

## Endoscopic papillary balloon dilation after sphincterotomy for difficult choledocholithiasis: A case-controlled study

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### Abstract

**AIM:** To evaluate the efficacy and safety of endoscopic sphincterotomy (EST) + endoscopic papillary large balloon dilation (EPLBD) *vs* isolated EST.

**METHODS:** We conducted a retrospective single center study over two years, from February 2010 to January 2012. Patients with large ( $\geq 10$  mm), single or multiple bile duct stones (BDS), submitted to endoscopic retrograde cholangio-pancreatography (ERCP) were included. Patients in Group A underwent papillary large balloon dilation after limited sphincterotomy (EST+EPLBD), using a through-the-scope balloon catheter gradually inflated to 12-18 mm according to the size of the largest stone and the maximal diameter of the distal bile duct on the cholangiogram. Patients in Group B (control group) underwent isolated sphincterotomy. Stones were removed using a retrieval balloon catheter and/or a Dormia basket. When necessary, mechanical lithotripsy was performed. Complete clearance of the bile duct was

documented with a balloon catheter cholangiogram at the end of the procedure. In case of residual lithiasis, a double pigtail plastic stent was placed and a second ERCP was planned within 4-6 wk. Some patients were sent for extracorporeal lithotripsy prior to subsequent ERCP. Outcomes of EST+EPLBD (Group A) *vs* isolated EST (Group B) were compared regarding efficacy (complete stone clearance, number of therapeutic sessions, mechanical and/or extracorporeal lithotripsy, biliary stent placement) and safety (frequency, type and grade of complications). Statistical analysis was performed using  $\chi^2$  or Fisher's exact tests for the analysis of categorical parameters and Student's *t* test for continuous variables. A *P*-value of less than 0.05 was considered statistically significant.

**RESULTS:** One hundred and eleven patients were included, 68 (61.3%) in Group A and 43 (38.7%) in Group B. The mean diameter of the stones was similar in the two groups ( $16.8 \pm 4.4$  and  $16.0 \pm 6.7$  in Groups A and B, respectively). Forty-eight (70.6%) patients in Group A and 21 (48.8%) in Group B had multiple BDS (*P* = 0.005). Overall, balloon dilation was performed up to 12 mm in 10 (14.7%) patients, 13.5 mm in 17 (25.0%), 15 mm in 33 (48.6%), 16.5 mm in 2 (2.9%) and 18 mm in 6 (8.8%) patients, taking into account the diameter of the largest stone and that of the bile duct. Complete stone clearance was achieved in sixty-five (95.6%) patients in Group A *vs* 30 (69.8%) patients in Group B, and was attained within the first therapeutic session in 82.4% of patients in Group A *vs* 44.2% in Group B (*P* < 0.001). Patients submitted to EST+EPLBD underwent fewer therapeutic sessions ( $1.1 \pm 0.3$  *vs*  $1.8 \pm 1.1$ , *P* < 0.001), and fewer required mechanical (14.7% *vs* 37.2%, *P* = 0.007) or extracorporeal (0 *vs* 18.6%, *P* < 0.001) lithotripsy, as well as biliary stenting (17.6% *vs* 60.5%, *P* < 0.001). The rate of complications was not significantly different between the two groups.

**CONCLUSION:** EST+EPLBD is a safe and effective technique for treatment of difficult BDS, leading to high

rates of complete stone clearance and reducing the need for lithotripsy and biliary stenting.

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**Key words:** Endoscopic papillary large balloon dilation; Bile duct stones; Endoscopic sphincterotomy; Cholelithiasis

**Core tip:** The technique described by Ersoz comprises endoscopic limited sphincterotomy followed by papillary large balloon dilation. In theory, it increases efficacy on the extraction of large bile duct stones, while reducing the risk of bleeding that would occur if a larger sphincterotomy had to be performed, particularly in patients with coagulopathy or surgically modified anatomy, and simultaneously reduces the risk of post endoscopic retrograde cholangio-pancreatography acute pancreatitis that occurs when isolated papillary balloon dilation is performed. In this case-controlled study, the combined technique achieved higher rate of complete stone clearance than isolated endoscopic sphincterotomy, and reduced the need for lithotripsy and biliary stenting, with a similar safety profile.

