Online Submissions: wjg.wjgnet.com
wjg@wjgnet.com
doi:10.3748/wjg.15.4298

World J Gastroenterol 2009 September 14; 15(34): 4298-4304
World Journal of Gastroenterology ISSN 1007-9327

BRIEF ARTICLES

Small sphincterotomy combined with endoscopic papillary large balloon dilation *versus* sphincterotomy

Hyun Gun Kim, Young Koog Cheon, Young Deok Cho, Jong Ho Moon, Do Hyun Park, Tae Hoon Lee, Hyun Jong Choi, Sang-Heum Park, Joon Seong Lee, Moon Sung Lee

Hyun Gun Kim, Young Koog Cheon, Young Deok Cho, Jong Ho Moon, Do Hyun Park, Tae Hoon Lee, Hyun Jong Choi, Sang-Heum Park, Joon Seong Lee, Moon Sung Lee, Institute for Digestive Research, Digestive Disease Center, Soonchunhyang University College of Medicine, Seoul 140-743, South Korea
Author contributions: Kim HG and Cheon YK contributed equally to this work; Cheon YK designed the research; Kim HG, Cheon YK, Cho YD, Park DH and Choi HJ performed the research and collected the data; Kim HG analyzed the data; Cheon YK, Moon JH, Lee TH, Park SH, Lee JS and Lee MS reviewed the data analysis and corrected the research design; Kim HG wrote the paper; Cheon YK revised and corrected the paper.
Correspondence to: Young Koog Cheon, MD, PhD, Associate Professor, Institute for Digestive Research, Department of Internal Medicine, College of Medicine, Soonchunhyang University, 657 Hannam-Dong, Yongsan-Gu, Seoul 140-743, South Korea. cyk@hosp.sch.ac.kr
Telephone: +82-2-7099202 Fax: +82-2-7099696
Received: May 12, 2009 Revised: July 24, 2009
Accepted: July 31, 2009
Published online: September 14, 2009

Abstract

AIM: To compare small sphincterotomy combined with endoscopic papillary large balloon dilation (SES + ELBD) and endoscopic sphincterotomy (EST) for large bile duct stones.

METHODS: We compared prospectively SES + ELBD (group A, *n* = 27) with conventional EST (group B, *n* = 28) for the treatment of large bile duct stones (≥ 15 mm). When the stone could not be removed with a normal basket, mechanical lithotripsy was performed. We compared the rates of complete stone removal with one session and application of mechanical lithotripsy.

RESULTS: No significant differences were observed in the mean largest stone size (A: 20.8 mm, B: 21.3 mm), bile duct diameter (A: 21.4 mm, B: 20.5 mm), number of stones (A: 2.2, B: 2.3), or procedure time (A: 18 min, B: 19 min) between the two groups. The rates of complete stone removal with one session was 85% in group A and 86% in group B (P = 0.473). Mechanical lithotripsy was required for stone removal in nine of 27 patients (33%) in group A and nine of 28 patients (32%, P = 0.527) in group B.

CONCLUSION: SES + ELBD did not show significant benefits compared to conventional EST, especially for the removal of large (≥ 15 mm) bile duct stones.

Key words: Sphincterotomy; Endoscopic; Balloon dilatation; Cholelithiasis; Lithotripsy

Peer reviewer: Masayoshi Ito, MD, Department of Endoscopy, Yotsuya Medical Cube, 5-5-27-701 Kitashinagawa, Shinagawa-ku, Tokyo 1410001, Japan

Kim HG, Cheon YK, Cho YD, Moon JH, Park DH, Lee TH, Choi HJ, Park SH, Lee JS, Lee MS. Small sphincterotomy combined with endoscopic papillary large balloon dilation *versus* sphincterotomy. *World J Gastroenterol* 2009; 15(34): 4298-4304 Available from: URL: http://www.wjgnet.com/1007-9327/15/4298.asp DOI: http://dx.doi.org/10.3748/wjg.15.4298

INTRODUCTION

The basic principle of common bile duct stone removal involves destruction or dilation of the bile duct orifice, which allows easy removal of the stone. Endoscopic sphincterotomy (EST) is accepted as the standard management for stone removal from the bile duct, but it is associated with serious complications such as hemorrhage, pancreatitis, perforation, and recurrent infection of the bile duct, which cause permanent functional loss of the sphincter of Oddi[1-4]. Endoscopic papillary balloon dilation (EBD) was introduced by Staritz *et al*[5] and has been accepted widely as an alternative to EST[6-10]. It has similar outcomes for common bile duct stone removal compared to EST, and has the advantages over EST of preserving papillary sphincter function and causing minimal complications such as hemorrhage and perforation[11-19]. Despite these advantages, EBD is associated with more severe and frequent occurrence of pancreatitis[20-22]. In addition, EBD has some technical difficulties for removing large stones because the biliary opening is not enlarged to the same degree as with EST[23].

