Biliary sphincterotomy dilation for the extraction of difficult common bile duct stones

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ABSTRACT

Background and aim: endoscopic retrograde cholangiopancreatography (ERCP) with biliary sphincterotomy (BS) is the usual method for extracting common bile duct stones. However, following BS and by means of extraction balloons and Dormia baskets a complete bile duct clearance cannot be achieved in all cases. We present a study on the impact that hydrostatic balloon dilation of a previous BS (BSD) may have in the extraction rate of choledocholithiasis.

Patients and methods: a prospective study which included 91 consecutive patients diagnosed with choledocholithiasis who underwent ERCP. For stone removal, extraction balloons and Dormia baskets were used, and when necessary BSD was employed.

Results: complete bile duct clearance was achieved in 86/91 (94.5%) patients. BSD was used in 30 (33%) cases. In these cases, extraction was complete in 29/30 (97%); 23 (76%) patients in the BSD group had anatomic difficulties or bleeding disorders. The most frequently used hydrostatic balloon diameter was 15 mm (60%). There were 7 (7.6%) complications: two self-limited hemorrhage episodes in the BSD group and one episode of cholangitis, one of pancreatitis, and three of bleeding in the group in which BSD was not used.

Conclusions: BSD is a very valuable tool for extracting common bile duct stones. In our experience, there has been an increase in the extraction rate from 73% (Rev Esp Enferm Dig 2002; 94: 340-50) to 94.5% ($p = 0.0001$, OR 0.1, CI 0.05-0.45), with no increase in complications.

Key words: Choledocholithiasis. ERCP. Biliary sphincterotomy. Papilla of Vater dilation.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) with biliary sphincterotomy (BS) is since first introduced in 1974 (1,2) the most common method for extracting common bile duct stones (CBDSs). After BS, CBDSs are extracted using Fogarty-type balloons and Dormia baskets.

However, after a single session of ERCP-BS it is not usually possible to extract 100% of choledocholithiasis using only balloons and baskets (3,4). Failure is frequently associated with a disproportion between CBDS size and sphincterotomy, which generally cannot be greater than 15 mm. Retained choledocholithiasis after a first ERCP procedure entails new endoscopic sessions, a variety of different kinds of lithotripsy to reduce the size of stones, patient referral for surgery, or a palliative method such as biliary plastic stent insertion (5).

For some years (6) biliary sphincterotomy dilation (BSD) or sphincteroplasty with large diameter hydrostatic balloons (between 10-20 mm) has been used for the extraction of oversized CBDSs that cannot pass through the sphincterotomy orifice. We present a prospective study conducted over two years (2007 and 2008) on our initial experience with this technique to extract difficult choledocholithiasis. The results are compared with another previously published (3) series of ours, in which for CBDS extraction after BS only balloons and Dormia baskets were used.

PATIENTS AND METHODS

ERCP, bile duct access, and BS were performed according to techniques previously described (7). All BSD procedures were performed by a single endoscopist (JGC). For ERCP conscious sedation was employed by means of midazolam and petidine. Patients

gave their consent for the intervention after proper medical information. ERCP devices in our unit (sphincterotomes, cannulae, catheters, etc.) include so-called "short guidewire" systems. Guidewires for access and exchange in the bile duct have a maximum length of 260 cm. This means that guidewires slide within the instruments a very short distance, and are largely parallel (Fig. 1). Short guidewire systems or rapid exchange systems have many advantages, including a reduction of fluoroscopy time (8).

After CBDs were diagnosed at ERCP, a BS as large as possible was performed. Sometimes factors such as a bleeding disorder, hemodialysis, or a juxta-diverticular position of the papilla of Vater resulted in a small BS. Choledocholithiasis removal was attempted by means of balloons and Dormia baskets. In the event that CBDs could not be extracted because of disproportion between choledocholithiasis size and sphincterotomy extent, or of a sharpening of the distal bile duct portion, BSD was used.

Method for balloon dilation in a previous biliary sphincterotomy

During the study period only one balloon (Hurricane, Boston Scientific) capable of sliding over the guidewire inserted in the bile duct with the *rapid exchange system* was available; it has a maximum diameter of 10 mm (Fig. 1). Hydrostatic balloons have a usual diameter of 12 to 20 mm (CRE, Boston Scientific), and they are not compatible with the *rapid exchange system*, so they must be glided completely throughout the length of a guidewire. In these cases, in order not to lose biliary cannulation, a short guidewire of the *rapid exchange system*

Fig. 1. Extraction balloon for common bile duct stones. As shown, it slides over the guidewire inserted in the bile duct only for the first few centimeters. The rest of the device is in parallel with the guidewire.

was left in the bile duct and, in parallel, a biliary dilation balloon was inserted using a long guidewire (450 cm in length), as shown in figure 2.

