Percutaneous Management of Extrahepatic Bile Duct Stones by Papillary Balloon Dilation and Pushing Using an Occlusion Balloon

RENG-HONG WU¹,² MATT CHUNG-YU CHEN¹ SHIH-CHIN CHANG¹ WEN-SHENG TZENG¹,² JE-LUNG FUNG¹

Department of Radiology¹, Chi-Mei Medical Center
Department of Medical Imaging and Radiological Sciences², Central Taiwan University of Science and Technology

To report our experience of percutaneous elimination of extrahepatic bile duct stones by occlusion balloon pushing after papillary balloon dilation.

Between May 2006 and November 2007, sixteen patients were treated percutaneously for extrahepatic bile duct stones. Thirteen patients were treated via transhepatic route, one patient via T-tube route, one patient via transcystic duct drainage route, and one patient via transhepatic gallbladder drainage route. The procedure had two main steps. The first step was dilation of the papilla of common bile duct by an angioplasty balloon, and the second step was antegrade pushing the stones into duodenum using an occlusion balloon.

The diameter of extrahepatic bile duct stone was 9 ± 2.4 mm. The number of stone was 1.4 ± 0.9. Successful stone removal was achieved in 14 patients (87.5%). Twelve patients required one session for complete stone clearance and two patients required two sessions. Technical failure was noted in two patients. The reasons for failure were dilated lower inserted cystic duct in one patient and intolerable pain during dilation and pushing in the other patient. Seven patients felt epigastric pain after the procedure, which subsided within two days. There was no significant procedure related bleeding or clinical symptoms of acute pancreatitis.

The percutaneous papillary balloon dilation and stone-push is a simple, effective and safe technique for treatment of patient with extrahepatic bile duct stones.

The incidence of choledocholithiasis occurs in 15 to 20 percent of patients with gallstones in whom the stone pass into the common bile duct via cystic duct [1]. Yet in 10 percent of choledocholithiasis, the gallbladder is normal. In addition, approximately 5 percent of patients who have undergone a cholecystectomy were reported to have a retained or recurrent stone [1].

The endoscopic management of extrahepatic bile duct stones is widely accepted because of its high successful rate and low complication rate [2]. However, the procedure has limitations especially when there is difficult anatomy, post-Billroth II reconstruction, patient’s intolerance, endoscopic phobia, or less experienced endoscopist. In these patients, a percutaneous management of extrahepatic bile duct stones is an alternative before resorting to surgery.

Percutaneous managements of extrahepatic bile duct stones can be achieved by using a Dormia basket or choledochoscopic lithotomy via a transhepatic route or T-tube route [3, 4, 5, 6]. By using Dormia basket, the successful rate has been shown to be 95%, and the complication rates have been reported to be around 4% [4, 5]. However, these procedures need a large tract and the waiting time for tract maturation is approximately 4-6 weeks [3, 7]. In addition, there are limitations on removal of the retained bile duct stone via T-tube tract, such as the tract should be perpendicular to common bile duct (CBD) to facilitate the stone removal [8].

Centola et al. [9] in 1981 described a patient in
whom they performed percutaneous papillary balloon dilation and flushed a small retained stone into the duodenum. Fataar et al. [10] in 1982 reported another case in which they dilated the papilla with a 5-mm balloon and pushed the stone with the same balloon. The advantages of percutaneous biliary balloon dilation and stone-push are that it can be performed via a small tract and does not require a tract maturation time. Here, we will present our experience on percutaneous management of extrahepatic bile duct stones.

MATERIALS AND METHODS

A consecutive series of 16 patients (7 male and 9 female, age 29-81, mean 61) with extrahepatic bile duct stones underwent percutaneous papillary balloon dilation and stone-push in our hospital between May 2006 and November 2007.

There were four different external cholangiodrainage routes being used in our cases before the stone-push procedure. Percutaneous transhepatic cholangiodrainage (PTCD) was performed in 13 patients. Eleven of these patients received PTCD due to acute biliary tract infection (69%). The indications of PTCD for the other two patients were failure of endoscopy (6%) and T-tube dislodgement with bile peritonitis (6%). One patient had stone-push via T-tube tract after recent cholecystectomy (6%). The reason for subsequent stone-push was that the choledochoscopy was unsuccessful in removing the CBD stone due to the acute angle between T-tube tract and distal CBD. One patient had transcystic duct drainage after recent cholecystectomy (6%) and the other patient had percutaneous transhepatic gallbladder drainage (PTGBD) (6%). In these patients, there were no symptoms or signs of acute biliary tree infection, or the infection had been controlled. The coagulopathy had been corrected to normal (international normalized ratio <1.5 and the platelet >50000 /uL). A cholangiogram was obtained to identify number and size of the biliary stones.

