

Biliary stone removal through the percutaneous transhepatic biliary drainage route, focusing on the balloon sphincteroplasty flushing technique: a single center study with 916 patients

Jong Soo Shin¹ · Hyung Jin Shim² · Byung Kook Kwak² · Hyun-Ki Yoon³

Received: 1 February 2017 / Accepted: 14 May 2017 / Published online: 6 June 2017
© Japan Radiological Society 2017

Abstract

Purpose To present our experience in biliary stone removal (BSR) through the percutaneous transhepatic biliary drainage (PTBD) route in 916 patients, and discuss its clinical usefulness.

Materials and methods From 2001 to 2015, 916 patients (479 male patients and 437 female patients; age range, 22–92 years; mean age, 67 years) with 52 recurring cases, so a total of 968 cases, were enrolled in this study and retrospectively reviewed. PTBD was performed in all patients. BSR was performed using a combination of a balloon sphincteroplasty flushing technique, a pushing technique after sphincteroplasty, and classical extraction technique, decided case by case.

Results A complete removal was achieved in 893 cases (92.3%) and the overall clinical success rate was 99.3%. Failure occurred in 7 cases (0.7%), and the causes of failure were stone impaction ($n = 5$) and intrahepatic bile duct stricture ($n = 2$). Sphincteroplasty was performed in 902 cases (93.2%). Balloon sphincteroplasty flushing technique was used in 829 (85.6%) cases. There was no major

complication. Transient minor complications were seen in 86 cases (8.9%).

Conclusions BSR through the PTBD route using a combination of techniques, including balloon sphincteroplasty flushing, is a safe and effective treatment modality to remove biliary stones.

Keywords Percutaneous transhepatic biliary drainage · Biliary stone removal · Biliary stone · Hepatolithiasis · Balloon sphincteroplasty flushing technique

Introduction

Biliary stones may be related to various clinical manifestations, such as upper abdominal pain, high fever, and obstructive jaundice. If a patient's condition progresses to cholangitis or biliary sepsis, biliary drainage is needed as soon as possible, and stone removal is necessary to complete the treatment.

Various methods, including surgical and non-surgical techniques have been used to remove biliary stones. As a surgical modality, laparoscopic biliary surgery has been widely used. It is very effective and relatively safe compared with the conventional open surgery [1]. However, laparoscopic surgery also requires general anesthesia and a more invasive procedure than non-surgical techniques.

As a non-surgical modality, endoscopic sphincterotomy (EST) and stone removal has been considered as a first treatment modality in the management of common bile duct (CBD) stones. However, biliary sphincter function is irreversibly damaged after EST, leading to duodenobiliary reflux and chronic inflammation of the biliary system [2]. EST is associated with bacterial colonization and the presence of cytotoxic components in bile and

✉ Hyung Jin Shim
shimhj@cau.ac.kr

¹ Department of Radiology, Hallym University Dongtan Sacred Heart Hospital, Hallym University College of Medicine, 7, Keunjaebong-gil, Hwaseong-Si, Gyeonggi-do 18450, Republic of Korea

² Department of Radiology, Chung-Ang University Hospital, Chung-Ang University College of Medicine, 102, Heukseok-ro, Dongjak-gu, Seoul 06973, Republic of Korea

³ Department of Radiology, Asan Medical Center, College of Medicine, University of Ulsan, 88, Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Republic of Korea

chronic inflammation, fibrosis, and reactive epithelial changes of the bile ducts [3]. It has complication rates of 5–15% with 1–3% mortality rates [4–6].

It is also difficult or impossible to perform an endoscopic procedure when the biliary duct cannot be accessed due to a duodenal diverticulum or previous gastrointestinal surgery, and in the presence of large and impacted stones, stones situated in the intrahepatic bile ducts, and patients' intolerance or phobia for endoscopy [7–9]. In such cases, percutaneous transhepatic stone removal is another important technique in the non-operative management of biliary stones [7, 8, 10].

We present our experience in BSR through the PTBD route in 695 patients, and analyzed the success rate and complications. And we describe the techniques for BSR, including the balloon sphincteroplasty flushing technique with its technical feasibility and usefulness.

