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# Balloon Sphincteroplasty and Post-Sphincterotomy Balloon Dilation

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## Abstract

Endoscopic dilation of the ampulla of Vater, or endoscopic balloon sphincteroplasty, has been practiced by endoscopists for over 25 years. After initial widespread application of the technique, its use has decreased, largely due to concerns of a high incidence of pancreatitis resulting from the dilation. More recently, balloon sphincteroplasty following biliary sphincterotomy has been demonstrated to be safe and effective for management of complex choledocholithiasis. Additionally, there remains a role for endoscopic balloon sphincteroplasty without prior sphincterotomy for select individuals with coagulopathy or anatomy that may preclude endoscopic sphincterotomy.

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## Introduction

Endoscopic balloon sphincteroplasty, or ‘ampullary balloon dilation’ (ABD), was initially described by Staritz et al. [1] in 1983 for the treatment of common bile duct stones and papillary stenosis. Since then, many endoscopists have used this technique as an alternative to endoscopic sphincterotomy (ES). Advocates of the technique argue that ABD may provide advantages including sphincter preservation [2–4], avoiding long-term sequelae of sphincterotomy such as sphincter stenosis and cholangitis [5–6], and a decreased risk of bleeding [7–9] compared to ES. In 2004, however, a randomized controlled multicenter study was published reporting a significant increase in morbidity and mortality of ABD compared with ES [10]. As a result, the routine use of the technique was largely abandoned until later reports demonstrated that ABD in *combination with* ES was effective, with acceptable complication rates compared with ABD alone.

Over recent years, enthusiasm for post-sphincterotomy, transampullary balloon dilation (PSBD) has increased, particularly as an adjunctive therapeutic tool for the extraction of difficult bile duct stones. A list of indications for ABD and PSBD are presented in table 1. In this chapter we will describe the technique for performing PSBD safely, as well as discuss the current literature supporting its use.

**Table 1.** Indications for ABD and post-sphincterotomy balloon dilation

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Extraction of difficult bile duct stones
Alternative to ES in coagulopathic patients
Alternative to ES in high-risk anatomy: Roux-en-Y, periampullary diverticula, intradiverticular ampulla, choledochoenteric anastomosis
Papillary stenosis
Removal of biliary parasites (e.g. <i>Ascaris</i> )

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**Table 2.** Equipment suggested for post-sphincterotomy balloon dilation

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Therapeutic duodenoscope
Pull-type sphincterotome
Electrocautery generator
Guidewire(s): short (260 cm) and/or long (450 cm)
8 and 10 mm × 4 cm biliary dilation balloons
Controlled radial expansion esophageal balloons, sizes 10–12, 12–15, 15–18 mm
Extraction balloon(s)
Extraction basket(s)
Mechanical lithotripter

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## Patient Preparation

Patients are instructed to consume nothing by mouth for at least 6 h prior to endoscopic retrograde cholangiopancreatography (ERCP). As with any ERCP, a complete list of medications and allergies are ascertained. It is preferred that patients discontinue anti-platelet (e.g., aspirin, clopidogrel) therapy 1 week prior to the procedure unless the risk-benefit ratio favors continuing such medications (e.g. recent drug eluting coronary stent placement). Oral anticoagulant therapy is discontinued days prior to the procedure and ‘bridged’ with heparin if indicated. Written informed consent is obtained as per institution policy.

Intravenous access should be established, and appropriate sedation determined. There is no modification in sedation requirements when ABD is planned. Any non-fixed dental prosthetics should be removed prior to inserting the bite block and beginning sedation. We prefer the patient be prone on the fluoroscopy table with the head turned to the right.

## Accessories

A list of suggested instruments and accessories are presented in table 2. A standard therapeutic duodenoscope is used along with any pull-type sphincterotome and guidewire. For ampullary dilation we use variety of balloon diameters ranging from 8 mm × 4 cm biliary dilation balloons (Hurricane Rx, Boston Scientific, Natick, Mass., USA) to the larger controlled radial expansion esophageal dilation balloons up to 18 mm (Boston Scientific). When a wire-guided device is desired for dilation in excess of 10 mm, the wire-guided controlled radial expansion balloons may be used over a 450-cm long 0.035-in diameter guidewire. The wire that comes

prepackaged with the balloon is removed and the balloon is then backloaded over the biliary wire and advanced into the duct. For stone extraction following ABD, any extraction balloon or basket can be employed. A mechanical lithotripter should also be available.

