Antegrade Papillary Balloon Dilation for Extrahepatic Bile Duct Stone Clearance: Lessons Learned from Treating 300 Patients

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ABSTRACT

Purpose: To report the authors’ experience with percutaneous papillary balloon dilation for extrahepatic bile duct stone clearance to the duodenum in 300 patients.

Materials and Methods: During a 16-year period, 300 patients with extrahepatic bile duct stones who underwent papillary balloon dilation were retrospectively evaluated. Two hundred eighty-six patients with retained extrahepatic bile duct stones were treated through a postoperative drain placed during cholecystectomy; 245 patients were treated through a T-tube route and 41 through a transcystic approach. In the remaining 14 patients, the procedure was performed through a newly created percutaneous transhepatic route. Success rates, technical features, reasons for failure, and complications were evaluated.

Results: Biliary duct stone removal after papillary dilation was successful in 288 patients (96%). In 244 patients, the procedure was successfully completed on the first attempt. Forty-three patients needed two sessions, and in one patient it took three sessions. Stone diameters ranged from 4 mm to 18 mm (mean, 8 mm). Two hundred fourteen patients had four or fewer stones (mean, 2.3), and 86 patients had more than four (mean, 8.8; range, 5–25). Two patients required surgical intervention after loss of transcystic drainage, with subsequent development of peritonitis. During the follow-up period (mean, 26.6 months), no clinical or laboratory abnormalities were observed.

Conclusions: Percutaneous antegrade papillary balloon dilation and stone clearance is a safe and effective tool in removing common bile duct stones. Some technical issues should be considered to achieve complete stone removal while minimizing the incidence of complications.

The incidence of cholelithiasis is approximately 10% in the adult population (1). Calculi are found in the biliary tract in 17% of patients presenting with symptoms that suggest the presence of cholelithiasis (2). Several surgical and nonsurgical techniques that are used to remove bile duct stones have been described in the literature. Endoscopic retrograde cholangiopancreatography and sphincterotomy are the preferred methods for patients with retained stones after a surgical procedure (3). However, in patients with an indwelling T tube or a transcystic catheter, or in patients with whom endoscopic retrograde cholangiopancreatography with sphincterotomy is not recommended or has failed, a percutaneous treatment is a valuable alternative.

Nonsurgical antegrade percutaneous removal of bile duct stones was first performed by Mondet and Mazzariello (4) with the use of an articulated forceps. This technique was later improved by Burhenne and collaborators (5) with the introduction of the use of biliary baskets to retrieve the stones.

Ever since that time, different methods have been described, and they include balloon-assisted pushing of bile duct stones into the duodenum with or without associated papillary balloon dilation. This technique is effective and safe for this purpose (6–11). In the authors’ hospitals, most surgeons have preferred to resolve residual cholelithiasis by means of percutaneous anterograde sphincteroplasty as a result of its effectiveness and low associated complication rate.

The purpose of this retrospective study is to report and analyze our experience with this technique, describing technical aspects of the procedure, its effectiveness, and outcomes in 300 cases.

MATERIALS AND METHODS

This study includes the experience of interventional radiology and members of minimally invasive intervention departments of three hospitals with extensive experience in
biliary interventional procedures. These institutions are referral centers for patients with biliary conditions. All operators followed the same treatment protocol. Our hospitals do not require institutional review board approval for a retrospective study such as this one.

From April 1992 to April 2008, 300 patients with a mean age of 52 years (range, 16–95 y)—123 male and 177 female—underwent percutaneous treatment for residual choledocholithiasis. In 286 patients with retained bile duct stones, the procedure was performed through a transcholedochal T tube \( (n = 245) \) or a transcystic catheter \( (n = 41) \) placed during surgery. Two hundred two patients had open cholecystectomy with placement of a T tube and 84 patients had laparoscopic cholecystectomy \( (41 \) with a transcystic catheter and 43 with transcholedochal T tubes).

