

Outcomes of Endoscopic Sphincteroplasty Using Large Balloon Dilatation for Difficult Common Bile Duct Stone Removal: A Single Endoscopist Experience

Chainarong Phalanusitthepha MD*,
Chotirot Augkurawaranon MD*, Tassanee Sriprayoon MD*,
Chananya Hokierti MD*, Thawatchai Akaraviputh MD*

* Siriraj GI Endoscopy Center, Minimally Invasive Surgery Unit, Division of General Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Objective: Endoscopic sphincteroplasty (ESPT) using a large CRE™ Wireguided balloon dilatation is an alternative technique in removing a difficult common bile duct (CBD) stone. However, the outcome and complications of endoscopic difficult CBD stone removal using ESPT have not been well demonstrated. The present study revealed the outcome of the technique which done by a single endoscopist.

Material and Method: Between January 2003 and December 2009, the retrospective study of ninety-three patients with CBD stones that underwent endoscopic retrograde cholangiopancreatography (ERCP) for stone removal and had difficulty were enrolled. ESPT using a large CRE™ Wireguided balloon dilatation was performed in 62 patients. The success rate of complete stone clearance and post ERCP complications were analyzed.

Results: In the aspect of complete stone removal, the success rate was 88.7%. Seven patients (11.3%) required adjunctive mechanical lithotripsy (ML) for complete stone clearance. This technique was associated with low complication rate (3.2%). Post ERCP bleeding was found in one patient (1.6%) with ESPT using a large CRE™ balloon dilatation. Mild post-ERCP pancreatitis occurred in only one patient.

Conclusion: ESPT using large diameter CRE™ Wireguided balloon dilatation after biliary sphincterotomy is an effective technique for a difficult CBD stone removal associated with a lower rate of complications. This procedure can avoid unnecessary surgical CBD exploration for stone removal.

Keywords: Endoscopic sphincteroplasty, Balloon dilatation, Mechanical lithotripsy, Common bile duct stone

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Endoscopic sphincterotomy (EST) with basket or balloon has been widely accepted as a standard treatment for removal of common bile duct (CBD) stones⁽¹⁾. Large CBD stones or the stones within small tapering of distal CBD can make this procedure more difficult and it may require an additional technique after EST is performed. Mechanical lithotripsy (ML) is commonly used after EST to crack and retrieve the large CBD stones^(2,3). However potential complications associated with ML such as impacted/trapped or broken basket, wire fracture, handle breakage, acute or delayed bleeding and biliary, or duodenal perforation could be occurred^(4,5). Other alternative techniques were

balloon dilatation alone, extracorporeal shockwave lithotripsy, and electrohydraulic lithotripsy in order to achieve complete ductal clearance^(6,7).

Endoscopic sphincteroplasty (ESPT) using large CRE™ Wireguided balloon dilatation after complete EST is an alternative method for the difficult CBD stone removal. This technique was considered to be 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⁽⁸⁾. The aim of the study was to demonstrate the early outcomes of ESPT using a large CRE™ Wireguided balloon dilatation after EST for extraction of the difficult CBD stone removal.

Correspondence to:

Akaraviputh T, Siriraj GI Endoscopy Center, Minimally Invasive Surgery Unit, Division of General Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

Phone: 0-2419-8006, Fax: 0-2412-1370

E-mail: thawatchai.aka@mahidol.ac.th

Material and Method

Ethics

This work had been carried out in accordance with the Declaration of Helsinki (2000) of the World Medical Association. The present study was approved

ethically by the Institutional Review Board, Faculty of Medicine Siriraj Hospital, Mahidol University (478/2552C1).

Study design

This was a retrospective study in Siriraj GI Endoscopy Center, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand. The study population consisted of all the patients who underwent therapeutic endoscopic retrograde cholangiopancreatography (ERCP) between January 2003 and December 2009. Ninety-three patients with difficult CBD stone removal were analyzed. ESPT was performed in 62 patients. Our hypothesis was that ESPT could increase success rate of complete stone removal. This was based on the results of the previous study⁽⁹⁾. Exclusion criteria were the 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.

