Original Article

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A Prospective Randomized Controlled Trial of Endoscopic Papillary Large Balloon Dilatation following Biliary Sphincterotomy versus Mechanical Lithotripsy for Removal of Difficult Common Bile Duct Stone

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ABSTRACT

Background: The large CBD stone is challenge for endoscopist to remove, because it would be difficult when using the standard technique. We herein performed a prospective randomized controlled trial comparing clinical outcomes including efficacy and complications of EPLBD versus ML in patients with "difficult" CBD stones.

Methods: Sixty patients at the NKC Institute of Gastroenterology and Hepatology, Songkla University, who met the diagnostic criteria for large CBD stones, were undergone ES and then randomized to EPLBD and ML groups. The success rate, complication rates and procedure time were compared between 2 groups.

Results: Sixty patients were diagnosed large CBD stones. Thirty one patients were randomized to EPLBD and 29 patients to ML. Four patients were excluded from each group and remain 27 (51.9%) patients in EPLBD group and 25 (48.1%) patients in ML group. The baseline characteristics including age, sex, comobidities, blood chemistry were not significant between both groups. By the first ERCP session, the complete stone removal rates were 66% in EPLBD group and 76% in ML group ($p = 0.05$). After crossover 5 from 8 patients and 4 from 5 patients were achieved complete stone removal by ML and EPLBD, respectively. The procedure time in successful stone removal session seem to be shorter in EPLBD group (12.25 ± 4.1 vs. 17.52 ± 10.53 minutes in EPLBD and ML groups, respectively) ($p = 0.037$). None developed acute pancretitis, but three patients (11.1%) developed mild, self-limited bleeding in EPLBD group. One patient developed post-ERCP cholangitis due to retained fragment stones which needed second ERCP. Self-limited bleeding from ES was occured in 2 patients (7.4%) from EPLBD group and 1 patient (4%) from ML group. There was no procedure related death, but one patient in ML group was dead from cholangiocarcinoma during long term follow up.

Conclusion: In difficult CBD stone, EPLBD consumed less procedure time while provided comparable effectiveness and complication rates with ML. EPLBD should be considered as an alternative procedure for removal of difficult CBD stones.

Key words : ERCP, endoscopic retrograde cholangiopancreatography, ES, endoscopic sphincterotomy, EPLBD, endoscopic papillary large balloon dilation, EML, endoscopic mechanical lithotripsy.

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INTRODUCTION

The common bile duct (CBD) stones is one of the leading indications for therapeutic ERCP. Endoscopic sphincterotomy (ES) followed by stone extraction, with retrieval balloons or baskets, is recommended as the standard treatment of CBD stones[1-2], which has success rate exceeds 90%[3-6]. However, the large CBD stones (size ≥1.5-2.0 cm)[8,9], hard consistency or squared-shape stones, those with discrepancy of stone size and distal bile duct segment, and limited ES by the presence of juxtaampullary diverticulum were considered to be difficult for stone clearance.

Mechanical Lithotripsy (ML), which was firstly described by Demling[10] in 1982 for stone fragmentation, is widely accepted as a rescue therapy in patients with difficult CBD stones. ML provides stones clearance rate in 51-100%[11]. Several case series reported success rate of ML in removal of CBD stones in the first session in 50-84% with low complication rate[17-21]. This varying rate of success depends on size, number and consistency of stones as well as anatomical variations[12-16].

Endoscopic papillary large balloon dilatation (EPLBD) after ES has been recently introduced for dealing with difficult CBD stones[22]. Preceding ES may facilitate balloon insertion across the papillary orifice. Theoretically, performing ES would separate the pancreatic orifice away from the biliary orifice, and avoid the radial force that would compress the pancreatic orifice. Therefore, the risk of pancreatitis following ES and EPLBD would be minimized. Most studies of EPLBD report the using of large-diameter balloon (12-20 mm) to dilate the sphincterotomized biliary orifice for removal of difficult CBD stones. However, most studies are retrospective, different in patient selection; the length of ES (limited versus full ES); inflation rates and duration of balloon dilation. The success rate was reported in 89-100 %[22-34]. A small proportion of the patients required ML as the supplementary therapy. Complication rate, particularly the concerned post-ERCP pancreatitis, was impressively low.