Materials and methods

Patients

This retrospective study was approved by our institutional review board. From January 2001 to December 2015, 916 patients (479 male patients and 437 female patients; age range, 22–92 years; mean age, 67 years) underwent BSR through the PTBD route in our intervention center. We excluded patients who were diagnosed with postoperative stricture of the bile duct, malignancy, and primary sclerosing cholangitis. The patient characteristics are presented in Table 1.

Thirty-eight of 695 patients underwent 2 separate BSR procedures, and seven of 695 patients underwent 3 separate BSR procedures, because of recurrent biliary stones. The period of recurrent biliary stones was 6 months or more. Therefore, 968 cases were enrolled in this study and retrospectively reviewed.

The biliary stones were diagnosed by computed tomography (CT) and/or ultrasonography. The direction of the PTBD route, location of the stones, method and number of procedures for BSR, sphincteroplasty or not, and results of the procedure including success rate and reason for failure, were analyzed on the medical and imaging records, retrospectively.

The symptoms of patients, initial and follow-up laboratory results, including complete blood count, liver enzymes, bilirubin, amylase and lipase levels, and procedure-related complications were obtained from the medical records.

Table 1 Patient characteristics

Total number of patients	916
Sex (male/female) (no.)	479/437
Age (years)	
Mean	67
Range	22–92
Recurrent patients (no.)	
2 times	38
3 times	7
Total	45
Total number of cases	968
Clinical presentation (no.)	
Cholangitis or biliary sepsis	322
Obstructive jaundice	374
Abdominal pain	87
Others	185

Procedure

All patients received broad-spectrum antibiotics beginning on the day before the PTBD, and continuing as long as the external catheter was in place. All patients were monitored continuously during the procedure. The procedure was performed under conscious sedation. Narcotic analgesics were administered intravenously as needed.

Percutaneous transhepatic biliary drainage was performed in all patients to relieve clinical symptoms, decompress the biliary system, resolve the edema on the biliary wall, and establish the tract for BSR. The initial PTBD tube was usually used an 8.5 French (Fr) drainage catheter. The first BSR procedure was performed 3 or 4 days after PTBD, and each BSR procedure was done with a 3- or 4-day interval. PTBD and BSR procedures were performed under fluoroscopic guidance (Axiom Artis dBA; Siemens, Germany, or Integris BV5000; Philips, the Netherlands).

We performed sphincteroplasty in most cases. The PTBD tube was replaced by an 8 Fr introducer sheath (Super Arrow-Flex; Arrow, Reading, PA, USA). For the sphincteroplasty, a 150-cm, 0.035-inch diameter guide wire (Radifocus Guide wire M; Terumo, Tokyo, Japan) was passed through the ampulla of Vater and the tip of the wire was placed into the jejunum via the duodenum, generally assisted by a 5 Fr angled tapered angiographic catheter (Kumpe catheter; Cook medical, Bloomington, IN, USA). The wire was exchanged with a stiff type 180-cm, 0.035-inch diameter guide wire (Amplatz Super Stiff; Boston Scientific, Natick, MA, USA).

A balloon catheter (ATB; Cook medical, Bloomington, IN, USA, or Synergy; Boston Scientific, Galway, Ireland) was inserted over the stiff type guide wire and

placed across the sphincter. The diameter of the balloon for sphincteroplasty was usually 8 mm or 10 mm in the case of non-dilated CBD. The size of the balloon was determined by the size of the biliary stones and the number of procedures for BSR. We never use a balloon of more than 10 mm in diameter in the case of non-dilated CBD, but more than 12-mm balloons were chosen for dilated CBD. The length of the balloon was 40 or 60 mm. The balloon was inflated with diluted contrast medium until the waist by the papillary sphincter disappeared. Inflation time was 10–20 s.

Prior to BSR, cholangiography with diluted contrast medium was obtained to define the anatomy of the biliary tree and to identify the size, number, and location of the stones. We used several techniques for BSR, case by case. The most frequently used technique was sphincteroplasty balloon-assisted flushing after stone fragmentation with basket. Stone pushing into the duodenum after sphincteroplasty was used as an alternative method.

After BSR, an 8.5 or 10.2 Fr drainage catheter was placed into the CBD again. After 3–5 days, cholangiography was obtained to determine whether the biliary tree was free of stones and that there was a free flow of contrast medium into the duodenum. In the presence of residual stones, the procedure was repeated. When there were no residual stones, the PTBD catheter was removed.

