 (IBM Corp., Armonk, New York, USA) was used for statistical analyses.

Because no studies have directly compared mechanical lithotripsy and cholangioscopy-guided laser lithotripsy success rates, we used pilot data from our own center to inform the sample size calculations, which were conducted with Stata 15.1 (Statacorp, College Station, Texas, USA). We assumed the success rate would be 90% in the laser lithotripsy group and 45% in the mechanical lithotripsy group. With these assumptions, a total of 32 patients randomized in a 1:1 ratio would provide 80% power to detect this difference in success rates at a 2-sided significance level of 5%.

Results

A total of 476 patients with CBD stones were screened and 372 patients were successfully treated by standard ERCP. Subsequently, the large CBD stones in 72 patients were successfully removed by adding EPLBD. Finally, 32 patients (6.7%) underwent randomization to mechanical ($n = 16$) or laser ($n = 16$) lithotripsy; in each group, 15 patients had large stones and 1 patient had floating stones (► Fig. 2).

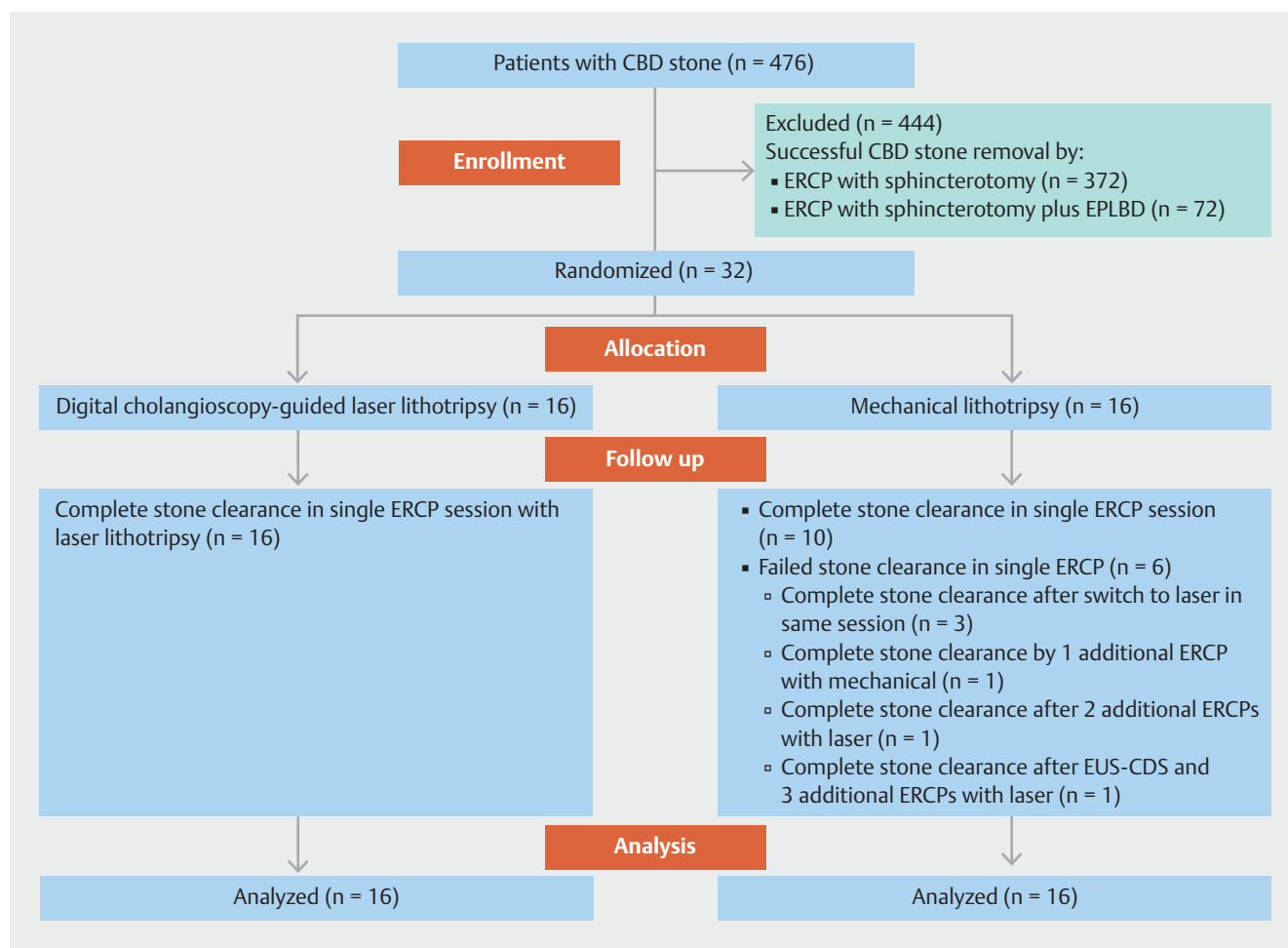
Baseline characteristics between the two groups, including age (63.1 vs. 62.7 years; $P = 0.96$), sex (% female: 69% vs. 56%; $P = 0.47$), prior sphincterotomy (56% vs. 63%; $P = 0.72$), CBD diameter (22.2 vs. 22.1 mm; $P = 0.99$), number of stones (2 vs. 2; $P > 0.99$), type of stone (% pigmented stone: 81% vs. 63%; $P = 0.43$), and size of CRE balloon were not significantly different (► Table 1).

