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Percutaneous removal of common bile duct stones using a modified balloon technique

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Abstract

To evaluate the effectiveness of percutaneous removal of common bile duct (CBD) stones using a modified balloon technique (balloon catheter sphincteroplasty and expulsion of the stones using half-captured balloons within the sheath) in patients difficult to treat with endoscopy.

Fifty patients underwent a modified balloon technique (balloon group), and 53 patients underwent CBD stone removal by the basket method (stone basket group) between 2016 and 2019. We compared the balloon and stone basket groups to evaluate the effectiveness of the modified balloon technique. Outcome variables such as demographics, technical success rates, procedural details, and complications were analyzed. Statistical analysis was performed using Student *t* test, Fisher exact test, or the χ^2 test.

The technical success rate in the balloon group was 66% (33/50) in 1 session, 32% (16/50) in 2 sessions, and 2% (1/50) in 3 sessions. That of the stone basket group was 45% (24/53) in 1 session, 38% (20/53) in 2 sessions, and 17% (9/53) in 3 sessions.

The total procedure time was significantly shorter in the balloon group (29.5 ± 15.1 minutes) than in the stone basket group (41.7 ± 20.2 minutes) ($P < .01$), whereas the number of stones was higher in the balloon group than in the stone basket group ($P = .03$). Maximal stone size, balloon size, pancreatitis, and hospitalization stay did not show statistical differences between the 2 groups. Most complications (9 patients, balloon group; 8 patients, stone basket group) were mild and transient. Major complications occurred in one patient in the stone basket group, who experienced hemobilia due to arterial injury caused by percutaneous transhepatic biliary drainage, which was treated by endovascular embolization without mortality.

The modified balloon technique is an effective and safe treatment method for CBD stone removal in patients presenting difficulties in the endoscopic approach.

Abbreviations: CBD = common bile duct, PTBD = percutaneous transhepatic biliary drainage.

Keywords: angioplasty, balloon, calculi, common bile duct, sphincteroplasty, transhepatic

1. Introduction

Endoscopic sphincterotomy and stone removal are known as the first modalities in the management of common bile duct (CBD) stones. However, endoscopic treatment is difficult in previous gastrointestinal surgery, duodenal diverticulum, and large and impacted stones.[1] To remove difficult CBD stones, alternative percutaneous methods, including the extraction of stones using baskets or forceps, expulsion of stones into the duodenum by baskets, angioplasty balloon catheters, or occlusion balloons, have been described.[2–4] Since Burhenne et al reported that Dormia baskets have high success rates and low complication rates, percutaneous techniques using baskets have been commonly used to remove biliary stones.[5] However, the basket method takes a long time to crush and remove multiple stones. In particular, small stones often remain when there is an accompanying structure in the ampulla of Vater. Thus, balloon dilatation of the sphincter of Oddi (Sphincteroplasty) and stone expulsion provided a reduction in the number of procedures.[4] However, there is a hassle of using 2 balloons (angioplasty balloon for sphincteroplasty, occlusion balloon to push stones) and the occlusion balloon may not have enough power to push the stones into the duodenum. Additionally, when using only an angioplasty balloon, it is difficult to remove a stone in the mid to upper CBD because the balloon length is longer than 4 cm. In order to enhance CBD stone removal, we performed sphincteroplasty with an angioplasty balloon and then expulsed the stones to the duodenum using the same balloon. At this time, the balloon was half-captured in the introducer sheath, so even at the angle of the hilar duct, it was possible to efficiently remove the CBD stone by providing pushability without damaging the intrahepatic duct (the modified balloon technique). Here, we aimed to evaluate the

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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effectiveness and safety of the modified balloon technique in CBD stone removal, and compare it with the stone basket method.

2. Materials and methods

2.1. Patient selection

This retrospective review of the patients' medical and imaging records was approved by our institutional review board, and written informed consent was waived. From January 2016 to June 2019, patients who underwent percutaneous treatment for biliary stones were included in a dedicated database. We excluded patients with concomitant intrahepatic duct (IHD) stones. Indications for percutaneous removal of stones were partial gastrectomy with Billroth II or Roux-en-Y gastrojejunostomy in 48 patients, periampullary diverticulum in 8 patients, and the patient's poor condition (e.g., low blood pressure) or rejection of the endoscopic procedure in 47 patients. When deciding to perform a modified balloon technique, we did not attempt in the patient with extremely dilated bile duct because we only used balloons up to 12 mm in size for stone expulsion. In addition, when the calculus was too large or too hard to be fragmented by stone baskets, we could not try to push the balloon. Therefore, the study population consisted of 103 patients. Among these, 50 patients underwent percutaneous removal of CBD stones by the modified balloon technique, and 53 patients underwent removal by a basket.

