Impact of endoscopic papillary large-balloon dilation on sphincter of Oddi function: a prospective randomized study

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Background and Aims: Endoscopic papillary balloon dilation (≤8 mm in diameter) preserves sphincter of Oddi (SO) function. However, it is still unknown whether papillary function is preserved after endoscopic papillary large-balloon dilation (EPLBD, ≥12 mm in diameter). We investigated SO function after EPLBD with or without endoscopic sphincterotomy (EST) by endoscopic manometry, up to 1 year after the procedure.

Methods: This was a prospective randomized study involving patients with bile duct stones ≥12 mm. Eighty-six patients who met the inclusion criteria were assigned randomly to either EPLBD alone or EST with EPLBD, and endoscopic manometric studies were performed. The primary outcome was comparison of the manometric data between the 2 groups and within each group both 1 week and 1 year after the procedure.

Results: One week after EPLBD alone and EST with EPLBD, the basal pressure of SO dropped from 30.4 (8.2) to 6.4 (8.4) mm Hg ($P < .001$) and 29.5 (18.9) to 2.9 (3.6) mm Hg ($P < .001$), respectively. SO function was not recovered at 1 year; the manometric measurements were similar to those taken at the 1-week time point in both groups. Similar outcomes were obtained in patients with EPLBD alone compared with those with EST and EPLBD, including the initial stone clearance rate (95.2% vs 97.7%, $P = .612$), the frequency of mechanical lithotripsy (21.4% vs 13.6%), and overall adverse events (11.9% vs 13.6%, $P = 1.0$) including the rate of pancreatitis after the procedure (7.1% vs 11.4%, $P = .714$). During an overall median follow-up of 17.8 months, the recurrence rate of bile duct stones was 16.7% in patients who underwent EPLBD alone and 15.9% in patients who underwent EST with EPLBD ($P = .924$).

Conclusions: Both EPLBD alone and EST + EPLBD resulted in persistent and comparable loss of SO function after 1 year. EPLBD alone has similar efficacy and safety to those of EST with EPLBD with respect to removal of large stones. (Gastrointest Endosc 2017;85:782-90.)

INTRODUCTION

Endoscopic papillary balloon dilation using balloons <8 mm in diameter (ie, small-balloon dilation) has been introduced as a less-invasive alternative method to reduce adverse events while removing stones effectively.[1] However, the use of balloons with a small diameter (≤8 mm) has limitations in bile duct opening when used to remove bile stones >10 mm in diameter. In addition, in many cases, insufficient dilation of the distal common bile duct (CBD) above the ampulla results in difficulty removing a stone captured in a basket, even when full endoscopic sphincterotomy (EST) can achieve dilation of the ampullary orifice. In approximately 10% to

Abbreviations: ANOVA, anaylsis of variance; CBD, common bile duct; EPBD, endoscopic papillary balloon dilation; EPLBD, endoscopic papillary large-balloon dilation; EST, endoscopic sphincterotomy; GB, gallbladder; IQR, interquartile range; ML, mechanical lithotripsy; SD, standard deviation; SO, sphincter of Oddi; SOM, sphincter of Oddi manometry.

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15% of cases, it is difficult to remove bile duct stones using the 2 methods described above.[2] EST combined with endoscopic papillary large-balloon dilation (EPLBD) has been used in these cases,[3] and the efficacy of EPLBD has been proven in many studies.[4-6] Large-balloon dilation not only opens the ampullary orifice more than small-balloon dilation or EST but also widens the distal bile duct, thereby reducing the mechanical lithotripsy (ML) rate and consequently reducing the fluoroscopy time in comparison with treating CBD stones with EST only.[7] It was thought that loss of SO function would occur much the same as with EST as a result of the widening the ampullary orifice; however, there are no objective studies on this.

