

# Outcomes of Endoscopic Sphincteroplasty Using Large Balloon Dilatation for Difficult Common Bile Duct Stone Removal at Dhulikhel Hospital

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## ABSTRACT

### Background

Endoscopic sphincteroplasty (ESPT) using a large Controlled Radial Expansion (CRE) Wire guided balloon dilatation has gained acceptance in removing a difficult common bile duct (CBD) stones.

### Objective

To evaluate effectiveness and complications of removing large and difficult bile duct stones with sphincterotomy combined with large balloon dilatation.

### Method

A total of 132 patients, from February 2014 to June 2017, who had biliary ductal calculus which was either greater than 15 mm or difficult to remove with standard technique, underwent Endoscopic Retrograde Cholangiopancreatography (ERCP) with Endoscopic sphincteroplasty using a large Controlled radial expansion wire guided balloon dilatation. The success rate of complete stone clearance and post Endoscopic Retrograde Cholangiopancreatography complications were analyzed.

### Result

There were 48 (36.4 %) male and 84 (63.6%) female patients with mean age of 55.48 ± 16.36 years. Stones were removed with sphincteroplasty in first attempt in 90 out of 132 (68.2%) patients, 26 out of 37 (70.27%) patients in second session and in all 7(100%) patients in third attempt. Five (11.90%) patients were lost to follow up and 4 were advised for surgery because of failure to remove stones by sphincteroplasty. Overall success of endoscopic sphincterotomy and large balloon dilatation in our study was 93.18%. Complications were seen in 17 (13.6%) patients; bleeding seen in 9 (6.8%) patients and mild pancreatitis in 8 (6.1%) patients. None of the patients had severe pancreatitis or perforation secondary to the procedure.

### Conclusion

Endoscopic sphincteroplasty after sphincterotomy is an effective and safe technique for a difficult common bile duct stone removal.

## KEY WORDS

*Common bile duct stone, Controlled radial expansion, Endoscopic sphincteroplasty*

## INTRODUCTION

Biliary ductal calculi are found in 15-17% of patients with symptomatic gall stones.<sup>1</sup> Despite various changes in the management of common bile duct (CBD) stones, the current standard of care is the Endoscopic Retrograde Cholangiopancreatography (ERCP) with Endoscopic Sphincterotomy (EST) and removal of stones via balloon or basket.<sup>2</sup> EST has a complication rate of 6-10% with a mortality of 0.5-1%.<sup>3,4</sup> Sphincterotomy can cause permanent destruction of the biliary sphincter, thus exposing biliary tree to reflux of the duodenal contents leading to bacterial colonization and chronic inflammation of the biliary tree, which theoretically increases the incidence of choledocholithiasis and tumors of the biliary origin.<sup>5</sup> Large CBD stones or the stones within small tapering of distal CBD can make stone extraction by ERCP with EST more difficult and may require an additional technique after EST is performed.

EST followed by large balloon dilation (ESLBD) was introduced by Ersoz et al.<sup>6</sup> in 2004 for removal of difficult CBD stones. Endoscopic sphincteroplasty (ESPT) using large CRE™ Wire guided balloon dilation after partial EST is proposed as an alternative to EST for the difficult CBD stone removal and has similar stone clearance rate, but has an increased risk of pancreatitis.<sup>7</sup> This technique is useful in patients with a large CBD stone, a stone in a narrowing distal CBD and in whom the papillary orifice still is smaller than the size of the CBD stone after EST.<sup>6</sup>

This study aims at evaluating effectiveness and complications of removing large and difficult bile duct stones with sphincterotomy combined with large balloon dilation.