## Technique

After preparing and sedating the patient, the major ampulla is identified in the second portion of the duodenum, and the bile duct is deeply cannulated with a sphincterotome and a 0.035-in guidewire (fig. 1). Cholangiography is performed to determine the goals of therapy.

### *Endoscopic Sphincterotomy and Post-Sphincterotomy Balloon Dilation*

We prefer this technique over ABD alone for the extraction of difficult bile duct stones and treatment of ampullary stenosis. We have found that PSBD can also facilitate stone extraction even for small stones (<10 mm) when the distal bile duct is strictured, has a small diameter, or is poorly compliant.

A complete biliary sphincterotomy is performed to the level of the transverse fold overlying the ampulla (fig. 2). We set the electrosurgical unit to the 'endocut' setting to optimize the amount of pure-cut and coagulation currents. Following sphincterotomy, the sphincterotome is exchanged over the wire for a dilation balloon (fig. 3). The initial balloon diameter is selected based primarily on the diameter of the bile duct and secondarily with consideration of the size of the stone. We most often start with a 10-mm (diameter) × 40-mm (length) balloon and perform a single inflation for 60 s. The balloon is positioned across the ampulla such that approximately one-half to two-thirds of the balloon is inside the common bile duct (fig. 4, 5), and the remainder endoscopically visible in the duodenum (fig. 6). After balloon dilation the papilla remains wide open (fig. 7). Stone extraction is then performed using either extraction balloons (which we prefer) or wire baskets (fig. 8). If unsuccessful, larger diameter balloon may be inflated and/or mechanical or electrohydraulic lithotripsy can be performed. Caution should be exercised against the routine use of larger sized balloons (>15 mm) given reports of severe complications and deaths with balloon sizes of 18–20 mm (see below).

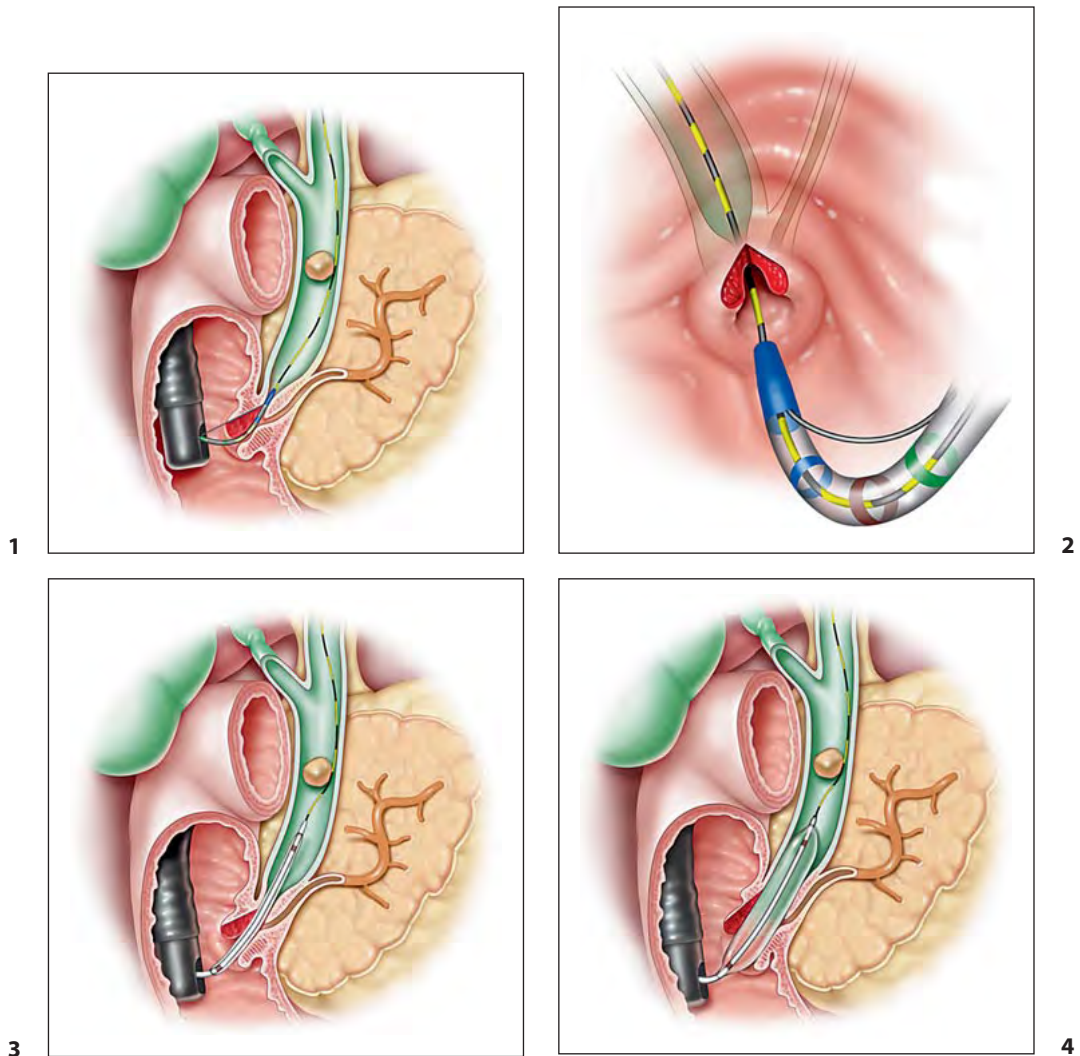
In patients with coagulopathy or altered or unfavorable anatomy, a limited sphincterotomy followed by PSBD can balance the risks of bleeding and pancreatitis with the effectiveness of the procedure (e.g. stone extraction).

