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Prospective Controlled Randomized Study of Large-Balloon-Dilatation versus Mechanical Lithotripsy for Large Bile Duct Stone

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Abstract

Background: There were limited data of large balloon dilation (LBD) versus mechanical lithotripsy (ML) in large bile duct stone removal.

Aims: To compare the efficacy of sphincterotomy (EST) with LBD or ML in removal of stone with a transverse diameter ≥ 15 mm.

Methods: 85 were prospectively randomized to EST-LBD (n=44) or EST- ML (n=41).

Results: The stone sizes were comparable (25.96+9.80 in EST-LBD *vs.* 24.75+8.30 mm in EST-ML, p=0.536). The initial stone clearance (ISC) rate was similar in both groups. The overall stone clearance (OSC) rate after ML rescue was 84.1% in ESTLBD and after LBD rescue was 80.5% in EST-ML (p=0.663). Stone >25 mm had lower ISC rate (50% versus 76.5% for stone <25 mm (p=0.012). In EST-LBD, the ISC rate for stone <25 mm was higher than for stone>25 mm (84% *vs.* 42%, p=0.003). The mean procedure time was shorter in EST-LBD than EST-ML (13.26 *vs.* 19.39 minutes, p=0.036). The complication rates were comparable between EST-ML and EST-LBD (26.8% *vs.* 20.4%, p=0.489).

Conclusions: EST-LBD is as effective and safe as EST-ML for large stone removal with less time consuming.

Keywords: Large balloon dilatation; Mechanical lithotripsy; Sphincterotomy

Introduction

The removal of large common bile duct stones (CBDS) is usually done by endoscopic sphincterotomy (EST) supplemented by mechanical lithotripsy (ML) [1]. Previous reports showed that EST with ML (EST-ML) had stone clearance rate of 38% to 73.5% [2-6]. Endoscopic papillary dilatation using a large balloon (LBD) after EST (EST-LBD) for removal of CBDS was first reported in 2003. Since then, many randomized control trials showed EST-LBD efficacy of 83 to 100% [7-23].

There was limited study comparing EST-LBD and EST-ML. One randomized study [21] compared EST-LBD with EST-ML in CBDS removal in 90 patients with 12- 20 mm stone and showed comparable stone clearance rate (97.7 *vs.* 91.1%, P=0.36). Unfortunately, the study was terminated prematurely due to a significant higher cholangitis in EST-ML. The aim of this study was to compare the efficacy of EST-LBD and EST-ML for CBDS removal of stone with the transverse diameter>15 mm or the stone's size was disproportionate to the lower bile duct segment with a ratio of transverse diameter of stone/lower bile duct diameter >50%(SS/DCBD >50%).

Methods

All patients aged>18 years with CBDS from December 2010 to May 2013 at our institute were enrolled into the study. Inclusion criteria were a bile duct stone with a transverse diameter ≥ 15 mm or the stone's size was disproportionate to the lower bile duct segment with a ratio of transverse diameter of stone/lower bile duct diameter >50%. Exclusion criteria were pregnancy, coagulopathy (international normalized ratio ≥ 1.5), platelet count<50,000, concomitant intrahepatic duct stones, acute pancreatitis or cholecystitis, surgically altered anatomy, pancreatic or biliary malignancy. Patients were randomized to EST-ML or EST-LBD group using random number generated by a computer in sealed envelopes. The study was approved by the institutional ethics committee. Informed consent was obtained in every patient prior to the procedure.

Procedures

ERCP was performed using a side view duodenoscope (TJF-160 R, Olympus Medical Systems Co. Ltd, Tokyo, Japan) under conscious sedation according to our protocol [24]. Antibiotic prophylaxis was not routinely used. All ERCPs were performed by one of the three experienced endoscopists (BO, SA, PS) or by trainees under supervision. The number together with the transverse and longitudinal diameters of stones, the configuration as well as the diameter of common bile duct were determined using the duodenoscope diameter as a reference. Sphincterotmy was done using ERBE®(200) with a default Endocut® setting to the transverse fold. All the stone removal were done by one of the experienced endoscopists. For LBD group, a CRE balloon (Boston Scientific Corp., USA) diameter was chosen according to the largest

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stone size or to the maximum of 20 mm. The balloon dilation was done for 60 seconds.

