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# Percutaneous Treatment of Common Bile Duct Stones: Results and Complications in 110 Consecutive Patients

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#### **Key Words**

 $\label{eq:Bile} \begin{array}{l} \text{Bile ducts} \cdot \text{Choledocholithiasis} \cdot \text{Interventional procedures} \cdot \\ \text{Therapy} \end{array}$ 

### Abstract

Background/Aims: Choledocholithiasis is a common complication of cholecystolithiasis, occurring in 15-20% of patients who have gallbladder stones. Endoscopic retrograde cholangio-pancreatography is the standard treatment. When this is not possible or not feasible, percutaneous transhepatic stone removal is an alternative treatment. In this retrospective study, we analyze 110 patients who were treated with percutaneous transhepatic removal of Common Bile Duct (CBD) stones. Patients and Methods: Between March 1998 and September 2013 110 patients (61 men, 49 women; aged 14–96, mean age 69.7 years) with confirmed bile duct stones were included. PTC was done using ultrasound and fluoroscopy. Balloon dilatation of the papilla was done with 8-12 mm balloons. If stone size exceeded 10 mm, mechanical lithotripsy was performed. Stones were then removed by percutaneous extraction or evacuation into the duodenum. *Results:* In 104 patients (104/110; 94.5%) total stone clearance of the CBD was achieved. A total of 12 complications occurred (10.9%), graded with the Clavien-Dindo

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E-Mail karger@karger.com www.karger.com/dsu scale as IVa, IVb, and V, respectively; hypoxia requiring resuscitation, sepsis and death due to ongoing cholangiosepsis (n = 1, 4, 1). Minor complications I, II, and IIIa included: small liver abscess, pleural empyema, transient hemobilia and mild fever (n = 1, 1, 2, 2). **Conclusion:** Percutaneous removal of CBD stones is an effective alternative treatment, when endoscopic treatment is contra-indicated, fails or is not feasible. It is effective, has a low complication rate and using deep sedation potentially requires only a very limited number of treatment sessions. © 2015 S. Karger AG, Basel

### Introduction

Choledocholithiasis is a common complication of cholecystolithiasis, occurring in 15–20% of patients who have gallbladder stones [1, 2]. The treatment of choice in patients with common bile duct (CBD) stones in particular after previous cholecystectomy or high risk patients is endoscopic retrograde cholangio-pancreatography

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(ERCP) with endoscopic sphincterotomy or endoscopic papillary balloon dilatation and stone removal [3, 4]. In other patients the laparoscopic one-step approach cholecystectomy combined with laparoscopic CBD stone removal might be considered [5]. The reported success rate of ERCP for removal of CBD stones varies from 84 to 96% [6-9]. However, endoscopic treatment may not be amenable or indicated in all patients with common bile duct stones. ERCP may be contraindicated in patients with a poor clinical condition, such as severe chronic lung disease. In addition to this, ERCP may not be feasible due to technical and anatomical reasons, such as duodenal stenosis, altered postsurgical anatomy (Billroth 2 gastrectomy, Roux-en-Y anastomosis, gastric bypass) or the inability to cannulate the papilla, for instance, as when the papilla is localized in a duodenal diverticulum.

In some cases cannulation of the papilla becomes successful, but the stones cannot be removed for other reasons such as perforation. In cases where cannulation of the papilla is not feasible, a so-called rendez-vous procedure can be performed. This procedure involves picking up a guidewire with the endoscope, which has been placed by a percutaneous transhepatic approach [10]. The guide wire is then used to get access to the bile duct and the stones can subsequently be removed.

When this is not possible or when endoscopy is not feasible, another therapeutic approach may be required and surgical exploration with stone removal or percutaneous transhepatic cholangiography and drainage (PTCD) combined with stone removal may be considered alternatives [9, 11-14]. Open duct exploration has a success rate of 92-96% but is associated with a substantial morbidity of 5-17% [5]. In these often old patients with significant comorbidity there is a complication rate of 7-8% and mortality rate of 2-4% [7, 9, 15]. One-stage laparoscopic CBD stone removal and cholestectomy has a success rate of 74-100% and a mortality and morbidity rate of 0-2% and 2-19.9% [7, 9, 15, 16], respectively. Percutaneous transhepatic removal of CBD stones is a minimally invasive alternative for surgical treatment. This approach is not commonly used for patients in whom ERCP treatment is not possible and only a few studies have reported the results of this procedure [17-23].