Data collection

Data were collected by retrospective medical record and database review including patient age, sex, indication for procedures, presenting symptoms, numbers of ERCP sessions, used of ML, pancreatic duct injection, and post ERCP complications. The number of stones, CBD diameters, and stone clearance were identified by an occluded cholangiogram. Bleeding, pancreatitis, perforation or adverse events that occurred within 30 days after the procedures were regarded as post ERCP complications according to the consensus guidelines in 1991⁽¹⁰⁾. Patient medical records were reviewed for pertinent demographic information. The research proposal had reviewed and approved by the Siriraj Ethical Committee for research in human.

Procedural methods

Prophylactic antibiotic was given to all patients. Sedation for the procedures consisted of a combination of propofol or fentanyl[®] and midazolam with buscopan[®] as needed for treating duodenal spasm. Each patient underwent a continuous cardiopulmonary monitoring throughout the procedure by an anesthesiologist. If the patient's condition were not appropriated for sedation, we would use general anesthesia for the procedures. The position of the patients was selected by endoscopist preference.

All procedures were done using an Olympus video duodenoscope (TJF160VR, Olympus Corporation, Tokyo, Japan). All patients had a pre-procedural evaluation by an anesthesiologist. All cases were commenced with a standard double lumen sphincterotome (Ultratome XL; Boston Scientific, Natick, USA) preloaded with contrast. If required, a guidewire (0.035" Jackwire; Boston Scientific, Miami, USA) was used to aid a biliary cannulation⁽¹¹⁾. If CBD cannulation was unsuccessful after 10 minutes or pancreatic duct cannulation occurred more than three times, precutting with a needle-knife papillotomy (Microtome; Boston Scientific, Natick, Massachusetts, USA) was performed⁽¹²⁾.

After obtaining cholangiogram, a complete biliary sphincterotomy (or maximum sphincterotomy, no additional cutting space) was done by the standard technique. After EST, a CBD stone retrieval was attempted using standard balloons or basket. If a CBD stone could not be extracted through the ampulla opening because of relatively large CBD stone or narrow distal CBD. Large CRE[™] Wireguided balloon (Esophageal/Pyloric CRE[™] Wireguided balloon dilatation catheter; Boston Scientific, Natick, USA) for ESPT was used with balloon maximum diameters up to 12 mm, 15 mm, or 20 mm. The size of CRE[™] Wireguided balloon was determined by the endoscopist using the diameter of the CBD stones and the degree of tapering of the distal bile duct. It would be placed in the distal part of CBD about half of its length under endoscopic and fluoroscopic control. The balloon was gradually inflated with contrast media, until the waistline was completely obliterated under fluoroscopic monitoring. The fully inflated CRE[™] Wireguided balloon was sustained in position for 20-30 seconds and was then deflated (Fig. 1). After papillary balloon dilatation, at least three attempts were made for CBD stone extraction using standard stone retrieval basket and/or balloons catheter. If CBD stone extraction remained persistently unsuccessful, the ML was performed for stone removal (Olympus BML-3Q) as adjunctive method. Finally, complete stone removal was documented with an occluded cholangiogram. Unfortunately, a 7-Fr. plastic stent placement would be performed if the stone impacted with wall of CBD without space for the opening of the basket. Prophylaxis hemostasis with injection of epinephrine (1:10,000) at sphincterotomy site was performed in patients with high risk of bleeding such as high level of serum total bilirubin, history of anticoagulant drugs. Post ERCP bleeding was defined

as a decrease in hemoglobin by 3 g/dl or more with melena or hematemesis after the procedure⁽¹⁰⁾. All endoscopic procedures were done by a single endoscopist (TA).

After completion of the ERCP, the patient was admitted to the hospital service for monitoring post-ERCP complications. The follow-up was reviewed by retrospective review of the patients' computerized medical records. Statistical analysis was performed using SPSS statistical software, version 18.0, SPSS, Inc., Chicago, IL, USA.