From Korea study[37], the author compared EPLBD with EML in 109 patients, whose stones were difficult to be removed. The reported success rate was 84.6% in EML and 74.3% in EPLBD, which was not significantly different. Stefanidis and college[38] recently conducted a prospective randomized controlled trial to compare EPLBD and EML in 90 patients with large bile duct stones (12-20 mm). The reported success rate was 91.1% in EML and 97.7% in EPLBD (p = 0.36) and the post-ERCP cholangitis rates were 13.3% in EML and 0% in EPLBD group.

As compared with ML, EPLBD seems to have less technical demand especially for community practice. At present, there is no compelling data to recommend that which modality is the better initial "rescue" treatment of difficult CBD stones. We herein performed a prospective randomized trial comparing clinical outcomes including efficacy and complication of ML versus EPLBD in patients with "difficult" CBD stones.

MATERIALS AND METHODS

Patients

From October 2009 to January 2011, patients, who were older than 18 years and diagnosed of or suspected of CBD stones either by clinical laboratoy or imaging techniques (ultrasonography, CT, MRI, or EUS), were screened for the study. Patients who had the shortest diamension of CBD stone ≥15 mm or tapering of distal CBD based on cholangiogram were defined as having difficult CBD stone and then were randomized to undergo ELPBD or ML. The exclusion criteria were pregnant, uncorrectable coagulopathy (platelet count <50,000/mm^3, or INR ≥1.5), concomitant intrahepatic duct stones, or failure of previous ML or ELPBD. The study was conducted at NKC institute, Songklanagarind hospital, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkla, Thailand. After performing the procedure, patients were discharge home, admitted at Songklanagarind hospital, or referred back to the general hospital, as directed by endoscopists' decision. The study protocol was approved by the ethical committee of the Prince of Songkla University and all informed consent were be obtained from every eligible patients prior to ERCP.

Procedures

ERCP was performed by three experienced endoscopists under conscious sedation using the combination of midazolam and meperidine. The prophylatic antibiotic was not routinely given. Selective biliary cannulation followed by cholangiogram was accomplished to confirm the presence of CBD stones. Size and number of stones and configuration of the CBD were recorded and assessed. The size of stones and CBD were measured on the fluoroscopic images

using the diameter of the endoscope shaft as the reference length. After maximal biliary sphincterotomy was performed, the concealed envelope containing simple randomization code was broken to assign the patients into EPLBD or ML group.

EPLBD was performed by placing the dilating balloon (CRE balloon, Boston Scientific, Natrick MA) over the guide wire across the papilla. The balloon size was chosen based on the size of the largest stone and the diameter of CBD. Usually, the endoscopist started with12-mm balloon, and the diluted contrast medium was used to inflate the balloon. The balloon is kept inflated for 45 second, and then deflated for 15 seconds before upsizing the larger balloons, if necessary. The step of inflation/deflation of incremental balloon dilation (up-to 20 mm.) is repeated until the waistline is completely obliterated or at the discretion of endoscopists.

Mechanical lithotripsy (ML) was performed by using the through-the-scope mechanical lithotriptor (Trapezoid basket, Boston Scientific Corp). Soehendra mechanical lithotriptor was used only in case of broken handle or fail to fragment the stone by manual force. Number of lithotripsy required for stone removal in each session was recorded. Failure of ML, resulting in retain stone, was defined when presence of inability to capture the stone, trapped or broken basket, or bile duct perforation caused by the basket.

After performing the randomized technique, EPLBD or ML, basket and/or balloon extraction were used to extract the stone. Complete stone clearance was confirmed by balloon-occlusion cholangiogram twice. The procedure time was defined as the interval between the beginning of the randomized technique until the end of the procedure. The procedure time was obtained only from the case who achieved complete stone clearance by the randomized procedure. If the randomized technique failed to remove the stone, the other technique was allowed for stone clearance. In case of unsuccessful bile duct clearance, despite using the two techniques, a biliary stent was placed, and the patient was rescheduled for another ERCP session within 4-6 weeks.

Assessment of Complications

As an out-patient setting, patients are kept under close observation for at least 4 hrs after the procedure, and discharged home if stable. Hospitalization for appropriate care is required if complications are documented or suspected. All immediate complications were defined and graded according to the consensus guideline (Cotton PB, *et al.*)[35]. Routine serum amylase measurement in asymptomatic patient was not done.

