



Percutaneous Cholecystolithotomy Using Cholecystoscopy

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The morbidity and mortality of cholecystectomy can increase to 10% in high surgical risk patients. The technique for percutaneous cholecystolithotomy consists of 3 steps: (1) percutaneous cholecystostomy, (2) tract dilation and cholecystolithotomy, and (3) tract evaluation and catheter removal. Cholecystoscopy is critical in guiding the lithotripsy probe for fragmentation of large stones and is useful for locating small stone fragments not seen in cholangiography. Cholecystoscopy is also useful for assessing ambiguous lesions and in distinguishing between stone vs debris or mass. Technical success rate of percutaneous cholecystolithotomy using cholecystoscopy ranges from 93% to 100%. Procedure related complication rate has been reported as 4%-15%. The most common complication is bile leak during the procedure or after catheter removal. Although recurrence rate of gallstones has been reported up to 40%, the symptom recurrence rate is much lower. Therefore, percutaneous cholecystolithotomy using cholecystoscopy can be an alternative to cholecystectomy in high surgical risk patients with symptomatic gallstones.

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Introduction

Acute calculous cholecystitis is a well-known complication of gallstones, which affects more than 20 million Americans and leads to annual costs exceeding US\$6 billion.¹ For most patients with acute cholecystitis, surgical removal of the gallbladder remains the optimal treatment, and a laparoscopic approach is preferable whenever

Abbreviations: EHL, electrohydraulic lithotripsy; ERCP, endoscopic retrograde cholangiopancreatography; ICD, implantable Cardioverter Defibrillator; US, ultrasound

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feasible.^{2,3} In patients without other medical problems, both conventional and laparoscopic cholecystectomy have mortality rates of less than 0.5%. However, the morbidity and mortality of cholecystectomy increase dramatically in high surgical risk patients—up to 10% mortality in elderly and medically comorbid patients.^{4,5} Such high surgical risk patients stand to benefit the most from non-surgical alternatives to cholecystectomy. Several investigators have reported percutaneous cholecystolithotomy to be a valuable nonsurgical approach for high surgical risk patients with symptomatic gallstones with or without cholecystoscopy.⁶⁻¹⁷ Percutaneous cholecystolithotomy is minimally invasive and can be used to remove any type, size, and number of stones in patients with both acute and chronic cholecystitis. For the last 30 years, we have been performing percutaneous cholecystolithotomy as an alternative to cholecystectomy in high surgical risk patients with symptomatic gallstones. Here, we describe our technique of percutaneous cholecystolithotomy using cholecystoscopy and clinical outcomes.

Indications and Contraindications for Percutaneous Cholecystolithotomy

Assessments of surgical risk can be based on the guidelines provided by the American Society of Anesthesiologists.¹⁸ Comorbid diseases that increase the risk of morbidity and mortality include serious cardiovascular diseases, pulmonary diseases, advanced liver cirrhosis, renal diseases, age over 75 years with multiple systemic complications, and more. Percutaneous cholecystolithotomy can be a safe and effective alternative therapeutic option in these high surgical risk patients.⁶⁻¹⁷ Contraindications for percutaneous cholecystolithotomy include uncontrolled systemic infection or sepsis, uncorrectable coagulopathy, intractable ascites, life expectancy of less than 6 months, among others.

Percutaneous Cholecystolithotomy

The technique for percutaneous cholecystolithotomy consists of 3 steps: (1) percutaneous cholecystostomy, (2) tract dilation and cholecystolithotomy, and (3) tract evaluation and catheter removal. Figure 1 shows the flow diagram of percutaneous cholecystolithotomy after percutaneous cholecystostomy catheter placement.

The entire procedure for most of the patients is performed with local anesthesia and conscious sedation with intravenous midazolam hydrochloride and fentanyl citrate. General anesthesia can be used in selected patients such as frail or elderly patients and several investigators have published

results of percutaneous cholecystolithotomy performed with routine use of general anesthesia.^{8,9,11,12} We have not required general anesthesia for most of cases in our practice^{7,13} although we use general anesthesia in some patients who have low pain thresholds.

Percutaneous Cholecystostomy

All patients not already receiving intravenously administered antibiotics are given a dose of antibiotics just before the initial gallbladder puncture. Percutaneous cholecystostomy is performed, guided by a combination of ultrasound and fluoroscopy. With use of the Seldinger technique, a 10-12 French catheter (Dawson-Mueller or Multipurpose Drain; Cook Medical, Bloomington, IN) is placed in the lumen of the gallbladder.

Transhepatic access into the gallbladder is usually considered to be important for cholecystostomy procedures since a transhepatic tract will stabilize the catheter and theoretically reduce bile leakage into the peritoneum compared to transperitoneal access.¹⁹ Transperitoneal access requires longer tract maturation time than transhepatic access does. Striving for transhepatic access often does not allow a fundus access. Preferred location of percutaneous access for cholecystolithotomy is the fundus of the gallbladder no matter whether it is transhepatic or transperitoneal access. This straight-line access into the fundus of the gallbladder along its long axis makes it easy to have a direct access with cholecystoscope to the stones and for removal of the entire stone burden. Lower body access can be acceptable in most cases with use of a flexible endoscope. If the existing access is not ideal for percutaneous cholecystolithotomy, a new access can be obtained at the gallbladder fundus. Once a new access is obtained, percutaneous cholecystolithotomy can be performed 4-6 weeks later, after maturation of the tract (Fig. 2).