To overcome these limitations, Ersoz *et al*[24] introduced EBD with conventional EST for the removal of large (⩾ 15 mm) bile duct stones that are difficult to remove by EBD alone. They have reported that EBD with conventional EST is more effective for the retrieval of large stones and shortens the procedure time. Recently, this technique has been modified slightly to endoscopic papillary large balloon dilatation (ELBD) with small incision EST, and many studies have reported on the outcome of stone removal and complication rate[25-27]. However, these studies on the efficacy of ELBD with SES have concentrated on small stones, of which the majority are ⩽ 1 cm[25,26]. Therefore, the effectiveness of SES with ELBD for large stone removal (⩾ 15 mm) has not been established.

We conducted a prospective randomized study to compare the efficacy and safety of SES + ELBD with conventional EST for the treatment of large (⩾ 15 mm) common bile duct stones.

MATERIALS AND METHODS

Patients

From June 2006 to December 2008, 55 patients were enrolled, and all patients were diagnosed as having common bile duct stones by endoscopic retrograde cholangiography (ERCP) or magnetic resonance imaging (MRI). In all patients, the stone was at least 15 mm in maximum diameter. The exclusion criteria for this study were the following: (1) bleeding tendency with INR > 1.5; (2) platelet count < 50000/mL; (3) anticoagulation therapy within 72 h of the procedure; (4) bilio-colic fistula; (5) stone size > 50 mm; (6) acute cholecystitis; (7) acute pancreatitis; (8) cholangitis; (9) intrahepatic duct stones; (10) pancreatobiliary malignancy; and (11) surgical history involving the biliary tree (not including the gall bladder) or gastrointestinal tract, such as the stomach or small bowel, which can alter the papillary location. Patients chosen for our study protocol were divided randomly into two groups according to the order of the procedure. Twenty-seven patients underwent SES + ELBD (group A) and 28 patients underwent conventional EST (group B). This study was approved by the institutional review board of our hospital, and all patients provide written informed consent before entering the study.

Methods

Management such as pharyngeal anesthesia and premedication before the procedure was carried out in the same manner as for general endoscopy, and ERCP was performed with a side-viewing endoscope (TJF240; Olympus, Tokyo, Japan). After the bile duct stones were visualized following cholangiography, the stone was removed according to each protocol. In group A, we made an incision to the mid-portion of the papilla with a pull-type sphincterotome (Figure 1A) and then inserted a CRE balloon (15, 16.5, or 18 mm; Boston Scientific, Natick, MA, USA) over a guidewire. Balloon dilation was performed using wire-guided hydrostatic balloon catheters placed across the papilla. The balloon was inflated with dilute contrast media until the waistline was obliterated under fluoroscopic monitoring (Figure 1B). Initially, we performed dilation with a 15-mm-diameter balloon, and if the balloon was not large enough to remove the stones, we repeated it with a larger balloon in the order 15 mm → 16.5 mm → 18 mm. When the papillary orifice was dilated after balloon dilation (Figure 1C), the stones were retrieved using a Dormia basket (Web™ extraction basket; Wilson-Cook Medical, Winston-Salem, NC, USA) (Figure 1D) or retrieval balloon catheter (double lumen retrieval balloon catheter; Boston Scientific). When the stones were not extracted from the biliary tract with initial basket trapping, mechanical lithotripsy (BML-4Q; Olympus) was performed to fragment the stones. In group B, EST was performed with a pull-type sphincterotome (KD-6Q; Olympus) as the standard method, which was accomplished by extending the incision up to the major horizontal fold of the papillary orifice. After EST, the stones were removed in the same way as in group A. If the stones could not be removed completely in one session, we performed another stone removal session in each group. Complete stone removal was documented with a final cholangiogram. The procedure time was measured as the time between selective cannulation and complete stone removal in the cases of successful stone removal in the first session. The maximum procedure time for the first session was limited to 40 min if the stone was difficult to remove in one session.