In this retrospective study we analyze 110 patients between 1998 and 2013 in our institution who were treated with percutaneous transhepatic treatment of CBD stones. The technique, the indications, the results and the complications of the procedure are evaluated.

# **Patients and Methods**

#### Patients

Informed consent was waived by the hospital ethics review board. Data were collected from all patients who were referred to the department of interventional radiology of our hospital for percutaneous treatment of suspected CBD stones between March 1998 and September 2013. Patients in whom CBD stones were confirmed and who were treated percutaneously were the subjects of this study.

Initially, patients presented at the gastroenterology department with biliary colic and/or jaundice and the diagnosis of choledocholithiasis (with or without cholangitis) was based on history, physical examination, laboratory results and imaging by means of transabdominal sonography, magnetic resonance cholangiographypancreatography, or computed tomography. All patients were referred to the radiology interventional unit by a gastroenterologist, because ERCP had failed or was considered technically not feasible or contraindicated. Patients with prior hepaticojejunostomy and/or patients with only intrahepatic stones were excluded from analysis because patients with hepaticojejunostomy and intraductal stones were a different patient category (these patients usually cannot be treated with ERCP and are therefore treated with percutaneous techniques as a primary treatment) and because these patients usually have a different underlying pathology. Patients in whom endoscopic stone removal was performed by a planned rendezvous procedure were also excluded; in these patients there was no intention to treat percutaneously.

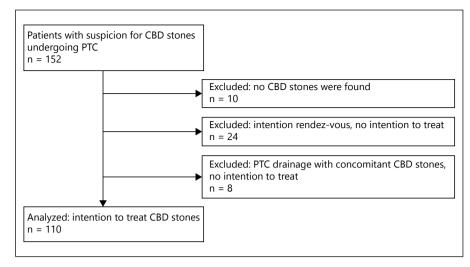
### Technique

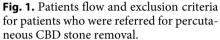
All patients received pre-procedure prophylactic i.v. broadspectrum antibiotics and intravenous analgesia (fentanyl 50–150  $\mu$ g) and intravenous sedation (midazolam 2.5–5.0 mg) during the procedure. In the last 2 years of the study patients received sedation and analgesia with propofol by nurses from the department of anaesthesiology. Blood pressure, pulse rate, and oxygen saturation were monitored during the procedure.

The choice whether to use a left-sided sub-xyphoid approach or a right-sided subcostal or intercostal approach was based on individual and anatomic considerations, such as the position of the liver, bile duct anatomy (as seen on pre-procedural imaging) and number, position, and size of the bile duct stones. The intrahepatic biliary system was approached from the left side in 59 (58/110; 52.7%) cases, from the right side in 45 (45/110; 40.9%) cases. In five patients (5/110; 4.5%) the biliary system was accessed via the gallbladder and in two patients (2/110; 1.8%) via a T-tube, which had been left in after cholecystectomy.

An ultrasound-guided puncture of the intrahepatic bile duct was performed using a 22G Chiba needle (Neffseth Percutaneous Access Set, Cook, Bloomington, Ind., USA). After placement of a catheter in the CBD, a percutaneous transhepatic cholangiogram (PTC) was performed to confirm the presence, location, number and size of the CBD stones. In most cases, an 8.5–10 French drainage catheter (Cook, Bloominton, Ind., USA) was placed for 3–4 days to decompress the biliary system and to provide relief from the symptoms of cholangitis when present.

In the following session stone removal was performed. The drainage catheter was replaced using a stiff guide wire (Amplatz extra stiff wire, Cook, Bloomington, Ind., USA) with the tip positioned through the sphincter of Oddi into the duodenum. An 8–10 Fr sheath (Cordis, Miami, Fla., USA) was inserted and a standard Per-





cutaneous Transluminal Angioplasty (PTA) balloon catheter (Cordis, Miami, Fla., USA) was advanced beyond the stones and positioned across the papilla. The sphincter was dilated by an 8-12 mm balloon, depending of the size of the largest stone, until no waist could be seen in the balloon on fluoroscopy; an overview of balloon dilatations used is presented in table 2. A second (safety) wire was placed through the papilla. The deflated balloon catheter was withdrawn and positioned proximal of the stones. After reinflating the balloon, the stones were pushed forward through the dilated sphincter into the duodenum. If the stone size exceeded 10 mm, mechanical lithotripsy was done using a Dormia basket (Olympus, Tokyo, Japan). The stone fragments were evacuated into the duodenum using the balloon catheter or Dormia basket and this intervention was necessary in forty-nine treatment sessions (49/180; 27.2%). Cholangiography was performed to confirm complete stone clearance in the CBD. Then a pigtail catheter was placed in the proximal part of the CBD. A drip infusion was connected to the drainage catheter (500 ml NaCl 0.9%/24 h) for a continuous fluid flow through the CBD to flush small stone fragments into the duodenum.