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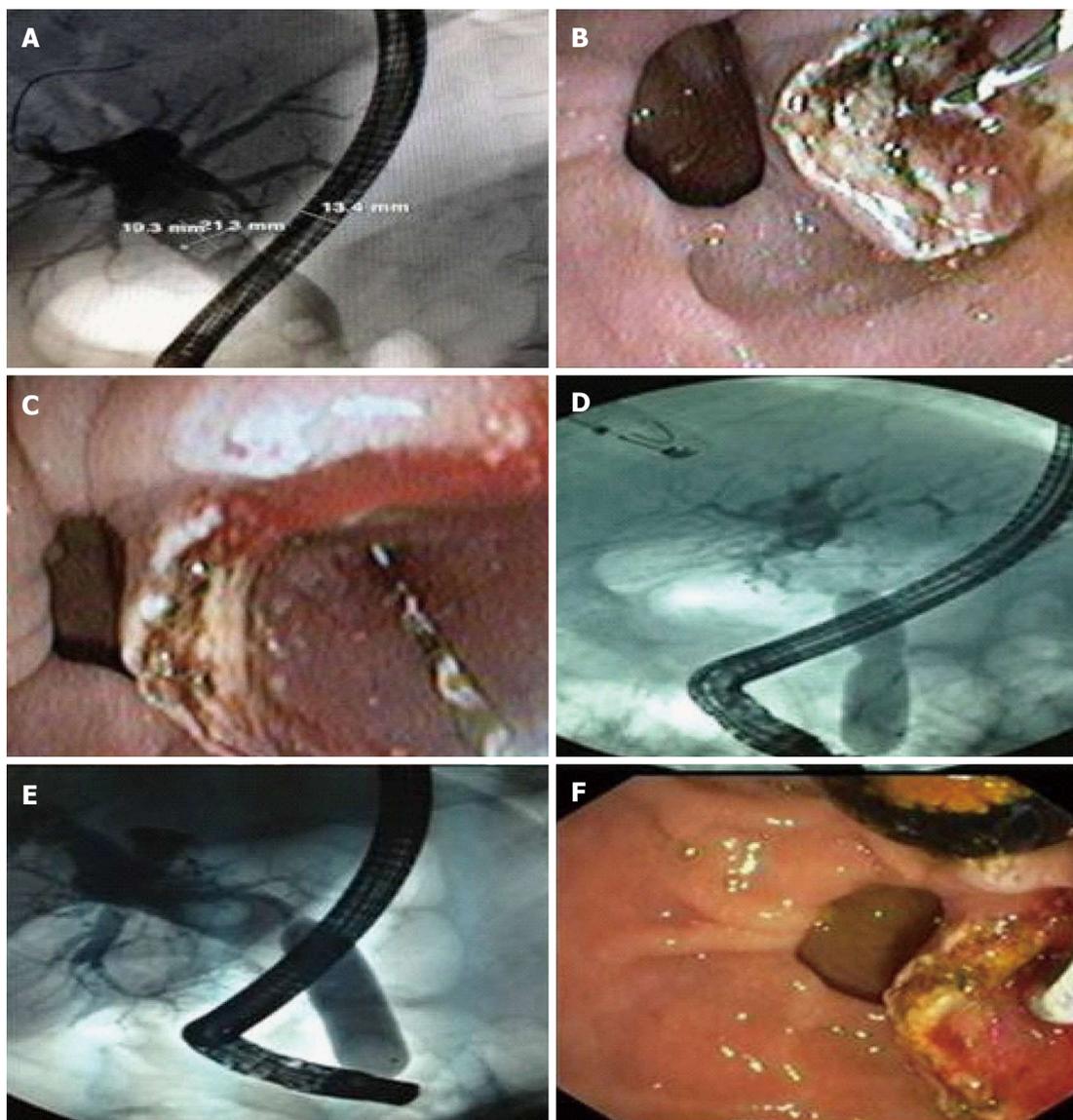
## INTRODUCTION