For the ML group, a 3 × 6 cm Trapezoid® stone retrieval basket (Boston scientific Corp., USA) was used. Crushing of the stone was done when simple stone extraction failed. The stone were retrieved with a basket and/or a retrieval balloon in both groups. When stone removal was unsuccessful with the designated treatment, then crossing over to the other treatment was done at the discretion of the endoscopist. A biliary plastic stent was placed in cases with failure and another ERCP would be scheduled at 8-12 weeks to remove the residual stones [25]. Procedural time was the time between insertion of the index stone retrieval device and the time when final cholangiogram was finished.

Assessments

Definition of term

Initial stone clearance was the clearance of CBDS without rescue therapy (ISC). Overall stone clearance was the clearance of CBDS accomplished with initial and rescue therapy (OSC). The primary outcome was the OSC rate at the index ERCP in each group. The secondary outcomes included procedure time, OSC rate of rescue therapy in each group, and complication rate. ERCP complications were defined and graded according to the consensus guideline [26]. The sedation associated complications were recorded.

Post ERCP management

Patients were observed for 3 to 4 hours after the procedure. Complications were treated as an inpatient basis. Telephone follow up to assess complications was obtained on day 1, 3 and 30. For patients with OSC, clinical and liver function test were assessed at two and twelve weeks respectively.

Statistical Analysis

Sample size calculation was based on an estimated mean success rate of approximately 62% for EST-ML from 5 studies [2-6] and a mean success rate of approximately 92% for EST + LBD from 17 studies [7-23]. To detect this difference of 30% with the power of 80% and alpha=0.05 using the two independent proportions (two-tailed test) method and allowing for 5% missing data, the required sample size was 39 in EST-ML and 35 in EST-LBD.

Statistical analyses were performed with Minitab® 1.5 statistical software and statistical release. The quantitative variables were presented as mean+standard deviation or median with range as appropriate. Qualitative variables were presented as the percentage or number or proportion. Categorical data were compared using Chi-square test or Fisher's exact test, where appropriate and the comparison of continuous data were analyzed using Student's t test. Logistic regression was performed to identify variables independently associated with success. A p-value of<0.05 was considered as statistical significant.

Results

Ninety patients were enrolled from December 2010 to May 2013. Five were excluded, 2 with bile duct stricture, 1 with failure of biliary cannulation, 1 with concomitant intrahepatic bile duct stone and uncooperative. Eighty five (47 female and 38 male) were randomized, 41 to EST-ML and 44 to EST-LBD.

The baseline characteristics, distribution of various stone size, mean stone size, number of stones, stones shape, number of patients with SS/DCBD or mean CBD size between the 2 groups were similar (Tables 1 and 2).

Outcomes

The ISC was similar between the two groups, 29/44 (65.91%) in EST-LBD and 27/41 (65.85%) in EST-ML, (Chi-square p=1.000). Nine of the 15 in the EST-LBD group and 14 of the 14 in the EST-ML group with failed stone removal were crossed over. OSC rate was significantly higher using ML in EST-LBD than using LBD in EST-ML (8/9 (88.9%) *vs.* 6/14 (42.9%), respectively), (Fisher's exact test, p=0.040).

The OSC rate for the first ERCP was 37/44 (84.1%) in EST-LBD and was higher than 33/41 (80.5%) in EST-ML but the difference was not significant (Chi-square, p= 0.663). However, the mean procedure time was significantly shorter in the EST-LBD than EST-ML (13.2 *vs.* 19.3 min; Student's t test, p= 0.036) (Table 3).