Technique for BSR

In the case of an intrahepatic duct stone or a large extrahepatic duct stone, we used a fragmentation with basket technique. These stones were snared or crushed by the stone basket (Nitinol stone basket; Cook medical, Bloomington, IN, USA) (Fig. 1), and fragmented stones were grasped and pulled out through the PTBD route or expelled into the duodenum by the balloon sphincteroplasty flushing technique or pushing technique.

The balloon sphincteroplasty flushing technique is for multiple small or medium sized common duct stones, or fragmented stones. Large stones, stones with a diameter of 15 mm or more, were crushed by a stone basket. The balloon was inflated with the diluted contrast medium and placed across the sphincter. After full extension of the balloon, we injected diluted contrast medium into the CBD through the sheath, and hydrostatic pressure of the bile duct was increased (Fig. 2). Then, the inflated balloon was advanced over the stiff type guide wire to the duodenum; simultaneously, saline flushing through the sheath was done. The stones were expelled into the duodenum by hydrostatic pressure (Fig. 2). This technique was repeated until the stone was evacuated completely from the CBD to the duodenum.

In the case of one or two small or medium sized common duct stones, we used a pushing technique. These stones were pushed into the duodenum with a balloon

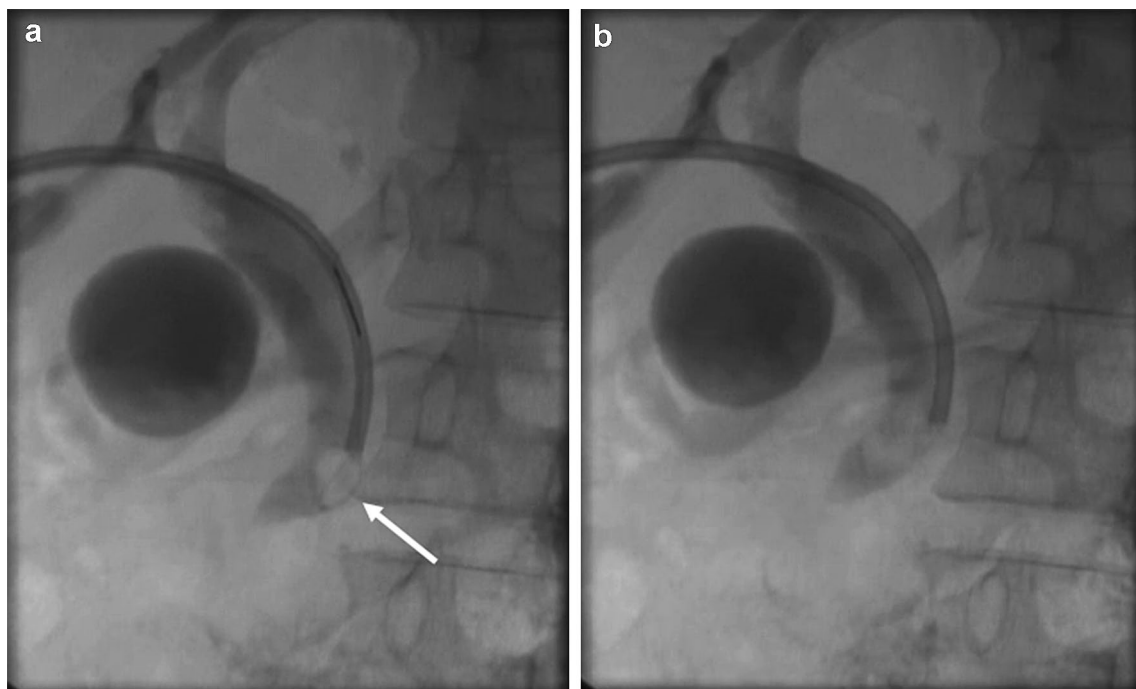


Fig. 1 A common bile duct stone fragmented by a stone basket. **a** A medium sized stone (*arrow*) in the distal common bile duct was grasped and crushed by the stone basket. **b** Fragmented stones are seen in the distal common bile duct