Measurements

Stone size and number and bile duct size were documented on the cholangiogram during ERCP. Stone size was assessed by comparing the largest diameter of the stone with the diameter of the TJF240 endoscope, as measured on the cholangiogram. The primary endpoint was the success rate for complete removal of stones within the initial ERCP session. The secondary outcomes included the time for the procedure of these initial-success cases, frequency of mechanical lithotripsy, and associated complications such as bleeding, pancreatitis, cholangitis, and perforation. To observe the complications, blood samples involving a complete blood count, liver function test, amylase, and lipase concentrations were taken before the procedure and 1 and 2 d after ERCP. Post-ERCP pancreatitis was defined as persistent abdominal pain of more than 24 h duration, associated with serum amylase more than three times the upper limit of normal. Bleeding complication was deemed a decrease in hemoglobin concentration of > 2 mg/dL or clinical signs of bleeding after the procedure, such as melena or hematemesis. Cholangitis was defined as a fever accompanied by leukocytosis and right upper quadrant pain after the procedure. All complications were classified and graded according to the consensus guidelines with some modification[28]. After the stones were removed, ductal clearance was confirmed with a cholangiogram during the procedure.

Statistical analysis

Statistical analysis was performed using the statistical

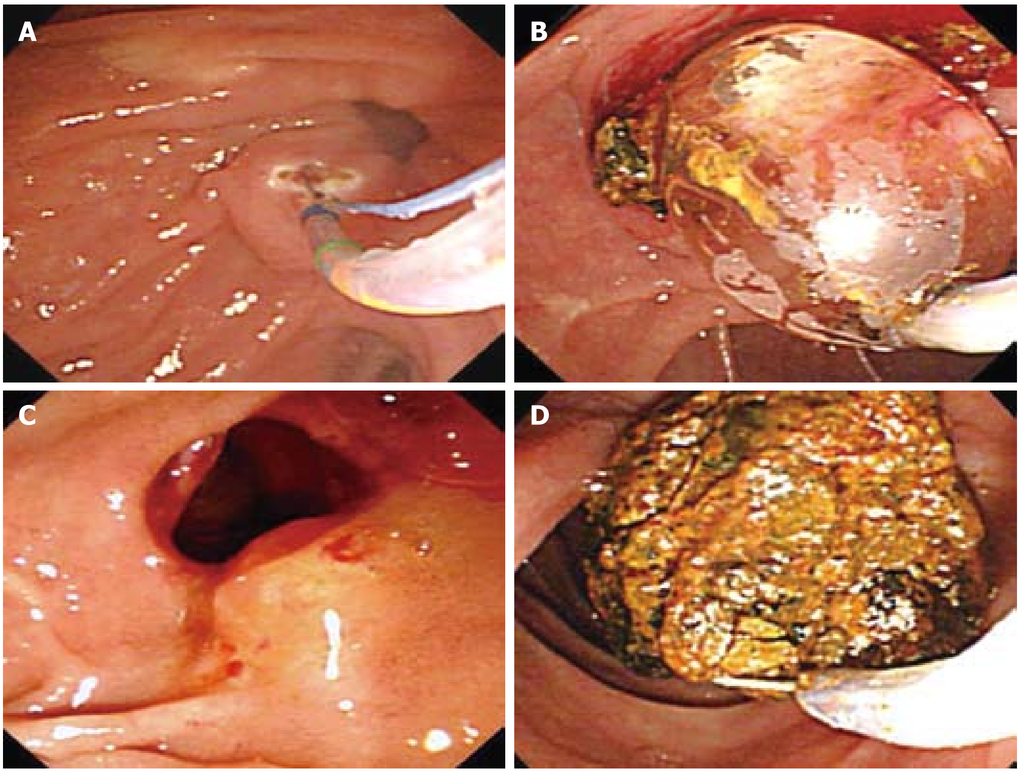

Figure 1 Endoscopic view. A: A small sphincterotomy using a pull-type sphincterotome; B: Endoscopic papillary balloon dilation with a large balloon after small endoscopic sphincterotomy; C: Dilated orifice after small EST + ELBD; D: Stone removal through the dilated orifice of the major papilla.

Table 1 Baseline characteristics of the patients

	Group A (n = 27)	Group B (n = 28)
Gender (M/F)	10/15	11/14
Mean age (yr)[1]	70.3 ± 8.7	69.8 ± 9.2
Mean diameter of stone (mm)[1]	20.8 ± 4.1	21.3 ± 5.2
Mean No. of stones[1]	2.2 ± 1.3	2.3 ± 1.2
Mean diameter of bile duct (mm)[1]	21.4 ± 6.3	20.5 ± 5.7
Periampullary diverticulum (%)	9 (33.3)	10 (35.7)
Previous cholecystectomy (%)	9 (33.3)	7 (25)
Distal CBD tapering (%)	11 (41)	10 (36)

[1]mean ± SD; CBD: Common bile duct.

SPSS for Windows version 12.0 (Chicago, IL, USA). Data are presented as the mean ± SD or median with range. Categorical parameters were compared using the χ^2 or Fisher's exact test, and continuous variables were compared with Student's t test. $P < 0.05$ was considered statistically significant.