2.2. Procedural technique

All procedures were performed by 1 of 3 interventional radiologists with 5 to 16 years of clinical experience. All patients received prophylactic broad-spectrum antibiotics to prevent and manage cholangitis. First, percutaneous transhepatic biliary drainage (PTBD) was performed in all patients to relieve the clinical symptoms. For the convenience of the procedure, the right IHD (segments 5 or 6) was primarily punctured in 93 patients. However, the segment 3 duct in the left lobe was punctured in 10 patients with non-dilated IHD of the right liver. The removal of CBD stones was attempted 3 to 4 days after PTBD to ensure tract maturation and subsiding of the cholangitis. Various analgesics such as lidocaine, midazolam, and fentanyl were administered depending on the patient's status. Preliminary cholangiography with diluted contrast material was performed to define the anatomy of the biliary tree and the number, size, and location of the stones. A hydrophilic guidewire (Terumo, Tokyo, Japan) was advanced through the ampulla of Vater into the duodenum, and the percutaneous tract was dilated to 10-Fr using graded dilators (St. Jude Medical, Plymouth, MN) over the guidewire. The guidewire was exchanged for a stiff guidewire (Terumo, Tokyo, Japan) if the route between the IHD and CBD was acute angled or tortuous. An 8-Fr sheath in a Wittich nitinol stone basket set (Cook) was inserted into the CBD proximal to the stones. If large (>1.5 cm) stones were noted on the cholangiography, we were trying to fragment with stone basket to facilitate pushing the balloon. Then, a modified balloon technique was performed, which was combined with sphincteroplasty of the sphincter of Oddi and stone expulsion using a Mustang balloon (Boston Scientific, Galway, Ireland) 10 to 12 mm in diameter and 4 cm in length. The size of the balloon did not exceed 12 mm to avoid complications such as pancreatitis, bleeding, and perforation. The balloon was inserted over the guidewire, positioned symmetrically across the papilla, and then inflated with diluted contrast medium until the waist disappeared. Inflation was maintained for 30 to 60 s and, occasionally, repeated. After dilatation, the balloon catheter was withdrawn proximal to the stones. Of the 4 cm-length balloon catheters, half-length was placed within the sheath, and the remaining half-length was inflated outside the sheath to facilitate stone removal (Fig. 1). The introducer sheath with the balloon was simultaneously pushed into the duodenum to increase the mechanical force. This maneuver was repeated as many times as necessary. The balloon and sheath were then removed, and a 10-Fr Dawson-Mueller drainage catheter (Cook, Bloomington, IN) was placed in the CBD. This catheter was maintained in place for 2 to 7 days to allow external drainage. Before removing the catheter, cholangiography was performed to determine if the biliary tree was free of stones and easy flow of the contrast media into the duodenum was seen, and the drainage catheter was withdrawn. The procedure was repeated if any stone remained.

2.3. Evaluation of data and definitions

We defined the group that used balloon for sphincteroplasty and stone expulsion as the balloon group, and the group that used only the stone basket as the stone basket group. According to these groups, patient characteristics and procedural details were analyzed and compared. The reviewed medical records included age, sex, comorbidity (e.g., diabetes, hypertension), history of previous gastrointestinal bypass surgery (e.g., Billroth II), total bilirubin, pre- and post-procedural pancreatic enzymes (e.g., amylase, lipase), hospitalization stay, procedural outcomes, and complications. Technical success was defined as complete clearance of bile ducts without flow disturbance from the CBD to the duodenum. The diagnosis of acute pancreatitis required at least 2 of the following 3 features: abdominal pain, elevated serum amylase or lipase at least 3 times greater than the upper limit of normal, or findings of acute pancreatitis on CT or MRI imaging.[6] Complications were categorized as major or minor according to the guidelines of the Society of Interventional Radiology (SIR) standards of practice committee.[7]

2.4. Statistical analysis

Continuous variables with normal distribution were analyzed with the Student *t* test and those with non-normal distribution were analyzed using the Mann–Whitney *U* test. Categorical data were assessed using Fisher exact test or the χ^2 test. All statistical analyses were performed using the Statistical Package for the Social Sciences for Windows, version 21.0 (SPSS, Inc., Chicago, IL).