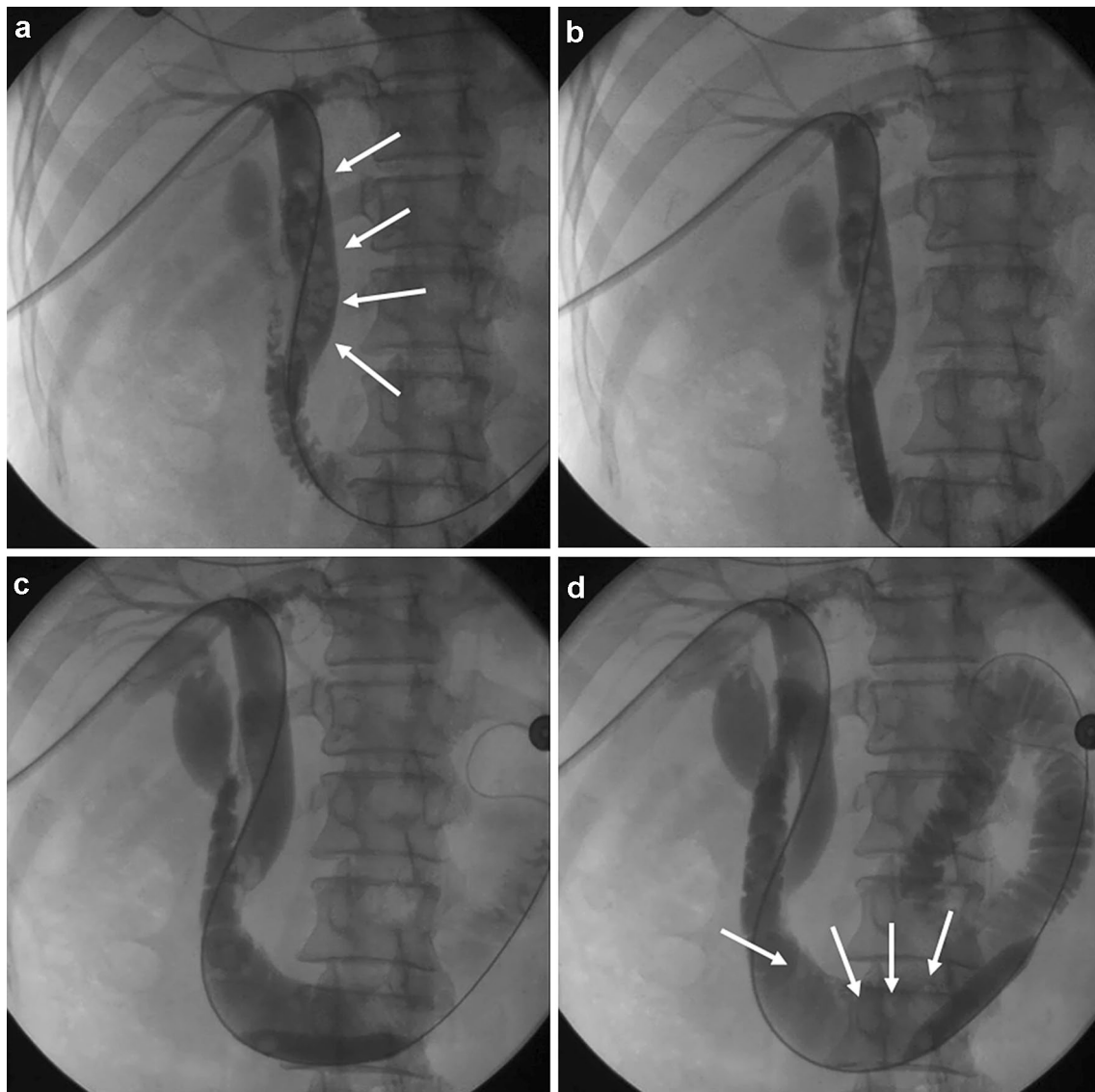


Fig. 2 Multiple small and fragmented stones were expelled into the duodenum by the balloon sphincteroplasty flushing technique. **a** Percutaneous transhepatic cholangiography shows multiple small and fragmented stones (*arrows*) in the common bile duct. **b** Sphincteroplasty was performed using a 10-mm balloon catheter. **c** After sphincteroplasty, diluted contrast medium was injected into the common bile duct through the sheath, consequently, hydrostatic pressure of the

catheter. After sphincteroplasty, the balloon was inflated with diluted contrast medium proximal to the stones and advanced over the stiff type guide wire through the papilla and into the duodenum (Fig. 3). This maneuver was repeated until the stone was evacuated completely from the CBD to the duodenum.

bile duct was increased. The extended balloon advanced over the stiff type guide wire to the duodenum, and simultaneously saline flushing was done. Soon after, the stones were expelled into the duodenum by hydrostatic pressure. **d** Post-procedural cholangiography shows no residual stone in the common bile duct, the stones (*arrows*) in the duodenum and free flow of contrast media into the duodenum

Definitions and study end-points

On cholangiogram after BSR, complete clearance of biliary stones was defined as complete removal. Clinical success was defined as residual biliary stones, but no floating stone and improvement of symptoms.