Written informed consent was obtained before the procedure. The patient was positioned in supine. The analgesics were intra-bile duct injection of 2% lidocaine 5-10 mL combined with intravenous morphine 3-5 mg or fentanyl 50-150 ug. First, the cholangiogram was repeated to identify the location of stones. The external drainage tube was changed to an 8 Fr. vascular introducer (10 cm, Radifocus Introducer II; Terumo, Tokyo, Japan). A hydrophilic guidewire (150 cm, Radifocus Guidewire; Terumo, Tokyo, Japan) was used to canalize the papilla of CBD and put it into duodenum. Then the guidewire was changed to a superstiff 145 cm guidewire (Boston Scientific, FL, and USA) by using a 4 Fr angiocatheter (65 cm, RC1, Super Torque; Cordis, Miami, USA). Next an angioplasty balloon (4 cm balloon length, Wanda; Boston Scientific, Galway, Ireland) was used to dilate the papilla twice and it was kept 30-60 seconds during dilation (usually, 4 atm is sufficient to open the papilla). The size of balloon was equal to or slightly larger than the short axis diameter of the largest stone. Then the balloon catheter was slowly withdrawn so that it did not pull the stone into intrahepatic duct or proximal to the entrance of introducer (when approach via T-tube or cystic duct). If the stone was in the intrahepatic duct or proximal to the entrance of introducer, spontaneous migration of stone to favorable location might occur after the sphincteroplasty or aspiration at distal CBD using an angiocatherter. Otherwise, the stone was being pulled down by using an occlusion balloon. Finally a 5 French-40 cm occlusion balloon catheter (5 mm or 9 mm, Python; Applied Medical, Rancho Santa Margarita, USA) was used to push the stone into duodenum. The size of occlusion balloon was slightly smaller than the diameter of CBD. During pushing, we could decrease the inflation volume of occlusion balloon to make it pass the papilla easier. The whole process was repeated 2 to 3 times after the visible stones were eliminated. During the procedure, introduction of air into bile duct should be avoided, because the air bubbles could mimic the stones in CBD. After the stones were eliminated, the introducer was exchanged for a prepapillary safety catheter (10 French Cliny Cholangio Entero Tube; Create Medic Co. LTD, Yokohama, Japan). A cholangiogram was repeated several days later. If there was residual bile duct stone, the stone-push procedure was repeated. If there was no residual stone and free passage of contrast medium from bile duct to duodenum was observed, the external drainage catheter was removed by clinician’s request. The procedures described above were illustrated in Fig. 1. Successful stone removal was defined as no more filling defect in the bile duct shown on follow-up cholangiogram.

All computations were done with the Statistical Package for Social Sciences (SPSS), version 10 (SPSS, Chicago, IL, USA). Data are reported as mean ± standard deviation in text.
RESULTS

There were no consequent complications associated with the procedure of PTCD or PTGBD. The size of bile duct stone was $9 \pm 2.4$ mm (range, 5-13 mm). The number of stone was $1.4 \pm 0.9$ (range, 1-4) in each patient. The size of angioplasty balloon was $9.7 \pm 1.7$ mm (range, 7-12 mm). The diameter of CBD before drainage was $14.1 \pm 4.3$ mm (range, 7-21 mm), and before stone-push was $10.7 \pm 2.1$ mm (range, 7-14 mm). The time spent from the initial cholangiogram to a new external catheter intubation was $30.9 \pm 15.5$ minutes (range, 13-77 min). The waiting time between external drainage tract created to stone removed was $17 \pm 11.8$ days (range, 3-36 days).

Successful stone removal was achieved in 14 patients (87.5%). The procedure in one patient was unsuccessful because of tortuous CBD and lower inserted cystic duct (the cystic duct was dilated and its orifice was very close to papilla) (Fig. 2). The stones escaped into the cystic duct during pushing by an occlusion balloon. This patient received conservative treatment after this procedure due to old age. Unfortunately, dislodgement of external drainage occurred four months later with no clinical symptoms of biliary tree obstruction or infection since that accident. The procedure in the other patient with a 12 mm stone was also unsuccessful because of intolerable pain during both balloon dilation and occlusion balloon pushing, despite of using analge-
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In addition, the lower half of CBD was obviously narrowed in this patient. She suffered from severe pain during dilating this portion of CBD. Finally, she received open choledocholithotomy to remove the stone. In 14 of the 16 patients (87.5%) only one session was needed to clear the extrahepatic bile duct stones. The other two patients took two sessions to clear the CBD stones because residual stones were found on follow-up cholangiogram. Some amorphous or cylindrical blood clots were found in distal CBD after papillary balloon dilation or stone-push in three patients (19%) (Fig. 3d). These blood clots could mimic CBD stones. However there is no hemobilia or tarry stool and no blood transfusion was required during follow-up period.