3. Results

3.1. Patient characteristics

The baseline characteristics of 103 patients (balloon group, n = 50; stone basket group, n = 53) who underwent percutaneous intervention for CBD stone are summarized in Table 1. Male sex and right-sided PTBD were statistically lower in the balloon group than in the stone basket group. There was no statistical difference between the balloon and stone basket groups: age (79.2 ± 8.7 versus 76.3 ± 9.1 years), diabetes (10 versus 17 patients), hypertension (24 versus 20 patients), total bilirubin

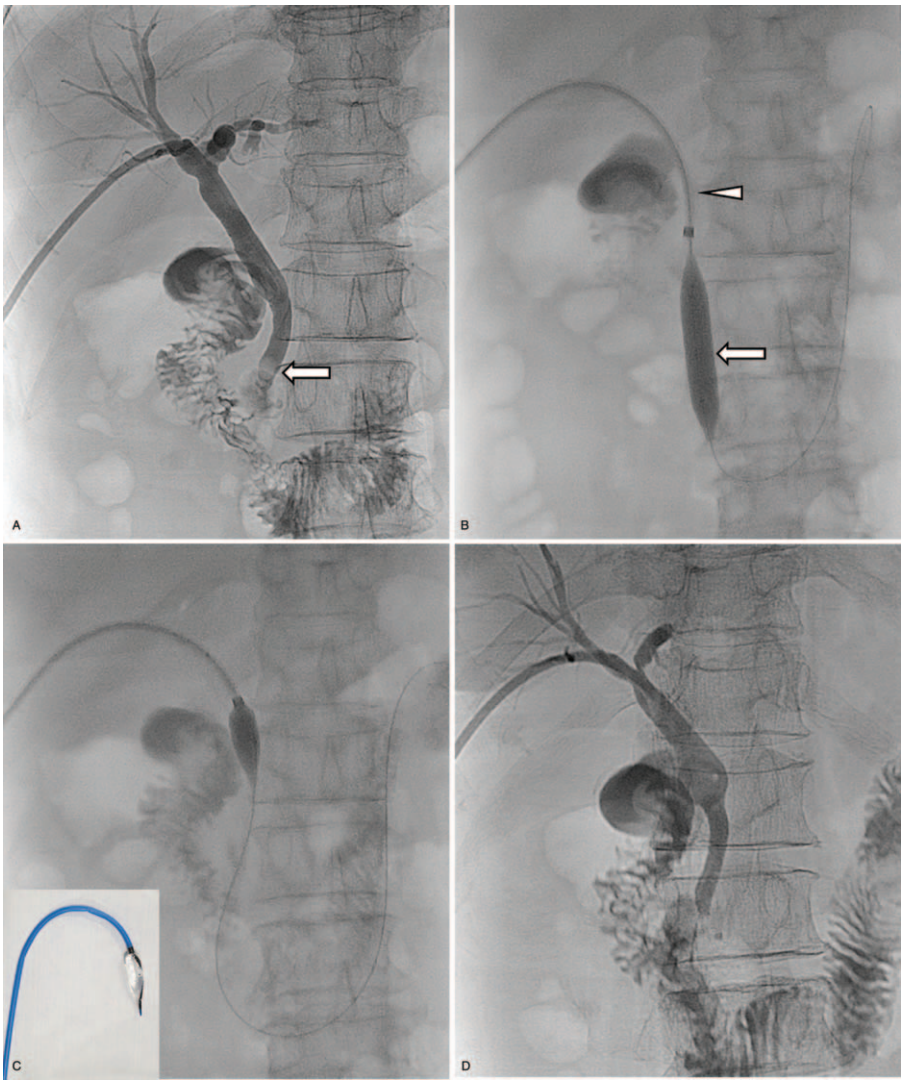

Figure 1. A 69-year-old woman with common bile duct (CBD) stones and related right upper quadrant pain. (A) Percutaneous transhepatic biliary drainage was performed before 4 days. Cholangiography shows distal CBD stones (arrow) up to 1.3 cm. (B) After inserting an 8-Fr sheath (arrowhead) through the transhepatic route, the ampullary sphincter is dilated using a 12mm-diameter × 4cm-length balloon catheter (arrow). (C) The half-captured balloon is located at the proximal CBD. Photograph shows a half-captured balloon catheter within the introducer sheath (Inset). The stones were completely pushed over the 0.035-inch wire into the duodenum. (D) Cholangiogram showing complete clearance of the stones.