Follow-up

Short term follow up by phone, within 24 hours and at day 1-7 after the procedure, was delivered in every out-patient setting. All patients were followed up at 1-month, follow by 3-month interval for one year after procedure at an out-patient clinic or by phone.

Data Analysis

The categorical viables were expressed as frequency (percentage), data between two groups were compared by Pearson's Chi-square or Fisher's exact, when appropriate. The continuous data with normal distribution were expressed as mean and standard deviation (SD), data between two groups were compared by unpaired *t*-test. The continuous data without normal distribution were expressed as median and range), data between two groups were compared by Wilcoxon rank sum test. A *p*-value of ≤ 0.05 was considered statistically significant.

RESULT

A total of 60 patients, who underwent ERCP and were defined to have difficult CBD stone, were included for randomization. Four patients in EPLBD group were excluded according to the missed diagnosis of cystic duct stone in 1 patient, distal CBD stricture in 1 patient, failed cannulation in 1 patient, and failed capture of the over size stone. The other 4 patients in ML were excluded according to combativeness patient in one patient, non difficult stone (no need of mechanical lithotripsy) in two patients, prematured termination of procedure due to hypoxemia in one patient. The remaining 52 patients were analyzed, 27 (51.9%) patients in EPLBD and 25 (48.1%) in ML group (Figure 1).

The demographic data between the study groups are summarized in Table 1. Out of 52 patients there were 19 (36.5%) male and 33 (63.5%) female patients. Their age ranged from 35-96 years with a mean age of 69.5 ± 14.2. The co-morbidities, blood test, and IPD or OPD setting were not significantly different betweent two groups. Most of patients had residence in the south