RESULTS

The gender ratio was similar in the two groups. The mean age was 70.3 years in group A and 69.8 in group B. The mean size of the stones was 20.8 mm (range 15-38.3 mm) in group A and 21.3 mm (range 15-48 mm) in group B. The mean number of stones was 2.2 in group A and 2.3 in group B. The maximal bile duct diameter did not differ significantly between the two groups. A peri-ampullary diverticulum was observed in nine patients in group A and 10 in group B. Sixteen (29%) patients had a history of cholecystectomy. A tapered common bile duct was observed in 11 (41%) patients in group A and 10 (36%) in group B (Table 1).

Overall, complete removal of bile duct stones in the first session was achieved in 46 (84%) patients, while nine required additional sessions. The causes of failure in the first session were incomplete stone capture with the mechanical lithotripsy basket as a result of a large stone (two cases each in groups A and B), stone impaction (one case in group A), procedure-induced bleeding (one case in group B), and incomplete retrieval because of multiple stones (one case each in groups A and B). The stone clearance rate in the first session between the two groups did not differ significantly, and was 84% in both groups (P = 0.473). Mechanical lithotripsy was used for nine (33%) patients in group A and nine (32%) in group B (P = 0.527). The mean procedure time was compared in the cases involving successful removal of the stone in the initial session and did not differ statistically between the two groups. All stones were removed completely in all patients within three sessions (group A: 1.27 ± 0.53 sessions, group B: 1.31 ± 0.71 sessions, P = 0.714). The number of sessions of mechanical lithotripsy and mean procedure times did not differ significantly between the two groups (Table 2).

We also divided each group into subgroups according to the stone size (2 cm) and compared the stone removal rate and application of mechanical lithotripsy. The complete stone removal rate for each subgroup in the first session was similar in both groups: 85.7% (group A) and 86.6% (group B) in the subgroups with stones <

Table 2 Results of endoscopic stone removal after small EST + ELBD *vs* EST (stone size ≥ 15 mm)

	Group A (n = 27)	Group B (n = 28)	P value
Stone removal in the first session (%)	23 (85)	23 (86)	0.473
Mechanical lithotripsy (%)	9 (33)	9 (32)	0.527
Mean procedure time (min)[1,2]	18 ± 12	19 ± 13	0.917
Mean therapeutic session[1]	1.27 ± 0.53	1.31 ± 0.71	0.714

[1]mean ± SD; [2]Calculated from initial success cases (n = 23 in both groups). Overall success rate of the first session: 84%.

Table 3 Comparison of overall application of mechanical lithotripsy according to the size of the stone in each group

	Group A (n = 27)		Group B (n = 28)	
	< 2 cm (n = 14)	≥ 2 cm (n = 13)	< 2 cm (n = 15)	≥ 2 cm (n = 13)
Stone removal in the first session (%)	12 (85.7)[a]	11 (84.6)[b]	13 (86.6)[c]	10 (76.9)[d]
Mechanical lithotripsy (%)	2 (14.3)[e]	7 (53.8)[f]	2 (13.3)[g]	7 (53.8)[h]

Overall application of mechanical lithotripsy: 17/50 (34%). P value: a *vs* b, not significant; c *vs* d, not significant; e *vs* f, 0.018; g *vs* h, 0.008.

Table 4 Comparison of stone removal in the first session and application of mechanical lithotripsy

	Group A (n = 11)	Group B (n = 10)	P value
Stone removal in the first session (%)	9 (81.8)	7 (70)	0.525
Mechanical lithotripsy (%)	6 (54.5)	6 (60)	0.801

2 cm in maximum diameter and 84.6% (group A) and 76.9% (group B) in the subgroups with stones ≥ 2 cm in maximum diameter. The rate of mechanical lithotripsy increased significantly with stone size irrespective of the group (P < 0.05 in each group, Table 3). Finally, we compared the stone removal rate in the first session and the need for mechanical lithotripsy in the cases with a tapered distal bile duct between the two groups. A tapered bile duct was deemed as one in which a portion of the distal common bile duct was narrowed with a steady curve on the cholangiogram. The stone removal rate was higher in group A (81.8%) than in group B (70%), but not significantly. In addition, the mechanical lithotripsy rate was similar between the two groups (Table 4).

Complications according to the consensus guidelines were not observed in either group, and we could not compare the complication rate between the two groups. Although mild amylase elevation less than three times the upper limit of normal was observed in four patients in group A (15%) and three in group B (11%), no instances of post-ERCP pancreatitis and cholangitis according to the consensus guidelines occurred in either group. We did not perform prophylactic pancreatic duct stenting during the procedure in any case. A small amount of bleeding was seen in four patients in group A (15%) and two in group B (7%). No procedure-related perforation was observed. Nine cases in which complete ductal clearance was not achieved in the first session underwent a second session on the next day or within a few days, and any additional protective procedure, such as biliary plastic stenting, was not performed until the next session.