After the interventional procedure, 9 of 16 patients (56%) felt epigastric pain that was well controlled by non-steroid anti-inflammatory drugs or narcotics, and the symptom subsided within two days. On the following day after the procedure, serum amylase or lipase was checked in 7 patients. Among them, elevated serum amylase was noted in one patient (from 265 U/L to 935 U/L). Yet, there was no epigastric pain being complained. No clinical symptom of acute pancreatitis was manifested and no further treatment was needed in all patients.

**DISCUSSION**

Choledocholithiasis is a common disease and may present as various clinical manifestations. The management of extrahepatic bile duct stones includes nonsurgical and surgical approaches. Endoscopic stone removal is the most popular choice of management for extrahepatic bile duct stones. However, in certain situations, the endoscopic management is not the best solution. These include difficult anatomy, post-Billroth II reconstruction, patient’s intolerance or endoscopic phobia. If a tract has been created between the skin and bile duct, percutaneous management of the stones is an alternative way to approach.

In this study, we used the percutaneous biliary balloon dilation to manage extrahepatic bile duct stones. The advantages of percutaneous management are that it can be performed via a small tract and does not require a tract maturation time. In our study, the waiting period between PTCD and stone-push was as short as 3 days and without significant complications such as hemorrhage or bile peritonitis after the procedure. However, the clinical condition of biliary tree infection must be controlled before patient undergoing this procedure.

The successful rate of stone clearance is 87.5% in our study. In the literature, successful rate is from 93 to 100% [11-15]. There are two failure cases in our study. In one case, the failure is due to the stone escaped into lower inserted cystic duct during push. In such condition, a mechanical fragmentation device such as Dormia basket [15] or electric hydraulic lithotripsy can be used to fragment the stones after papillary dilation. Small stones and fragments of about 3 mm in diameter frequently pass spontaneously through the papilla to duodenum [4]. The other failed procedure is due to stone being impacted at middle portion of CBD, causing intractable pain during dilation and stone-push. The cause of stone impaction probably is related to spasm of
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One study suggested administration of 1 mg glucagon to relax the sphincter of Oddi before the procedure was effective for the management of CBD spasm [13].

Regarding pain control during the procedure, in addition to intra-bile duct injection of lidocaine [11], we also used morphine in few initial patients. However, patients still complained of pain. We then changed to fentanyl, and the pain became more tolerable. Unfortunately, one patient in our study still could not tolerate the discomfort despite of using lidocaine and fentanyl. In the future, general anesthesia may be necessary for such patient.

There are three reasons, reported in the literature, contributing to the failure of stone elimination procedure. One reason is marked dilation of CBD, the second reason is large stone, and the other is tortuous T-tube tract [15]. Presently, the literature reported that CBD larger than 15mm [11] and 30mm [12] could contribute to failure. The marked dilated CBD could be a problem when pushing the stone over a guidewire. The stone could be easily escaped. According to our data, the diameter of CBD was reduced after adequate drainage. Therefore, it seems the stone-push procedure should be delayed for a couple of days for the cases with marked CBD dilation.

There is no major complication in our study. A few patients suffered from epigastric discomfort after the procedure. The symptoms were well controlled by non-steroid anti-inflammatory drugs or narcotics and most of the symptoms were subsided one day later. Transient elevation of serum level of amylase or lipase was noted in one case, but there was no clinical evidence of acute pancreatitis. Our results were similar to those of previous studies [11, 12]. Procedure-related acute pancreatitis was reported with an incidence around 1% [13, 15].

Little blood clot in CBD was observed in our study with an incidence of 19%, which may interfere the identification of CBD stone during stone-push.

![Figure 3](image_url)

Figure 3. 74-year-old male who had undergone PTGBD because of cholangitis. a. The cholangiogram shows spiral course of cystic duct. b. Successful catheterization from gallbladder to duodenum by using a combination of 4 French angiocatheter and a 0.021 inch soft-tip microguidewire. There was no significant vasovagal reflex during manipulation. c. A 7 mm stone (arrow) was pushing by occlusion balloon. d. The follow-up cholangiogram shows amorphous blood clot in CBD. The papilla was patent. These blood clots were resolved on following cholangiogram.
Compared with other studies which reported the incidence of blood clot in CBD ranging from 4% [13] to 41% [14], the occurrence of blood clot in our study seemed compatible with other studies.