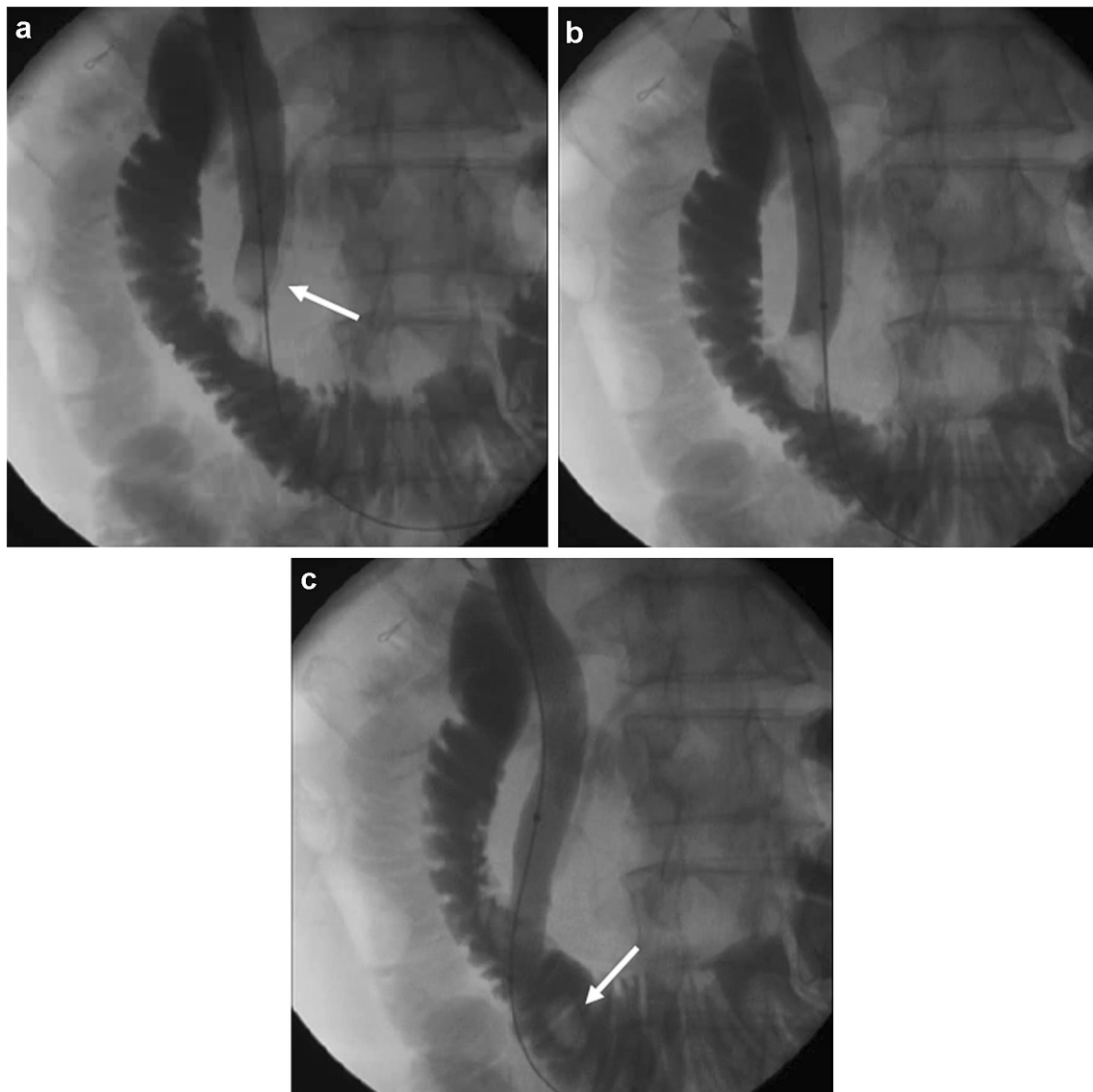


Fig. 3 A common bile duct stone was pushed into the duodenum using a balloon catheter. **a** Percutaneous transhepatic cholangiography shows a medium sized single stone (*arrow*) in the distal common bile duct. **b** After sphincteroplasty (not shown), the stone was