DISCUSSION

EST is the most frequently used endoscopic technique for the clearance of stones from the bile duct. Its success rate exceeds 90%, and it has been accepted as the best nonsurgical treatment for common bile duct stones[29-33]. However, EST is still associated with an 8%-12% rate of acute complications, such as bleeding, perforation, cholangitis, and post-procedure pancreatitis[11,25,34-37]. In addition, it permanently destroys the biliary sphincter, which can lead to chronic complications, such as duodenal biliary reflux, bacterial contamination, and chronic inflammation of the biliary system[11].

EBD was introduced by Staritz *et al*[5] in 1983 as an alternative method for the removal of bile duct stones. The main advantage of this technique is that it does not involve cutting the biliary sphincter, therefore preserving its function. However, major limitations of EBD exist, including difficulty in removing large stones and a high incidence of pancreatitis. Since balloon dilation does not enlarge the sphincter of Oddi to the same extent as EST, large stone removal with EBD is difficult, and mechanical lithotripsy is required more often than with EST[11,21]. As a result, there is a need to modify the EBD technique to remove large bile duct stones and reduce the risk of pancreatitis. Similarly, EST is not a good method if the stones are too large to remove. Stone fragmentation procedures such as mechanical lithotripsy are required in this situation, regardless of the approach method. Ersoz *et al*[24] first reported the use of EST followed by papillary balloon dilation. They reported an 83% success rate in the first session with a 7% rate of mechanical lithotripsy in 58 patients in whom endoscopic removal of bile duct stones using standard EST and balloon/basket extraction had failed. Recently, multiple published series have shown that the overall first session success rates of stone removal with EBD following EST ranged from 80% to 100%[24,25,27,38], and these success rates were similar to those of EST. Although some recent studies have reported that the stone clearance rate for the initial session of EBD following EST is high, the outcome for large stone removal by ELBD following EST remains controversial. Since previous data from ELBD studies have included various sizes of stones, especially small stones < 1 cm, and comparison studies between SES + ELBD and conventional EST for large stone (≥ 15 mm) removal are not sufficient[25,26,39]. Therefore, we could not clarify the effectiveness of ELBD following EST for large stone removal.

In our present study, we compared SES + ELBD to conventional EST in terms of usefulness and safety for the treatment of large stones. We also evaluated the number of applications of mechanical lithotripsy and compared this with previous studies, which reported that EST + ELBD reduced the use of mechanical lithotripsy[24,25,39]. The number of patients enrolled in our study was limited by the stone size and exclusion criteria. However, these criteria enabled us to compare the outcomes between the two groups more objectively.

Our findings showed that the initial success rate for the clearance of common bile duct stones was same in both groups and it was not significantly different. A previous series of EST + ELBD gave first session success rates of 70%-99% and mechanical lithotripsy rates of 1%-11%[24-27,39]. In contrast, we had a 33% mechanical lithotripsy rate in group A and a 32% rate in group B. Compared to previous reports, the frequency of mechanical lithotripsy was markedly higher[24-27,39], which might be attributable to the large stones (⩾ 15 mm).

Previous studies likely reported lower rates of mechanical lithotripsy, because of smaller stones[25,26,39], or a wider sphincterotomy[24,40]. Of course, the frequency of mechanical lithotripsy might be related to various factors, such as the extent of EST, size of the stone and balloon, and shape of the stone and common bile duct. Removing large stones (⩾ 15 mm) in patients with a tapered common bile duct without stone fragmentation might be difficult, despite orifice dilation using large balloon dilation. A retrospective pilot study of 50 patients revealed that patients that required mechanical lithotripsy were more often characterized by large stones combined with a tapered distal common bile duct rather than either of these features alone[41].

Other recent studies have revealed that SES + ELBD reduced the frequency of mechanical lithotripsy and gave better results for the removal of stones[25,27,39].

However, in our study, mechanical lithotripsy was not reduced with SES + ELBD, and no difference in the frequency of mechanical lithotripsy was observed between the two groups. We needed a stone fragmentation method such as mechanical lithotripsy, although we used a large balloon (maximum, 18 mm) to dilate the orifice; the larger stone size was associated with more frequent mechanical lithotripsy. The CRE balloon had a length of 8 cm, of which approximately half was positioned in the distal bile duct. Considering this point, we speculate that part of the terminal and distal bile duct could be dilated simultaneously using balloon dilation, and if the stone was small enough to pass through the dilated bile duct, it could be removed more easily. To remove large stones, however, some EST and large balloon dilation may help to dilate the sphincter of Oddi orifice, to allow the passage of large stones. Large balloon dilation alone cannot stretch the wall of the distal bile duct to the degree necessary for the effective removal of large stones. Hence, the configuration and wall lumen tension of the terminal bile duct may be more important factors for the removal of large stones than the size of the balloon and dilation of the bile duct. Therefore, if a stone is too large to remove *via* the dilated terminal bile duct and sphincter of Oddi, stone fragmentation using mechanical lithotripsy, for example, might be inevitable.