After approximately 1 to 2 days cholangiography was performed to confirm CBD clearance and if so, the external drain was removed. If residual stones were left, the procedure was repeated until all stones were removed.

#### Definition of Terms

The number of sessions needed for stone clearance was defined as a session planned as a stone removal procedure, or when this was not planned for stone removal but stones were removed as well. PTC sessions with no planned stone removal where not added, for example, biliary fluid drainage or cholangiographies were not required to confirm total stone clearance.

The percutaneous treatment of CBD stones was considered successful if all stones were removed and the CBD was clear during final cholangiography. A failure was defined as a procedure that was technically not feasible (e.g., not feasible to enter and/or pass through the common bile duct, complication) or if a stone could not be removed.

A complication was defined as an unintentional event during hospital admission leading to additional treatment or longer hospital stay than anticipated. Complications where registered per stone removal session. All complications were graded with the Clavien-Dindo scale for surgical complications [24].

#### Data Collection

The interventional radiology database, in which data of all patients who undergo percutaneous bile stone removal are collected, was used. For inclusion and exclusion criteria, the previous history and clinical data were reviewed using the Electronic Patient Record (EPR) from the Academic Medical Centre and letters of referring clinicians. All available imaging studies and radiology reports from the patients of the study group were reviewed using a PACS system (Picture Archiving and Communication System, Agfa, Brussels, Belgium). Details about the size and number of the stones were documented as well as the balloon size used for balloon dilatation, whether or not a Dormia basket was used, the number of sessions and the complications during the procedure. The size of stones was estimated based on a comparison with the height of vertebra which was considered to be approximately 3 cm [25]. Clinical data from the admission period after the procedure, including complications, were obtained once more from the EPR from the AMC and discharge letters of referring clinicians.

#### Results

#### Patients

From March 1998 to September 2013, 153 patients were referred to the intervention radiological department to confirm the presence or absence of CBD stones. After initial cholangiography, ten patients had no CBD stones and were excluded. Thirty-three patients were excluded because there was no intention to treat, these patients had CBD stones. Reasons for these exclusions were, a rendezvous procedure, only drainage preformed, surgical intervention, this were 24, 5 and 3 patients, as shown in figure 1.

	n (%)	SD
Mean age	69.7 (14–96)	16.2
Gender		
Men	61 (55.5)	
Women	49 (44.5)	
Cholecystectomy		
None	73 (66.4)	
Recently	14 (12.7)	
In past	23 (20.9)	
Number of stones		
1	43 (39.1)	
>1	67 (60.9)	
Size of stones, cm		
<1	46 (41.8)	
< and > 1	21 (19.1)	
≥1	37 (33.6)	
Unknown	6 (5.5)	
ERCP treatment	ERCP	ERCP not
	failed,	preformed,
	n (%)	n (%)
Billroth 2 gastrectomy	15 (13.6)	10 (9.1)
Roux-en-Y anastomosis	14 (12.7)	18 (16.4)
Duodenal divertikel	9 (8.2)	1 (0.9)
Complications	5 (4.5)	0 (0.0)
Technical difficulties	13 (11.8)	0 (0.0)
Condition of patient	0 (0.0)	9 (8.2)
Gastric bypass	0 (0.0)	3 (2.7)
Unclear	4 (3.60	9 (8.2)
Total	60 (54.5)	50 (45.5)

Values are given in n (percentage) and standard deviation (SD). Data important for treatment was collected, such as age, gender, gallbladder status, number and size of the CBD stones. Furthermore, indication for percutaneous treatment was collected.