Fourteen cases were related to endoscopic failures or contraindication to endoscopic retrograde cholangiopancreatography with or without sphincterotomy. Ten patients had endoscopic failures. Four patients had previous gastric surgery, which precluded the endoscopic approach. These patients did not have postoperative drainage, and a percutaneous transhepatic approach was necessary to gain access to the biliary tract (Fig 1).

**Technique**

Cholangiography was performed to confirm number, size, and location of stones. All procedures were performed under mild sedation (intravenous midazolam) with analgesic agents (diclofenac or ketorolac) and atropine, and all patients received prophylactic broad-spectrum antibiotics (ampicillin/sulbactam). In our institutions, a single 0.5-mg dose of atropine is routinely used in biliary dilation procedures for its antispasmodic effect and for avoidance of nausea, vomiting, and vasovagal responses.

Among patients with T tubes placed during open cholecystectomy or laparoscopic cholecystectomy, all papillary dilation procedures were performed at least 21 days after cholecystectomy (mean, 24 d) after a mature tract had been obtained. Among patients with transcystic catheters, the percutaneous procedure was performed at least 28 days after laparoscopic cholecystectomy (mean, 30 d).

The procedure was started by exchanging the external catheter over a 145-cm, 0.035-inch guide wire with its soft tip placed distally in the biliary tree. After exchanging the external tube, a standard 6-F angiographic multipurpose or Cobra catheter (Cook, Bloomington, Indiana) was inserted over the guide wire. Passage across the papilla into the duodenum was made over a hydrophilic 0.035-inch angled guide wire (Terumo, Tokyo, Japan). When a distal position in the duodenum was reached, the hydrophilic guide wire was exchanged for a 145-cm Amplatz super-stiff guide wire (Boston Scientific, Natick, Massachusetts). The catheter was then pulled out. A peripheral balloon angioplasty catheter (Cook or Boston Scientific) was inserted over the stiff guide wire and positioned across the papilla. The balloon was gently inflated until the waist of the papillary sphincter disappeared; then the balloon was immediately deflated with negative pressure via a 20-mm syringe. The plunger was kept retracted with the use of a surgical clamp to create a vacuum.

Papillary dilation was performed with only one balloon catheter if the stone diameter was 12 mm or less. For larger stones (12–18 mm), two or three balloons of increasing diameters were sequentially used in the attempt to avoid the
possibility of lacerating the common bile duct or papilla. This sequential balloon dilation was always done within the same procedural session, even with large stones. Dilation maneuvers stopped when the balloon diameter was slightly larger (by 1–2 mm) than the largest stone diameter. The largest balloon used for papillary dilation was 20 mm. When calculi were located proximally or were pushed up into the intrahepatic tree during the balloon exchange maneuvers, an angled tapered angiographic catheter was used to pull the stones down into the distal common bile duct. Calculi were pushed into the duodenum with the combination of the angled catheter and the guide wire or over the guide wire with an angioplasty balloon inflated at low pressure (Fig 2).

In a subgroup of 21 patients with cystic catheters and an acute cystic/main bile duct angle, a distal junction, or a left cystic/main bile duct junction, only balloon dilation was performed, without pushing maneuvers (Fig 3).

In patients with percutaneous biliary drainage, papillary balloon dilation was performed 6–10 days (mean, 8 d) after tube implantation to allow tract maturation in accordance with described techniques. In this group of patients, 8-F vascular sheaths were used. These sheaths were not used in postsurgical tracts.

Regardless of the biliary tree access, at the end of the procedure, an 8-F pediatric feeding tube was inserted over the guide wire and the multiperforated tip was left in the main bile duct for external drainage. This tube was maintained in place for 5 days to allow drainage and prevent complications related to papillary edema.

Patients were hospitalized for the dilation procedure and discharged 24 hours later if there were no complications. Antibiotic agents (ampicillin/sulbactam) were given orally and discontinued after 48 hours. We considered that the intervention was successful when cholangiography showed that the biliary tree was free of residual stones and fragments and flow of contrast material through the papilla and into the duodenum was shown, without evidence of complications.