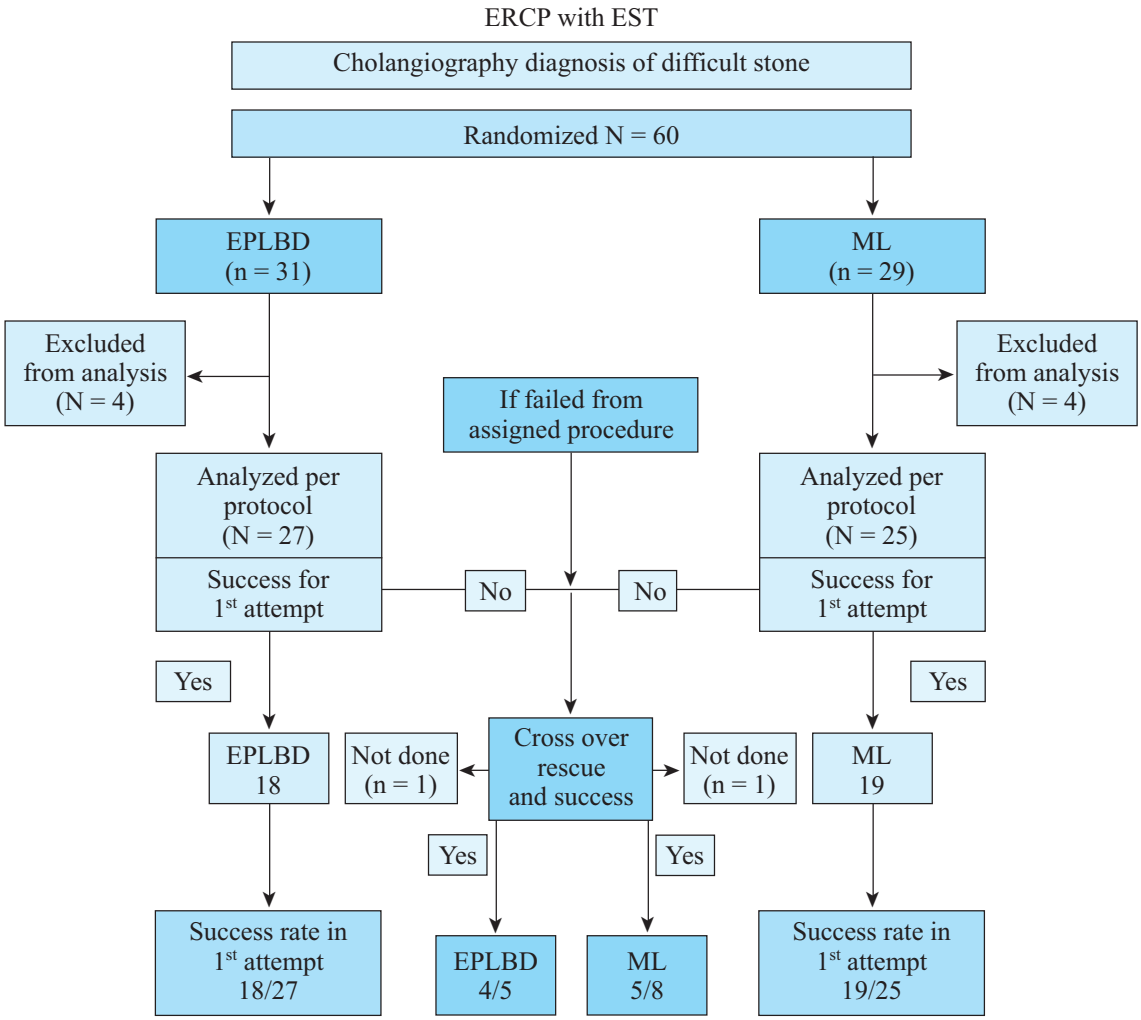

Figure 1. Flow diagram of the study.

of Thailand and was performed as OPD setting.

The characteristics of stone and common bile duct were shown in Table 2. The findings were presented as mean ± SD or median (range) depending on whether they are normally distributed or not. The mean ± SD of the shortest diameter of the stone were 18.9 ± 4.8 and 17.7 ± 2.7 mm. in EPLBD and ML group, respectively $p = 0.135$). The median (range) of the largest diameter of the stone in EPLBD group was 25.9 (15-56) mm. where as the mean in ML group was 23.8 ± 7.8 mm (range 16-47 mm.) ($p = 0.171$). The mean ± SD of the largest diameter of the CBD were 22.0 ± 6.3 and 20.9 ± 4.0 in EPLBD and ML group, respectively ($p = 0.064$). The number, shape, and type of stones were not significantly different between two groups.

The success rate, procedure time, and complications were presented in Table 3. The success rate of EPLBD was 66% compared with 76% in ML group, not reach the statistical significance ($p = 0.05$). The mean ± SD of procedure time of successful randomized procedure were 12.25 ± 4.1 min in EPLBD compared with 17.52 ± 10.53 min from ML ($p = 0.037$).

Three patients (11.1%) in EPLBD group, but none in ML group, developed self-limited bleeding. There was no pancreatitis in both groups. Post-ERCP cholangitis, from retained fragment of the stone, occurred only in one patient from ML group. The patient underwent 2nd ERCP in day 3 after the first ERCP and resulted in complete stone clearance. Five of eight patients (62.5%), who failed EPLBD, were successfully treated with ML in the same ERCP session, while four of five patients (80%), who failed ML, were successfully treated with EPLBD in the same ERCP session. Two patients, one from each group, were not considered to crossover. One patient from EPLBD group had tapering shape of distal CBD and the stone size was

Table 1. Baseline characteristics of the patients

	Total (n = 52)	EPLBD (n = 27)	ML (n = 25)	*p*-value (95% CI)
Gender (M/F) (%)		27 (51.9%)	25 (48.1%)	0.880
Male	19 (36.5)	10 (37.0)	9 (36.0)	
Female	33 (63.5)	17 (63.0)	16 (64.0)	
Age (years) (mean ± SD)	69.5 ± 14.2	69.6 ± 11.5	69.4 ± 17.2	.016
(range)	(35-96)	(39-88)	(35-96)	(-7.9, 8.1)
Co-morbidities, n (%)				
HT	10 (19.2)	4 (14.8)	6 (24)	NA
DM	6 (11.5)	2 (7.4)	4 (16)	
HT-DM	3 (5.7)	2 (7.4)	1 (4)	
CAD	1 (1.9)	0 (0)	1 (4)	
No	28 (53.8)	18 (66.7)	10 (40)	
NA	4 (7.7)	1 (3.7)	3 (12)	
Type of patients, n (%)				
OPD	35 (67.1)	18 (66.7)	17 (68.0)	NA
IPD PSU	6 (11.3)	3 (11.1)	3 (12.0)	
IPD outside	11 (21.6)	6 (22.2)	5 (20.0)	
Recent antibiotic used				
Yes	8 (15.4)	5 (18.5)	3 (12.0)	NA
No	44 (84.6)	22 (81.5)	22 (88.0)	
Blood test (mean ± SD)				
Hb (g/dL)		11.3 ± 1.7	11.8 ± 1.9	0.664
WBC		6848 ± 2810	9119 ± 4219	0.174
PT		11.4 ± 1.5	11.7 ± 1.3	0.657
Alkaline phosphatase (IU/L)		415.6 ± 17.7	319.3 ± 222.8	0.231
Total bilirubin (mg/dL)		3.6 ± 3.8	2.6 ± 2.8	0.127