The ISC rate by stone size

When all patients were categorized as stone > 25 mm group and stone ≤ 25 mm group then the ISC rate for stone ≤ 25 mm was significantly higher (39/51, 76.5%) for stone >25 mm (17/34, 50%) (Chi-square, p= 0.012). In EST-LBD group, the ISC rate for stone ≤ 25 mm was 21 of 25, (84%) which was significantly higher than 8 of 19 (42%) for stone > 25 mm, (Chi-square, p=0.003). In EST-ML group, the ISC rates for stone ≤ 25 mm and for stone > 25 mm were not significantly different (18/26, 69.2% *vs.* 9/15, 60%, respectively,

	EST-ML N=41	EST-LBD N=44	P-value
Gender, F/M	23/18	24/20	0.886
Mean age, years ± SD	68.7 ± 15.5	66.4 ± 15.2	0.506
Total bilirubin (mg/dl), mean+SD	2.21+2.20	3.18 + 4.02	0.192
ALP (IU/ml) mean+SD	309 + 209	385 + 358	0.263
Prior sphincterotomy, n (%)	3 (7.32)	4 (9.09)	0.81
Gallstones, n (%)	22 (53.66)	24 (54.54)	0.886
Periampullary diverticulum, n (%)	19 (46.34)	26 (59.09)	0.389
F: Female; M: Male ALP: Alkaline Phosphatase			

Table 1: Patient's baseline characteristics in EST-ML and EST-LBD groups.

	EST-LBD -44	EST-ML -41	P-value
Distribution of Stone by size*			
stone ≥ 15-<20 mm	12	16	-
stone ≥ 21-<25 mm	13	10	-
stone ≥ 25-<30 mm	8	5	-
stone ≥ 30 mm	11	10	0.66
Mean stone size (mm), mean ± SD (range)+	25.96 ± 9.80 (15-56)	24.75 ± 8.30 (15.3-47.0)	0.536
No. of stones, n (%)*			
1	21	16	-
2	6	12	-
3	13	9	-
4	4	4	0.347
Shape of stone*			
Square	10	12	-
Non square	34	29	0.491
Discrepancy of stone/CBD, n (%)*	12 (27)	7 (17)	0.259
Common bile duct diameter (mm), mean ± SD (range)+	22.43 ± 6.20 (15-37.6)	22.36 ± 5.27 (14-36.6)	0.953
*Chi-square, +Student's t test			

Table 2: Characteristics of stones and CBD configuration in EST-ML and EST-LBD groups.

Chi-square, p=0.550). When the ISC rate was compared between the treatment group categorized by stone ≤ 25 mm or > 25 mm. For stone ≤ 25 mm, the ISC rate in EST-LBD was 21/25 (84%) compared with 18/26 (69.2%) in EST-ML but the difference was insignificant (Chi-square, p=0.328), moreover, the mean procedure time in EST-LBD was similar to that in EST-ML (16.3 ± 13.8 min *vs.* 19.5 ± 15.7 min, respectively, Student t test, p=0.630). For stone > 25 mm, the ISC rate in EST-LBD was 8/19 (42.1%) which was lower than 9/15 (60%) in EST-ML (statistically not significantly, Chi-square, p=0.300) and the procedure time between these two groups were similar (33.14 ± 6.98 *vs.* 34.33 ± 0.63 min, Student's t test p= 0.673).

OSC was achieved in 70/85 (82.4%) patients and all these patients were doing well at 12 weeks visit.

In the remaining 15 (17.6%) with incomplete CBDS clearance, 9 had CBDS clear with additional ERCP(s), 6 required one session and 1 each required 2, 3 and 5 sessions. One had spontaneous stone passage. Two had incomplete stone clearance despite multiple ERC attempts and one patient was referred for surgery and one was lost to follow up, 2 required surgery due to perforation and 1 was lost to follow up. The ultimate overall stone clearance was 80/85 (94.11%).