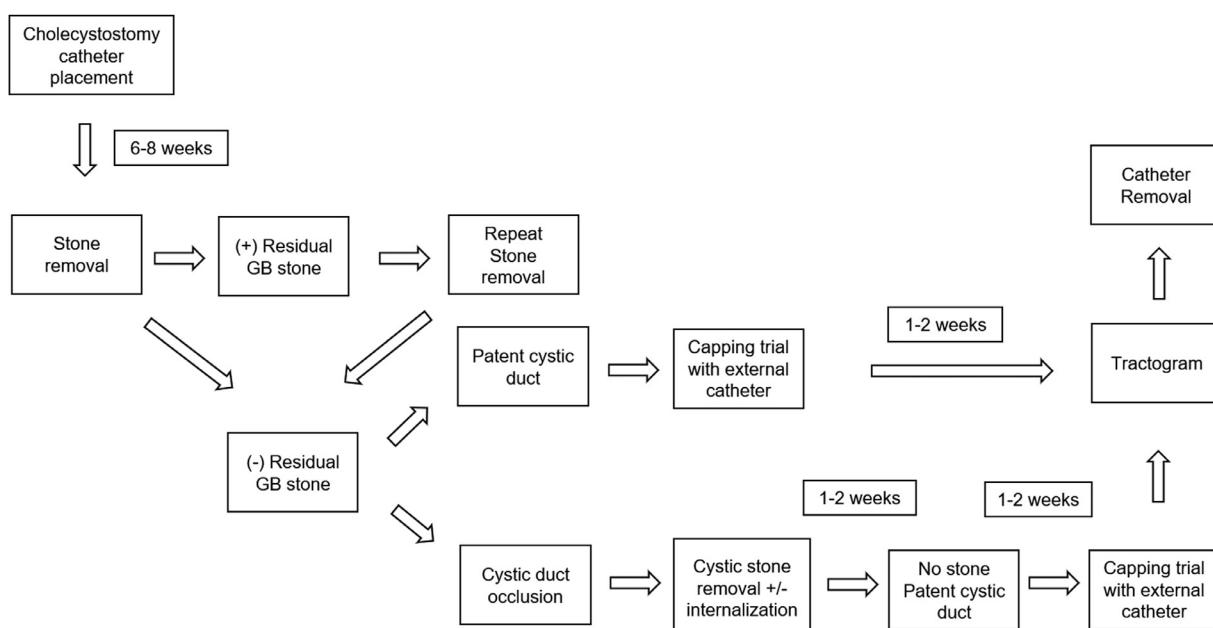


Figure 1 Flow diagram of percutaneous cholecystolithotomy using cholecystoscopy in high surgical risk patients with symptomatic gallstones.