### *Ampullary Balloon Dilation without Sphincterotomy*

In situations where sphincterotomy is either contraindicated or technically difficult, ABD can be performed without sphincterotomy. The principles and technique are similar to PSBD described above, though we start with a smaller balloon diameter (6 or 8 mm). Some authors advocate placement of a prophylactic pancreatic stent at the conclusion of the procedure to decrease the risk of post-dilation/post-ERCP pancreatitis; when pancreatic cannulation is readily obtained it is our practice to do so.

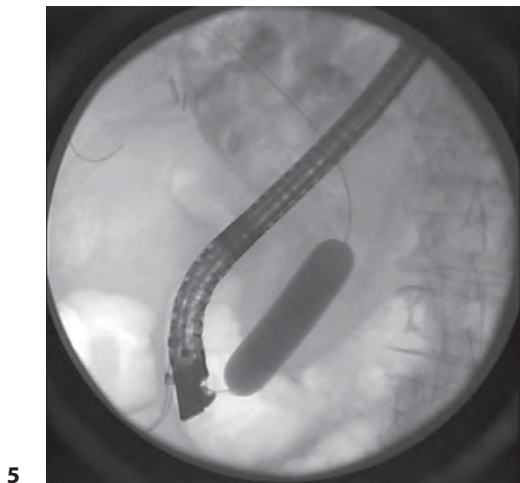
### *Complications*

The most common early complications of ampullary dilation are pancreatitis and bleeding. In a recent Cochrane review of 14 randomized controlled trials, pancreatitis occurred twice as often in patients treated with ABD compared with ES (8.6 vs. 4.3%) [11]. The same review showed that



**Fig. 1.** The bile duct is deeply cannulated with a sphincterotome and a 0.035-in guidewire.  
**Fig. 2.** A complete biliary sphincterotomy is performed to the level of the transverse fold overlying the ampulla.  
**Fig. 3.** The sphincterotome is exchanged an over-the-wire for a dilation balloon.  
**Fig. 4.** The balloon is positioned across the ampulla such that approximately one-half to two-thirds of the balloon is inside the common bile duct.

bleeding and infection were significantly less common in ABD than ES (0.1 vs. 4.8% and 2.5 vs. 5.0%, respectively). Perforation is rare (0.3–0.5%). Late ‘complications’ include recurrent choledocholithiasis (5.5%) and cholecystitis (1.3%), neither of which are likely to be directly related to ABD itself (most of these cases occurred in patients in whom the gallbladder was left in situ) [11]. There is less data available regarding complications after PSBD, with rates of pancreatitis and bleeding ranging from 0 to 8%.