The limitation of sphincteroplasty and stone elimination using an occlusion balloon is related to the stone size. In order to have the stone passing the papilla, the angioplasty balloon should be slightly larger than the short axis diameter of the largest stone. With larger balloon, it could cause more injury to papilla. At present, the literature showed that the largest stone size which could be managed by occlusion balloon ranged from 10 to 22 mm [11, 12, 14]. In our study, the stone as large as 13 mm can be managed. To avoid unnecessary injury to the papilla, Garcia-Garcia et al. showed that stones as large as 20 mm could be eliminated after 10 or 12 mm balloon sphincteroplasty when combined with mechanical fragmentation device [15].

Another limitation for percutaneous method to treat CBD stone is that it needs “a percutaneous route”. In the retained CBD stone after cholecystectomy, a T-tube or a transcystic duct drainage usually exists. For such patient, our technique is feasible and reasonable. However, for the cases with CBD stone obstruction, endoscopic method could provide one stop shop. It could relieve the obstruction and remove the stone just in the same examination, regardless of the various degree of biliary tree dilatation. However, if CBD obstruction cannot be managed by endoscopic approach or if the endoscopist is unavailable, PTCD and following sphincteroplasty and stone-push might be a good alternative for selective cases.

Although there is no direct comparison between endoscopic sphincterotomy (EST) and percutaneous sphincteroplasty plus stone-push in the literature, the EST has higher risk of bleeding than with endoscopic papillary balloon dilation (EPBD) [16, 17]. The EPBD preserve more function of sphincter of Oddi than EST does [16, 18, 19] and may prevent long-term complications and reduce the risk of papillary stenosis, cholangitis and cholecystitis [16, 20]. In an animal study, there is no muscular tear of sphincter after 8 mm balloon dilation [21]. This is an important consideration in treatment of young patient. EPBD is associated with an increased risk of pancreatitis due to the circumferential trauma to biliary sphincter (EPBD: 7.4% versus EST: 4.3%) [2]. The percutaneous papillary balloon dilation also shows low incidence of pancreatitis [11-14]. One reason is less manipulation on pancreatic duct as compared to endoscopic management, and the other reason is a safety catheter for external biliary drainage after stone elimination [13].

In order to perform sphincteroplasty and stone-push, the approach of PTCD through right hepatic lobe is preferable. In anatomy, the course of CBD is convex to left side. There is a simple inverted “C-shape” route if PTCD is performed via right hepatic lobe. However, when the approach is performed via left hepatic lobe, the route became more complex, as a “sigmoid-shape”. This may increase technical difficulty during pushing the stone, especially when CBD is dilated. In 11 of 12 patients in our study, the PTCD route was done via right hepatic lobe. The only patient whose PTCD approach via left hepatic lobe was one of the two failures. The left hepatic route made the stone more easily escape into dilated lower inserted cystic duct. Despite of increased technical difficulty, there is no increased failure rate reported in the literature with left hepatic lobe approach [13].

In conclusion, the percutaneous papillary balloon dilation and stone-push is a simple, effective and safe technique for treatment of patient with extrahepatic bile duct stones.

#### REFERENCE

經皮利有用氣球擴張乳頭部以及使用阻塞氣球將結石推入十二指腸來處理肝外膽管結石

吳仁宏 1,2   陳烱毓 1   張世欽 1   曾文盛 1,2   方瑞隆 1

奇美醫學中心 放射診斷科 1
中臺科技大学 醫學影像暨放射科學系 2

描述藉由經皮的方式利有用氣球擴張乳頭部以及使用阻塞氣球將結石推入十二指腸來處理肝外膽管結石。

從民國九十五年五月到九十六年十一月總共有十六例病患藉由經皮的方式來處理肝外膽管結石，其中十三例病患經由穿肝的路徑、一例經由 T 形造瘻管、一例經由膽囊管引流路徑以及一例經由穿肝膽囊引流管路徑。此技術主要分為兩大步驟：一為使用血管成形術之氣球擴張乳頭部；其次為使用阻塞氣球順勢將結石推入十二指腸。

結石大小平均為 9 ± 2.4 毫米，每位病患的結石數目平均為 1.4 ± 0.9 颗。14 例病患之結石有成功移除，其中 12 例僅需施行一次手術；另外兩例則施行了二次手術。手術失敗的原因包含擴張的低位膽囊管以及無法忍受手術的疼痛。術後總共有七例發生上腹痛的症狀，但其症狀均在兩天內緩解。並沒有明顯的出血或是急性胰臟炎的發生。

經皮利有用氣球擴張乳頭部以及使用阻塞氣球推石術為一簡單、有效且安全的手術，可以用來處理肝外膽管結石的病患。