Endoscopic sphincterotomy (EST), first described by Classen *et al*<sup>[1]</sup> in 1974, remains the standard procedure for the treatment of bile duct lithiasis. Some years later, in 1983, Staritz *et al*<sup>[2]</sup> described endoscopic papillary balloon dilation (EPBD), which emerged as an alternative to EST, with comparable efficacy in patients with up to 3 bile duct stones (BDS) and  $\leq 10$  mm of diameter<sup>[3]</sup>. EPBD is associated with a lower risk of bleeding than EST, although an increased risk of post endoscopic retrograde cholangio-pancreatography (ERCP) acute pancreatitis has been reported<sup>[3-10]</sup>. When performed to a diameter that does not exceed 10 mm, EPBD may preserve the function of the sphincter of Oddi<sup>[11,12]</sup>, reducing late complications such as recurrence of biliary stones and papillary stenosis<sup>[13-15]</sup>. However, both techniques have limitations in the setting of large ( $\geq 10$  mm) BDS. Indeed, the completion of a large sphincterotomy may be limited by local anatomy and is associated with a higher risk of bleeding, while performing EPBD above 10 mm is associated with an increased risk of post-procedural acute pancreatitis<sup>[3-9]</sup>. Because of these considerations, in the setting of large BDS the biliary orifice often cannot be safely opened wide enough to enable their extrac-

tion, and additional mechanical lithotripsy is often needed<sup>[6,16-19]</sup>. To overcome these limitations, in 2003, Ersoz *et al*<sup>[20]</sup> described the technique of endoscopic papillary large diameter (12-20 mm) balloon dilation after limited sphincterotomy (EST+EPLBD), for the treatment of large BDS. This combines the advantages of EST and EPBD by increasing the efficacy of stone extraction while minimizing complications of both EST and EPBD when used alone<sup>[20,21]</sup>. This technique introduced a new concept that is different from isolated EPBD, as it actually results in the rupture of the orifice and permanent loss of the sphincter. It is progressively gaining widespread acceptance, with many authors reporting promising results regarding its efficacy and safety over the last few years<sup>[10,11,18, 21-29]</sup>. In this study, we aimed to evaluate the efficacy and safety of EST+EPLBD in the treatment of difficult BDS, performing a comparative analysis with a control group of patients submitted to isolated EST.

## MATERIALS AND METHODS

This was a retrospective single center study, covering a 2-year period, from February 2010 to January 2012. Patients meeting the following inclusion criteria were consecutively included: (1) referral for ERCP because of bile duct lithiasis; (2) 18 years of age or older; (3) informed consent obtained before ERCP; (4) large BDS identified at ERCP ( $\geq 10$  mm in diameter, single or multiple); and (5) deep cannulation of the bile duct achieved without precut. Patients with previous ERCP, ongoing acute pancreatitis or cholecystitis, history of previous gastric or biliary surgery (except for cholecystectomy), severe haemostatic disorders, intrahepatic lithiasis and concomitant pancreatic or biliary malignant disorders were excluded. According to the study design, patients who underwent EST+EPLBD were included in Group A, while patients who were submitted to EST alone were allocated to a control group (Group B). Every ERCP was performed using Olympus® TJF 160 VR or TJF 145 side-viewing endoscopes. Patients were under propofol sedation assisted by an anaesthesiologist. Deep biliary cannulation was generally attained with a triple lumen sphincterotome (Papillotome knife, wire-guided type, Olympus®). Stone size and number were documented on the initial diagnostic cholangiogram at ERCP. EST was performed over a 0.035 guide wire (Hydra Jagwire® guide wire, Boston Scientific Corp.®). Patients in Group A underwent papillary balloon dilation using a through-the-scope balloon catheter for oesophageal/pyloric dilation (CRE® wire-guided balloon dilatation catheter, Boston Scientific Microvasive®), gradually inflated to 12-18 mm according to the size of the largest stone and the maximal diameter of the distal bile duct on the cholangiogram. The biliary sphincter was considered adequately dilated when the waist of the balloon had completely disappeared in the fluoroscopic image. The fully expanded balloon was maintained in position for 60 s and then deflated and removed (Figure 1). Stones were removed using