Permanent loss of SO function by EST is a likely cause of duodenobiliary reflux, bacterial contamination of the biliary tract, subsequent late adverse events including stone recurrence, cholangitis, or liver abscess.[8,9] Compared with EST, small-balloon dilation causes little trauma to the papilla and preserves sphincter function. Indeed, several studies found SO function to be unaffected after small-balloon dilation.[10,11] Although it is still under debate whether preservation of SO function is clinically beneficial, one study showed that long-term biliary adverse events were higher in the EST group than in the small-balloon dilation group.[12] However, it remains to be determined whether papillary function is preserved after EPLBD. Hence, this prospective randomized study compared SO function in a group of patients who received EPLBD alone using balloons $\geq$12 mm in diameter and patients who received EST with EPLBD. Clinical outcomes of the 2 groups were also analyzed.

METHODS

Patients

Inclusion and exclusion criteria were as follows. Inclusion criteria were age 18 to 85 years, informed consent obtained before ERCP, CBD diameter $\geq$12 mm, and bile duct stones visualized at ERCP with at least one bile duct stone $\geq$12 mm (transverse diameter). Exclusion criteria were stone transverse diameter >35 mm, acute pancreatitis, a history of previous sphincterotomy, previous endoscopic papillary balloon dilation (EPBD), choledochoduodenal fistula, coagulopathy or anticoagulant/antiplatelet therapy, Billroth II or Roux-en-Y reconstruction, medications known to affect the SO (calcium channel blockers, nitrates, opiates, and anticholinergics) taken within 48 hours of the procedure, or benign or malignant biliary stricture. Before enrollment, an initial cholangiogram was obtained and the diameter of the CBD at its most dilated part, as well as the transverse size of the largest stone, were assessed in comparison with the diameter of the shaft of the endoscope. Randomization was performed during the initial ERCP when patients were assessed according to the inclusion or exclusion criteria. The patients were assigned randomly to EPLBD alone or EST with EPLBD by computer-generated block randomization (size 4) and a random number list.

Patients underwent SO manometry (SOM) studies without the use of antispasmodic agents before either EPLBD alone or EST with EPLBD. The Ethics Committee of our hospital approved the study, and all patients gave written informed consent before entering the study. This study was registered with CRiS.nih.go.kr (KCT0000877).

Endoscopic procedures

As determined previously,[6] large-diameter balloon dilation uses a balloon diameter $\geq$12 mm. A dilation balloon (Maxforce, Microvasive Scientific Corporation, Mass) was passed over a prepositioned guidewire and placed in the bile duct opening. The stone diameter was estimated based on the relationship between the diameter of the stone and the diameter of the endoscope shaft, as measured on the cholangiogram. In the EPLBD alone group, balloon dilation was performed using wire-guided hydrostatic balloon catheters placed across the papilla without performing EST. The size of the balloon used was chosen according to the diameter of the bile duct. The balloon was inflated using diluted contrast media until the waistline was obliterated under fluoroscopic monitoring. The fully expanded balloon was maintained in position for 30 seconds and then deflated and removed. The first stone extraction attempt was performed using standard extraction methods with a Dormia basket and/or a retrieval balloon. When stones were not extracted outside the biliary tract by the initial basket trapping, ML (BML-4Q, Olympus, Tokyo, Japan) was performed to fragment the stones. In the EST with EPLBD group, mid-incision EST (incision to the mid-portion of the papilla) was performed before balloon dilation using a pull-type sphincterotome (KD-6Q, Olympus, Tokyo, Japan) following a standard method. After papillary incision, EPLBD was performed as described above. All patients were kept under observation in the hospital for at least 24 hours after the initial ERCP.

Endoscopic manometry

Patients underwent SOM before, 1 week after, and 1 year after EPLBD alone or after EST with EPLBD. SOM was performed using our previously described method.[13] The basal sphincter pressure was recorded as the baseline pressure between phasic waves using the duodenal luminal pressure as a zero reference. Recording was sustained for a minimum of 30 seconds but generally for more than 1 minute; pressures were recorded in at least 2 leads. The 4-point method was used to determine the most representative segment for measurement of basal pressure. The 4 lowest points in the highest sustained sphincter pressure zone were read and averaged using this method. The mean of all basal sphincter recordings (combining all leads and all pull-through) was used as the basal sphincter pressure for data analysis. The SO phasic