Patients were scheduled for a 5-day visit to evaluate the presence of remaining stones or fragments. If the biliary tree was free of calculi with easy flow of contrast material to the duodenum, the catheter was removed. If calculi remained, manual flushing of saline solution or contrast material through the catheter was performed to push stones or fragments in a transpapillary direction. The external catheter was then closed and left in place for 7–10 days in these cases. After this period of time, a follow-up cholangiogram was obtained; if residual calculi were not found, the external catheter was removed. If residual calculi were found, patients were hospitalized and a new dilation and pushing procedure, with a larger...
balloon, was performed. The follow-up process consisted of clinical examinations as well as liver function, amylase, and lipase laboratory tests.

RESULTS

Two hundred fourteen patients had one to four stones (mean, 2.3) and 86 patients had more than four stones (mean, 8.8; range, 5–25). Stone sizes ranged from 4 mm to 18 mm. The procedure was successful in 288 patients (96%).

In 244 patients, all calculi were removed after the first attempt. In 44 of these patients, the bile ducts were cleared after external tube closure. Seventeen of these patients were treated with only balloon dilation. Forty-three patients with more than eight stones needed a second attempt and one patient with 25 stones needed three procedures (Figs 4, 5).

Regarding the subgroup of 21 patients with cystic catheters in whom only balloon dilation was performed, the biliary tree was cleared of stones after external drainage tube closure in 17 patients, three underwent a second dilation procedure, and external drainage was lost before control cholangiography in one patient. In this latter case, magnetic resonance cholangiography was performed at 6-month follow-up and did not demonstrate residual stones. Mean procedural time was 37 minutes (range, 20–80 min; Table 1).

The procedure was well tolerated. Some patients reported mild pain in the upper abdomen during balloon sphincter dilation, which was controlled with intravenous analgesic agents.

Technical failure occurred in 12 patients related to severe tortuosity of the tract. In nine of these cases, the biliary tree could not be reached because of an excessively tortuous tract; seven of these patients had transcystic catheters and the other two had transcholedochal T tubes. Access to the biliary tree was lost in five patients after laparoscopic cholecystectomy before balloon dilation was performed. Three of them were treated immediately by endoscopic sphincterotomy but two developed bile peritonitis and were referred for surgical drainage and successful bile duct exploration.

In three patients with main bile duct dilation and multiple small calculi, pushing maneuvers were difficult and unsuccessful. In these patients, stone extraction was completed with an endoscopic retrograde procedure with the use of a Dormia basket and an extractor balloon, without previous sphincterotomy.

Mean follow-up period was 26.6 months (range, 6–36 mo). Early and long-term follow-up did not reveal clinical evidence of cholangitis, bleeding, or pancreatitis. Ninety-two percent of patients were followed up to evaluate outcome. Only mild transient increase of serum amylase levels occurred in 38% of patients, which resolved during the first 7 days after the procedure (Table 2).

DISCUSSION

Endoscopic sphincterotomy with subsequent calculus removal has been reported as a successful therapeutic tool in more than 90% of patients with common bile duct calculi. In institutions with experienced endoscopists, it is currently the treatment of choice. If this procedure is unsuccessful, percutaneous transhepatic removal offers an alternative to surgery (1,2). Intraoperative cholangiography is performed routinely in the authors’ institutions. In some cases, sur-
geons prefer to not resolve multiple or complex cholelithiasis during cholecystectomy to avoid extending operative time.

Percutaneous bile duct stone extraction via a postsurgical tract has an established role in the treatment of main bile duct stones. Multiple percutaneous techniques have been described, including transhepatic or postoperative tract approaches (6–11).

Percutaneous methods for common bile duct stone extraction—as described by Mazzariello (4) with the use of forceps or by Burhenne et al (5) with the use of Dormia baskets—are associated with a success rate of nearly 95% and only a 4% complication rate. However, these methods for percutaneous stones removal require a large tract diameter and tract dilation maneuvers to reach the stone.