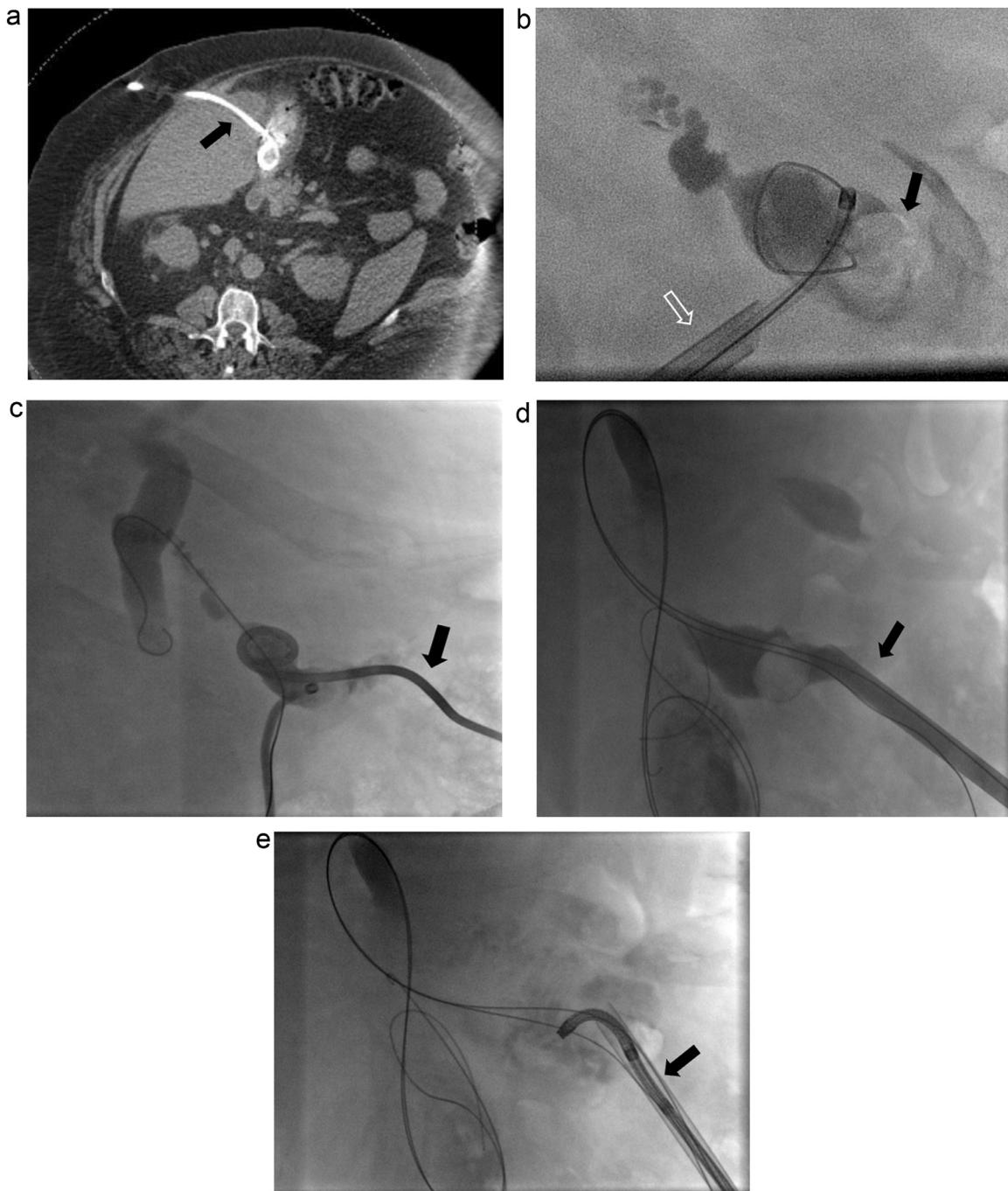


Figure 2 56-year-old man with gallstones and multiple comorbidities including morbid obesity. (a) CT shows a cholecystostomy catheter (arrow) with transhepatic access into the lower body of gallbladder. (b) Cholangiogram shows a large stone (arrow) in the fundus of the gallbladder. A 24F 17 cm (open arrow) sheath was too short to get into the gallbladder lumen due to his body habitus. (c) A new cholecystostomy catheter (arrow) was placed into the gallbladder. A new access was obtained to left side of abdomen because his abdomen had shifted to left side due to morbid obesity (d, e) About 10 weeks later, after successful placement of a 24F 17 cm sheath (arrow) into the gallbladder, a gallstone was successfully removed using cholecystoscopy (arrow) with EHL probe.

Tract Dilatation

Although initial cholecystostomy catheter placement is generally performed as an inpatient procedure, tract dilation and percutaneous cholecystolithotomy can be performed on an outpatient basis. The entire procedure for most patients is performed with local anesthesia and moderate sedation. Frail or elderly patients may need general anesthesia for percutaneous cholecystolithotomy and might need to be admitted

for observation. A single dose of antibiotics (ceftriaxone or ciprofloxacin) is administered intravenously just before tract dilatation and percutaneous cholecystolithotomy. There are varying recommendations for waiting time for tract dilatation and percutaneous cholecystolithotomy. Some authors performed percutaneous cholecystolithotomy using cholecystoscopy about 2 weeks after initial cholecystostomy catheter placement.^{14,15} However, we recommend 6-8 weeks before