Complications according to the consensus guidelines did not occur in our study, which may be related to the small number of patients enrolled. No procedure-related pancreatitis occurred. Only amylase elevation less than three times the upper limit of normal was observed in seven patients (four in group A and three in group B). Perforation did not occur in any patient.

A small amount of bleeding was observed in six patients in our study. Of these, stone removal was postponed to the next session for one patient in group B, but this case did not meet the criteria for bleeding complications according to the consensus guidelines[28]. Other bleeding complications were easily controlled using argon-plasma coagulation, epinephrine spray, or compression by the balloon. Ersoz *et al*[24] have reported a 9% bleeding rate in their EST + ELBD group, especially in patients with a tapered distal bile duct. With the larger balloon, the higher rate of bleeding could have been attributable to the moderate degree of EST. In addition, they performed major EST in their study. In the SES + ELBD group, the reported rate of bleeding ranged from 0% to 4.5%, and all of the cases were relatively mild[25,39,40].

In conclusion, SES + ELBD did not show significant benefits compared to conventional EST and reducing the rate of mechanical lithotripsy, especially for the removal of large (⩾ 15 mm) bile duct stones. Regarding the occurrence of complications, SES + ELBD showed a similar level of safety compared to conventional EST. Hence, SES + ELBD is a good alternative to conventional EST for the removal of large stones, especially for the unskilled endoscopist. However, a large-scale study of patients is required to clarify the difference in the efficacy of the two procedures.

COMMENTS

Background

Many recent studies on small sphincterotomy combined with endoscopic papillary large balloon dilation (SES + ELBD) have reported on the outcome of stone removal and the complication rate. As previous studies concentrated on the efficacy of small bile duct stone removal, the effectiveness of ELBD with SES for large stone removal (⩾ 15 mm) has not been established.

Innovations and breakthroughs

Other recent studies have revealed that SES + ELBD reduced the frequency of mechanical lithotripsy and gave better results for the removal of stones. However, the present study found that SES + ELBD did not reduce the need for mechanical lithotripsy in removing large (⩾ 15 mm) bile duct stones. Large balloon dilation alone cannot stretch the wall of the distal bile duct to the degree necessary for the effective removal of large stones. To remove large stones, the configuration and wall lumen tension of the terminal bile duct may be more important factors than the size of the balloon and dilation of the bile duct. Therefore, if a stone is too large to remove *via* the dilated terminal bile duct, stone fragmentation might be inevitable.

Applications

For the removal of large common bile duct stones, SES + ELBD is a good alternative to conventional endoscopic sphincterotomy (EST), especially for the unskilled endoscopist. However, a large-scale study is required to clarify differences in the efficacy of the two procedures.

Terminology

Endoscopic papillary balloon dilation (EBD), an alternative method with similar outcomes compared to EST, is associated with frequent, severe pancreatitis. SES + ELBD is a modified EBD technique.

Peer review

In this study, the numbers of the patients are too small to compare infrequent complications like bleeding or pancreatitis. However, it may be difficult to enroll many more patients with large bile duct stones.

REFERENCES

1 **Sand J**, Airo I, Hiltunen KM, Mattila J, Nordback I. Changes in biliary bacteria after endoscopic cholangiography and sphincterotomy. *Am Surg* 1992; **58**: 324-328

2 **Kurumado K**, Nagai T, Kondo Y, Abe H. Long-term observations on morphological changes of choledochal epithelium after choledochoenterostomy in rats. *Dig Dis Sci* 1994; **39**: 809-820

3 **Greenfield C**, Cleland P, Dick R, Masters S, Summerfield JA, Sherlock S. Biliary sequelae of endoscopic sphincterotomy. *Postgrad Med J* 1985; **61**: 213-215

4 **Freeman ML**, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, Moore JP, Fennerty MB, Ryan ME, Shaw MJ, Lande JD, Pheley AM. Complications of endoscopic biliary sphincterotomy. *N Engl J Med* 1996; **335**: 909-918

5 **Staritz M**, Ewe K, Meyer zum Büschenfelde KH. Endoscopic papillary dilation (EPD) for the treatment of common bile duct stones and papillary stenosis. *Endoscopy* 1983; **15** Suppl 1: 197-198