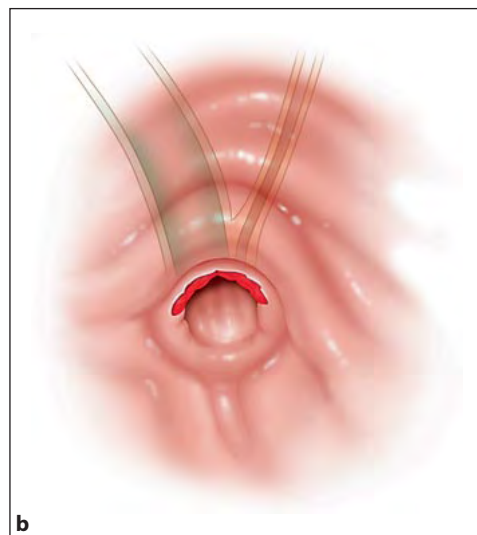
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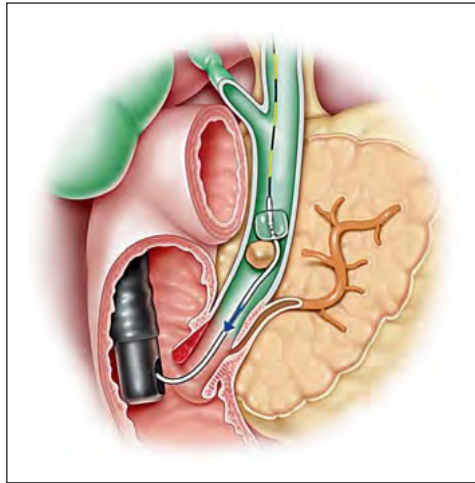
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**Fig. 5.** Fluoroscopic image of a completely inflated biliary dilation balloon is seen within the distal bile duct. Inflation of balloon with contrast agent allows for a nice determination of the dilation 'waist'.

**Fig. 6.** The balloon is positioned across the ampulla such that approximately one-half to two-thirds of the balloon is inside the common bile duct and the remainder endoscopically visible in the duodenum. Each inflation is held for 60 s.

**Fig. 7. a** Endoscopic view of PSBD. After PSBD, the enlarged opening of the biliary orifice is appreciated. Biliary epithelium of the distal CBD can be seen. We prefer this technique over ABD alone for the extraction of difficult bile duct stones and treatment of ampullary stenosis. We have found that PSBD can also facilitate stone extraction even for small stones (<10 mm) when the distal bile duct is strictured, has a small diameter, or is poorly compliant. **b** Schematic view of PSBD. The objective of balloon dilation after sphincterotomy is to have 'permanent' sphincterotomy, which facilitates the removal of large stones. In the absence of prior sphincterotomy, endoscopic removal of stones can result in more damage to the papillary region or even distal impaction.



**Fig. 8.** Stone extraction is then performed using either extraction balloons (which we prefer) or wire baskets.

## Outcomes

### *Preservation of Sphincter of Oddi Function*

Long-term manometric studies have shown that ES destroys physiologic sphincter function [12] and may therefore predispose the biliary tract to reflux of gastroduodenal contents and bacterial colonization, which theoretically could lead to higher rates of cholangitis, recurrent bile duct stones due to deconjugation of bilirubin by bacteria, and malignancy from chronic inflammation. At least three studies have demonstrated preservation of sphincter morphology or function following ABD compared with ES [2–4]. Though sphincter function is still present, basal and peak pressures as well as contraction frequency are lower following ABD in both the short- and long-term when compared with pre-procedure manometry.

Despite preservation of sphincter function and a relatively preserved barrier between the biliary system and the gastroduodenal environment, a Cochrane review found no differences in cholangitis, recurrent bile duct stones, or malignancy in long-term follow-up of patients randomized to either ABD or ES [11].

### *Extraction of Bile Duct Stones*

There were numerous randomized controlled studies reported between 1995 and 2005 comparing ABD with ES for the extraction of bile duct stones (table 3). The majority of these used a maximal balloon diameter of 8 mm. A recent Cochrane review demonstrated a lower likelihood of stone extraction during the first attempt with ABD, though a 2004 meta-analysis showed that overall success rates were equivalent [11, 13]. Additionally, mechanical lithotripsy was required more often in the ABD group than the ES group. Though ABD has been shown to have a significantly lower risk of bleeding than ES, the rate of pancreatitis is significantly increased. This higher risk of pancreatitis was highlighted in a well-publicized randomized, controlled multicenter study published in 2004 by DiSario et al. [10]. In this study, there was a significant increase in morbidity (18 vs. 3%) of ABD compared with ES, which was mainly accounted for by an increased incidence of mild to moderate pancreatitis (10 vs. 1%) and severe pancreatitis (5 vs. 0%). There were also 2 deaths in the ABD group, both due to complications of severe pancreatitis. Based on this study and the other available literature, the authors