One-hundred-ten patients were included in the study group (61 men, 49 women; aged 14–96, mean age 69.7 years). Twenty-four patients (23/110; 20.9%) had their gallbladder removed in the past and fourteen patients (14/110; 12.7%) only recently. Seventy-three patients (73/110; 66.4%) still had their gallbladders. Forty-three patients (43/110; 39.1%) had one CBD stone; in sixtyeight patients (67/111; 60.9%) more than one CBD stone was present. In forty-six patients (46/110; 41.8%) the CBD stone was smaller than one centimeter; in twentytwo patients (21/110; 19.1%) CBD stones were found of varying sizes, both smaller and larger than one centimeter; thirty-seven patients (37/110; 33.6%) had one or more CBD stones larger than one centimeter and in six patients (6/110; 5.5%) the size of the CBD stones was un-

#### Table 2. Treatment characteristics

	n (%)
Number of patients with	
1 treatment	60/110 (54.5)
2 treatments	29/110 (26.4)
3 or more treatments	15/110 (13.6)
Total number of treatments	179
Successful treated patients	104/110 (94.5)
Failed treatments	6/110 (5.5)
Mean treatments	1.6
Median	1
Complications Davien-Dindo grade	
I	2/110 (1.8)
II	2/110 (1.8)
IIIa	2/110 (1.8)
IIIb	0/110 (0.0)
IVa	1/110 (0.9)
IVb	4/110 (3.6)
V	1/110 (0.9)
Approach	
Left	58/110 (52.7)
Right	45/110 (40.9)
Via gallbladder	5/110 (4.5)
Via T-drain	2/110 (1.8)
Dilatation	
Yes	139/179 (77.7)
No	40/179 (22.3)
Lithotripsy	
Yes	131/179 (73.2)
No	48/179 (26.8)

Values are given in n (percentage) or mean and median. After treatment all resulting data was collected, such as number of treatments and their results, complications and technical details.

known. Sixty-one patients (60/110; 54.5%) had undergone failed ERCP prior to the percutaneous procedure. In the remaining fifty patients (50/110; 45.5%) ERCP was not attempted. The patient characteristics are shown in table 1.

# Success Rate of Percutaneous CBD Stone Removal

In 103 patients (104/110; 94.5%) total stone clearance of the CBD was achieved. One to six sessions of removal were performed with a median of 1.6 treatments. First time success was achieved in sixty patients (60/110; 54.5%) and success in two sessions was achieved in twenty-nine patients (29/110; 26.4%, cumulative 80.9%). Success after three sessions or more was achieved in fifteen patients (15/110; 13.5%, cumulative 94.5%).

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In six patients (6/110; 5.5%) total stone clearance was not obtained. Causes for failure were haemobilia (n = 2), stone impactation (n = 2), and too wide a CBD configuration (n = 2). Three patients went for subsequent rendezvous procedures; two patients declined further treatment and the catheter was left in for biliary drainage. One patient died before further treatment was attempted.

## Complications

In the 179 sessions, 12 complications (12/179; 6.7%) where observed. This resulted in a complication rate of 10.9% (12/110). Complication rates were classified with the Clavien-Dindo Classification of Surgical Complications scale [24]. Two patients (1.8%) were graded with scale I complications due to the manipulation of the catheter along a large stone; these patients experienced a transient period of hemobilia. One of these patients developed a sub-capsular biloma. Two other patients (1.8%) were graded with scale II complications; both these patients experienced a short time of fever. They were successfully treated with a regimen of antibiotics. Two patients (1.8%) were graded with scale IIIa scale complications. One patient developed a small abscess at the bile duct puncture site, which was aspirated and treated with antibiotics. In one patient, the manipulation of the catheter caused a puncture through the CBD wall and pleura and a pleural empyema was formed; this was treated with drainage. No patients were graded IIIb scale complications. One patient (0.9%) had to be resuscitated during the procedure because of sedation-induced hypoventilation and is graded IVa. Four patients (3.6%) went through a period of sepsis, which was successfully treated with antibiotics. These patients were graded IVb although not all of them were admitted to the intensive care unit. Finally one patient (0.9%) died of an ongoing cholangiosepsis, despite the intensive care treatment. The complications developed by this patient are shown in table 2.

### Discussion

The present study showed 110 patients all of whom were treated with percutaneous transhepatic treatment for removal of CBD stones. The technique, the indications, the results and the complications of the procedure, and predictive factors for success and failure were evaluated.