**Figure 1** Combined endoscopic technique: Limited endoscopic sphincterotomy followed by endoscopic papillary large balloon dilation.

a retrieval balloon catheter (V-System single-use triple lumen stone extraction balloon, Olympus<sup>®</sup>) and/or a Dormia basket (Web<sup>®</sup> extraction basket, Wilson-Cook Medical Inc.<sup>®</sup>). When necessary, mechanical lithotripsy (BML 4Q, Olympus<sup>®</sup>; Fusion Lithotripsy Basket, Wilson-Cook Medical<sup>®</sup>) was performed to fragment the stones prior to removal. Complete clearance of the bile duct was documented with a balloon catheter cholangiogram at the end of the procedure. In the case of residual lithiasis, a biliary 7 Fr double pigtail plastic stent was placed and a second ERCP was planned within 4-6 wk. Some patients were sent for extracorporeal lithotripsy prior to subsequent ERCP. At the end of each ERCP, 100 mg rectal indomethacin was routinely given. Prophylactic antibiotics were not routinely administered. The primary efficacy endpoint was the success rate regarding complete clearance of the bile duct. Secondary endpoints included other efficacy criteria (number of ERCP until achievement of complete stone extraction, use of mechanical or

extracorporeal lithotripsy, biliary stenting) and assessment of the safety of the procedure (occurrence of complications such as bleeding, pancreatitis, cholangitis or perforation, which were classified and graded according to the 1991 consensus guidelines)<sup>[30]</sup>. To assess complications, blood samples for complete blood count, liver function tests and serum levels of amylase, lipase and C-reactive protein were routinely obtained 24 h after the procedure.

#### **Ethical considerations**

This was a retrospective case-controlled study. All patients provided written consent to undergo ERCP and were informed of the risks and potential benefits of the procedures.

#### **Statistical analysis**

Statistical analysis was performed using SPSS version 16.0 (SPSS<sup>®</sup> Inc., Chicago, IL, United States). Categorical parameters were analyzed using  $\chi^2$  or Fisher's exact tests

**Table 1 Population baseline characteristics**

Characteristics	EST+EPLBD	EST	P value
n	68 (61.3%)	43 (38.7%)	
Age (yr)	70.8 ± 13.4	72.8 ± 12.4	NS
Female gender	45 (66.2%)	28 (65.1%)	NS
Multiple lithiasis	48 (70.6%)	21 (48.8%)	0.005
Largest stone diameter (mm)	16.8 ± 4.4 (12-30)	16.0 ± 6.7 (10-30)	NS
Bile duct diameter (mm)	17.1 ± 3.4 (8-35)	16.4 ± 7.2 (8-30)	NS
Presence of biliary stricture	4 (5.9%)	2 (4.7%)	NS
Balloon dilation diameter (mm)			
12	10 (14.7%)		
13.5	17 (25.0%)		
15	33 (48.6%)		
16.5	2 (2.9%)		
18	6 (8.8%)		

EST: Endoscopic sphincterotomy; EPLBD: Endoscopic papillary large balloon dilation; NS: Not significantly.

and continuous variables were analysed by Student's *t* test. Quantitative data were summarized as the mean ± SD. A *P*-value of less than 0.05 was considered statistically significant.