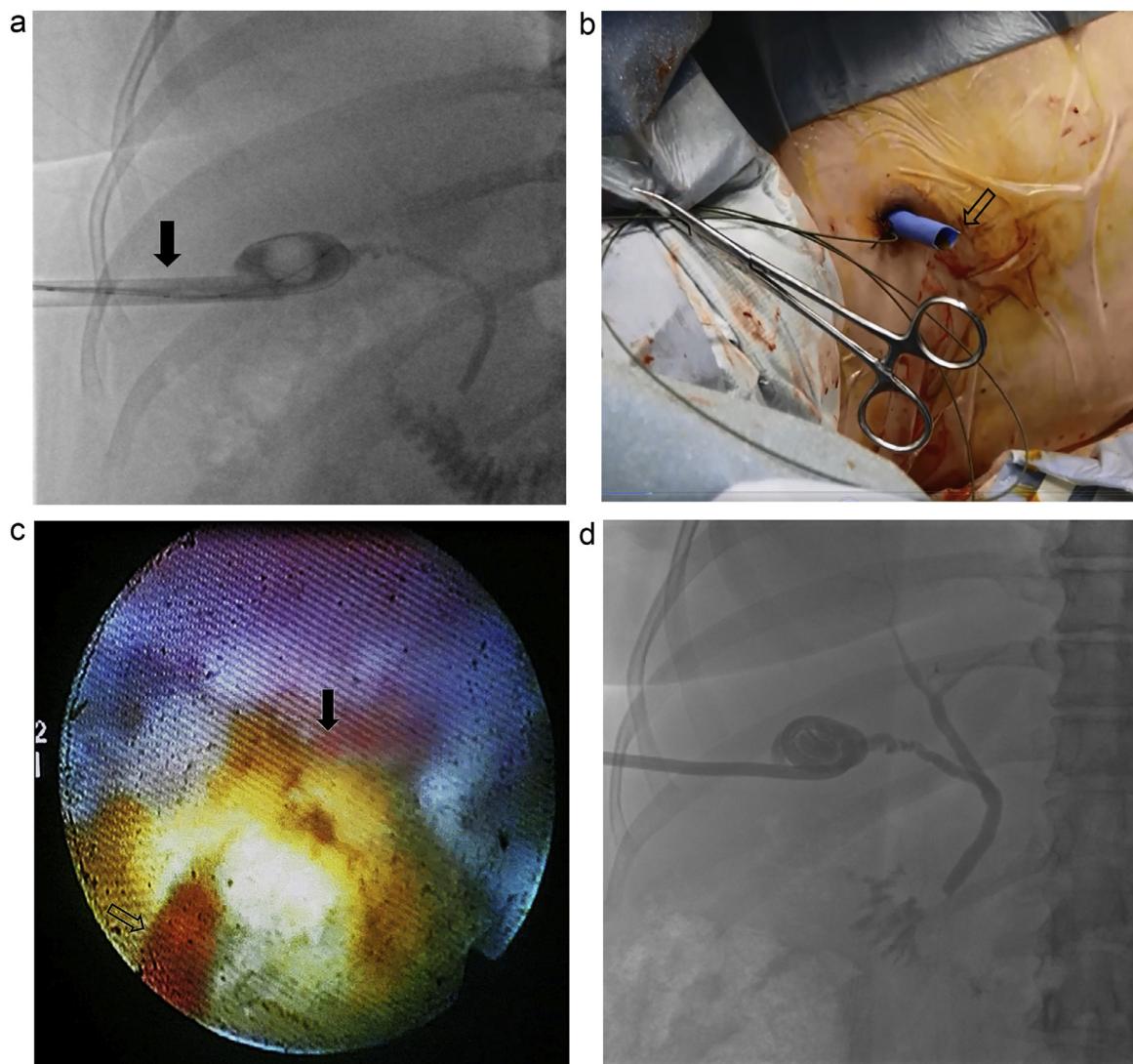


Figure 3 47-year-old woman with about a 22 mm gallstone and with multiple comorbidities including status post-ICD (implantable cardioverter defibrillator). (a) The tract was dilated using an 8 mm high-pressure nephrostomy balloon (Nephromax, Boston Scientific) and a 24F × 17 cm sheath (arrow) was placed. (b) Outer portion of the sheath (arrow) was cut to 3-4 cm for easy use of cholecystoscopy and irrigation technique. (c) A stone (arrow) was fragmented with cholecystoscopy with intracorporeal EHL (open arrow). Fragmented stones were removed with irrigation technique and stone basket, and a 16F catheter was placed. (d) One week follow-up cholangiogram shows no residual stone and patent cystic duct. The catheter was removed after tractogram.

attempting tract dilation and percutaneous cholecystolithotomy considering stability of the tract and possible bile leakage from an immature tract.^{7,13}

The degree to which the tract must be dilated depends on the size of the endoscope that will be used. Our endoscopes used for cholecystoscopy are 15F (3 mm) in diameter. The sheath must have an inner diameter larger than the outer caliber of the endoscope because endoscopy requires continuous infusion of fluids to distend the system and allow visualization. Extra room is needed to allow the irrigation fluid to flow out through the sheath around the endoscope. Otherwise, the irrigation fluid could build up and increase the pressures within the gallbladder, increasing the risk of pain and sepsis. Therefore, we routinely use an 18F or 24F sheath for 15F cholecystoscopy to accommodate the scope and the irrigation outflow. We prefer to use a 24F sheath because the larger

sheath can get larger fragments out without the need for as much fragmentation. We used to perform coaxial dilatation with an 18F biliary dilator set (Cook Medical, Bloomington, IN) or 24F Amplatz dilator set (Cook Medical, Bloomington, IN). Recently, we switched to a nephrostomy balloon system (8 mm balloon with 24F × 17 cm sheath) (Nephromax, Boston Scientific, Galway, Ireland) because it is possible to place the 24F sheath with a single 8 mm balloon dilatation of tract. We started using a 10F cholangioscope (SpyGlass, Boston Scientific, Natick, MA) for percutaneous cholecystolithotomy. This scope can be used with a 14-16F sheath.

Cholecystolithotomy Using Cholecystoscopy

The existing cholecystostomy is removed over a stiff guidewire. A second guidewire is placed as a safety wire. Use of a safety

