

## Contribution of Surgical Procedures Including Insertions of Implants, Stents, and Pacemakers to Longevity Prospective Controlled Randomized Study of Large-Balloon-Dilatation Versus Mechanical Lithotripsy for Large Bile Duct Stone

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### ABSTRACT

The removal of large common bile duct stones (CBDS) is usually done by endoscopic sphincterotomy (EST) supplemented by mechanical lithotripsy (ML). Previous reports showed that EST with ML (EST-ML) had stone clearance rate of 38% to 73.5%. 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%. There was limited study comparing EST-LBD and EST-ML. One randomized study 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%). 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. 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. Sphincterotomy 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 endoscopist. There were limited data of large balloon dilatation (LBD) versus mechanical lithotripsy (ML) in large bile duct stone removal. To compare the efficacy of sphincterotomy (EST) with LBD or ML in removal of stone with a transverse diameter  $\geq 15$  mm. 85 were

prospectively randomized to EST-LBD (n=44) or EST-ML (n=41). 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 EST-LBD 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%,  $p=0.489$ ). EST-LBD is as effective and safe as EST-ML for large stone removal with less time consuming. 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. This may be 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. 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. 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. No cholangitis occurred in our study in contrast to 13.3% found in the other study despite routine antibiotics prophylaxis. 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. 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. 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 . In our study, the success rate for stone >25 mm was significantly lower than stone  $\leq$  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  $\leq$  25 mm. The number of stone  $\geq$  3 was the only significant predictor of failure in EST-ML, whereas, multiple factors, namely, stone  $\geq$  25 mm, SS/DCBD >50% and the number of stone  $\geq$  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 , 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 .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 .The role of EST in LBD for CBDS removal was debatable .Partial ES may be preferred if ES was planned to be used .The optimal duration of balloon inflation was also not well-established .In last,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  $\leq$  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 .

**Keywords:** Large balloon dilatation; Mechanical lithotripsy;Sphincterotomy