6 **Kawabe T**, Komatsu Y, Tada M, Toda N, Ohashi M, Shiratori Y, Omata M. Endoscopic papillary balloon dilation in cirrhotic patients: removal of common bile duct stones without sphincterotomy. *Endoscopy* 1996; **28**: 694-698

7 **Mathuna PM**, White P, Clarke E, Merriman R, Lennon JR, Crowe J. Endoscopic balloon sphincteroplasty (papillary dilation) for bile duct stones: efficacy, safety, and follow-up in 100 patients. *Gastrointest Endosc* 1995; **42**: 468-474

8 **Yasuda I**, Tomita E, Enya M, Kato T, Moriwaki H. Can endoscopic papillary balloon dilation really preserve sphincter of Oddi function? *Gut* 2001; **49**: 686-691

9 **May GR**, Cotton PB, Edmunds SE, Chong W. Removal of stones from the bile duct at ERCP without sphincterotomy. *Gastrointest Endosc* 1993; **39**: 749-754

10 **Mac Mathuna P**, White P, Clarke E, Lennon J, Crowe J. Endoscopic sphincteroplasty: a novel and safe alternative to papillotomy in the management of bile duct stones. *Gut* 1994; **35**: 127-129

11 **Bergman JJ**, Rauws EA, Fockens P, van Berkel AM, Bossuyt PM, Tijssen JG, Tytgat GN, Huibregtse K. Randomised trial of endoscopic balloon dilation versus endoscopic sphincterotomy for removal of bileduct stones. *Lancet* 1997; **349**: 1124-1129

12 **Komatsu Y**, Kawabe T, Toda N, Ohashi M, Isayama M, Tateishi K, Sato S, Koike Y, Yamagata M, Tada M, Shiratori Y, Yamada H, Ihori M, Kawase T, Omata M. Endoscopic papillary balloon dilation for the management of common bile duct stones: experience of 226 cases. *Endoscopy* 1998; **30**: 12-17

13 **Ochi Y**, Mukawa K, Kiyosawa K, Akamatsu T. Comparing the treatment outcomes of endoscopic papillary dilation and endoscopic sphincterotomy for removal of bile duct stones. *J Gastroenterol Hepatol* 1999; **14**: 90-96

14 **Ueno N**, Ozawa Y. Endoscopic sphincter dilation in patients with bile duct stones: immediate and medium-term results. *J Gastroenterol Hepatol* 1999; **14**: 822-826

15 **Toda N**, Saito K, Wada R, Kawabe T, Shiratori Y, Mitsushima T, Omata M. Endoscopic sphincterotomy and papillary balloon dilation for bile duct stones. *Hepatogastroenterology* 2005; **52**: 700-704

16 **Isayama H**, Komatsu Y, Inoue Y, Toda N, Shiratori Y, Tsujino T, Yamada H, Saitou K, Kawabe T, Omata M. Preserved function of the Oddi sphincter after endoscopic papillary balloon dilation. *Hepatogastroenterology* 2003; **50**: 1787-1791

17 **Takezawa M**, Kida Y, Kida M, Saigenji K. Influence of endoscopic papillary balloon dilation and endoscopic sphincterotomy on sphincter of oddi function: a randomized controlled trial. *Endoscopy* 2004; **36**: 631-637

18 **Tanaka S**, Sawayama T, Yoshioka T. Endoscopic papillary balloon dilation and endoscopic sphincterotomy for bile duct stones: long-term outcomes in a prospective randomized controlled trial. *Gastrointest Endosc* 2004; **59**: 614-618

19 **Fujita N**, Maguchi H, Komatsu Y, Yasuda I, Hasebe O, Igarashi Y, Murakami A, Mukai H, Fujii T, Yamao K, Maeshiro K. Endoscopic sphincterotomy and endoscopic papillary balloon dilatation for bile duct stones: A prospective randomized controlled multicenter trial. *Gastrointest Endosc* 2003; **57**: 151-155

20 **Kozarek RA**. Balloon dilation of the sphincter of Oddi. *Endoscopy* 1988; **20** Suppl 1: 207-210

21 **Arnold JC**, Benz C, Martin WR, Adamek HE, Riemann JF. Endoscopic papillary balloon dilation vs. sphincterotomy for removal of common bile duct stones: a prospective randomized pilot study. *Endoscopy* 2001; **33**: 563-567

22 **Disario JA**, Freeman ML, Bjorkman DJ, Macmathuna P, Petersen BT, Jaffe PE, Morales TG, Hixson LJ, Sherman S, Lehman GA, Jamal MM, Al-Kawas FH, Khandelwal M, Moore JP, Derfus GA, Jamidar PA, Ramirez FC, Ryan ME, Woods KL, Carr-Locke DL, Alder SC. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. *Gastroenterology* 2004; **127**: 1291-1299