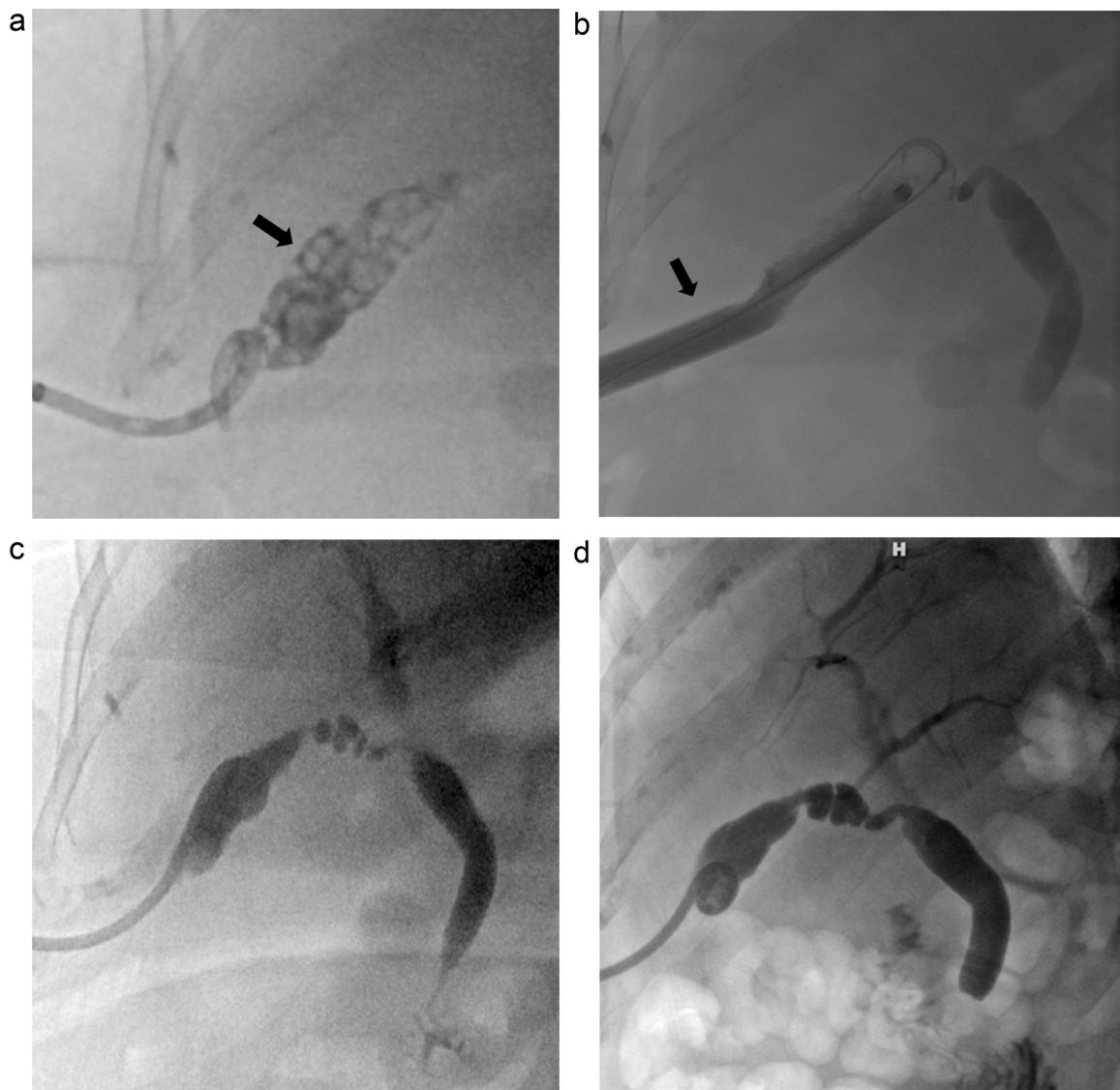


Figure 4 81-year-old woman with multiple small stones and high surgical risk. (a) Cholangiogram shows multiple small stones (arrow). (b) After placement of 24F sheath (arrow), multiple small stones were removed with irrigation technique and stone basket. Cholecystoscopy was used for locating small stones which were not seen on cholangiogram. (c) Two weeks follow-up cholangiogram shows no residual stone and patent cystic duct. The catheter was capped. (d) The patient tolerated capping trial of the catheter and after another 2 weeks follow-up cholangiogram shows no residual stone and a patent cystic duct. The catheter was removed.

wire is critical. Loss of access to the gallbladder during stone manipulation can be catastrophic though if the tract is mature it may be easier to regain access into the gallbladder lumen. The tract is dilated using an 8 mm high-pressure nephrostomy balloon (Nephromax, Boston Scientific) and a 24F \times 17 cm sheath is placed. The outer portion of the sheath can be cut to the 3-4 cm for the easy use of cholecystoscopy and irrigation technique (Fig. 3). The most efficient method of small stone removal is irrigation of the gallbladder with a small catheter passed directly through the sheath (Fig. 4).

Larger stone removal is performed through the sheath by using a combination of fluoroscopic guidance and direct visualization with a flexible cholecystoscopy (Olympus America). The flexible cholecystoscopy is 15F (5 mm) in diameter and has a 2 mm working channel. With use of the working channel, stones are removed from the gallbladder

with standard baskets and graspers. Stones too large to be removed through the sheath are fragmented with an intracorporeal electrohydraulic lithotripsy (EHL) probe (Fig. 3)^{7,20,21} or intracorporeal laser lithotripsy.²² Intracorporeal EHL or laser lithotripsy is the fastest and most efficient way to fragment stones into pieces small enough to be removed through the sheath. Laser lithotripsy may offer some safety advantages, but also requires more expensive equipment than EHL lithotripsy.²² Cholecystoscopy is critical in guiding the lithotripsy probe for fragmentation of large stones^{7,20,21} and is useful for locating small stone fragments not seen on cholangiogram. Direct visualization with the scope is the only way to be sure that the probe is on the stone; firing the EHL probe while it is in contact with the gallbladder wall could lead to bleeding or perforation. Cholecystoscopy is also useful for assessing ambiguous lesions seen on cholangiogram

