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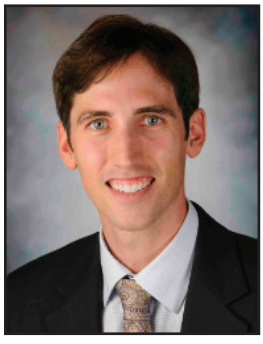
Too Large a Stone or Too Small an Outlet: A Case Series of Endoscopic Large Balloon Dilation Following Sphincterotomy for Large Biliary Stones



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In this case series of 38 patients, we review our experience with large balloon dilation to treat large (>1cm) common bile duct (CBD) stones not amenable to conventional extraction therapies. We evaluated for presence of sphincterotomy, extension or new sphincterotomy, stone size and number, use and method of lithotripsy if required, number of endoscopies required for CBD clearance, and procedure-related complications. We suggest that large balloon dilation in the presence of sphincterotomy (ESLBD) is a safe and effective method that gastroenterologists in the community may use to treat large stone choledocholithiasis.

INTRODUCTION

In up to 80% of cases with choledocholithiasis, endoscopic sphincterotomy (EST) with extraction balloon is sufficient for successful ductal clearance and is considered standard practice in the United States.[1] Historically, endoscopic balloon dilation (EBD, also known as sphincteroplasty) has been an alternative therapy to EST; however, it is not a first line treatment due to concern for post endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis with rates reported from 7-16%.[2,3]

Five to 15% of CBD stones are not amenable to standard extraction methods, often due to size.[4] Alternative techniques including intra-ductal stone fragmentation with laser, hydraulic, or mechanical lithotripsy may be necessary for clearance.

Large balloon dilation (12-20mm) with adjunctive sphincterotomy is an available treatment of large

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common bile duct stones. This technique has been termed "endoscopic sphincterotomy with large balloon dilation" (ESLBD). As the name implies, ESLBD involves a sphincterotomy followed by balloon dilation of the ampulla. The method seeks to combine the safety profile of EST with the lower risk of bleeding and perforation of EBD. At our institution, EBD is often combined with EST, with or without additional lithotripsy to treat common bile duct stones that have been refractory to standard retrieval methods.

METHODS

Patients

Records of over 450 ERCPs performed from January 2010 to February 2012 were reviewed. Adult patients (age >18) referred for retained bile duct stones that underwent sphincteroplasty with controlled radial expansion (CRE) balloon dilation were included in the series. Patients with CBD stones <1cm, a history of cholangiocarcinoma, or pancreatic duct stones were not included. Written informed consent was obtained from all patients or legal representatives.

Endoscopic Procedures

All procedures were performed under conscious sedation guided by the attending gastroenterologist or general anesthesia performed by an anesthesiologist. Upon successful cannulation of the CBD, a cholangiogram was performed to evaluate stone burden. Fluoroscopy was used in all procedures. If a new or extended sphincterotomy was required, EST was then performed in standard fashion between the 11 and 1 o'clock position. Incision extension proceeded along the longitudinal axis of the intramural segment of the CBD while paying careful attention to the depth of the incision. Following EST, CRE balloon dilation utilizing a 10-20 mm balloon was performed, with waist effacement and full inflation for 60 seconds. The balloon was filled with contrasted fluid for ease of fluoroscopic visualization. When necessary, lithotripsy (mechanical or laser) was performed for stone fragmentation. An extraction balloon was used to retrieve stones and stone remnants in all cases. Cholangiogram and/or cholangioscopy were performed prior to conclusion of all ERCPs to assess for complete ductal clearance of stones. If incomplete stone removal was observed, a plastic stent was placed for biliary decompression, and the patient was scheduled for a follow-up ERCP in 4-6 weeks. Any subsequent ERCPs were performed in a similar fashion as described above.

Table 1. Patient Characteristics

No. Patients	n	%
Male	9	24
Female	29	76
	median	**range**
Age	60	19-87
Prior Sphincterotomy	**n**	**%**
yes	32	84%
no	7	16%

Analysis

In addition to patient age and gender, the presence of a previously placed stent, evidence of a prior sphincterotomy, stone size and number, use and method of lithotripsy if required, evidence of ductal clearance on cholangiogram, total number of endoscopies required, and any procedure related complications were recorded. Stones were manually measured using Synapse (Fujifilm) comparing the side view endoscope as a reference for 11mm. Data were collected and summarized using Microsoft Excel v12.1.7.

RESULTS

A total of 38 patients met the criteria for review, 29 females (76%) and 9 males (24%) with a median age of 60 years old (range 19-87). Thirty-two patients (84%) had evidence of a prior sphincterotomy, 10 of whom underwent extension of the existing sphincterotomy. The remaining patients underwent primary sphincterotomy. Thirty patients (79%) had a stent in place on the first endoscopy. The mean size of the dominant stone was 17.3 mm (SD 7.8, range 12-52 mm) in the longest dimension.