Fig. 2. Dilation balloons 12 to 20 mm in diameter cannot glide through the short guidewire of the *rapid exchange system* (260 cm long). In these cases, the short guidewire was left to secure biliary access. Dilation balloons were inserted through a long guidewire 450 cm in length.

The choice of the diameter of an inflated balloon (10 to 20 mm) was done according to characteristics such as choledocholithiasis size and narrowing of distal bile duct. A mixture of water and radiographic contrast was used to inflate the balloon; in this way it could be observed fluoroscopically. In general, the balloon remained inflated for a minute. One of the most crucial aspects of BSD is the disappearance of the waist on the balloon in the narrowest part of the distal bile duct (Fig. 3). The complete sequence of the BSD procedure is shown in figure 4.

If after BSD the bile duct could not be cleansed of choledocholithiasis, a biliary plastic stent was inserted for biliary drainage and to prevent cholangitis. ERCP was terminated and other options were considered, mainly new ERCP sessions.

Fig. 3. a. Sharpening of the distal common bile duct secondary to intradiverticular papilla. b. The dilation balloon has been inflated up to 15 mm in diameter. The waist in the distal bile duct still remains. c. Finally, the balloon is inflated up to 18 mm and an adequate dilation is achieved.

Fig. 4. The whole procedure of biliary sphincterotomy dilation to extract difficult common bile duct stones. a. Magnetic resonance cholangiography showing two middle-sized common bile duct stones. b. The papilla of Vater is positioned at the bottom of a diverticulum. Biliary sphincterotomy cannot be enlarged enough to allow stone extraction. c. Sphincterotomy dilation by means of a hydrostatic balloon 18 mm in diameter. d. Common bile duct stones in the duodenum after extraction.

Patient follow-up after ERCP

All patients remained in hospital at least overnight after the endoscopic procedure to rule out possible complications (9). Complications were graded according to a classical prior consensus (10).

RESULTS

During the study period the total number of patients with CBDSs was 91 and BSD was used in 30 (33%) patients (Table I). A complete bile duct clearance was achieved in 86/91 (94.5%) of patients in the overall series, obviously including the successful 29/30 (97%) cases in which BSD was employed.

The group of patients in which BSD was applied consisted of 18 males (60%) and 12 women (40%), with a mean age of 74.6 years (range 41-97, SD12.3). The average duration of ERCP was 45.3 minutes (range 20-100, SD 21). For papillary dilation balloons between 10 and 18 mm in diameter were used. The most commonly employed diameter was 15 mm (60%). The mean diameter of stones was 13 mm (range 9-20, SD 3). The mean number of bile stones per patient was 3 (range 1-15, SD 3.5). Four patients had also a large amount of biliary sludge.

In total there were 7 (7.6%) complications. Three pancreatitis (all mild-moderate), three bleeding episodes requiring the transfusion of two red-cell packs, and one episode of cholangitis that was fatal in one patient (mortality 1/91 = 1% of the number of choledocholithiasis and 1/263 = 0, 3% of all ERCPs carried out in this period of time). Two bleeding events out of seven complications occurred in the BSD group (2/30 = 6.6%).

The BSD group showed the following risk factors (Table I): 9/30 (30%) had a bleeding disorder with prolonged INR that had not been properly corrected (hemodialysis, poor control of chronic treatment with warfarine, and high risk for embolism such as prosthetic heart valves). In 13 patients (43%) the papilla of Vater was located in a juxtadiverticular position or hidden in a diverticulum that precluded an adequate sphincterotomy extension (Fig. 4). Finally, one patient had a gastrectomy with Billroth II reconstruction in whom only a minimum sphincterotomy was performed.

When comparing the extraction rate of choledocholithiasis in this series of patients who underwent BSD (94.5%) with another series previously published also by us (3), in which only balloons and Dormia baskets were used for CBDS extraction, and in which an extraction rate of 73% was found, the difference is clearly significant in favor of the current series with BSD ($p = 0.0001$, OR 0.1, CI 0.05-0.45).