Factors associated with failure

For the whole group, the mean ± SD diameter of stone in 29 with failure was 28.30 ± 11.30 mm which was significantly larger than 23.86 ± 7.36 mm in 56 patients with success (Student's t test, p= 0.010) and multivariate logistic regression analysis showed the transverse diameter of stone, SS/DCBD >50% and the number of stones ≥ 3 were significant predictors of stone clearance failure (Table 4). In EST-LBD group, the stone size in the failure group was significantly larger than in the success group (31.22 ± 12.70 mm vs 23.27 ±6.60 mm; Student's t test, p=0.009) with larger CBD size as well as SS/DCBD>50% associated with more failure. In EST-ML group, the stone size between the success and failure were not significantly different (24.50 ± 8.18 *vs.* 25.24 ± 8.83 mm; Student's t test, p=0.790) but the SS/DCBD >50% was associated with failure (Table 5). Multivariate logistic regression analysis of the subgroup showed that, in the EST-ML group, the number of stones ≥ 3 was a significant predictor of failure whereas, in the EST-LBD group, the longitudinal diameter of stone, the number of stones ≥ 3 and SS/DCBD >50% were significant predictors of failure (Table 6).

Adverse events

The adverse event (AE) rates did not differed significantly between the two groups (9/43 (20.5%) in EST-LBD *vs.* 11/41 (26.8%) in EST-ML, (Table 7). Bleeding was the most common complication (4/43 (9.0%) in EST-LBD *vs.* 4/41 (9.7%) in EST-ML, Chi-square, p=0.916). One patient in EST-ML group developed mild pancreatitis that responded to conservative treatment. Perforation occurred in two patients (2/85, 2.3%), however, both of these patients had uneventful recovery.

	EST-LBD N=44	EST-ML N=41	P-value
Complete stone removal before rescue therapy, n/total (%)	29/44(65.91)	27/41(65.85)	1
Number of patients with crossed over treatment, n/total (%)	9/15 (60)	14/14 (100)	0.017
Complete stone removal in crossed over Rx, n/total (%)	8/9 (88.88)	6/14 (42.86)	0.04
Total complete stone removal, n (%)	37 (84.09)	33 (80.49)	0.663
Mean procedure time (minutes) ± SD	13.26 ± 9.70	19.39 ± 12.41	0.036
Rx: Treatment			

Table 3: Outcome of EST-ML and EST-LBD groups.

Variable	Level	OR	95% CI	P-value
Method	EST-ML	1	-	-
	EST-LBD	1.57	0.53, 4.70	0.412
Transverse diameter of stones	Per mm	0.81	0.71, 0.93	0.001
Discrepancy Of stone/CBD size	No	1	-	-
	Yes	0.13	0.03, 054	0.003
No. of stone	1 or 2	1	-	-
	≥ 3	0.24	0.08, 0.71	0.008

Table 4: Multivariate logistic regression analysis of parameters associated with failure for the whole group.

Variable	Level	OR	95%CI	P-value
EST-ML No. of stones	1 or 2	-	-	-
	≥ 3	0.47	0.23, 0.95	0.003
EST-LBD Longitudinal diameter of stone	Per mm	0.84	0.74, 0.95	0.002
Discrepancy of stone/CBD size	No	-	-	-
	Yes	0.04	0.03, 0.41	0.003
No. of stones	1 or 2	-	-	-
	≥ 3	0.38	0.16, 0.91	0.004

Table 6: Multivariate logistic regression analysis of parameters associated with failure for the EST-ML and EST-LBD groups.

	EST-LBD	EST-ML	P-value
Mild PEP	0	1(2.4)	-
Post ERCP bleeding	4 (9.09)	4 (9.76)	-
Mild ES bleeding	2 (4.55)	3 (7.32)	-
Moderate ES bleeding	2 (4.55)	1 (2.44)	-
Perforation	1 (2.27)	1 (2.44)	-
Desaturation	0	1 (2.44)	-
Any adverse events	9 (20.45)	11 (26.83)	0.489
PEP: Post ERCP Pancreatitis			

Table 7: Adverse events in EST-ML and EST-LBD groups (No. of Case (%)).