23 **Baron TH**, Harewood GC. Endoscopic balloon dilation of the biliary sphincter compared to endoscopic biliary sphincterotomy for removal of common bile duct stones during ERCP: a metaanalysis of randomized, controlled trials. *Am J Gastroenterol* 2004; **99**: 1455-1460

24 **Ersoz G**, Tekesin O, Ozutemiz AO, Gunsar F. Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract. *Gastrointest Endosc* 2003; **57**: 156-159

25 **Minami A**, Hirose S, Nomoto T, Hayakawa S. Small sphincterotomy combined with papillary dilation with large balloon permits retrieval of large stones without mechanical lithotripsy. *World J Gastroenterol* 2007; **13**: 2179-2182

26 **Heo JH**, Kang DH, Jung HJ, Kwon DS, An JK, Kim BS, Suh KD, Lee SY, Lee JH, Kim GH, Kim TO, Heo J, Song GA, Cho M. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. *Gastrointest Endosc* 2007; **66**: 720-726; quiz 768, 771

27 **Kochhar R**, Dutta U, Shukla R, Nagi B, Singh K, Wig JD. Sequential endoscopic papillary balloon dilatation following limited sphincterotomy for common bile duct stones. *Dig Dis Sci* 2009; **54**: 1578-1581

28 **Cotton PB**, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, Liguory C, Nickl N. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991; **37**: 383-393

29 **Cotton PB**. Endoscopic management of bile duct stones; (apples and oranges). *Gut* 1984; **25**: 587-597

30 **Ikeda S**, Tanaka M, Matsumoto S, Yoshimoto H, Itoh H. Endoscopic sphincterotomy: long-term results in 408 patients with complete follow-up. *Endoscopy* 1988; **20**: 13-17

31 **Lambert ME**, Betts CD, Hill J, Faragher EB, Martin DF, Tweedle DE. Endoscopic sphincterotomy: the whole truth. *Br J Surg* 1991; **78**: 473-476

32 **Hawes RH**, Cotton PB, Vallon AG. Follow-up 6 to 11 years after duodenoscopic sphincterotomy for stones in patients with prior cholecystectomy. *Gastroenterology* 1990; **98**: 1008-1012

33 **Bergman JJ**, van der Mey S, Rauws EA, Tijssen JG, Gouma DJ, Tytgat GN, Huibregtse K. Long-term follow-up after endoscopic sphincterotomy for bile duct stones in patients younger than 60 years of age. *Gastrointest Endosc* 1996; **44**: 643-649

34 **Miller BM**, Kozarek RA, Ryan JA Jr, Ball TJ, Traverso LW. Surgical versus endoscopic management of common bile duct stones. *Ann Surg* 1988; **207**: 135-141

35 **Sherman S**, Ruffolo TA, Hawes RH, Lehman GA. Complications of endoscopic sphincterotomy. A prospective series with emphasis on the increased risk associated with sphincter of Oddi dysfunction and nondilated bile ducts.

Gastroenterology 1991; **101**: 1068-1075

36 **Riemann JF**, Lux G, Förster P, Altendorf A. Long-term results after endoscopic papillotomy. *Endoscopy* 1983; **15** Suppl 1: 165-168

37 **Rösch W**, Riemann JF, Lux G, Lindner HG. Long-term follow-up after endoscopic sphincterotomy. *Endoscopy* 1981; **13**: 152-153

38 **Cheon YK**, Fogel EL. ERCP topics. *Endoscopy* 2006; **38**: 1092-1097

39 **Itoi T**, Itokawa F, Sofuni A, Kurihara T, Tsuchiya T, Ishii K, Tsuji S, Ikeuchi N, Moriyasu F. Endoscopic sphincterotomy combined with large balloon dilation can reduce the procedure time and fluoroscopy time for removal of large bile duct stones. *Am J Gastroenterol* 2009; **104**: 560-565

40 **Cha SW**, Choi GY, Go H, Kim AN, Yang HW, Lee YJ, Jung SH. Endoscopic large balloon sphincterotomy for removal of large bile duct stones in patients with high risk of major endoscopic sphincterotomy related complications (abstract). *Gastrointest Endosc* 2007; **65**: AB220

41 **Misra SP**, Dwivedi M. Large-diameter balloon dilation after endoscopic sphincterotomy for removal of difficult bile duct stones. *Endoscopy* 2008; **40**: 209-213

S- Editor Tian L **L- Editor** Kerr C **E- Editor** Yin DH