Table 1

Patient baseline characteristics.

Characteristic	Balloon group (n = 50)	Stone basket group (n = 53)	*P* value
Age (yr)	79.2 ± 8.7 (52–92)	76.3 ± 9.1 (47–95)	.107
Gender, male	24	37	.024*
Diabetes	10	17	.146
Hypertension	24	20	.293
Total bilirubin (mg/dL)	2.9 ± 2.7	2.6 ± 2.1	.556
Right sided PTBD	42	51	.048*
Pre-procedural pancreatitis	8	3	.089
Post-procedural pancreatitis	1	1	1.000
Hospitalization stay (d)	17.1 ± 12.1	14.1 ± 6.9	.128

Values are presented as number or mean ± SD.
* Statistically significant.

(2.9 ± 2.7 versus 2.6 ± 2.1 mg/dL), pre-procedural pancreatitis (8 versus 3 patients), post-procedural pancreatitis (1 versus 1 patient), and hospitalization stay (17.1 ± 12.1 versus 14.1 ± 6.9 days).

3.2. Outcome of biliary stone removal

Table 2 summarizes the procedural details. Technical success in the balloon group was achieved in 33 patients (66%) in 1 session, 16 patients (32%) in 2 sessions, and 1 patient (2%) in 3 sessions. Technical success in the stone basket group was achieved in 24 patients (45%) in 1 session, 20 patients (38%) in 2 sessions, and 9 patients (17%) in 3 sessions ($P = .015$). The total procedure time was significantly shorter in the balloon group (29.5 ± 15.1 minutes) than in the stone basket group (41.7 ± 20.2 minutes) ($P < .01$). A single stone was seen in 10 patients in the balloon group and 22 in the stone basket group. Two to 4 stones were

Table 2

Outcome of biliary stone removal.

Characteristic	Balloon group (n = 50)	Stone basket group (n = 53)	*P* value
Technical success			.015*
One session	33 (66%)	24 (45%)	
Two sessions	16 (32%)	20 (38%)	
Three sessions	1 (2%)	9 (17%)	
Total procedure time (min)	29.5 ± 15.1 (12–76)	41.7 ± 20.2 (15–88)	.001*
Number of stones			.031*
1	10	22	
2–4	27	25	
≥5	13	6	
Maximal Stone Size (mm)	16.0 ± 5.9 (5–32)	17.0 ± 6.7 (7–31)	.437
Balloon Size			
10mm	10	–	
12mm	40	–	
Complication			.894
Major	0	1	
Minor	9	8	
None	41	44	

Values are presented as number or mean ± SD.
* Statistically significant.

seen in 27 patients in the balloon group and 25 in the stone basket group. Five stones and more were seen in 13 patients in the balloon group and 6 patients in the stone basket group ($P = .03$). The maximal stone size was not statistical different between the balloon group (16.0 ± 5.9 mm) and the non-balloon group (17.0 ± 6.7 mm). Twenty-four patients (48%) of the balloon group underwent the fragmentation of large stones with stone baskets before pushing the balloon. The balloon size of balloon group was 10 mm in 10 patients and 12 mm in 40 patients. A major complication occurred in 1 patient in the stone basket group, the patient had hemobilia on follow-up tubography 2 days after stone removal. The next day, the patient presented with melena and decreased hemoglobin count. On diagnostic angiography, active bleeding from the right inferior hepatic artery was seen near the PTBD puncture site. The bleeding was treated by endovascular embolization using gelatin sponge particles. The following minor complications were observed in 9 patients in the balloon group and in 8 patients in the stone basket group: 1 patient in the balloon group showed bile peritonitis with subcapsular biloma and complicated ascites on the follow-up CT after stone removal. Since the biloma and ascites were small, the patient underwent conservative management; transient symptoms such as nausea, vomiting, and abdominal pain were observed after the procedure in 6 patients in the balloon group and 7 patients in the stone basket group, respectively. Mild hemobilia occurred in 2 patients in the balloon group and one patient in the stone basket group. The transient hemobilia was treated with saline irrigation. There was no procedure-related mortality during follow-up.

4. Discussion

The most common techniques to remove CBD stones are extraction with Dormia baskets in interventional radiology and more frequently, sphincterotomy in therapeutic endoscopy. However, less attention has been paid to percutaneous papillary balloon dilatation. Thus, we compared the modified balloon technique and the Dormia basket technique in CBD stone removal. To our knowledge, no study has compared these 2 techniques.