	EST-LBD			EST-ML		
	Success (29)	**Failure -15**	**P-value**	**Success -27**	**Failure (14)**	**P-value**
CBD size, (mm) mean ± SD (range)	20.93 ± 5.12	25.32 ± 7.22	0.024	21.24 ± 4.72	24.50 ± 5.76	0.06
	(15-37.6)	(16-36)	-	(15-37.6)	(16-36)	-
Longest diameter of stones (mm), mean ± SD (range)	23.27 ± 6.60	31.22 ± 12.7	0.009	24.50 ± 8.18	25.24 ± 8.83	0.79
	(15.4-41.5)	(15-56)	-	(15.4-41.5)	(17-45)	-
No. of stones						
1 or 2	20	7	-	22	6	-
≥ 3	9	8	0.15	5	8	0.012
Discrepancy of stone/CBD sizes	2	10	0	2	5	0.026

Table 5: Stone characteristic between the success and failure groups at first index ERCP before cross over.

Discussion

In our study, the ISC rates in the first ERCP session were 65.91% and 65.85% in EST-LBD and EST-ML, respectively which were much lower than another study [12]. This may due to the larger stones (ranging from 15-56 mm) in our study whereas the stone size in the other study was 12-20 mm [21]. The OSC rate at the first ERCP in both groups in our study was not significantly different and was in the range of 83%-100% reported in other studies [7-23]. The overall complication rates in our study in EST-ML was 26.83% which was slightly higher than 20.0% in Stefanidis et al. study [21]. No cholangitis occurred in our study in contrast to 13.3% found in the other study despite routine antibiotics prophylaxis [21]. However, the complication rates in EST-ML was not significantly different from EST-LBD in our study.

EST-LBD required significantly less time than EST-ML and this was in accordance to the results of other reports [27,28]. The mean stone size of 25.96 in EST-LBD group was larger than the mean of 12.7-20.8 mm in most of other studies of LBD [7-23]. However, one retrospective study in 35 patients with a mean stone size of 26.11 mm, which was comparable to our study, with EST-LBD showed a clearance rate of 88.6%.

The stone size associated with more failure reported in other studies varied from >15 to 26 mm [8,19,21,22,29-31]. In our study, the success rate for stone >25 mm was significantly lower than stone ≤ 25 mm both for the whole group and EST-LBD group. Stone>25 mm greatly decreased the success rate of EST-LBD to 42.1% compared with 84% in stone ≤ 25 mm. The number of stone ≥ 3 was the only significant predictor of failure in EST-ML, whereas, multiple factors, namely, stone ≥ 25 mm, SS/DCBD >50% and the number of stone ≥ 3, were significant predictors of failure in EST-LBD. One major factor that contributing to the high failure rate in EST-LBD for stone>25 mm was the maximal balloon size was set to 20 mm to minimize the risk of perforation [28], which was smaller than the stone size.

The rescue by using ML in EST-LBD was significantly more effective than a rescue by LBD in EST-ML. ML provided an option for stone crushing and stone size was the most common factor of failure in patients with failed stone removal in EST-LBD, so stone crushing is a viable option to deal with the problem. The common cause of failure in EST-ML was failed stone capture (data not shown) so the widening of ampulla opening by a LBD rescue was not an appropriate option to solve the problem [29].

The AE rates were not significantly different between the two groups and were comparable to the prevalence reported in the literature. However, perforation occurred in two patients (2/85, 2.3%) which was slightly higher than the reported range of 0-1.7% in the literature [27,28].

The role of EST in LBD for CBDS removal was debatable [27,28]. Partial ES may be preferred if ES was planned to be used [27]. The optimal duration of balloon inflation was also not well-established [27].

In conclusion, EST-LBD is as effective as the EST-ML in the management of relatively large bile duct stones, but is less time consuming. Stone>25 mm was associated with more failure than stone ≤ 25 mm in the EST-LBD treatment group. The strategy of EST-LBD first for large stone supplemented with ML rescue in case of failure seem to be a suitable strategy [30,31].

Conflict of Interest

All authors have no conflicts of interests to declare.

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