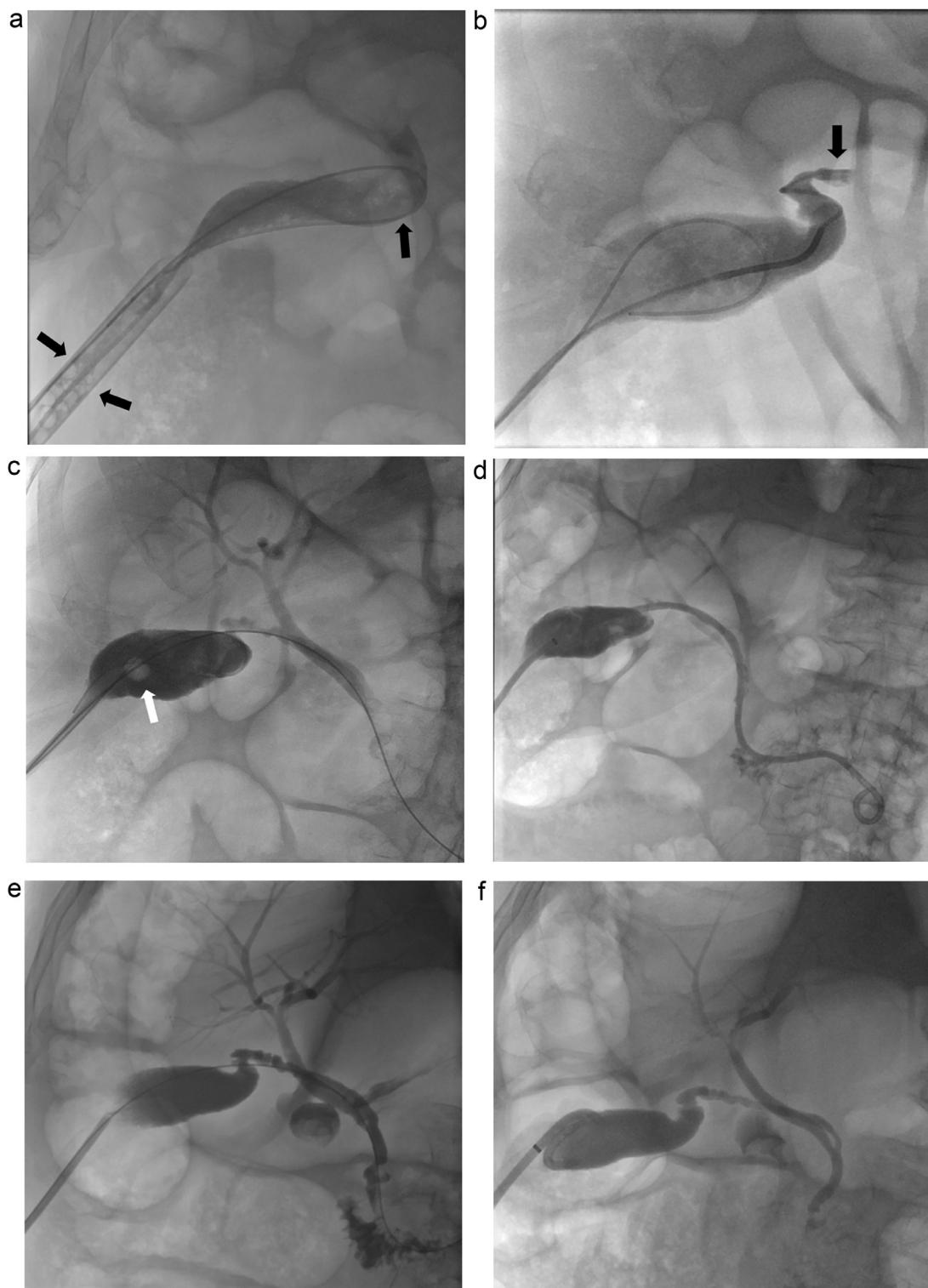


Figure 5 92-year-old man with multiple stones and high surgical risk. (a) After placement of the 24F sheath, multiple stones (arrows) were removed with irrigation technique, stone basket, and cholecystoscopy. (b) Follow-up cholangiogram 2 weeks later showed cystic duct occlusion (arrow) without residual gallstone (c) The cystic duct was cannulated and cystic duct stone was removed using occlusion balloon catheter (arrow). (d) A 10F internal and external biliary catheter was placed. (e) One week follow-up cholangiogram shows patent cystic duct. A 10F catheter was placed and the catheter was capped. (f) The patient tolerated capping trial of the catheter and another 1 week follow-up cholangiogram shows no residual stone and a patent cystic duct. The catheter was removed.