Some other percutaneous techniques have also been described, including choledochoscopy with lithotripsy, but the devices required to perform these procedures are not universally available and their use is usually technically difficult. Passage of calculus through the ampulla of Vater without dilation with use of balloon occlusion pusher catheters or a modified Dormia basket with a soft tip have also been reported (7,11). These pushing maneuvers are difficult to perform because of the tendency of the occlusion balloon or baskets to buckle or deform if the papillary sphincter is not dilated, leading to higher rates of pancreatitis (12).

Reports of successful anterograde balloon dilation of the ampulla of Vater for the treatment of common bile duct calculi—through a T-tube tract, a transcystic catheter, or a transeptic approach—have also been described as safe and successful techniques (6,9–11,13–16).

Endoscopic papillary dilation was originally introduced by Staritz et al (17), and different groups have described this technique as an alternative to sphincterotomy (17–19). The relative advantage of endoscopic sphincteroplasty versus sphincterotomy is avoidance of bleeding and preservation of sphincter function. Dilation of the papilla preserves function in most cases, preventing chronic reflux of the duodenal contents into the biliary tree (20).

Endoscopic sphincteroplasty does not appear to have gained acceptance in the endoscopic community. Reluctance to use this technique is probably related to the belief that sphincter dilation carries a high risk of complications. The most frequent complication of retrograde papillary balloon dilation is pancreatitis, with reported incidences ranging from 4% to 35% (21–24).

Figure 4. The number of stones does not represent a contraindication for papillary dilation and bile duct clearance. A 92-year-old woman underwent cholecystectomy and choledochoenterostomy. The patient had severe cardiac arrhythmia, and surgery was interrupted. Attempted endoscopic sphincterotomy was unsuccessful. (a) Cholangiogram obtained 1 month after cholecystectomy shows multiple stones involving the hepatic, choledochal, and cystic ducts. (b) A 10-mm balloon was used to dilate the papilla. (c,d) Stones were pushed to the duodenum during three sessions; 25 calculi were counted. Stones are seen as filling defects in the duodenum. (e) Final cholangiogram shows complete clearance of calculi.
In the radiologic literature, antegrade papillary balloon dilation has been described with a low rate of pancreatitis, ranging from 0% to 1.5% (13–16). We consider the differences in the reported rates of such complications to be related to issues associated with the percutaneous steps performed during the interventional procedure. During antegrade techniques, the pancreatic duct is never cannulated. In patients with common bile duct stones, transient papillary edema occurs after papillary dilation, making an external drainage after the procedure mandatory to control papillary edema and diminishing the risk of cholangitis or pancreatitis. A third issue is that, with endoscopic papillary techniques, standardized balloon diameters are used (eg, 8 mm or 10 mm) and complementary maneuvers and baskets are frequently needed for stone removal. Percutaneous antegrade dilation techniques are performed with the use of balloons with diameters slightly larger (by 1–2 mm) than the largest stone diameter, avoiding the need for baskets and reducing procedural time. Also, with antegrade dilation maneuvers, the balloon is advanced over a transpapillary guide wire via Seldinger technique. This less traumatic approach is not usually used with endoscopic techniques. The aim of the present study was not to compare antegrade balloon sphincteroplasty versus endoscopic series of...
retrograde balloon dilation; however, reported complications rates between these two techniques are quite different (13–16,21–24).

In the present study, antegrade papillary dilation did not lead to serious complications such as acute pancreatitis, bleeding, or cholangitis, even with large balloons. Patients described transient discomfort during the time of sphincter dilation. Hence, we decided to inflate the balloon gently and slowly until the waist of the papillary sphincter disappeared; then, the balloon was rapidly deflated with negative pressure. Some investigators routinely keep the balloon inflated for 30–60 seconds and sometimes repeat inflation with the same balloon (13,14,16), but we do not. We do not keep the balloon inflated to avoid blocking the normal drainage of pancreatic ducts, and we do not repeat inflation with the same balloon.