pushed into the duodenum through the sphincter using a balloon catheter over the stiff type guidewire. **c** The stone (*arrow*) is seen in the duodenum

Complications were classified as major and minor according to the guidelines of the Society of Interventional Radiology Standards of Practice Committee [11]. Minor complications were defined as those requiring no therapy or nominal therapy, including spontaneous improvement on conservative management. Major complications were defined as those requiring major additional therapy, those

Table 2 Percutaneous transhepatic biliary drainage route

PTBD route	Cases (<i>n</i> = 968)	%
Right	696	71.9
Left	223	23.0
Both	49	5.1

Table 3 Distribution of biliary stones

Location	Cases (<i>n</i> = 968)	%
Intrahepatic duct	553	57.1
Extrahepatic duct	154	15.9
Combined	261	27.0

Table 4 Procedure-related complications

Complication	Number
Major complication	0
Minor complication	86
Abdominal pain	37
Nausea/vomiting	21
Fever/chill (mild cholangitis)	18
Minimal hemobilia	10

necessitating an unplanned increase in the level of care or prolonged hospitalization, and those resulting in permanent adverse sequelae or death.

Results

PTBD route and distribution of biliary stones

The procedure was performed through the right PTBD route in 696 (71.9%) of 968 cases and the left PTBD route in 223 (23.0%) of 968 cases (Table 2). Bilateral PTBD routes was used in 49 cases (5.1%) (Table 2).

The distribution of biliary stones in the extrahepatic duct, intrahepatic duct and both extrahepatic and intrahepatic ducts were 553 cases (57.1%), 154 cases (15.9%), and 261 cases (27.0%), respectively (Table 3).

Technical results and clinical outcomes

Complete removal was achieved in 893 cases (92.3%). And clinical success was achieved in 68 cases (7.0%). The overall clinical success rate was 99.3%. The procedure failed in 7 cases (0.7%), and causes of failure were stone impaction (*n* = 5) and intrahepatic bile duct stricture (*n* = 2).

The total number of procedures for all 968 cases was 2807 procedures, and the mean number of procedures for a patient was 2.9 (varying between 1 and 9 procedures). The mean period of BSR, from insertion to removal of PTBD catheter, was 13.8 days (between 2 and 38 days). Sphincteroplasty was performed in 902 cases (93.2%). The balloon sphincteroplasty flushing technique was used in 829 cases (85.6%).

There were no major complications, such as bleeding, perforation or acute pancreatitis. Transient minor complications, such as nausea, vomiting, abdominal pain, mild cholangitis and minimal hemobilia, were seen after the procedure in 86 cases (8.9%) (Table 4). The symptoms resolved with conservative treatment within 1 or 2 days.

Discussion

Biliary stone disease constitutes the major etiology of non-malignant biliary obstructions. CBD stones and hepatolithiasis are common diseases in East Asia [12]. Treatment is mandatory in symptomatic patients and recommended in asymptomatic patients because serious complications, such as obstructive jaundice, cholangitis, and biliary sepsis can occur [13].

Multiple modalities including open and laparoscopic surgery, or endoscopic and percutaneous techniques, are available for the treatment of biliary stones. Since its introduction [14], EST and stone removal has become the first line of treatment for biliary stones [5]. However, this technique has several disadvantages and may not be successful in various clinical situations.

Recently, endoscopic papillary large balloon dilation (EPLBD) has been introduced for large stones [15]. In this technique, the biliary orifice is opened to a much greater extent than that in EST. However, this technique may lead to perforation; it is the most serious complication of this procedure [16]. And it is likely that the functionality of the sphincter of Oddi can be destroyed completely after EPLBD. The subsequent duodenobiliary reflux may therefore cause additional complications during long-term follow-up [17].