Example images are shown in ► Fig. 3. One patient with a floating stone above a tapering CBD who was randomized to mechanical lithotripsy (► Fig. 3a) had one cholesterol stone with a diameter×length of 14×30 mm; the widest bile duct was 14.5 mm, and the distal bile duct diameter was 4 mm. Another patient who was randomized to laser lithotripsy

(► Fig. 3b) had one brown pigmented stone with a diameter × length of 16.8×21.7 mm; the widest bile duct was 30.3 mm, and the distal bile duct diameter was 9 mm.

Stone clearance rate

Success rates of CBD stone clearance in the first ERCP session were 63% and 100% in the mechanical and laser lithotripsy groups, respectively ($P < 0.01$) (► Table 1). In six patients, mechanical lithotripsy was considered a failure because the procedure time was longer than 120 minutes ($n = 1$) or there was disintegration failure ($n = 5$). The latter group were crossed over to laser lithotripsy and three patients achieved stone clearance within the same session. One patient had a total stone clearance time including laser lithotripsy that was longer than 120 minutes, and therefore data from this patient were censored. This patient later required two additional sessions of laser lithotripsy for complete CBD stone clearance. In the remaining patient, after crossover to laser lithotripsy, the cholangioscope could not be inserted through the ampulla owing to an unstable position of the duodenoscope; this patient underwent an endoscopic ultrasound-guided choledochoduodenostomy to create a fistula tract that would allow the passage of the cho-



► Fig. 2 Flow chart of the study. CBD, common bile duct; EPLBD, endoscopic papillary large-balloon dilation; ERCP, endoscopic retrograde cholangiopancreatography; EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy.

► **Table 1** Demographic data and results of mechanical lithotripsy and cholangioscopy-guided laser lithotripsy.