**Table 3.** ABD compared with ES for bile duct stone extraction

Reference (first author)	Study design	n	Maximal balloon diameter mm	Success %		Complications %		Comments
				ABD	ES	ABD	ES	
May 1993 [24]	Retro	9	8	100	n/a	22	n/a	stones <8 mm
Mac Mathuna 1995 [25]	Retro	100	8	78	n/a	5	n/a	stones <12 mm
Minami 1995 [4]	RCT	40	8	100	100	10	10	stones <12 mm
Bergman 1997 [9]	RCT	202	8	89	91	17	24	1 death in ABD
Ochi 1999 [26]	RCT	110	8	93	98	2	6	stones <15 mm
Arnold 2001 [27]	RCT	60	8	77	100	30	17	ABD: 2 severe pancreatitis
Bergman 2001 [16]	RCT	34	8	88	78	19	39	all Billroth II patients
Yasuda 2001 [3]	RCT	70	8	100	100	6	9	
Fujita 2003 [28]	RCT	282	8	99	100	15	12	ABD: increased risk of pancreatitis
Vlavianos 2003 [29]	RCT	202	10	87	87	7	3	ABD: 1 severe pancreatitis
DiSario 2004 [10]	RCT	237	8	97	93	18	3	ABD: 2 deaths
Tanaka 2004 [30]	RCT	32	8	100	100	22	22	
Mugica 2007 [15]	Retro	53	10	98	n/a	13	n/a	high-risk anatomy
Tsujino 2007 [31]	Retro	1,000	8	96	n/a	9	n/a	

Retro = Retrospective cohort; RCT = randomized controlled trial.

concluded that balloon dilation of the sphincter of Oddi for stone extraction ‘should be avoided in routine practice’.

Because of these 2004 reports, endoscopists were reluctant to adopt balloon sphincteroplasty as a standard technique. There are a number of unique circumstances in which ABD without sphincterotomy should still be considered an appropriate option. In patients with coagulopathy, such as those with cirrhosis, ABD significantly decreases the risk of hemorrhage [7, 8, 14].

**Table 4.** PSBD compared with ES for bile duct stone extraction

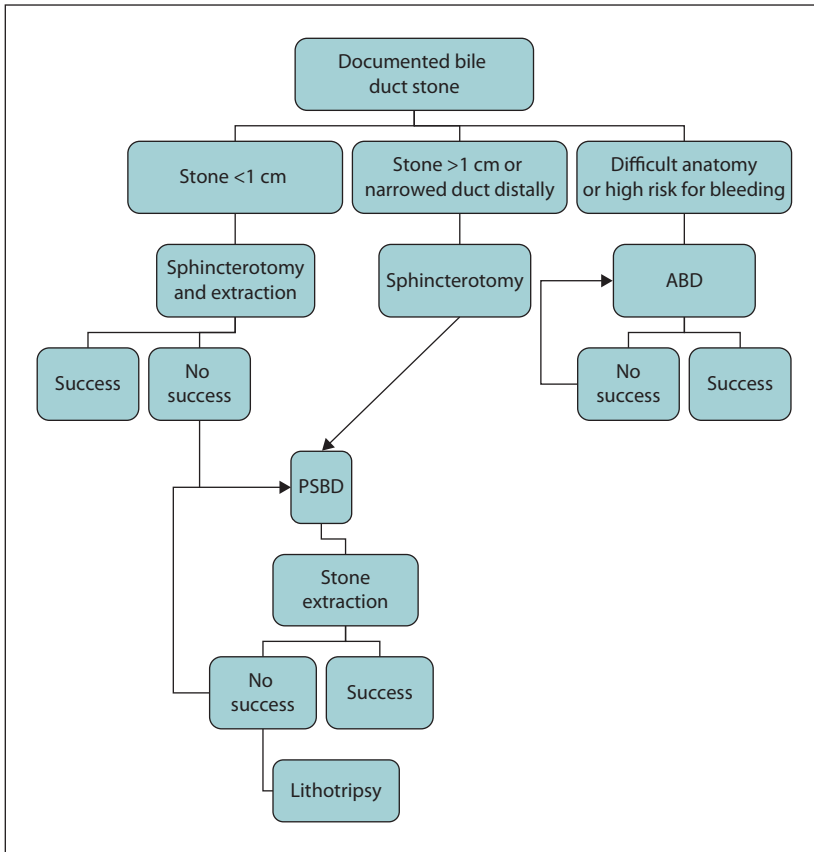
Report	Study design	n	Maximal balloon mm	Success %		Complications %		Comments
				PSBD	ES	PSBD	ES	
Ersoz 2003 [18]	Retro	58	20	88	n/a	16	n/a	all ES failures
Heo 2007 [19]	RCT	200	20	97	98	5	7	
Maydeo 2007 [32]	Prosp	60	10	95	n/a	8	n/a	all ES failures
Minami 2007 [33]	Prosp	88	20	99	n/a	5	n/a	limited ES
Yoo 2007 [20] <sup>1</sup>	Prosp	166	20	83	n/a	7	n/a	2 deaths
Attasaranya 2008 [21]	Retro	103	18	95	n/a	5.4	n/a	1 cystic duct perforation
Misra 2008 [34]	Retro	50	20	100	n/a	14	n/a	all ES failures
Kowalski 2009 [17]	Retro	69	15	86	n/a	5.8	n/a	1 perforation in Roux-en-Y