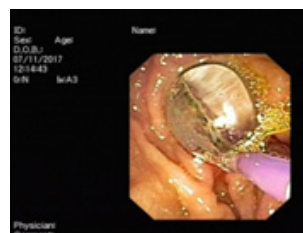
## METHODS

This was a retrospective non-randomized descriptive study which was conducted at Dhulikhel Hospital, Kathmandu University Hospital from February 2014 to June 2017. A total of 132 patients with biliary ductal calculus, either greater than 15 mm or difficult to remove with standard techniques, underwent ERCP with endoscopic sphincterotomy and balloon sphincteroplasty. Exclusion criteria included patients with prior biliary surgery, history of complete bile duct stricture, pancreatic or biliary malignancy, concomitant intrahepatic duct stone, hemorrhagic diathesis, septic shock with disseminated intravascular coagulation and severe acute pancreatitis. A proforma was filled for all the patients involved in the study. Prerequisites for ERCP were hemoglobin level of more than 8 g/dl and an INR of less than 1.5. The procedure was done under intravenous sedation using Propofol 150-250 mg, Fentanyl 0.5 mg and Glycopyrrolate 0.2 mg with some patients receiving Hyospan 10 mg for excessive peristalsis. Each patient underwent continuous cardiopulmonary monitoring throughout the procedure by

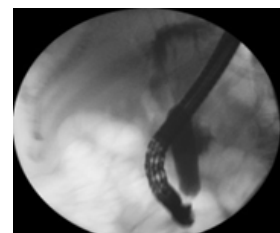
an anesthesiologist. Position of the patients was selected as per endoscopist's preference.

ERCP was done using side viewing duodenoscope (TJF160VR, Olympus Corporation, Japan). Electrosurgical unit (ERBE, Germany,) was used at a setting of blended current. All cases were commenced with a standard double lumen sphincterotome preloaded with hydrophilic tip guidewire. Precutting with a needle-knife papillotome was performed if CBD cannulation was unsuccessful after 15 minutes or pancreatic duct cannulation occurred more than three times.

Sphincterotomy was done to its full length by extending the incision to major horizontal fold crossing the intramural portion of bile duct after obtaining cholangiogram. After EST, a CBD stone retrieval was attempted using standard balloons or basket. In cases of failed attempt to remove stones, CRE balloon was passed over the guide wire with balloon positioned across the ampulla with its midpoint at the level of sphincter. Balloon was gradually filled with saline under endoscopic guidance with balloon maximum diameters up to 10 mm, 12 mm, or 15 mm. The size of CRE™ Wire guided balloon was determined by the endoscopist using the diameter of the CBD stones and the degree of tapering of the distal bile duct. The fully inflated CRE™ Wire guided balloon was sustained in position for 20-30 seconds and was then deflated (fig. 1, 2, 3). Stones were then removed with either balloon or basket (fig. 4). In cases where stones could not be removed, 8-10 French plastic stent was placed and the procedure was repeated after 6 weeks. The patients were referred to surgery after more than 2 attempts of failed stone extraction where the stones were impacted with tapering of the distal CBD.



**Figure 1.** Endoscopy showing an inflated balloon placed 75% outside the papilla



**Figure 2.** Fluoroscopy shows the balloon is inflated gradually to a maximum diameter across the papilla



**Figure 3.** Endoscopy showing dilated papilla after sphincteroplasty



**Figure 4.** Endoscopy showing extracted stone

All procedures were carried out as day case. Post procedure, patients were kept nil per oral for 4 hours and discharged after 4 hours if no complications occurred during the time. The patients who had pain abdomen were admitted in ward and serum amylase was sent. Complications were defined and graded as per the consensus.<sup>8</sup> Post-ERCP pancreatitis was defined as persistent abdominal pain associated with an elevation of amylase serum level greater than 3 times the upper limit of normal value. Hemorrhage was defined as the presence of clinical evidence as melena or hematemesis, decrease of hemoglobin levels by at least 2 g/dl, transfusion need or direct endoscopic visualization. Post-ERCP cholangitis was defined as fever (> 38° C), leucocytosis and abdominal pain.

Statistical analysis was performed using SPSS statistical software, version 18.0, SPSS, Inc., Chicago, IL, USA.