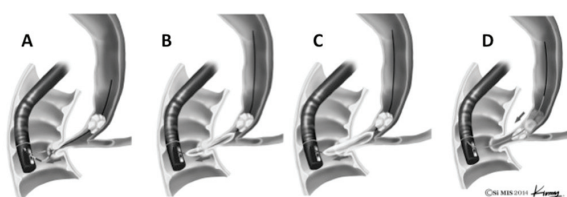


Fig. 1 Technique of endoscopic sphincteroplasty (ESPT). A) Endoscopic sphincterotomy was performed. B) The CRE balloon was inserted over the guidewire and C) inflated until the waist disappeared. D) Finally the large CBD stone was removed by standard balloon retriever.

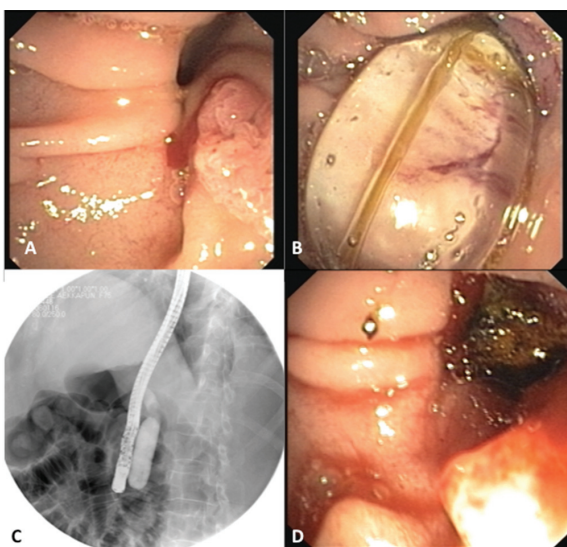


Fig. 2 A) Endoscopy shows a normal papilla with juxtaduodenal diverticulum. B) Endoscopy shows a large inflated balloon was placed 50% outside the papilla. C) Fluoroscopy shows the balloon is inflated gradually to a maximum diameter across the papilla until the notch of the balloon disappears, and the inflated balloon is sustained for 20-30 seconds. D) A large stone extracted via a dilated papilla and distal CBD after large balloon sphincteroplasty.

Results

Patients characteristics

Ninety-three patients (39 men, 53 women; mean age 68±15.21 years, range 35-96 years) were reviewed. The presenting symptoms of the patients were abdominal pain in 33 patients (35.5%) and ascending cholangitis in 28 patients (30.1%). There were 30 patients (32.3%) underwent prior ERCP with plastic stenting due to failure of CBD stone extraction using standard balloon or basket. Sixty-two ERCP procedures were performed using ESPT with a large CRE™ Wireguided balloon dilatation (Table 1).

Clearance of bile duct stones

The difficult CBD stones were successfully retrieved in 55 procedures (88.7%). Seven procedures (11.3%) required adjunctive ML for complete stone clearance. Plastic stent placement was done in

Table 1. The results of endoscopic treatment in the patients with difficult CBD stone removal

	Patients, n (%)
Number of ERCP procedures	62
Position of the patients	
Left lateral	57 (97.9)
Prone	0
Supine	5 (2.1)
Anesthesia	
TIVA	61 (98.4)
GA	1 (1.6)
Periampullary diverticulum	24 (38.7)
PD injection	4 (6.5)
Diameter of CBD	
<1 cm	1 (1.6)
1-1.5 cm	38 (61.3)
>1.5 cm	23 (37.1)
Number of CBD stones	
1 stone	31 (50.0)
2 stones	12 (19.4)
>2 stones	19 (30.6)
Complete stone removal	55 (88.7)
Plastic stent placement	3 (4.8)
Prophylaxis hemostasis with adrenaline	3 (4.8)
Complications	
Bleeding	1 (1.6)
Mild pancreatitis	1 (1.6)

ERCP = endoscopic retrograde cholangio-pancreatography; TIVA = trans-intravenous anesthesia; GA = general anesthesia; PD = pancreatic duct; CBD = common bile duct

patients who were suspected CBD stricture or impacted CBD stones.