**RESULTS**

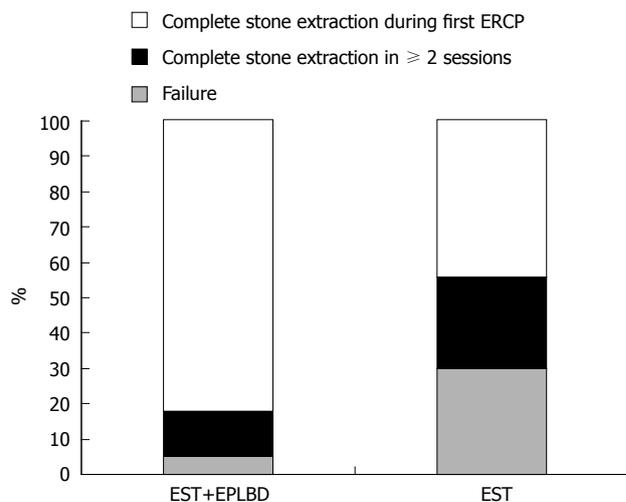
From February 2010 to January 2012, 111 patients with large BDS meeting the inclusion criteria were enrolled in the study. Sixty-eight (61.3%) patients underwent EST+EPLBD and were included in Group A. Group B, the control group, included 43 (38.7%) patients who underwent isolated EST, with no subsequent papillary balloon dilation. Forty-eight (70.6%) patients in Group A and 21 (48.8%) in Group B had multiple BDS (*P* = 0.005). The mean diameter of the stones was 16.8 ± 4.4 and 16.0 ± 6.7 in Groups A and B, respectively (*P* = Not significant). Overall, balloon dilation was performed up to 12 mm in 10 (14.7%) patients, 13.5 mm in 17 (25.0%), 15 mm in 33 (48.6%), 16.5 mm in 2 (2.9%) and 18 mm in 6 (8.8%) patients, taking into account the diameter of the largest stone and that of the bile duct. Baseline characteristics of patients in both groups are summarized in Table 1.

Complete stone clearance was achieved in sixty-five (95.6%) patients in Group A *vs* 30 (69.8%) patients in Group B, and was attained within the first therapeutic session in 82.4% of patients in Group A *vs* 44.2% in Group B (*P* < 0.001). The mean number of ERCP sessions until complete clearance of the bile duct was 1.1 ± 0.3 in Group A *vs* 1.8 ± 1.1 (*P* < 0.001) in Group B. Failure to obtain bile duct clearance occurred in 3 (4.4%) patients in Group A *vs* 13 (30.2%) patients in Group B (*P* < 0.001). Mechanical lithotripsy was performed with a lithotripsy basket in 10 (14.7%) patients in Group A and in 16 (37.2%) in Group B (*P* = 0.007). Additionally, 8 (18.6%) patients in Group B were sent to extracorporeal lithotripsy, *vs* none of the patients in Group A (*P* < 0.001). A plastic biliary stent was placed in 12 (17.6%) patients

**Table 2 Efficacy outcomes**

Efficacy outcomes	EST + EPLBD	EST	P value
Complete stone removal	65 (95%)	30 (70%)	< 0.001
Complete stone removal in single session	56 (82.4%)	19 (44.2%)	< 0.001
Number of ERCP until complete stone removal	1.1 ± 0.3	1.8 ± 1.1	< 0.001
Mechanical lithotripsy	10 (14.7%)	16 (37.2%)	0.007
Extracorporeal lithotripsy	0	8 (18.6%)	< 0.001
Plastic biliary stenting	12 (17.6%)	26 (60.5%)	< 0.001
Failure	3 (4.4%)	13 (30.2%)	< 0.001

EST: Endoscopic sphincterotomy; EPLBD: Endoscopic papillary large balloon dilation; ERCP: Endoscopic retrograde cholangio-pancreatography.



**Figure 2 Efficacy of endoscopic sphincterotomy + endoscopic papillary large balloon dilation vs isolated endoscopic sphincterotomy for the treatment of difficult bile duct stones.** EST: Endoscopic sphincterotomy; EPLBD: Endoscopic papillary large balloon dilation; ERCP: Endoscopic retrograde cholangio-pancreatography.

in Group A, *vs* 26 (60.5%) patients in Group B (*P* < 0.001), because of persistent BDS in all cases except for two patients in Group B, in whom the stents were placed because of ongoing cholangitis and delayed clearance of the contrast at the end of the procedure. Efficacy outcomes are summarized in Table 2 and Figure 2.