*NA = not applicable

large (21 × 26 mm) which was unable to capture. The other one from ML group had multiple large stones, the largest one was 23 × 29 mm., which impacted the CBD and was unable to capture (Figure 2-4.)

DISCUSSION

This is a prospective randomized controlled study to compare EPBLD versus ML for removal of difficult common bile duct stone. We reported the success rate of difficult stone removal in the first attempt which were 66% in EPLBD vs. 76% in ML ($p = .050$). Even the outcome of success rate in our study there were in range of previous studies (Table 4 and 5), but its seem to be lower than our expectation. During study period, we had observed our achievement may be affected by the size of the stone, we used the shortest dimension of the largest of stone (≥ 15 mm. of diameter) as a lower limit instead of the largest diameter. While almost all of previous studies used the largest diameter as an inclusion criteria. And some studies had set the upper limit of the stone size. This may affected the success rate which was limited by the technique or the capacity of the equipments eg. size of balloon or basket which might be smaller than the stone. To overcome this problem, in the future study, we should set cut-off point for the largest of the shortest dimension of stone. The sample size of our study did not reach the expected number. It was limited by the duration of study and the nature of difficult CBD stone, which had prevalence of about 5-10% of all CBD stone cases.

We designed to cross over the technique of stone removal after failure of the first one, according to our concern of patient safety and to reflex the real-life situ-

Table 2. Features of stone and CBD

	EPLBD (n = 27)	ML (n = 25)	*p*-value
The shortest diameter of stone, mm. median (range), mean ± SD	17.75 (15-35) 18.9 ± 4.8	17.0 (15-23) 17.7 ± 2.7	
The largest of diameter of stone, mm. median (range), mean ± SD	25.9 (15-56)	23.8 ± 7.8 (16-47)	0.171
The largest of diameter of common bile duct, mm. median (range), mean ± SD	20.8 (15-37.6) 22.0 ± 6.3	20.9 ± 4.0 (14-28.3)	0.064
Number of the stone, n (%)			
1	13 (48.2)	9 (36.0)	0.116
2	4 (14.8)	9 (36.0)	0.165
≥ 3	9 (33.3)	7 (28.0)	0.906
No data	1 (3.7)	0 (0)	
Shape of the shortest stones (%)			NA
Oval	10 (37.0)	11 (44.0)	
Square	9 (33.3)	7 (28.0)	
Round	8 (29.7)	6 (24.0)	
Bullet	0 (0)	1 (3.4)	
Type of stones (N = 27) (%)			NA
Hard	6 (22.2)	4 (16.0)	
Muddy	4 (14.8)	8 (32.0)	
Pigmented	2 (7.4)	1 (3.4)	
No data	15 (55.6)	12 (48.0)	

*NA = not applicable

Table 3. Results of ERCP with ES for stone removal compared between EPLBD vs. ML.

Total (n = 52)	EPLBD (n = 27)	ML (n = 25)	*p*-value (95% CI)
Overall success in stone removal			
In first attempt, n (%)	18 (66.0)	19 (76.0)	0.050 (-.129, .390)
Total times success in first attempt, min (mean ± SD)	12.25 ± 4.1	17.52 ± 10.53	0.037 (-11.9, -1.36)
Complication (n)			
Early complication with self limited			NA
Acute pancreatitis	0	0	
Cholangitis	0	0	
Bleeding	3 (11.1)	0	
Perforate			
Early complication not relate with procedure			NA
Acute pancreatitis	0	0	
Cholangitis	0	1 (4.0)	
Bleeding	2 (7.4)[#]	1 (4.0)	
Perforate	0	(0)	
Long term FU		1 dead from CCA	