In the present series of 300 patients, a high success rate of bile duct clearance was achieved (96%), which is similar to the results of other series of antegrade papillary balloon sphincteroplasty (13,14,16). Most of our treatment failures and complications were related to severe tortuosity and small transcystic catheters as well as poorly matured tracts and T-tube losses.

As we gained more experience, some procedural steps were modified, particularly in patients who had undergone laparoscopic cholecystectomy with cystic duct drainage, because many cystic ducts ran parallel, joining to the common bile duct at an acute angle or by its left side. In such conditions, it is very difficult to gain access to the proximal biliary tree and to push the stones. In these cases, pushing maneuvers can be very hazardous, and they were not attempted. In cases with difficult anatomy, the sphincter was dilated with a balloon diameter slightly larger than the largest stone a few days after the external postprocedure drain was closed. Stone-grasping forceps were not necessary. In most patients, a cholangiogram obtained 7–10 days after tube closure had revealed bile duct clearance. In only three of 21 patients treated exclusively with dilation via transcystic approach was a second procedure necessary. We highlight that caution must be taken, and one must not involve the cystic duct in balloon dilation when there is an unfavorable cystic/common bile duct junction.

The authors also emphasize that percutaneous anterograde sphincteroplasty can be safely and effectively performed in the presence of several and/or large bile duct stones. These conditions do not represent a contraindication for this technique. This procedure may also be performed through a transcystic approach, even with difficult anatomy. The “balloon-dilate and wait” technique introduces a useful alternative in the treatment of residual calculi, avoiding further maneuvers in many cases and making the procedure more cost-effective. However, if possible, we prefer to clear all stones during one procedure.

Even though a 96% success rate is high, our observations are in accordance with other authors in that percutaneous sphincteroplasty is not a cost-effective procedure, compared with the similar endoscopic procedure, and that cost can increase when transhepatic drainage is necessary (25). However, clinical effectiveness is not necessarily related to cost effectiveness. Balloon antegrade sphincteroplasty may be performed during the laparoscopic cholecystectomy by a transcystic duct approach (26). In our opinion, if this procedure is performed with the Seldinger technique, the over-the-wire balloon replacements appear cumbersome during laparoscopic bile duct exploration, without a mature tract and with pneumoperitoneum. However, the use of balloons without wire support across the papilla is hazardous and might cause pancreatitis to develop. In addition, devices employed in the percutaneous approach, like guide wires and balloons designed for angiographic procedures, are long and difficult to use during the laparoscopic surgery. In view of these issues, we are developing and trying short-shafted angled-tip balloon catheters that might be used during the laparoscopic procedure through a transcystic approach.

As mentioned earlier, transient papillary edema occurs after papillary dilation and an external postprocedure drainage is crucial, diminishing the risk of cholangitis or pancreatitis. This issue is particularly evident in cases of tiny biliary ducts in which the edema sometimes completely occludes the lumen of the papilla (27).

The present study demonstrates the effectiveness of the percutaneous antegrade technique, and describes some modifications of these techniques learned through the experience. The authors would like to promote the use of the antegrade papillary dilation technique during laparoscopic surgery through a transcystic approach. If this technique is used, contraindications to this access will be reduced (ie, ≤ 5 stones, stones ≤ 9 mm, anatomic variants of cystic tract).

Dilation of the cystic duct will not be necessary, as happens with the use of baskets. Particularly, the use of percutaneous techniques would avoid a less safe choledochal laparoscopic access or the requirement for residual calculi to be resolved in a second procedure after cholecystectomy, making the whole treatment more cost effective.

Further studies are necessary to evaluate if balloon dilation alone, without pushing maneuvers, might be as effective and safe for the treatment of retained common bile duct stones. The development of new devices could simplify the performance of this technique during laparoscopic cholecystectomy by a transcystic duct approach during the same treatment session.

REFERENCES