CBD stones are a common problem; the ERCP procedure is the treatment of choice. However, when ERCP cannot be done an alternative treatment option is required. In this study the CBD stones were removed via a transhepatic percutaneous route. This resulted in a successful clearance of stones in 94.5% of the patients with a Clavien-Dindo grade IV or higher complication rate of 5.5% and a mortality rate of 0.9%. These results are in the same range of those reported for the widely used technique of CBD stone removal, ERCP, with a success rate of 84-96% and complication and mortality rates of 3-16% and 0-4%, respectively [6-9]. The results are also in the same range of those reported for surgical open duct exploration. Open duct exploration had a success rate of 92-96%, a complication rate of 7-8%, and a mortality rate of 2-4% [7, 9]. Laparoscopic ductal exploration has proven successful in 74-100% of cases with complications and death occurring in 2-17 and 0-2%, respectively [5, 7, 9, 16].

Despite these promising results, published reports on percutaneous CBD stone removal are scarce. Previous studies on percutaneous stone removal were performed in a heterogeneous patient population ranging from patients with intrahepatic stones to patients with previous hepaticojejunostomy and stone removal via T-tube track (17-23)(16-22). The present study is performed in a homogeneous population with CBD stones, without cases with a hepaticojejunostomy and without intrahepatic stone disease. The primary goal was to remove the stones by the percutaneous transhepatic route with papillary balloon dilatation. Therefore, the results of the present study may be more applicable to the subset of patients that may benefit most from this minimally invasive technique: patients with CBD stones, in whom ERCP failed or was considered not feasible or contraindicated.

The present study showed a success rate (104/110; 94.5%) comparable to previous reports (87-95%). These studies used the same techniques as described in our study (17-23)(16-22). Our complication rate, defined as an unintentional event during hospital admission, however, is difficult to compare with other studies. In total, twelve (12/110; 10.9%) complications were registered. These complications were graded by the Clavien-Dindo scale. Other studies only mention major complications (pancreatitis, severe hemorrhage and death). Only one of these major complications occurred in our study group. In our group we observed four events (4/110; 3.6%) of sepsis and one patient had sedation-induced hypoventilation due to the sedative medication and was successfully resuscitated. This resulted in a IVa, IVb, and V complication rates of 5.5%. In our study, we defined fever as a complication because it is considered an underlying infection, although it may have also been the result of cholangitis

and cholangiosepsis that was associated with choledocholithiasis in twenty-four patients (24/110; 21.8%).

The disadvantage of percutaneous stone removal is the higher number of sessions compared to endoscopic or surgical removal techniques. Only in 54.5% (60/110) of the patients stone removal was achieved in the first session, while some required up to six sessions, compared to ERCP and surgical treatment in which stone removal is usually achieved even in the first procedure. This is partially explained by the use of analgesia, instead of general anesthesia, for the percutaneous technique, which results in a narrow time window for the procedure. With the use of general anesthesia in eligible patients, it is no longer needed to use a stepwise procedure and stone clearance may be achieved in one session.

After failed endoscopic CBD stone treatment, two treatment options remain: surgical duct exploration or percutaneous CBD stone removal. Laparoscopic techniques, such as transcystic ductal exploration and choledochotomy have proven successful. In the setting of concurrent laparoscopic cholecystectomy, the laparoscopic removal of CBD stones may be an attractive treatment in a single procedure [7, 26]. However, laparoscopic CBD stone removal is technically demanding. It is often time consuming and requires advanced laparoscopic skills, including intracorporeal suturing, which may not be available in most centers [7, 26–28]. Therefore, the percutaneous treatment, being less invasive than surgery, may be more appropriate as a second option to remove choledochal stones if ERCP fails, especially in poor surgical candidates in whom general anesthesia is not possible.

Limitations of this study are its retrospective nature, inability to have follow up and hospital stay due to the referral pattern of these patients. Patients were referred by different physicians from different hospitals. After treatment, patients returned to the hospital from where they came. And hospital stay and follow up were not possible for employees of the AMC hospital.

#### Conclusion

Percutaneous removal of CBD stones is a nonsurgical alternative, when endoscopic treatment is contraindicated, fails or is not feasible. It is effective, has a low complication rate and has potentially a low number of sessions without the need for general anesthesia. We recommend that if facilities and expertise are available, the use of percutaneous treatment should be considered before surgery is performed, in particular, if cholecystectomy has already been performed in the past.

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