Complete ductal clearance was accomplished

Table 2. Results

Stone Size	mean (mm)	standard deviation
all patients	17.3	7.8
requiring repeat endoscopy	23.7	12.1
required lithotripsy	21.4	10.4
without lithotripsy	14.3	2.7
Stone Number	**n**	**%**
1	18	47.4
2	9	23.7
3 or more	11	28.9
Procedures Required for Ductal Clearance		
1	27	71.1
2	9	23.7
3 or more	2	5.3
Need for Lithotripsy		
mechanical	2	5.3
laser	13	34.2
both	1	2.6
no lithotripsy	22	57.9
Serious Complications		
pancreatitis	1	2.6
bleeding	1	2.6
Minor Complications		
abdominal pain	2	5.3

with a single endoscopy in 27 patients (71%) and in 36 patients (95%) after the second session. One patient required 3 procedures for clearance, and another had not achieved clearance after 4 procedures at the time of data collection.

Lithotripsy of any kind was required in 16 cases (42%). Holmium laser lithotripsy was used in 13 of 16 cases (81%) and mechanical lithotripsy was used in 2 cases (13%). Mechanical lithotripsy was unsuccessfully attempted in one patient and followed by laser in the same procedure. In the remaining 22 cases (58%), no lithotripsy was required.

Serious complications were noted in 2/38 (5.3%) of patients. One patient developed post-ERCP pancreatitis that resolved after 3 days of hospitalization, IV fluids and pain management prior to discharge. Another patient required hospitalization for significant postoperative bleeding. Bleeding resolved spontaneously after the patient received a single blood transfusion. Two patients (5.3%) had postoperative abdominal pain without pancreatic lipase elevation and were hospitalized overnight then discharged the following day. There were no instances of perforation, cholangitis, or other complications.

DISCUSSION

Endoscopic balloon dilation was conceived in an effort to decrease risk of bleeding and perforation associated with EST, with the added benefit of preserving the sphincter of Oddi. Its proponents cite decreased rates of infection and cholecystitis compared to EST in the setting of an intact gallbladder.[5] However, EBD is known to have twofold-increased rate of post ERCP pancreatitis compared to EST.[6] In addition, Disario and colleagues published results of a randomized controlled trial testing EBD vs EST in 237 patients which was ended prematurely after 2 patients in the EBD group died from complications of severe pancreatitis.[7] For these reasons, EST is the dominant technique in clinical practice.

Large bile duct stones present a unique problem, however, as a sphincterotomy greater than 10-15mm may lead to increased risk of perforation. If the diameter of the stone exceeds this, it is unlikely to fit through the ampulla in one piece. Introduced by Ersoz et al., endoscopic sphincterotomy with large balloon dilation (ESLBD) has emerged as a treatment modality for large or difficult to manage common bile duct stones.[8] It is useful in the management of bile duct stones greater

than 10 mm, stones obstructed by distal bile duct strictures, or impacted stones.

By making a limited sphincterotomy, ESLBD reduces the risk of bleeding and perforation compared to EST alone while potentially maintaining a low rate of post ERCP pancreatitis. As compared to conventional endoscopic balloon dilation, ESLBD utilizes a larger caliber (12-20 mm) balloon with dilation limited to 2 to 3 mm larger than native duct diameter, creates pathway of lower resistance and larger orifice to facilitate the removal of larger stones. Since EST is performed first, the endoscopist is able to distinguish the biliary and pancreatic openings, reducing the risk of pancreatitis associated with EBD.[9]

Multiple groups have demonstrated successful clearance rates with similar low complication rates using this technique. In a multicenter analysis of 103 patients, Attasaranya et al. demonstrated successful stone clearance in 95% of cases utilizing the ESLBD technique, a 6% complication rate, and failure of complete stone clearance in only 5% of patients.[10] In 2007, Heo et al. published a trial randomizing 200 patients with bile duct stones (mean 15 mm) to ESLBD (12-20 balloon) or standard EST.[11] Overall, outcomes were similar between the two groups regarding successful stone removal (97% vs. 98%), large (>15 mm) stone removal (94.4% vs. 96.7%), utilization of mechanical lithotripsy (8% vs. 9%), and complication rates (5% vs. 7%). The first meta-analysis comparing ESLBD to EST was conducted by Feng et al. in 2012 and included 790 patients from seven randomized trials.[12] The authors conclude that ESLBD is no less effective and probably safer for removal of large CBD stones. Additionally, given lower risk of bleeding associated with dilation, numerous authors recommend its use in patients with underlying coagulopathy or the need for post-procedure anticoagulation.

This series adds to the body of literature that ESLBD is a safe and effective therapy. The mean stone size of 17.3mm stands among the largest published cohorts. In experienced hands, the occurrence of complications is low. Adjuvant lithotripsy may be required, but can often be avoided and occasionally an additional endoscopy is needed. Based on this series, we propose that endoscopists performing EST in the community should consider adding ESLBD to their toolset for the treatment of large common bile duct stones as it may reduce the need for tertiary center referral and the costs of duplicate procedures.

Future research should be directed at long-term outcomes of ESLBD. Further investigation is needed to compare outcomes of laser and mechanical lithotripsy in combination with ESLBD. Optimal balloon size, duration of dilation, and extent of sphincterotomy all require additional research to maximize the effectiveness of this very promising approach. ■

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