In the balloon group, the technical success rate was higher even with fewer attempts, and the total procedure time was shorter than that of the stone basket group. In the balloon group, multiple stones were more frequent than in the basket group. The percutaneous extraction of stones with Dormia baskets is still a common interventional procedure, but it takes a lot of time to crush and remove the stones and frequently requires repeated sessions when multiple stones exist.[8–11] Because bile stasis is an important factor in the pathogenesis of bile duct stones, and concomitant bile duct stones and biliary stricture is not rare, it is difficult to efficiently treat CBD stones with a stone basket alone.[12] Centola et al[13] described percutaneous balloon dilatation of the sphincter for stone removal, since then, several studies have reported high success rates,[4,14] but it is inconvenient to replace the sphincteroplasty balloon with an occlusion balloon for stone removal. Liu et al[15] have recently reported cases of sphincteroplasty and expulsion of CBD and gallbladder stones to the duodenum with the same angioplasty balloon. The study, however, was a pilot study with only 17 patients and did not describe the number of stones, the specific profile of the balloons, and the procedure time. Considering the authors' insistence on using baskets to fragment large stones and the repeated removal of the remaining stones, it would have been difficult to remove stones efficiently using angioplasty balloons. The modified balloon technique described in this study has advantages over percutaneous biliary stone removal technique using a Dormia basket or occlusion balloon, in terms of the procedure time and cost savings. The CBD is approximately 72 mm long on average and has an arciform course with an angulation of 132.6° going to the duodenum.[16,17] In case of percutaneous access, the angle between the introducer sheath and CBD becomes sharper, and it is difficult to efficiently push the stones in a narrow space of the CBD with an angioplasty balloon. The modified balloon technique can improve pushability by pushing the sheath and the half-captured balloon simultaneously, while the length of the balloon is briefly adjusted and easily handled in a narrow space of the CBD to push the stone away. In addition, sphincteroplasty allows the removal of small residual stones by

widening the exit, and it reduces the number of additional procedures.

The majority of endoscopists are concerned about papillary balloon dilatation due to the increased risk of pancreatitis. However, in the present study, post-procedural pancreatitis occurred in 1 patient in the balloon and stone basket groups, respectively. This is attributed to the fact that the size of the balloon was not too large, such as 10 to 12 mm, and all stones > 1.5 cm were primarily fragmented with the basket and then expulsed with the balloon, which could remove large and multiple stones with little pancreatitis. Recently, Tringali et al[18] reported that papillary balloon dilatation using a large balloon (≥ 10 mm) was as effective as endoscopic sphincterotomy without increasing the risk of pancreatitis. Gil et al[4] and Garcia et al[14] reported that papillary balloon dilation through the percutaneous transhepatic route was effective and procedure-related pancreatitis was extremely rare, which is consistent with the results of this study.

Most complications of the modified balloon technique were mild and transient, but 1 major complication such as severe hemobilia causing hemodynamic instability occurred in the stone basket group. Percutaneous transhepatic insertion of the introducer sheath can lead to intrahepatic vascular damage with up to 1.4% of mortality.[14] The reason for no death in our study was that we minimized arterial hemobilia by performing biliary drainage while approaching the bile duct as far as possible to the peripheral site under ultrasound guidance. In addition, our technique needed only an 8-Fr sheath for the transhepatic approach; hence, the maturation of the tract was not necessary.

Our study has several limitations. First, this was a non-randomized and retrospective study; thus, selection bias might have occurred. Furthermore, the small number of patients in this single-center study limits its generalizability. Second, we only used 10 to 12 mm balloons because of concerns about known complications such as pancreatitis, perforation, and bleeding. In some cases of large stones, we primarily used a basket to fragment the stone and then performed a modified balloon technique. This may have led to an overestimation of the effectiveness of the modified balloon techniques. Therefore, a randomized control study will be needed to use larger balloons and compare it with other stone removal techniques.

In conclusion, the percutaneous modified balloon technique is an effective and safe treatment for CBD stones without major complications. It can be an alternative treatment for patients with difficulties in the endoscopic approach.

Author contributions

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Writing – review & editing: Sang Min Lee, Ho Cheol Choi, Jung Ho Won, Jae Min Cho, Dae Seob Choi, Mi Jung Park, Sung Eun Park, Jong Joon Shim.

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