DISCUSSION

ERCP-BS is, since 1974, the usual method for choledocholithiasis extraction. However, up to 30% of times a disproportion between CBDS size and the extent of the endoscopic incision in the papilla of Vater (biliary sphincterotomy) makes it impossible to remove them (3,4). Sometimes, as in 13 (43%) of the cases reported in this study, the position of the papilla of Vater within a duodenal diverticulum makes it difficult to achieve a

Table I. Characteristics of patients undergoing endoscopic balloon dilation of a biliary sphincterotomy for extraction of challenging common bile duct stones

Patient	Age	Gender	Balloon diameter for sphincteroplasty (mm)	Number of CBDSS	Size of the biggest CBDS (mm)	ERCP time (minutes)	Observations
1	73	M	15	5	13	70	
2	71	M	18	2	19	20	Juxtadiverticular papilla, prolonged INR
3	51	M	15	1	14	35	
4	81	M	18	Profuse biliary sludge		100	Billroth II gastrectomy
5	73	M	15	2	16	60	Juxtadiverticular papilla
6*	83	F	18	1	20	40	Juxtadiverticular papilla
7	83	M	15	15	16	45	Prolonged INR
8	83	M	15	2	18	30	Juxtadiverticular papilla
9	71	M	10	3	14	90	Juxtadiverticular papilla
10	83	F	12	8	15	70	Juxtadiverticular papilla
11	78	M	12	2	13	35	Juxtadiverticular papilla
12	66	F	15	1	14	30	Prolonged INR, patient on hemodialysis
13	71	F	15	1	11	25	Intradiverticular papilla
14	72	M	12	Profuse biliary sludge		45	
15	91	M	15	1	10	30	Intradiverticular papilla
16	51	F	12	1	9	20	
17	80	F	10	1	10	20	Intradiverticular papilla
18	97	M	10	1	9	40	
19	71	F	15	2	11	40	Intradiverticular papilla
20	81	M	15	10	10	65	
21	82	F	15	2 + profuse biliary sludge		60	
22	80	M	15	1	20	70	
23	73	M	15	2 + profuse biliary sludge		40	
24	81	F	15	1	11	35	Prolonged INR
25	58	M	15	3	11	55	Prolonged INR
26	62	M	15	1	11	40	Juxtadiverticular papilla
27	81	F	15	1	11	25	Prolonged INR
28	41	F	12	2	9	20	Prolonged INR, T-tube in place
29	85	M	15	2	11	40	Prolonged INR
30**	87	M	18	4	11	65	Intradiverticular papilla, prolonged INR

*Complete extraction failure and hemorrhage after dilation. **Hemorrhage after dilation. M = male; F = female; INR = prothrombin time measure; CBDS = common bile duct stones or choledocholithiasis.

wide incision without risking to perforate the duodenum. On other occasions, as in 9 (30%) of our patients, a bleeding disorder limited the extension of BS to prevent bleeding.

Balloon dilation of the papilla was first performed and reported by Staritz in 1982 (11). This dilation was carried out without previously cutting the sphincter of Oddi (sphincterotomy), and was proposed as an alternative for choledocholithiasis removal instead of BS. In the 1990s this procedure was generalized. The main purpose was to preserve sphincter function, especially in younger patients. However, there were some deaths reported from severe pancreatitis as caused by dilating the papilla with no previous sphincterotomy (12). We also had a similar case (13).

Nevertheless, the results of papillary dilation or sphincteroplasty without prior BS are different in Eastern versus Western countries. For reasons not well known, papillary dilation without a prior incision of the papilla produces very few pancreatitis cases in Eastern patients.

A vast majority of communications on this topic come from Japan (14).

Papillary dilation after sphincterotomy seems to be a different procedure than papillary dilation without a prior incision. As BS separates the pancreatic and biliary orifices, perhaps the expansive force of the inflated balloon is directed toward the bile duct rather than toward the Wirsung, and the incidence and severity of acute pancreatitis after BSD does not seem to be a major complication (15).

Our study aimed to ascertain the impact that BSD may have in the rate of complete CBDS extraction. In 2002 we published a series (3) in which, after BS, only baskets and extraction balloons were used for cleaning the common bile duct. The results (73% of complete extraction) were similar to those of many other series in which only simple extraction devices were used. In turn, this was the usual practice in most hospitals in the second and even third level. The advent of BSD in the therapeutic arma-

mentarium of the biliopancreatic endoscopist represents, in our opinion, one of the most important milestones in ERCP. In our center, after using BSD, the rate of common bile duct cleaning became 94.5% in a single session.