## RESULTS

### Patient Characteristics

Patient characteristics are shown in Table 1. A total of 132 patients with stones greater than 15 mm or difficult to remove with standard techniques were enrolled in this study. Out of 132 patients, 48 (36.4%) were male and 84 (63.6%) were female with mean age of 55.48 ±16.36. Most of the stones (63.6%) were diagnosed with Ultrasonography followed by MRCP (34.1%), CT (1.5%) and Endoscopic Ultrasound (0.8%). Procedure was done in prone position in 130 (98.5%) patient and in left lateral position in 2 (1.5%) patients. ERCP was done under total Intravenous Anesthesia in 131 (99.2%) patient and General anesthesia (GA) in 1 (0.8%) patient. Most of them had previous precut (75%) and periampullary diverticulum was seen in 12 (9.1%) patients. However, injection of contrast in the Pancreatic Duct (PD) occurred in 1 (0.8%) patient. Papilla was dilated with CRE Balloon up to 15 mm in 60 (45.5%) patients, 12 mm 60 (45.5%) patients and 10 mm in 12 (9.1%) patients.

### Clearance of bile ducts stones

Outcome of ERCP is shown in Table 2. Stones were removed with sphincteroplasty in first attempt in 90 out of 132 (68.2%) patients. Out of 42 remaining patients, 5 (11.90%) were lost to follow up, and were excluded from final result. Twenty six out of 37 patients (70.27%) had stone cleared in the second attempt. Surgery was advised to 4 patients because of failure to remove stones by sphincteroplasty after second attempt. All 7 patients had stone cleared in the third attempt. Seventy seven (58.3%) patients had more than 2 stones, 16 (12.1%) had 2 stones and 39 (29.5%) had 1 stone. After stone clearance, plastic stent was placed in 48 (36.4%) patients because of cholangitis and suspected residual stone. Overall success of endoscopic sphincterotomy and large balloon dilatation in our study was 93.18%.

**Table 1. Patient Characteristics**

Characteristics	N (%)
<b>Total patients</b>	<b>132</b>
<b>Mean age (years) ± SD</b>	<b>55.48 ±16.36</b>
<b>Men/Women</b>	<b>48/84</b>
<b>Method of Diagnosis</b>	
USG 84 (63.6%)	84 (63.6%)
MRCP	45 (34.1%)
EUS	1(0.8%)
CT	2(1.5%)
<b>Position of the patient</b>	
Left lateral	2(1.5%)
Prone	130 (98.5%)
Supine	0
<b>Type of Anesthesia</b>	
TIVA	131 (99.2%)
GA	1 (0.8%)
Local	0
<b>Previous Precut</b>	
Yes	99 (75.0%)
No	33(25.0%)
<b>Periampullary Diverticulum</b>	
Yes	12 (9.1%)
No	120 (90.9%)
<b>PD Injection</b>	
Yes	1 (0.8%)
No	131 (99.2%)
<b>Dilatation upto</b>	
10 mm	12 (9.1%)
12 mm	60 (45.5%)
15 mm	60 (45.5%)
<b>Number of CBD stones</b>	
1 stone	39 (29.5%)
2 stones	16 (12.1%)
>2stones	77 (58.3%)

### Post ERCP Complications

Post ERCP Complications is shown in Table 3. Post ERCP complications were bleeding and mild pancreatitis, which occurred in 13.6% of the cases. Bleeding occurred in 9 (6.8%) patients and was controlled with adrenaline injection in 6 patients and coagulation current in 3 patients. Mild pancreatitis requiring admission was seen in 8 (6.1%) patients. However, none of the patients had severe pancreatitis or perforation after the procedure.

**Table 2. Outcome of ERCP**

Outcome	N (%)
Complete Stone Removal	123(93.18%)
Stone Removal in 1 <sup>st</sup> attempt	90/132(68.2%)
Stone Removal in 2 <sup>nd</sup> attempt	26/37(70.27%)
Stone Removal in 3 <sup>rd</sup> attempt	7/7(100%)

**Table 3. Post ERCP Complications**

Complications	N (%)
Bleeding	9 (6.8)
Mild Pancreatitis	8 (6.1)
Both	1(0.8)
None	114 (86.4)

## DISCUSSION

### Patient Characteristics

For the treatment of bile duct stones, ERCP has achieved a very high success rate; however around 10 % of the stones are considered "Difficult to Extract".<sup>9,10</sup> There are various techniques such as mechanical lithotripsy, nasobiliary catheter placement and ESWL, and Laser lithotripsy that can be done for these "Difficult to Extract" stones, but they are difficult, time-consuming and have many complications.