Post ERCP complications

There were some post ERCP complications encountered after ESPT such as bleeding and mild pancreatitis. There was 3.2% in the total complication rate after the procedures. Post ERCP bleeding occurred in one patient using large CRE™ Wireguided balloon dilatation (Maximum diameter 20 mm). The patient required a repeat endoscopy with an endoscopic intervention without a surgical treatment. Post ERCP pancreatitis was occurred in only one elderly patient using large CRE™ Wireguided balloon diameter (20 mm) dilatation owing to large multiple CBD stones. She developed fever, abdominal pain radiating to the back, which was treated with conservative treatment. None of the patients developed retroduodenal perforation or required any surgical interventions.

Discussion

The present study showed that ESPT using larger CRE balloon dilatation after adequate sphincterotomy is the effective method for extraction of a large CBD stone, particularly when the CBD stone was larger than a papillary orifice or diameter of distal CBD. The overall success rate of CBD stone clearance using ESPT was high (88.7%). The result was similar to the previous study but associated with lower complication rate (10.9% vs. 3.2%)⁽⁹⁾.

The post ERCP complication in the present study was bleeding from the ampullary orifice and mild pancreatitis. The incidence of post-procedure bleeding ranges from 0% to 9% in previous studies⁽⁹⁾. The cause of post-procedure bleeding might be the result of EST preceding large balloon dilatation. Therefore, performing EST before large balloon dilatation should be avoided in patients with coagulopathies. Post ERCP pancreatitis was documented in only one patient in each group. It was not clear what contributed to the cause of pancreatitis in these patients because pancreatic duct injection, EST, large balloon dilation, or ML procedures are known to have acute pancreatitis as a complication. No perforation was encountered in the study. Compared with endoscopic papillary balloon dilation, the risk of pancreatitis after EST with a large balloon dilatation was low based on our results and of other reported studies⁽¹⁴⁻¹⁶⁾. For this result, we recommend using the CRE balloon not bigger than 15 mm in diameter.

The increased risk of acute pancreatitis was described after endoscopic balloon dilation of papillary sphincter with standard-diameter balloon⁽¹⁷⁾. Endoscopic balloon dilatation alone may cause transmural inflammation and intramucosal hemorrhage⁽¹⁸⁾. Five prospective randomized controlled trials of an endoscopic papillary balloon dilation versus EST were performed, and their incidence rate of pancreatitis after endoscopic papillary balloon dilation was 4.9% to 20%⁽⁸⁾. It is probable that EST before a large balloon dilation might enable free access of a balloon catheter to the common channel and prevent pressure effect on the orifice of main pancreatic duct. Therefore, the pancreatic duct is injured less often, and fewer pancreatic complications may result. However, the evidence was insufficient to elucidate the rationale. In our opinion, EST with a large CRE™ Wireguided balloon dilatation may be considered as a safer alternative method than endoscopic papillary balloon dilatation alone for removal difficult bile duct stones.

We have used CRE™ Wireguided balloon with maximum diameter of 12, 15, or 20 mm in a given patient with the largest balloon diameter (20 mm) for patients with an unusually large CBD stone. These 20 mm diameter balloons had also been used in a more recent study⁽¹⁹⁾. However, if a CBD stone size was larger than length of the CRE™ Wireguided balloon or larger than the diameter of the balloon, the stone could not be removed after using ESPT. ML was required in 11.3% of cases, which is similar to the data of a recent multicenter series⁽²⁰⁾. However, after using ESPT, ML could be done with a high success rate. Complete stone clearance was achieved without complications in all the patients.