In a subanalysis of efficacy outcomes, taking into consideration the number and size of the stones, patients submitted to EST+EPLBD had a trend towards a higher rate of complete stone extraction at first ERCP session when a single stone was present (95.0% *vs* 77.1%, *P* = 0.072), and a higher use of plastic stents when multiple stones were present (22.9% *vs* 5.0%, *P* = 0.072), while none of the efficacy outcomes was influenced by the size of the stones in this group of patients. Conversely, in Group B, the number of stones did not seem to influence any of the efficacy outcomes, while the size of the stones seemed to be the key factor for their successful removal. Indeed, patients with smaller stones had significantly higher rates of complete bile duct clearance at first session (13 ± 4 mm *vs* 18 ± 8 mm, *P* = 0.029) and lower

rates of biliary stenting ( $18 \pm 8$  mm *vs*  $13 \pm 3$  mm,  $P = 0.042$ ). Moreover, patients with larger stones were more frequently referenced to extracorporeal lithotripsy ( $20 \pm 8$  mm *vs*  $15 \pm 6$  mm,  $P = 0.065$ ).

Regarding procedural-related complications, in our series 9/68 (13.2%) patients in Group A and 2/43 (4.7%) in Group B developed mild to moderate post-ERCP pancreatitis. This resolved with conservative treatment in less than 72 h, apart from two cases in Group A who required up to 10 d of hospitalization. In Group A, 7 (77.8%) patients who developed post-ERCP acute pancreatitis had been dilated up to 15 mm, and in the other 2 patients (22.2%) the papilla had been dilated to 13.5 mm. Significant bleeding did not occur in any of the patients in Group A, but in 2 (4.7%) patients from Group B. One patient in Group A (1.5%) and 1 patient in Group B (2.3%) developed acute cholangitis, both with good clinical evolution and short hospitalizations under conservative management. No cases of perforation or mortality occurred in our series. Overall, in Group A, the size of the stones did not influence the prevalence of complications ( $15 \pm 1$  mm in patients with complications *vs*  $17 \pm 5$  mm in patients without complications,  $P = 0.086$ ), although more complications occurred in the case of multiple BDS (9/48, 18.8% *vs* 1/20, 5.0%,  $P = 0.138$ ). In patients from Group B, the rate of complications did not seem to be influenced either by the size ( $16 \pm 7$  mm in patients with complications *vs*  $18 \pm 8$  mm in patients without complications,  $P = 0.582$ ) or the number of stones (single stone: 2/24, 8.3% *vs* multiple stones: 3/19, 15.8%,  $P = 0.019$ ).

## DISCUSSION

Over the last few years, the technique of using EPLBD after limited EST has been increasingly recognized as an important therapeutic option for patients with large BDS<sup>[10,11,18,21-29]</sup>. In our series, this approach proved to be highly effective in patients with large BDS when compared to the performance of EST alone, with no significant increase of complications. Indeed, patients who underwent EST+EPLBD had significantly higher rates of complete stone clearance (95.6% *vs* 69.8%), and this was achieved more often within the first therapeutic session (82.4% *vs* 44.2%). Moreover, the need for mechanical or extracorporeal lithotripsy was significantly lower (14.7% *vs* 37.2% and 0 *vs* 18.6%, respectively), as was the use of plastic biliary stents (17.6% *vs* 60.5%). These outcomes did not seem to be influenced by the size of the stones, but there was a trend towards higher rates of complete stone clearance at first ERCP (95.0% *vs* 77.1%) and reduced biliary stenting (5.0% *vs* 22.9%) in patients with a single bile duct stone. Conversely, in patients submitted to isolated EST, efficacy outcomes were mainly influenced by the size of the stones, rather than by its number. It must be stated, however, that this was a non-randomized retrospective case-controlled study, where the decision to perform isolated EST or EST+EPLBD was made on an