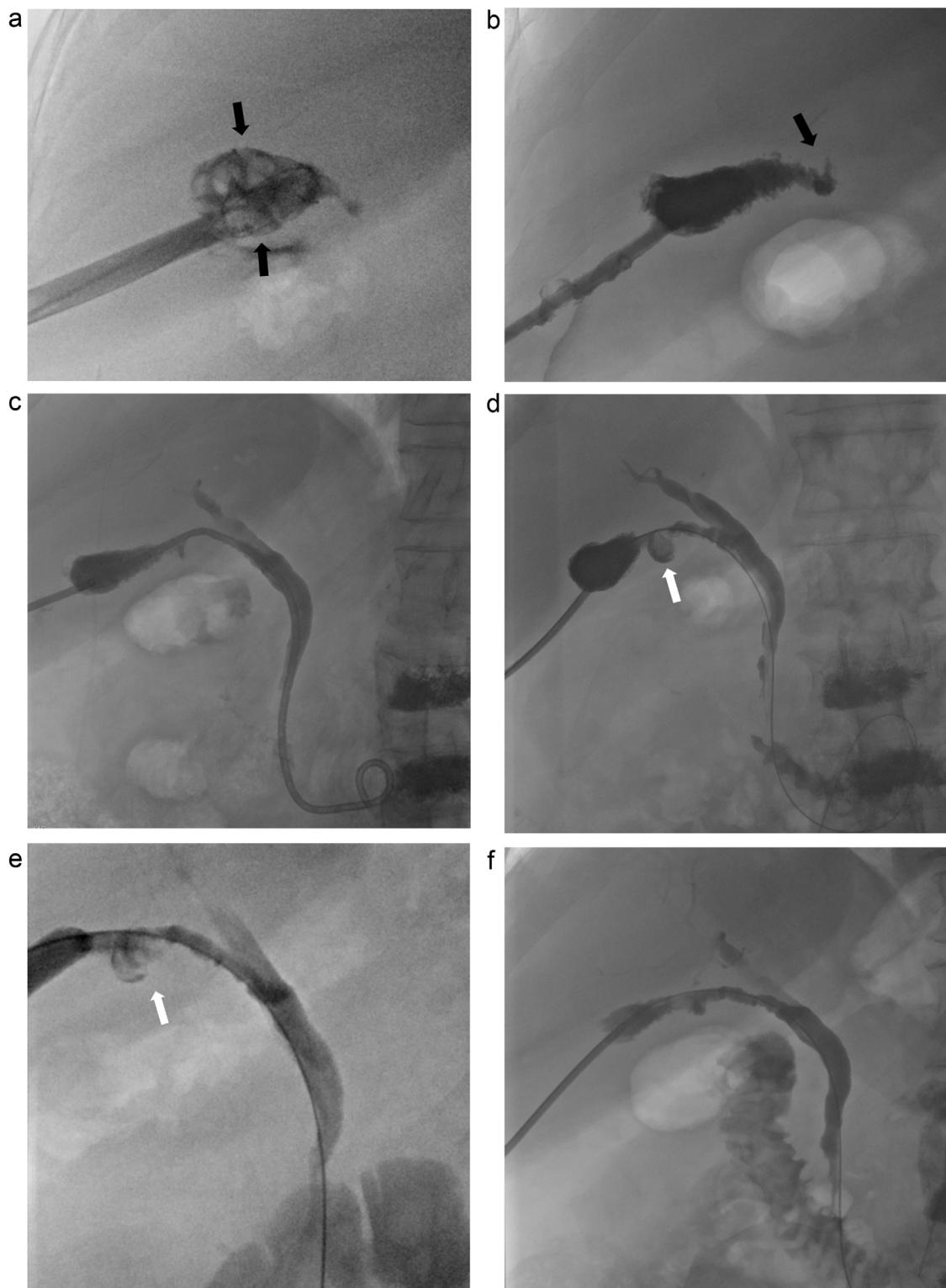


Figure 6 65-year-old man with multiple stones and high surgical risk. (a) After placement of 24F sheath, multiple stones (arrows) were removed with irrigation technique, stone basket, and cholecystoscopy. He underwent another session of percutaneous cholecystolithotomy and the stones were completely removed. (b) Two week follow-up cholangiogram showed cystic duct occlusion (arrow). The cystic duct was cannulated and (c) a 10F internal and external biliary catheter was placed. (d) One week follow-up cholangiogram shows a small stone (arrow) in the cystic duct which was previously not seen. (e) This stone was removed with an occlusion balloon and cholecystoscopy with EHL probe. (f) Another 1 week follow-up cholangiogram shows no residual stone and a patent cystic duct. The catheter was removed.

Table 1 Outcomes of Percutaneous Cholecystolithotomy Using Cholecystoscopy for the Management of High Surgical Risk Patients With Symptomatic Gallstones

Author/Year (Reference)	Number of Patients	Endoscope	Technical Success Rate	Recurrence Rate	Complication Rate
Chiverton et al/1990 ⁽⁸⁾	60	18F	93% (56/60)	NA	8% (5/60)
Gillams et al/1992 ⁽⁹⁾	113	26F rigid	95% (107/113)	8% (9/113)	13% (15/113)
Picus et al/1992 ⁽¹³⁾	58	15F flexible	97% (56/58)	NA	12% (7/58)
Ohashi/1998 ⁽¹⁴⁾	53	15F flexible	96% (51/53)	2.5% (1/40)	4% (2/53)
Kim et al/2000 ⁽¹⁵⁾	26	15F flexible	100% (26/26)	14% (3/22)	15% (4/26)
Patel et al/2018 ⁽¹⁶⁾	13	7.95F, 16.5F, 22.5F rigid	100% (13/13)	8% (1/13)	15% (2/13)

and for distinguishing between stone vs debris or mass. The resulting stone fragments are removed using either the Wittich Nitinol stone basket (Cook Medical, Bloomington, IN) through the sheath or a small basket/grasper through the working channel of the endoscope and irrigation technique.

Large stones are more difficult to remove and time-consuming for fragmentation with the EHL probe. Stone fragmentation with an ultrasonic lithotripsy device through 22.5F or 26F rigid cholecystoscopy^{9,16} can be done easily and more quickly compared to EHL probe. However, direct access to the stones and a larger sheath (24F sheath for 22.5F scope and 30F sheath for 26F scope) are required for the use of rigid endoscope.

At the termination of the cholecystolithotomy session, a 12-16F catheter (Dawson-Mueller or Multipurpose Drain, Cook Medical, Bloomington, IN) is placed into the gallbladder lumen depending on the size of the lumen. If additional cholecystolithotomy sessions are required, they are performed with the same technique as described above. These additional sessions usually result in the removal of several small residual stones and/or fragments. Cholecystolithotomy is judged to be complete when cholangiography and direct visualization of the gallbladder lumen with flexible endoscopy show no filling defects or stones and a patent cystic duct.

Cholangiography is also used to examine the cystic duct and common bile duct for stones. Our study showed cystic duct stones in 25% of patients (15/58) and common bile duct stones in 17% of patients (10/58).¹³ The management of cystic duct and common bile duct stones is essential to allow successful completion of the cholecystolithotomy procedure. If there is cystic duct occlusion, cystic duct cannulation can be performed by using a hydrophilic coated guidewire (Glidewire, Terumo Medical, Somerset, NJ) with 4F or 5F catheter. If there is a stone in the cystic duct, this stone can be removed percutaneously through the gallbladder using baskets and/or occlusion balloon catheter (Figs. 5 and 6). If it is not possible to remove the cystic duct stone completely by using stone baskets or occlusion balloon catheter, fragmentation can be done by passing a catheter through the cystic duct next to the stone and leaving the internal and external catheter in place for 1-2 weeks (Figs. 5 and 6). The catheter causes the stone to crumble into smaller fragments as well as passively dilates the cystic duct, allowing easier manipulations. If there is a stone in the common bile duct, this stone can be removed by endoscopic retrograde cholangiopancreatography or can be pushed into the

duodenum with a balloon occlusion catheter after balloon sphincterotomy.