The main limitations of our 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

Balloon dilatation after biliary sphincterotomy with large diameter CRE™ balloon is an effective technique for removal large CBD stone. This procedure obviates the need for unnecessary ML or surgery and associated with lower rate of therapeutic ERCP complications.

What is already known on this topic?

Difficult CBD stone removal is still the challenge for endoscopic surgeon. There are many alternative treatments such as ERCP with plastic stenting, lithotripsy, ESWL, and laparoscopic surgery. The data of balloon dilatation using CRE balloon dilatation is still limited.

What this study adds?

The data confirms that Balloon dilatation after biliary sphincterotomy with large diameter CRE™ balloon is an effective technique for large CBD stone removal.

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Author contributions

Thawatchai Akaraviputh performed the majority of experiments; Tassanee Sriprayoon co-ordinated and provided the collection of all material; Chainarong Phalanusitthepha and Chotirot Augkurawaranon collected some data. Chananya Hokierti created the drawing figure. Thawatchai Akaraviputh designed the study and wrote the manuscript.

Potential conflicts of interest

None.

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ผลการรักษานิวในท่อทางเดินน้ำดีแบบยากด้วยการส่องกล้องถ่างขยายโดยใช้บอลูนขนาดใหญ่: ประสิทธิภาพของแพทย์ส่องกล้องเดี่ยว

ชัยณรงค์ พลาสินิตเทพา, โชติรส อังกูรวรานนท์, ทศนีย์ ศรีประยูร, ชนัญญา ท่อเกียรติ, ธวัชชัย อัครวิพุธ

วัตถุประสงค์: การส่องกล้องถ่างขยายโดยใช้บอลูนขนาดใหญ่เป็นทางเลือกหนึ่งในการนำนิวแบบยากออกจากท่อทางเดินน้ำดีร่วม อย่างไรก็ตามยังไม่มีรายงานที่ชัดเจนของผลการรักษาและภาวะแทรกซ้อนที่เกิดจากวิธีนี้ การศึกษานี้ได้แสดงให้เห็นถึงผลการรักษาของวิธีนี้โดยแพทย์ส่องกล้องเดี่ยว

วัสดุและวิธีการ: การศึกษาย้อนหลังระหว่าง เดือนมกราคม พ.ศ. 2546 ถึง เดือนธันวาคม พ.ศ. 2552 มีผู้ป่วยทั้งหมด 93 ราย ที่มีนิวในท่อทางเดินน้ำดีร่วม และได้รับการส่องกล้องทางเดินน้ำดีเพื่อทำการคิบนิวออกด้วยความยากลำบาก มีผู้ป่วยทั้งหมด 62 ราย ที่ได้รับการถ่างขยายด้วยบอลูนขนาดใหญ่ โดยศึกษาอัตราความสำเร็จในการเอานิวออกได้หมดและภาวะแทรกซ้อนหลังการส่องกล้องทางเดินน้ำดี

ผลการศึกษา: อัตราความสำเร็จในการคิบนิวออกได้อย่างสมบูรณ์สูงถึงร้อยละ 88.7 มีผู้ป่วย 7 ราย (ร้อยละ 11.3) ที่จำเป็นต้องใช้การขบนิวด้วยเครื่องมือขบนิวร่วมด้วย พบว่ามีอัตราการเกิดภาวะแทรกซ้อนร้อยละ 3.2 มีผู้ป่วย 1 ราย ที่มีภาวะเลือดออก (ร้อยละ 1.6) และ 1 ราย ที่มีภาวะตับอ่อนอักเสบเกิดขึ้น (ร้อยละ 1.6)

สรุป: การส่องกล้องถ่างขยายด้วยบอลูนขนาดใหญ่เป็นวิธีที่มีประสิทธิภาพในการเอานิวออกจากท่อทางเดินน้ำดีร่วม มีอัตราการเกิดภาวะแทรกซ้อนต่ำ และสามารถหลีกเลี่ยงการผ่าตัดเปิดท่อทางเดินน้ำดีโดยไม่จำเป็น