	Mechanical lithotripsy, n = 16	Laser lithotripsy, n = 16	P value
Age, mean (SD), years	63.1 (20.05)	62.7 (18.51)	0.96
Female; n (%)	11 (68.8)	9 (56.3)	0.47
Prior sphincterotomy, n (%)	9 (56.3)	10 (62.5)	0.72
CBD diameter, mean (SD), mm	22.2 (7.38)	22.1 (6.7)	0.99
Stone diameter, mean (SD), mm	17.6 (3.37)	19.5 (5.63)	0.28
Stone number, mean (SD), n	2 (1.59)	2 (1.32)	>0.99
Stone type, n (%)			0.43
▪ Cholesterol	3 (18.8)	6 (37.5)	
▪ Black pigment	5 (31.3)	5 (31.3)	
▪ Brown pigment	8 (50.0)	5 (31.3)	
Indication for lithotripsy, n (%)			>0.99
▪ Very large stone	15 (93.8)	15 (93.8)	
▪ Very large stone with tapering distal CBD	1 (6.2)	1 (6.2)	
Dilation balloon size, n (%)			0.75
▪ 12 mm	1 (6.7)	1 (6.7)	
▪ 13.5 – 15 mm	7 (46.7)	9 (60.0)	
▪ 15 – 18 mm	7 (46.7)	5 (33.3)	
Complete stone clearance by selected technique, n/N (%)	10/16 (62.5)	16/16 (100)	<0.01
Complete clearance after crossover to other technique in one single ERCP session, n/N (%)	13/16 (81.3)	N/A	N/A
Procedure time, mean (SD), minutes	83 (46)	66 (28)	0.23
Stone clearance time, mean (SD), minutes	53 (41)	39 (23)	0.26
Fluoroscopic time, mean (SD), minutes	21:27 (12:17)	11:12 (7:30)	<0.01
Cumulative DAP, mean (SD), mGycm ²	40744.5 (24661.7)	20988.8 (14851)	0.04
Patients requiring > 1 ERCP session to achieve stone clearance, n (%)	3 (18.8)	0 (0)	0.23
Complications, n (%)	2 (12.5)	1 (6.3)	0.76
▪ Mild sphincterotomy bleeding	1 (6.3)	0	
▪ Mild pancreatitis	1 (6.3)	1 (6.3)	
Length of hospitalization, median (IQR), days	1 (1 – 5)	1 (1 – 2.25)	0.27

CBD, common bile duct; DAP, dose area product; ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile range; N/A, not applicable; SD, standard deviation.

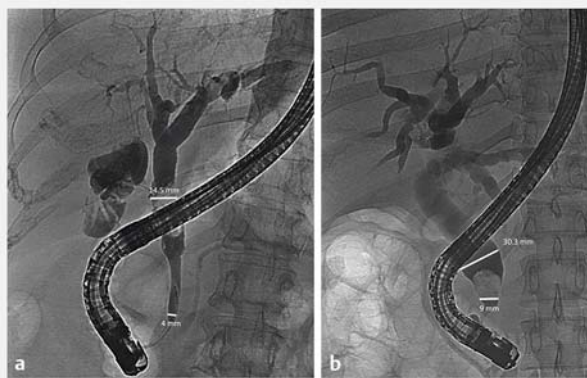
langioscope; stone clearance was achieved after three sessions of laser lithotripsy.

Secondary outcomes

The total procedure times (83 vs. 66 minutes; $P = 0.23$) and stone clearance times (53 vs. 39 minutes; $P = 0.26$) for mechanical vs. laser lithotripsy were not significantly different. The mean fluoroscopic time (21 vs. 11 minutes; $P < 0.01$) and mean DAP (40 745 vs. 20 989 mGycm²; $P = 0.04$) was signifi-

cantly higher in the mechanical lithotripsy group compared with the laser lithotripsy group.

Adverse events were not different between mechanical and laser lithotripsy (13% vs. 6%; $P = 0.76$). One patient from each group developed mild post-ERCP pancreatitis, and one patient in the mechanical lithotripsy group had an immediate mild post-sphincterotomy bleed, which was successfully treated with diluted adrenaline injection and did not require blood



► **Fig. 3** Examples of patients with very large stones and tapering of the distal common bile duct (CBD). **a** A patient with a CBD diameter of 14.5 mm at the widest point and 4 mm at the distal CBD underwent successful stone clearance by mechanical lithotripsy. **b** A patient with a CBD diameter of 30.3 mm at the widest point and 9 mm at the distal CBD underwent successful stone clearance by cholangioscopy-guided laser lithotripsy.

transfusion. The median length of hospitalization after ERCP was 1 day in both groups ($P = 0.27$).

Two patients with stones floating above a tapering CBD achieved successful stone clearance in a single ERCP session. Procedure time, stone clearance time, DAP, and length of hospital stay in these two patients were 55 vs. 42 minutes, 30 vs. 33 minutes, 22 274 vs. 24 517 mGycm², and 6 vs. 2 days in the mechanical vs. laser lithotripsy patients, respectively. The patient in the mechanical lithotripsy group developed mild post-ERCP pancreatitis whereas the other patient did not experience any post-ERCP complications.