Percutaneous treatment of bile duct stones was initiated by Mondet in 1962, and was followed by the work of Mazzariello, who used specially designed forceps to remove the stones through the postoperative sinus tract [18]. The technique of expulsion of biliary stones into the duodenum with the use of catheters through the T-tube tract was introduced [19], and percutaneous transhepatic stone extraction and expulsion into the duodenum has been reported [20, 21].

Percutaneous balloon dilatation of the sphincter for stone removal was first reported in 1981 [22]. Since then, balloon dilatation of the sphincter of Oddi has widely been used for BSR [7, 8, 10, 23]. Clinical and experimental studies showed that balloon sphincteroplasty was not associated with stricture and dysfunction of the sphincter in the long term [24, 25]. Some studies noted that balloon sphincteroplasty was very safe, effective, and advantageous for the preservation of papillary function

[26, 27]. In our study, we performed balloon dilatation of the sphincter of Oddi in 902 cases (93.2%), and we did not experience any serious complications, such as acute pancreatitis.

The pushing technique for CBD stones using a balloon catheter has been reported, and the study presents that the pushing technique is safe and effective [10]. However, the pushing technique sometimes may result in failure, even in experienced hands. Major reasons for failure include a large stone, multiple stones, and dilated CBD [7, 10]. In addition, the pushing technique is not efficient for tiny or small fragmented stones.

We introduce the balloon sphincteroplasty flushing technique. Advantages of this technique are simple and simultaneous performance of sphincteroplasty and BSR without exchange, movement or reposition of the balloon catheter. In addition, this technique is suitable for most biliary stones, even multiple, very small or fragmented, and large stones, which are not possible to remove by the pushing technique. In this study, the balloon sphincteroplasty flushing technique was used in 829 cases (85.6%).

In our study, the rate of complete removal was 92.3%. Our result is in concordance with previous published reports [8–10, 26–28]. The clinical success rate was 99.3%. Complete removal of intrahepatic duct stones significantly helps to reduce the incidence of possible complications. Therefore, even in the case of an impacted stone, aggressive interventional procedures, aimed at complete removal, should be considered [29]. We tried to remove the residual intrahepatic duct stones repeatedly without giving up. And we achieved a high success rate compared with the previous published reports [26, 28]. This result is within the range of published results of EST and stone removal [12, 17].

On the other hand, the mean number of BSR procedures was 2.9 in our study, and our result reflects a higher number of procedures than the previous studies [10, 26–28]. This result leads to a prolonged hospital stay; however, we think that it is a factor in the high clinical success rate.

Various major and minor complications of BSR have been reported in the previous studies [10, 26–28]. In our large study, transient minor complications such as nausea, vomiting, abdominal pain, mild cholangitis and minimal hemobilia were seen in 8.9% of cases, and the symptoms were easily controlled by conservative treatment. There were no major complications and there was no procedure-related mortality.

Our study has several limitations. First, this is a non-randomized, retrospective study where all data were collected through a review of the medical and imaging records. Second, this study did not perform statistical analysis as a clinical observational study, but this study

included a large number of patients. Third, we did not compare with the results of endoscopic stone removal, including EST and ELPBD.