Tract Evaluation and Catheter Removal

If the patient is stable without any symptoms such as abdominal pain and fever after 2-3 hours of observation in the recovery area, the patient can be discharged with the cholecystostomy catheter draining externally. Patients return for outpatient follow-up at 1-2 week intervals. If there is no residual stone and presence of a patent cystic duct on cholangiogram, the cholecystostomy catheter is capped to effect internal drainage. If the patient tolerates this capping trial, the catheter is removed 1-2 weeks later (Fig. 1).

We routinely inject contrast material into the cholecystostomy tract over a guide wire before catheter removal ("tractography") to confirm tract integrity. If there is intraperitoneal leakage of contrast material, we replace the catheter in the gallbladder lumen and defer catheter removal. If the tract is intact to the skin, we remove the cholecystostomy catheter from the gallbladder.^{7,13}

Clinical Outcomes

Table 1 summarizes outcomes of percutaneous cholecystolithotomy using cholecystoscopy for the management of high surgical risk patients with symptomatic gallstones. Six

Table 2 Complications From Previous Studies^(8,9,13-16)

Complications (Numbers)

Bile leak (n = 10)
GB perforation (n = 3)
GB wall bleeding (n = 3)
Transient cholangitis (n = 3)
Acute pancreatitis (n = 2)
Cystic duct injury (n = 1)
Skin site infection (n = 6)
Catheter dislodgement (n = 1)
Deep vein thrombosis (n = 1)
Respiratory arrest (n = 1)
Bradycardia from vagal response (n = 6)
GI bleeding (n = 1)
Colonic fistula (n = 1)

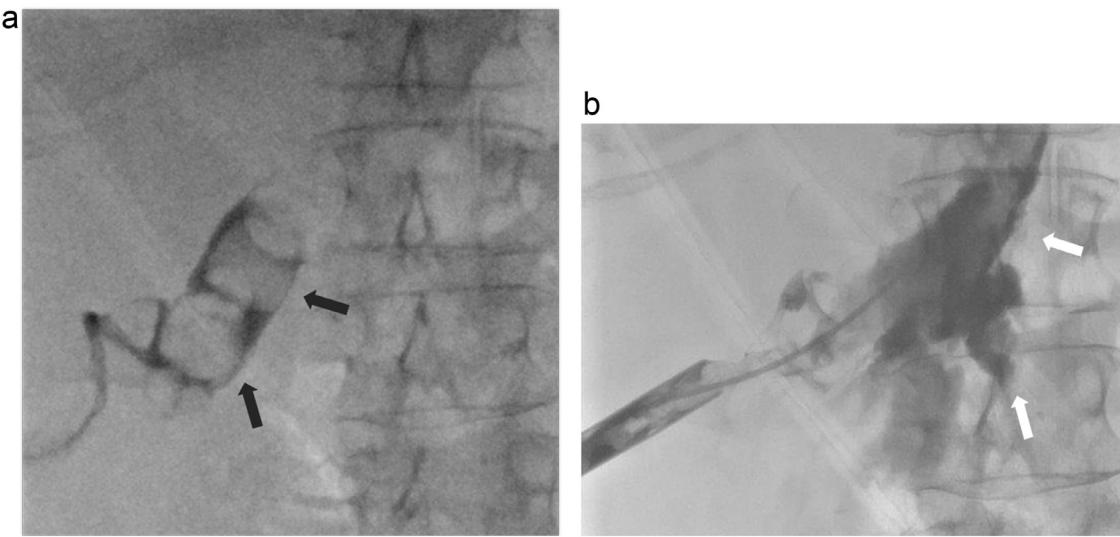


Figure 7 65-year-old woman with multiple stones and metastatic breast cancer. (a) Cholangiogram shows multiple large stones (arrows) (b) After placement of a 24F sheath, the stones were partially removed. During the procedure, there was contrast extravasation (arrows) outside of gallbladder. Therefore, the procedure was aborted and a 12F catheter was placed.

studies evaluated a total of 323 patients (range for individual studies was 13-113 patients).^{8,9,13-16} Technical success rate of percutaneous cholecystolithotomy was 93%-100%. The main cause of technical failure was cystic duct stone.⁹ The other causes of technical failure were small contracted gallbladder, diffuse blood oozing from the gallbladder wall,¹³ cystic duct injury, and bleeding.¹⁴ The number of sessions of percutaneous cholecystolithotomy ranged from 1 to 6 for complete stone removal. Procedure related complication rate was reported as 4%-15%.^{8,9,13-16} Table 2 summarizes complications from the previous studies. The most common complication was bile leak during the procedure or after catheter removal. Other common complications were gallbladder perforation (Fig. 7), gallbladder wall bleeding, acute pancreatitis, and transient cholangitis. Recurrence rate of gallstones has been reported from 2.5% to 14% (Table 1). Our study showed that over a mean clinical follow-up period of 33 months, 8 of 65 patients (12%) developed recurrent symptoms and 12/30 (40%) had recurrent gallstones on follow-up ultrasound (mean: 14 months).¹⁷ Our study concluded that the risk of gallstone recurrence after percutaneous cholecystolithotomy is notable, but the symptom recurrence rate is much lower.

Conclusion

Technical success rate of percutaneous cholecystolithotomy using cholecystoscopy ranges from 93% to 100%. Although recurrence rate of gallstones has been reported up to 40%, the symptom recurrence rate is much lower. Therefore, percutaneous cholecystolithotomy using cholecystoscopy can be an alternative to cholecystectomy in high surgical risk patients with symptomatic gallstones.

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