Endoscopic papillary balloon dilatation (EPBD) using low-diameter balloons was first described by Staritz et al. in 1983 as an alternative to EST, but safety concerns prevented an extended use, especially increased post ERCP pancreatitis risk.<sup>11,12</sup> Subsequent studies have shown good results with EPBD.<sup>13-15</sup> Thus, with small to moderate sized bile duct stones, EPBD is effective but removal of larger stones becomes difficult as the biliary opening is enlarged to a lesser extent as compared with EST.<sup>16</sup> To overcome this limitation of traditional balloon dilation, Hoe et al. introduced a combined method of EST and LBD which also had a lower risk of pancreatitis.<sup>17</sup>

Ersoz et al. in 2003 combined EST with dilatation using large diameter 12-20 mm balloons and concluded that stones could be removed with the combination of two techniques if stones are not removed with one technique.<sup>6</sup> They reported an overall clearance rate of 93% and a complication rate of 15.5% which is very much similar to the present study (Success rate 91% and Complication rate 13.6%).

Randomized trial done by Bergmann, et al. showed that the more the number and larger the size of stones, the more the number of sessions are required to clear the bile ducts.<sup>18</sup> In our study, 42 (31.8%) patients had incomplete removal of stones in first session. Out of these, 5 were lost to follow up.

## REFERENCES

- Rhodes M, Sussman L, Cohen L, Lewis MP. Randomised trial of laparoscopic exploration of common bile duct versus postoperative endoscopic retrograde cholangiography for common bile duct stones. *Lancet*. 1998; 351: 159-61.
- Binmoeller KF, Schafer TW. Endoscopic management of bile duct stones. *J Clin Gastroenterol*. 2001; 32: 106-18.
- Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ et al. Complications of endoscopic biliary sphincterotomy. *N Engl J Med*. 1996; 335: 909-18.

In the second session, there were 37 patients out of which 26 had their stones cleared while 4 patients were referred for surgery as the stones were impacted with tapering of the distal CBD. All 7 patients in the third session had their stones cleared. Baron, et al. and Vlavianos, et al. concluded that the major obstacle to the successful removal of biliary stones is large size >15 mm, barrel shaped stones, stricture or tapering of distal CBD.<sup>19,20</sup>

The post ERCP complications in the present study were bleeding from the ampullary orifice and mild pancreatitis. Bleeding was seen in 9 (6.8%) patients. The incidence of post-procedure bleeding ranges from 0 to 9% in other studies.<sup>21</sup> Another study from Turkey had cited bleeding rate of 9% with EST/EPBD establishing bleeding as a potential complication in patients with tapered distal CBD.<sup>12</sup>

The incidence of pancreatitis in published studies varies from 0 to 3% for EST and LBD.<sup>22</sup> Moderate and severe pancreatitis was not seen in this study. Mild pancreatitis was seen in 6.1% which is higher in comparison to previous studies due to accidental pancreatogram. Accidental pancreatogram has been reported as an independent risk factor for the development of post-ERCP pancreatitis.<sup>23,24</sup> It has also been hypothesized that performing the dilatation after EST could reduce the pressure towards the pancreatic duct. None of the patients in this study had perforation which is similar to the study done by Heo et al.<sup>17</sup>

The major limitations of this study are the small sample size and retrospective analysis, which might have contributed to the underestimation of complication rates. The authors believe that a randomized controlled trial in a larger scale should be conducted to better answer the outcome between the procedures.

## CONCLUSION

Large balloon dilation after endoscopic biliary sphincterotomy is a simple, safe and effective technique in removing large bile duct stones, in patients with distal CBD narrowing or in whom the size of stone is greater than the size of CBD. This procedure obviates the need for unnecessary Mechanical Lithotripsy or surgery and is associated with lower rate of therapeutic ERCP complications.

- Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc*. 1991; 37: 383-93.
- Bergman JJ, van Berkel AM, Groen AK, Schoeman MN, Offerhaus J, Tytgat GN, et al. Biliary manometry, bacterial characteristics, bile composition, and histologic changes fifteen to seventeen years after endoscopic sphincterotomy. *Gastrointest Endosc*. 1997; 45: 400-5.
- 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 [PMID: 12556775 DOI: 10.1067/mge.2003.52]

7. Oh MJ, Kim TN. Prospective comparative study of endoscopic papillary large balloon dilation and endoscopic sphincterotomy for removal of large bile duct stones in patients above 45 years of age. *Scand J Gastroenterol.* 2012; 47: 1071-1077 [PMID: 22934594 DOI: 10.3109/00365521.2012.690046]
8. Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc.* 1991;37:383-93.
9. Binmoeller KF, Bruckner M, Thonke F, Soehendra N. Treatment of difficult bile duct stones using mechanical, electrohydraulic and extracorporeal shock wave lithotripsy. *Endoscopy.* 1993;25:201-6. 4.
10. McHenry L, Lehman G. Difficult bile duct stones. *Curr Treat Options Gastroenterol.* 2006;9:123-32.
11. Staritz M, Ewe K, Zum M, Büschenfelde KH. Endoscopic papillary dilation (EPD) for the treatment of common bile duct stones and papillary stenosis. *Endoscopy.* 1983; 15 (Suppl 1): 197-8
12. DiSario JA, Freeman ML, Bjorkman DJ, Macmathuna P, Petersen BT, Jaffe PE, et al. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. *Gastroenterology.* 2004; 127:1291-9.
13. Bergman JJ, van Berkel AM, Groen AK, Schoeman MN, Offerhaus J, Tytgat GN, et al. Biliary manometry, bacterial characteristics, bile composition, and histologic changes fifteen to seventeen years after endoscopic sphincterotomy. *Gastrointest Endosc.* 1997; 45: 400-5.
14. Minami A, Nakatsu T, Uchida N, Hirabayashi S, Fukuma H, Morshed SA, et al. Papillary dilation vs sphincterotomy in endoscopic removal of bile duct stones. A randomized trial with manometric function. *Dig Dis Sci.* 1995; 40: 2550-4.
15. Kawabe T, Komatsu Y, Tada M, Toda N, Ohashi M, Shiratori Y et al. Endoscopic papillary balloon dilation in cirrhotic patients: removal of common bile duct stones without sphincterotomy. *Endoscopy.* 1996; 28: 694-8.
16. DiSario JA, Freeman ML, Bjorkman DJ, Macmathuna P, Petersen BT, Jaffe PE. et al. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. *Gastroenterology.* 2004; 127: 1291-9.
17. Heo JH, Kang DH, Jung HJ, Kwon DS, An JK, Kim BS, et al. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. *Gastrointest Endosc.* 2007; 66: 720-6.
18. Bergman JJ, Rauws EA, Fockens P, van Berkel AM, Bossuyt PM, Tijssen JG, et al. Randomised trial of endoscopic balloon dilation versus endoscopic sphincterotomy for removal of bile duct stones. *Lancet.* 1997; 349: 1124-9
19. 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: 1455-60.
20. Vlavianos P, Chopra K, Mandalia S, Anderson M, Thompson J, Westaby D. Endoscopic balloon dilatation versus endoscopic sphincterotomy for the removal of bile duct stones: a prospective randomised trial. *Gut.* 2003; 52: 1165-9
21. Maydeo A, Bhandari S. Balloon sphincteroplasty for removing difficult bile duct stones. *Endoscopy.* 2007; 39: 958-61
22. Heo JH, Kang DH, Jung HJ, Kwon DS, An JK, Kim BS, et al. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. *Gastrointest Endosc.* 2007; 66: 720-6.
23. Freeman ML, DiSario JA, Nelson DB, Fennerty MB, Lee JG, Bjorkman DJ, et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. *Gastrointest Endosc.* 2001;54:425-34.
24. Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, et al. Complications of endoscopic biliary sphincterotomy. *N Engl J Med.* 1996;335:909-18.