BSD is also a simple procedure, which does not prolong mean procedural time (16) and has few complications. Among them, bleeding is most frequently reported (17). We have used this technique successfully in patients with coagulation disorders and/or taking warfarine, and/or even treated with hemodialysis, which poses a significant risk factor for bleeding after BS.

In our series we encountered two self-limited bleeding episodes that required two red cell packets for transfusion. As in other series (18), no pancreatitis occurred.

Our study, in a second-level hospital, adds to the growing scientific knowledge (19) that BSD is an excellent technique for the extraction of large and/or multiple bile stones from the common bile duct. It can be used in case of anatomical difficulties (juxta-diverticular papilla, sharpening of the distal bile duct...), coagulation disorders, and previous surgery (Billroth II gastrectomies). Furthermore, it is a safe technique that does not increase ERCP-BS complications, and can be performed satisfactorily in second-level hospitals.

REFERENCES

1. Classen M, Demling L. Endoskopische Sphinkterotomie der Papilla Vateri und Steinextraktion aus dem Ductus Choledochus. *Dtsch Med Wochenschr* 1974; 99: 496-7.
2. Kawai K, Akasaka Y, Murakami K, Tada M, Kohli Y, Nakajima M. Endoscopic sphincterotomy of the ampulla of Vater. *Gastrointest Endosc* 1974; 20: 148-51.
3. García-Cano Lizcano J, González Martín JA, Pérez Sola A, Morillas Ariño MJ. Success rate of complete extraction of common bile duct stones at first endoscopy attempt. *Rev Esp Enferm Dig* 2002; 94: 340-50.
4. García-Cano J. Success rate for complete choledocholithiasis extraction by means of endoscopic retrograde cholangiopancreatography. *Surg Endosc* 2004; 18: 1681-2.
5. García-Cano Lizcano J, González Martín JA, Taberna Arana L, Racionero M, Morillas Ariño MJ, Pérez Sola A. Prótesis biliares plásticas en cálculos coledocianos no extraíbles endoscópicamente. *Revista de la ACAD* 2003; 19: 3-6.
6. 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.
7. García-Cano J, González-Martín JA. Bile duct cannulation: success rates for various ERCP techniques and devices at a single institution. *Acta Gastroenterol Belg* 2006; 69: 261-7.
8. García-Cano J, Palomo Sánchez JC, Gómez Ruiz CJ. ERCP without fluoroscopy in a pregnant woman with a common bile duct stone. *Rev Esp Enferm Dig* 2008; 100: 100-1.
9. García-Cano Lizcano J, González Martín JA, Morillas Ariño J, Pérez Sola A. Complicaciones de la colangiopancreatografía retrógrada endoscópica. Estudio en una unidad pequeña de CPRE. *Rev Esp Enferm Dig* 2004; 96: 163-73.
10. 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.
11. Staritz M, Ewe K, Meyer zum Büschenfelde KH. Endoscopic papillary dilatation, a possible alternative to endoscopic papillotomy. *Lancet* 1982; 1: 1306-7.
12. Disario JA, Freeman ML, Bjorkman DJ, et al. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. *Gastroenterology* 2004; 127: 1291-9.
13. García-Cano J. Fatal pancreatitis after endoscopic balloon dilation for extraction of common bile duct stones in an 80-year-old woman. *Endoscopy* 2006; 38 :431.
14. Ito Y, Tsujino T, Togawa O, et al. Endoscopic papillary balloon dilation for the management of bile duct stones in patients 85 years of age and older. *Gastrointest Endosc* 2008; 68: 477-82.
15. Nathwani R, Banwait K, Salese L. Post-sphincterotomy transampullary balloon dilation is not associated with an increased incidence of post-ERCP pancreatitis. *Gastrointest Endosc* 2007; 65: AB221.
16. Espinel J, Pinedo E. Large balloon dilation for removal of bile duct stones. *Rev Esp Enferm Dig* 2008; 100: 632-6.
17. Attasaranya S, Sherman S. Balloon dilation of the papilla after sphincterotomy: rescue therapy for difficult bile duct stones. *Endoscopy* 2007; 39: 1023-5.
18. Attasaranya S, Cheon YK, Vittal H, et al. Large-diameter biliary orifice balloon dilation to aid in endoscopic bile duct stone removal: a multicenter series. *Gastrointest Endosc* 2008; 67: 1046-52.
19. Espinós JC, De la Serna C, González-Carro P, et al. Large balloon papillary dilation after endoscopic sphincterotomy: a one year nationwide multicenter study. *Endoscopy* 2008; 40(Supl. 1): A204.