individual basis at the time of each examination. Thus, a possible selection bias influencing the results could be considered, particularly concerning the relatively low overall successful clearance rates (69.8%) and stone clearance in the first ERCP session of isolated EST (44.2%). In this group of patients, the size of the largest stone was the key factor influencing incomplete clearance, biliary stenting or referral for extracorporeal lithotripsy. Nonetheless, the mean diameter of the stones was comparable between Group A ( $16.8 \pm 4.4$  mm) and Group B ( $16.0 \pm 6.7$  mm), and also the prevalence of larger stones, up to 30 mm, was similar in both groups of patients. In our experience, EST+EPLBD was the preferred technique when multiple large BDS were detected in the initial cholangiogram, being chosen as first-line approach in this particular setting significantly more often than EST alone. The presence of bile duct strictures, such as papillary stenosis, has been reported to be manageable by papillary balloon dilation, although the safety of this approach has not been fully elucidated for EPLBD, and may constitute a limiting factor. In our series, 4 patients with biliary strictures were submitted to EPLBD up to 12 mm, allowing for stone removal with no complications. Overall, failure to obtain a complete clearance of the bile duct occurred in only 3 (4.4%) patients in Group A, as compared to nearly one third of patients in Group B (30.2%). Some authors had reported that by reducing the need for mechanical lithotripsy (5.7% *vs* 25.0%,  $P < 0.01$ ), EST+EPLBD additionally reduced the total procedure time and radiation exposure<sup>[11,31]</sup>, however these outcomes were not evaluated in our study.

Our results challenge the conclusions of a recent meta-analysis of 7 randomized controlled trials that included 790 patients, comparing EST+EPLBD with EST<sup>[32]</sup>. The authors reported that both techniques resulted in similar outcomes for overall successful clearance rates of BDS (97.4% *vs* 96.4%,  $P = 0.54$ ) and stone clearance in the first ERCP session (87.9% *vs* 84.2%,  $P = 0.21$ ), although EST+EPLBD significantly decreased the use of mechanical lithotripsy (OR: 0.51,  $P = 0.01$ ). Regarding biliary stenting, some authors have reported that the temporary placement of plastic stents may be able to fragment large BDS, and that this could possibly constitute an alternative method for clearing difficult stones not amenable to extraction at the first attempt<sup>[33,34]</sup>. In our study, 60.5% of patients submitted to EST alone required the placement of at least one plastic biliary stent, while this was the case in just 17.6% of patients who underwent EST+EPLBD.

Beyond improving efficacy outcomes, this combined technique has been shown to potentially reduce the complications typically associated with the performance of EST or EPBD alone. The risk of pancreatitis after EPBD seems to be related to the pressure overload on the orifice of the main pancreatic duct during balloon dilation, particularly when dilations are performed above the diameter of 10 mm or if the balloon is inflated very abruptly<sup>[3-10,35,36]</sup>. Conversely, the combined EST+EPBD approach does not appear to increase significantly the

risk of post-ERCP pancreatitis. This may be due to the fact that EST guides the orientation of the dilating balloon towards the common bile duct, thus preventing the pressure overload on the main pancreatic duct<sup>[20]</sup>. The risk of post-EPLBD pancreatitis may, however, be increased in the case of lower bile duct diameter or longer procedure time<sup>[29]</sup>. In our study, we could not exclude that the comparable rate of post-EPLBD (9/68, 13.2% *vs* 2/43, 4.7%) might be related to the relatively low case number in this series. Patients from Group A had a trend towards increased complications when two or more BDS were present. Although differences were not statistically significant, it should be noted that 9/10 patients who experienced a complication after EST+EPLBD, particularly acute pancreatitis, presented with multiple BDS. Conversely, in patients from Group B, the rate of complications did not seem to be influenced either by the size or the number of the stones. In a recent meta-analysis<sup>[32]</sup>, EST+EPLBD was associated with fewer overall complications than EST (5.8 *vs* 13.1%,  $P = 0.0007$ ). In particular, bleeding occurred less frequently with EST+EPLBD than with EST (OR: 0.15,  $P = 0.002$ ), suggesting that compression by ballooning may be effective for haemostasis. The authors did not find significant differences in post-ERCP pancreatitis, perforation and cholangitis. Based on EST+EPLBD being associated with fewer cases of significant bleeding, it may be reasonable to recommend this technique for the removal of difficult BDS in patients with underlying coagulopathy or need for anticoagulation, as well as for those in whom the local anatomy may increase the risks of a large sphincterotomy, such as patients with periampullary diverticulum<sup>[37]</sup>, Billroth II gastrectomy<sup>[38,39]</sup> or Roux-en-y anastomosis<sup>[40]</sup>. The risk of duodenal perforation during EST+EPLBD seems quite low, possibly due to the fact that EST guides the orientation of the dilation and controls the impact of its radial force, which is furthermore monitored in real time by the endoscopist, both endoscopically and fluoroscopically.