There was no recurrent cholangitis or evidence of recurrent CBD stones at the 6-month follow-up in both groups. Comparison between patients with successful and failed mechanical lithotripsy demonstrated that a stone >30 mm was associated with failure ($P < 0.01$), whereas a stone width >15 mm, stone-to-duct width ratio >0.9, stone shape, or prior sphincterotomy were not associated with failure ($P > 0.05$) (► **Table 2**).

► **Table 2** Factors associated with successful and failed mechanical lithotripsy.

	Successful (n = 10)	Failed (n = 6)	P value
Stone length > 30 mm, n (%)	0 (0)	4 (67)	<0.01
Stone width > 15 mm, n (%)	6 (60)	6 (100)	0.23
Stone-to-duct width ratio > 0.9, n (%)	3 (30)	3 (50)	0.61
Oval shape, n (%)	8 (80)	6 (100)	0.50
Prior sphincterotomy, n (%)	5 (50)	4 (67)	0.63

Discussion

This is the first randomized study to directly compare two techniques of biliary stone lithotripsy – cholangioscopy-guided laser lithotripsy vs. mechanical lithotripsy – in very large stones that failed to be cleared by EPLBD or that were not amenable to EPLBD owing to the stone floating above a tapering CBD. We confirmed that the CBD stone clearance rate within the first session of ERCP by laser lithotripsy was significantly higher than that of mechanical lithotripsy. Patients undergoing laser lithotripsy also had lower radiation exposure than those undergoing mechanical lithotripsy. However, the complication rates of the two techniques were not different. Although the procedure and stone extraction times tended to be shorter when laser lithotripsy was used, this was not significant statistically.

Traditionally, a large stone that failed to be removed after standard sphincterotomy, would be subjected to mechanical lithotripsy as a rescue method [14]. Recently, international and UK guidelines [2, 10] have recommended that EPLBD can be used and may be preferred over mechanical lithotripsy because it reduces procedure time [7] and overall complications compared with mechanical lithotripsy [10]. EPLBD is contraindicated for biliary stricture [10] and a significantly tapered distal CBD because of the increased risk of perforation [23]. The available size range for balloon dilation is 12–20 mm; however, a balloon size of ≤15 mm is more frequently used in order to reduce serious events [10, 23]. Therefore, in patients with associated stricture or a significantly tapered distal CBD or a stone larger than the balloon size, EPLBD has tended to fail in stone clearance. In the present study, the mean stone sizes were 18–19 mm, indicating that they were too large to be removed by EPLBD alone.

Mechanical lithotripsy was introduced in 1982 [24], and since then has been widely used for the management of difficult bile duct stones because it was readily available and a relatively simple procedure [1]. However, the efficacy of mechanical lithotripsy has been limited by the stone size (i.e. if larger than the basket size of 30 mm) [4, 25, 26], stone impaction [27], and associated stricture [4]. The reported success rates of mechanical lithotripsy in difficult stones ranged from 51% to 100% [4]. In the present study, the success rate by first mechanical lithotripsy session was 63%, which is in line with previously reported rates [4, 20]. The reasons for disintegration failure were stone size larger than the basket (two patients), stone impacted within the bile duct (two patients), and an unstable scope position, which could not maintain the lithotripter in position (one patient). We arbitrarily limited the time frame of disintegration failure at 20 minutes because we believed that without procedural progression in 20 minutes the chance of success will be reduced. We also limited the stone clearance time to 120 minutes in order to standardize the practice between both groups, to reduce possible bias, and to ensure balance between patient safety and procedure success. This time frame was in line with that reported in a large multicenter study [19].

Cholangioscopy allowed visualization of the bile duct and reduced the need for fluoroscopy during lithotripsy. Single-operator catheter-based cholangioscopy provided a significantly higher success rate for the treatment of difficult bile duct stones than other systems [28]. The digital version of the cholangioscope (2015) had improved image resolution, and incorporated a dedicated irrigation and suction port, and a more bendable tip compared with the first-generation model (fiber-optic, 2007) [16]. These improvements might have contributed to the increased stone clearance rate, from 71% when using the first version [29] to 99% [19]. The present study demonstrated that the stone clearance rate in a single ERCP session with laser lithotripsy was 100%. Interestingly, laser lithotripsy rescued three of the five patients (60%) whose stones could not be captured by the mechanical lithotripsy basket, achieving stone clearance within the same ERCP session. Two other patients in whom mechanical lithotripsy had failed could not be rescued by laser lithotripsy in a single session because the procedure time was longer than 120 minutes (one patient) or the duodenoscope was unstable, leading to technical failure (one patient). However, these patients could be managed by repeated laser lithotripsy or laser lithotripsy performed through the endoscopic ultrasound-guided choledochoduodenostomy tract, respectively. None of the patients required surgery. In our experience, we found the following limitations: 1) a biliary stricture smaller than 3.5 mm diameter precluding insertion of the cholangioscope; 2) unstable position of the duodenoscope making it difficult to maintain a good cholangioscope position; 3) stone location at the very distal CBD causing difficulty in cholangioscope control.