*NA = not applicable
[#]exclude group by exclusion criteria

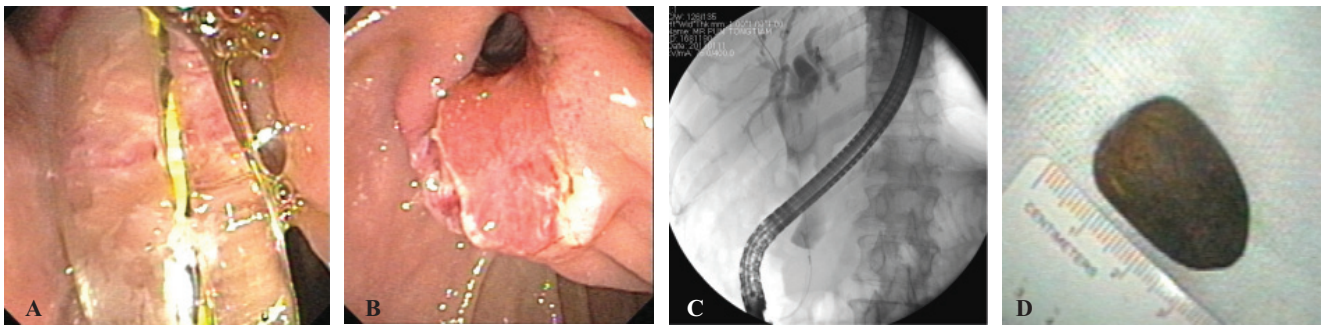

Figure 2. A ERCP with EST followed EPLBD.
B Post dilatation by 15-18 mm CRE balloon.
C Stone was removed with trapezoid.
D The stone size 24.3 × 36.1 mm.

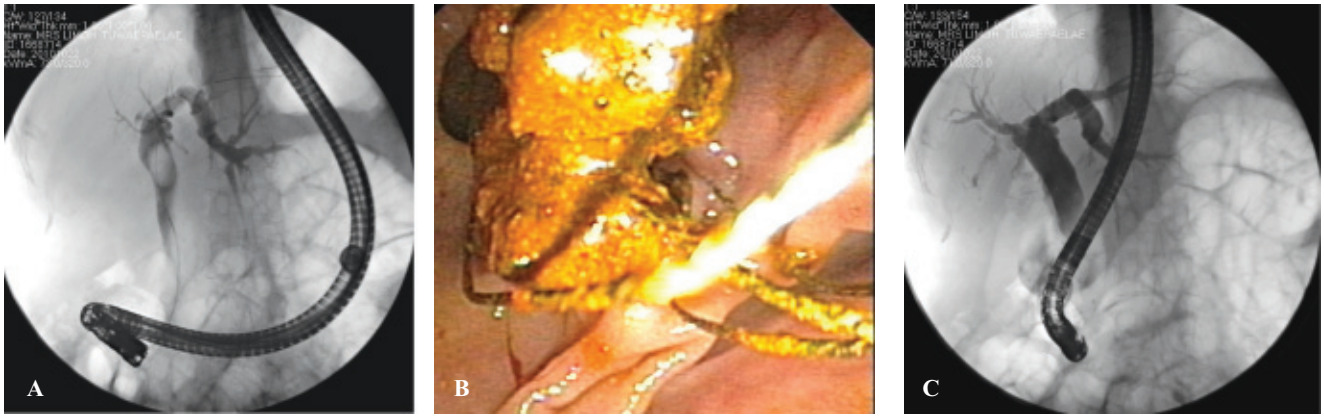

Figure 3. A Cholangiography showed stone size of 17 × 27 mm, CBD size of 18 mm.
B Stone was capture with trapezoid and fragment by lithotriptor.
C Final cholangiogram after ML.