Finally, the most frequent long-term complication after bile duct stone extraction is the recurrence of symptomatic BDS<sup>[3,41,42]</sup>. The recurrence rate seems to be higher in patients who undergo EST (6%-24%)<sup>[43,44]</sup> than in those submitted to EPBD alone, which may be due to the preservation of the sphincter of Oddi in the latter group, preventing the chronic reflux of duodenal contents and bacteria into the biliary tree. Currently, our patients are enrolled in a controlled prospective study to evaluate the rate of recurrence of BDS after EST+EPLBD. One study evaluated the recurrence rate and the risk factors in 100 patients with BDS after EST+EPLBD, *vs* a control group of 109 patients submitted to EST alone<sup>[13]</sup>, with a mean follow-up of over 30 mo in both groups. The recurrence rate was similar in patients who underwent EST+EPLBD (11.0%) and EST (13.8%). The larger diameter of the bile duct was the only risk factor for stone recurrence in this study<sup>[13]</sup>.

In conclusion, EST+EPLBD should be considered among the first line therapeutic options for the treatment of difficult bile duct lithiasis. The results from our study

showed that it is an effective technique for the management of large BDS, being superior to isolated EST in all efficacy outcomes, with no significant increase of complications.

## COMMENTS

### Background

The combined endoscopic technique of limited sphincterotomy followed by papillary large balloon dilation, described by Ersoz *et al* in 2003, is an attractive approach for the removal of large bile duct stones. In a recent meta-analysis, it was found to achieve high rates of complete bile duct stone clearance while reducing the use of mechanical lithotripsy.

### Research frontiers

In this study, the authors aimed to evaluate the efficacy and safety of endoscopic papillary large balloon dilation after sphincterotomy in the treatment of large ( $\geq 10$  mm) bile duct stones, in a comparative analysis with a control group of patients with similarly large bile duct stones that was submitted to isolated sphincterotomy.

### Innovations and breakthroughs

In the authors' case-controlled study, the combined technique achieved higher rate of complete stone clearance than isolated endoscopic sphincterotomy (EST), and this was more often achieved within the first therapeutic session, reducing the need for further endoscopic retrograde cholangio-pancreatography. Moreover, it reduced the need for lithotripsy and biliary stenting, with a similar safety profile.

### Applications

The results of this study suggest that the use of endoscopic papillary balloon dilation after limited sphincterotomy should be considered among the first line therapeutic options for the treatment of difficult bile duct lithiasis.

### Terminology

Endoscopic papillary balloon dilation involves the progressive dilation of the papillary orifice after limited sphincterotomy, using a through-the-scope oesophageal/pyloric balloon catheter, gradually inflated up to the size of the largest stone and/or the maximal diameter of the distal bile duct according to the cholangiogram. Mechanical lithotripsy is performed when there is a need to fragment the stones prior to removal, using a through-the-scope lithotripsy basket under radiologic guidance. Extracorporeal lithotripsy focuses high-pressure shock wave energy to fragment the stones while minimizing energy exposure to adjacent tissues.

### Peer review

In this study, the authors concluded that EST followed by papillary large balloon dilation can achieve a higher rate of complete stone clearance and a less need for lithotripsy and biliary stenting, with equivalent safety to isolated sphincterotomy.

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