Retro = Retrospective cohort; Prosp = prospective, uncontrolled; RCT = randomized controlled trial.

<sup>1</sup> Abstract only.

In the most recent study of 21 coagulopathic patients with cirrhosis (mean INR 1.9, platelets 65,000/mm<sup>3</sup>), the incidence of procedure-related hemorrhage was 0% compared with 30% in a historical control group [8]. Another group of patients in whom ABD may have an acceptable risk-benefit ratio are those with anatomy that makes sphincterotomy either dangerous or technically difficult, e.g. Billroth II gastrectomy, periampullary diverticula, intradiverticular ampulla, or small ampulla [15, 16]. When possible, a limited sphincterotomy prior to dilation is preferred, however it is not always feasible.

The mechanisms leading to the high rates of pancreatitis following ABD, including severe and lethal cases, are not well understood. It has been hypothesized that an expanding balloon against an intact sphincter may cause transmural inflammation and edema which transiently obstructs the pancreatic os and flow of pancreatic secretions [2]. It has subsequently been postulated that performing either a limited or a full biliary sphincterotomy, directed away from the pancreas os, may limit the pressures transmitted toward the pancreatic duct, as the expanding balloon will track along the path of least resistance (i.e., toward the apex of the sphincterotomy) [17]. This technique of PSBD was first reported by Ersoz et al. [18] in 2003 in a group of 58 patients who had failed conventional ES for stone extraction. Esophageal dilating balloons were used up to a size of 20 mm. Success was achieved in 88% of patients, though an overall complication rate of 16% was reported. The majority of complications were due to bleeding; only 3% of patients developed pancreatitis.



**Fig. 9.** Algorithm for deciding when to employ PSBD for extraction of bile duct stones.

Over the past few years, enthusiasm for post-sphincterotomy balloon dilation has increased, with several additional reports demonstrating high success rates and a low incidence of complications in patients who fail initial standard ES and stone extraction (table 4). There has, however, been only one randomized controlled trial comparing PSBD with ES alone, which demonstrated equivalent efficacy and complication rates [19]. Caution is advised when using larger balloon sizes (18–20 mm), as 2 deaths and 1 cystic duct perforation were reported in two of the studies [20, 21]. Overall, the risk of hemorrhage following PSBD in recent reports has been variable, ranging from 0 to 8%.

#### *Less Common Indications*

There are few published reports describing ABD or PSBD for other indications. Limited data suggest PSBD may be useful for the treatment of papillary stenosis [17, 22]. There is a single case report describing ABD for the extraction of *Ascaris lumbricoides*; the author suggests ABD be used instead of ES for this purpose because of data suggesting ES as a risk factor for new or recurrent biliary ascariasis [23].

## Conclusion

Endoscopic sphincteroplasty via ABD should be considered as an alternative to ES in patients with difficult or high-risk anatomy, and in those who are at high risk for post-sphincterotomy hemorrhage. For the routine extraction of bile duct stones, however, we do not recommend ABD alone given the preponderance of data demonstrating an increased risk of pancreatitis in addition to several deaths. We advocate that ES with standard stone extraction technique be attempted first for stones <1 cm. If stone removal is unsuccessful, or for stones >1 cm, or in the relatively common scenario of narrowing or stricture of the distal CBD, ES followed by post-sphincterotomy balloon dilation should be considered as a safe and appropriate alternative (for suggested algorithm, see fig. 9). PSBD uses techniques that are familiar to the endoscopist and are easily applied. The growing body of evidence suggests that PSBD is both safe and effective, and we expect that more endoscopists will adopt PSBD as a useful technique for therapeutic interventions during ERCP.

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