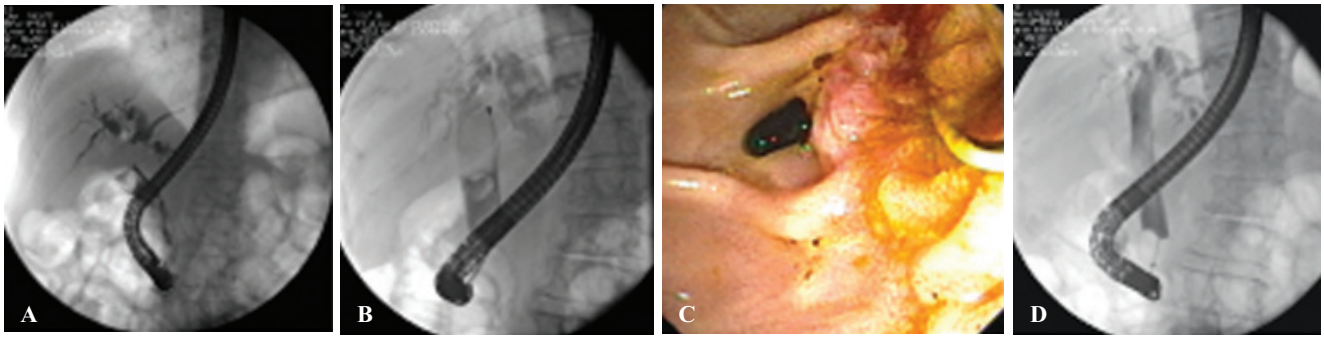

Figure 4. Two patients in EPLBD and ML whose outcome were failed and no crossover. A-EPLBD & B-C ML group
A Large CBD stones with distal CBD tapering
B Large compact CBD stones and could not capture
C One small stone was removed
D The 4th ERCP and accomplishment of stone removal.

Table 4. Summarized data of previously reported of ML.

Study	No of patients (n)	Mean stone size (mm) ± SD	% success rate on first session
Schneider[17] 1988	209	13 ± 3 × 18 ± 9	58.4
Chung[12] 1991	68	24	83.8
Cipolletta[4] 1997	162	21.7 ± 6.7	73.5
Katsinelos[18] 2003	35	16.0	77.0
Chang[19] 2005	304	16.7	69.4
Lee SH[20] 2007	102	22.8 ± 1	50.5
Gutiérrez[7] 2006	134	19.3	58.0
Total	**1014**	**13-24**	**67.12**

Table 5. Summarized data from previously reported EPLBD.

	No. of procedure	Balloon size (mm)	Mean largest stones	% sucess in first session	% use of lithotripsy	Over all	Pancreatitis
Ersoz[22] 2003	58	12-20	16/18	83	7	9 (16)	2 (3) (all mild)
Jeung[33] 2004	100	12-20	16.0 ± 0.7	83	0.7	5	4
Minami[23] 2007	88	Up to 20	14 ± 3	99	1	5 (6)	1 (1) (mild)
Espinel[24] 2007	22	12-20	13 ± 4	100	5	0	-
Yoo[25] 2007	166	15-20	16.1 ± 5.4	83	NM	11 (6.6)	-
Kang[26] 2007	100	12-20	NM	97	8	5 (5)	-
Park[27] 2007	70	25-20	NM (all >15)	100	16	13 (19)	-
Cho[28] 2007	69	NM	17.5/18.2	91	NM	5 (7)	-
Maydeo[29] 2007	62	12-15	16	92	5	5 (8.3)	0
Cha[30] 2007	38	15-20	18.9 ± 5.3	95	3	1 (3)	0
Attasaranya[31] 2008	73	12-18	13**	95	27	6 (6)	0
Itoi[34] 2008	53	15-20	14.8 ± 3.5	96	6	2	1.9
Draganov[32] 2009	44	10-15	12.7	84	5	6.8	0
Total	**1063**	**12-20**	**12.7-18.9**	**92.15**			

ation. But in some cases we chose to insert the stent and repeated the procedure when we considered that the patient were at risk if we continuing the procedure. The success rate after crossover in each groups were satisfied.

Over all of complication of our study was comparable with other studies. EPLBD group seemed to have more bleeding episodes, but the difference was not reach the statistical significant. There was no acute pancreatitis in this study. It might result from our protocol which design to perform EPLBD after complete sphincterotomy in order to prevent the injury to pancreatic orifice. Acute cholangitis was occured in ML group because of the retain stone fragment, but the stone was cleared by following ERCP.

In the subset of successful EPLBD, the procedure time was statistically shorter than ML. However, the difference of time was only 5 minutes. This seemed to have less clinical impact of the shorter procedure time. In the practice, using balloon dilation might be easier than mechanical lithotripsy. However, theoretically the combination of widening of the passage and fragmentation of the passenger would rather use in combination. Further study is needed to confirm this hypothesis.

For the conclusion, EPLBD consumed less procedure time while provided comparable effectiveness and complication rates with ML in difficult CBD stone. EPLBD should be considered as an alternative procedure for removal of difficult CBD stones.

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