In conclusion, the results of this study show that BSR through the PTBD route using a combination of techniques, including balloon sphincteroplasty flushing, is a safe and effective treatment modality to remove biliary stones. In addition, the balloon sphincteroplasty flushing technique could be used as an effective and useful technique for BSR.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Ricciardi R, Islam S, Canete JJ, Arcand PL, Stoker ME. Effectiveness and long-term results of laparoscopic common bile duct exploration. *Surg Endosc*. 2003;17:19–22.
2. Freeman ML. Complications of endoscopic sphincterotomy: a review. *Endoscopy*. 1997;29:288–97.
3. 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.
4. 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.
5. Miller BM, Kozarek RA, Ryan JA Jr, Ball TJ, Traverso LW. Surgical versus endoscopic management of common bile duct stones. *Ann Surg*. 1988;207:135–41.
6. Neoptolemos JP, Carr-Locke DL, Fraser I, Fossard DP. The management of common bile duct calculi by endoscopic sphincterotomy in patients with gallbladders in situ. *Br J Surg*. 1984;71:69–71.
7. Ilgit ET, Gurel K, Onal B. Percutaneous management of bile duct stones. *Eur J Radiol*. 2002;43:237–45.
8. Ozcan N, Erdogan N, Baskol M. Common bile duct stones detected after cholecystectomy: advancement into the duodenum via the percutaneous route. *Cardiovasc Intervent Radiol*. 2003;26:150–3.
9. Park YS, Kim JH, Choi YW, Lee TH, Hwang CM, Cho YJ, et al. Percutaneous treatment of extrahepatic bile duct stones assisted by balloon sphincteroplasty and occlusion balloon. *Korean J Radiol*. 2005;6:235–40.
10. Gil S, de la Iglesia P, Verdu JF, de España F, Arenas J, Irurzun J. Effectiveness and safety of balloon dilation of the papilla and the use of an occlusion balloon for clearance of bile duct calculi. *Am J Roentgenol*. 2000;174:1455–60.
11. Sacks D, McClenny TE, Cardella JF, Lewis CA. Society of interventional radiology clinical practice guidelines. *J Vasc Interv Radiol*. 2003;14:S199–202.
12. Cheon YK, Cho YD, Moon JH, Lee JS, Shim CS. Evaluation of longterm results and recurrent factors after operative and nonoperative treatment for hepatolithiasis. *Surgery*. 2009;146:843–53.

13. Lee SK, Kim MH. Updates in the treatment of gallstones. *Expert Rev Gastroenterol Hepatol*. 2009;3:649–60.
14. Kawai K, Akasaka Y, Murakami K, Tada M, Koli Y. Endoscopic sphincterotomy of the ampulla of Vater. *Gastrointest Endosc*. 1974;20:148–51.
15. 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;57:156–9.
16. Park SJ, Kim JH, Hwang JC, Kim HG, Lee DH, Jeong S, et al. Factors predictive of adverse events following endoscopic papillary large balloon dilation: results from a multicenter series. *Dig Dis Sci*. 2013;58:1100–9.
17. Yasuda I, Itoi T. Recent advances in endoscopic management of difficult bile duct stones. *Dig Endosc*. 2013;25:376–85.
18. Mueller PR. Biliary interventions: a historical perspective. *Semin Intervent Radiol*. 1996;13:197–200.
19. Fennessy JJ, You KD. A method for the expulsion of stones retained in the common bile duct. *Am J Roentgenol*. 1970;110:256–9.
20. Perez MR, Oleaga JA, Freiman DB, McLean GL, Ring EJ. Removal of a distal common bile duct stone through percutaneous transhepatic catheterization. *Arch Surg*. 1979;114:107–9.
21. Dotter CT, Bilbao MK, Katon RM. Percutaneous transhepatic gallstone removal by needle tract. *Radiology*. 1979;133:242–3.
22. Centola CA, Jander HP, Stauffer A, Russinovich NA. Balloon dilatation of the papilla of Vater to allow biliary stone passage. *Am J Roentgenol*. 1981;136:613–4.
23. Meranze SG, Stein EJ, Burke DR, Hartz WH, McLean GK. Removal of retained common bile duct stones with angiographic occlusion balloons. *Am J Roentgenol*. 1986;146:383–5.
24. Mac Mathuna P, Siegenberg D, Gibbons D, Gorin D, O'Brien M, Afdhal NA, et al. The acute and long-term effect of balloon sphincteroplasty on papillary structure in pigs. *Gastrointest Endosc*. 1996;44:650–5.
25. 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.
26. Garcia-Garcia L, Lanciego C. Percutaneous treatment of biliary stones: sphincteroplasty and occlusion balloon for the clearance of bile duct calculi. *Am J Roentgenol*. 2004;182:663–70.
27. Garcia-Vila JH, Redondo-Ibanez M, Diaz-Ramon C. Balloon sphincteroplasty and transpapillary elimination of bile duct stones: 10 years' experience. *Am J Roentgenol*. 2004;182:1451–8.
28. Ozcan N, Kahriman G, Mavili E. Percutaneous transhepatic removal of bile duct stones: results of 261 patients. *Cardiovasc Intervent Radiol*. 2012;35:621–7.
29. Yoo SM, Shim HJ, Kwak BK, Lee HY, Lim SJ, Park HJ, et al. Residual intrahepatic stones after percutaneous biliary extraction: long-term follow up of complications. *J Korean Radiol Soc*. 1997;37:285–9.