Recently Buxbaum et al. [20] reported a randomized study comparing conventional therapy with laser lithotripsy in patients with a bile duct stone larger than 1 cm. The “conventional methods” included mechanical lithotripsy and papillary dilation. However, these methods were allowed in both groups, and therefore the study did not directly compare laser and mechanical lithotripsy. Mechanical lithotripsy and papillary dilation were utilized 67% vs. 50% and 44% vs. 14% in the conventional vs. laser lithotripsy groups, respectively. Furthermore, the majority (71%) of papillary dilation was performed using a small balloon (<12 mm). The laser lithotripsy was performed using the first version of the cholangioscope with laser setting at only 10W power. The stone clearance rate was significantly higher in the laser lithotripsy group vs. the conventional group (93% vs. 67%), but procedure time was longer (121 vs. 81 minutes), whereas the fluoroscopy times were not different. We speculated that the higher success rate of laser lithotripsy in the present study compared with that reported by Buxbaum et al. was due to a larger balloon size for papillary dilation (more than 50% of patients in the present study had balloons ≥ 15 mm) [10,30], lower proportion of cholesterol stones (which are considered to be hard stone) [31], use of a newer version of the cholangioscope, and a higher energy laser setting (20W) [19]. Procedure times reported by Buxbaum et al. [20] were significantly longer in the laser lithotripsy group than conventional groups, and the authors explained that this was because of the complexity of the laser lithotripsy procedure.

However, without a protocol that limits procedure time, endoscopists might unintentionally and persistently perform their preferred procedure. Additionally, mechanical lithotripsy was also utilized in half of the patients in the laser lithotripsy group, and therefore the addition of this technique might be expected to yield longer procedure times and no difference in fluoroscopy times. Furthermore, we allowed “a crossover technique” in patients whose randomized technique failed; this in turn resulted in no patient requiring surgery in our study.

Fatal perforation has previously been reported after performing EPLBD in a significantly tapered distal CBD [23]; therefore, we did not perform EPLBD in two patients whose distal CBD was smaller than one-third of the widest bile duct (“floating stone”). One patient was randomized in each group and both techniques demonstrated a successful stone clearance within a single session of ERCP. Although we could not formally compare statistical parameters between these two patients, the present study demonstrated that both mechanical and laser lithotripsy were feasible in this situation.

A previous study by Deprez et al. [32] demonstrated that laser lithotripsy reduced overall costs by 11% when compared with mechanical lithotripsy because of the higher stone clearance rate, which resulted in a lower surgery rate. However, the analyses were based on the success rates of two different studies without direct comparison between laser and mechanical lithotripsy. We did not aim to perform the cost-effective analysis in our study because the interpretation and analyses of our data might not be widely applicable to other countries owing to different circumstances, decision models, and variable costs that might contribute to different outcomes.

One limitation of our study relates to the small sample size. Our study was powered on success rates between the randomized arms, and showed statistically significant differences in stone clearance and radiation exposure in the laser vs. mechanical lithotripsy groups. However, we also noted lower adverse event rates and procedure times in the laser lithotripsy group, though these were not statistically significant. A larger study would give more precise estimates in these study parameters between techniques.

In conclusion, although mechanical lithotripsy is the standard of care for a very large CBD stone after failed EPLBD, where available, cholangioscopy-guided laser lithotripsy is considered the better option for the treatment of this entity as it provides a higher success rate with shorter fluoroscopy time and lower radiation exposure.

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Competing interests

None

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