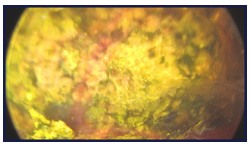

Multi-institutional Retrospective Study of Percutaneous Cholangioscopy-Assisted Lithotripsy for Inoperable Calculous Cholecystitis

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ABSTRACT

Purpose: This study aimed to assess the safety and efficacy of percutaneous lithotripsy for gallstone eradication in patients with calculous cholecystitis with stones >1 cm.

Materials and Methods: Multi-institutional institutional review board approved retrospective review of patients who presented with calculous cholecystitis and were not determined to be surgical candidates. All patients underwent percutaneous cholecystostomy tube placement for acute infection, which was later exchanged for a large sheath for ShockPulse (Olympus, Tokyo, Japan) lithotripsy and stone destruction. Review parameters included procedural technical and clinical data, including clinical presentation, mean length of hospital stay, and postintervention symptom reduction.

Results: Twelve patients (mean age, 74.6 years; range, 52–94 years; 6 men and 6 women) underwent large-bore sheath (24–30 F) cholangioscopy-assisted gallstone destruction via rigid lithotripsy. The size of the gallstones ranged from 1.2 to 4.0 cm. All patients had prior cholecystostomy access for a mean of 25 weeks before gallstone extraction to ensure tract maturation via transhepatic or transperitoneal access. The technical success rate in single-session stone removal was 100%, with no major procedure-related adverse events. All patients were symptom- and pain-free after the procedure. The mean procedure time was 111.5 minutes, and the mean fluoroscopy time was 19.2 minutes. The median length of hospital stay was 1 day after the procedure. The mean time from percutaneous lithotripsy to biliary tube removal was 35 days (range, 17–45 days).

Conclusions: Fluoroscopy-guided percutaneous rigid lithotripsy is a safe and effective procedure for gallstone destruction and extraction in patients who are poor surgical candidates with large lumen-occupying cholelithiasis.

ABBREVIATIONS

EHL = electrohydraulic lithotripsy, PCT = percutaneous cholecystostomy tube, SD = standard deviation, SIR = Society of Interventional Radiology, US = ultrasound

Calculous cholecystitis is a common disease that affects nearly one-quarter million people in the United States (1). In fact, acute cholecystitis may account for up to 3%–10% of causes of acute abdominal pain in patients (2). Cholecystitis is caused by inflammation of the gallbladder most commonly secondary to gallstones in the extrahepatic bile ducts, including the cystic and common bile ducts (3). The current standard management of calculous cholecystitis is cholecystectomy in patients who are deemed to be appropriate surgical candidates (4). However, some patients presenting with acute cholecystitis are not suitable surgical candidates. This is especially true for patients with a contraindication to receiving general anesthesia, concomitant biliary sepsis, or a history of prior failed cholecystectomy or in those who are likely to convert to open cholecystectomy (5–10).

In patients considered to be at high risk of surgery, percutaneous cholecystostomy tube (PCT) placement is a minimally invasive alternative treatment with a highly successful cure rate for acute calculous cholecystitis, with up to 91% of patients successfully resolving their infection (5).

PCT placement is particularly advantageous in critically ill patients because of its low adverse event rate and minimally invasive nature of execution (5). However, cholecystostomy tubes may carry a burden of prolonged postprocedural care in patients with comorbidities

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RESEARCH HIGHLIGHTS

- Twelve patients with inoperable calculous cholecystitis and chronic cholecystostomy drains underwent large-bore cholangioscopy-assisted gallstone lithotripsy for stones measuring 1.2–4.0 cm.
- Technical success with complete evacuation of stones and fragments was achieved in 100% after 1 session, with no major adverse events.
- The median length of hospital stay was 1 day. Cholecystostomy drains were removed after a mean of 35 days, and all patients were free of symptoms and stones at the 3-month follow-up.

precluding them from laparoscopy or open cholecystectomy. A recent review of a nationwide administrative data set in the United States found that as many as two-thirds of patients who receive cholecystostomy tubes for acute cholecystitis do not undergo subsequent cholecystectomy within the following year (6). In patients who cannot undergo surgery and require long-term PCT, the drain becomes a physical hindrance in someone who may be otherwise well-abled. Maintaining a percutaneous tube for a prolonged period can become tedious because the drain requires regular exchanges to preserve patency.

Interval cholecystectomy is the preferred treatment for patients with transient surgical contraindications; however, if patients continue to have symptoms and/or are chronically considered to be high-risk surgical candidates, gallstones may be extracted percutaneously with the gallbladder left in place, as shown in **Figure 1** (10–14). The process of initial cholecystostomy tube placement, gallstone removal, and eventual PCT removal often consists of a series of procedures, allowing the implementation of the proper catheters, sheaths, and cholangioscopy to remove the stones percutaneously with the option of direct visualization. Although small stones (<1 cm) can be retrieved via a basket or even simply irrigated from the gallbladder via a large access sheath, stones >1 cm cannot easily be extracted because they are limited by the lumen of even 30-F sheaths.

Lithotripsy to fracture stones aids in simplifying the eradication process of cholelithiasis. Electrohydraulic lithotripsy (EHL) and holmium laser devices are advantageous in the destruction of bile salt stones, although these fibers have limited pulse number use and create debris, which obscures visualization. Furthermore, larger cholesterol stones (>1 cm) may require several procedures and probes to achieve complete destruction and removal of these cholelithiases. Patel et al (15) described the outcomes of gallstone removal via lithotripsy for patients with chronic contraindications to cholecystectomy. This study included several different lithotripsy techniques. The current study aimed to characterize the safety and assess the effectiveness of percutaneous fluoroscopy-guided large-bore (24-30 F) gallstone extraction using lithotripsy (ShockPulse-SE; Olympus, Tokyo, Japan) to circumvent this size limitation and ultimately fracture, remove, and treat an otherwise inoperable calculous cholecystitis.

STUDY DETAILS

Study type: Retrospective, observational, descriptive study

Level of evidence: 4 (SIR-D)

MATERIALS AND METHODS

A retrospective multi-institutional study was performed with approval from the MedStar Washington Hospital Center internal review boards at 2 large academic hospitals. Patients who underwent percutaneous cholangioscopy-assisted large-bore (24–30 F) gallstone extraction via lithotripsy for calculous cholecystitis at both institutions between September 2020 and August 2022 were reviewed for inclusion in this study. Each patient chart was examined for demographic characteristics, including age, sex, ethnicity, and race. The inclusion criteria included all patients who underwent lithotripsy for gallstone extraction. The exclusion criteria included patients who had gallstones with a size of <1 cm and who did not undergo lithotripsy for stone removal. Additional parameters reviewed were procedural technical and clinical data, including the details of clinical presentation, mean length of hospital stay, and postintervention symptom reduction.

Twelve nonconsecutive patients underwent gallstone destruction via lithotripsy at 2 large academic hospitals between September 2020 and February 2022. The cohort included 6 male and 6 female patients with a mean age of 74.6 years (standard deviation [SD], 12.4 years; median, 75.5 years; range, 52–94 years) (**Table 1**). Patients' gallstones ranged from 1.2 to 4.0 cm in maximum diameter based on cross-sectional measurements, confirmed on fluoroscopic cholangiography. The preoperative laboratory values are included in **Table 2**, which were notable for 11 patients who had a total bilirubin levels count of $<10.0 \times 10^9$/L and for 1 who had a total bilirubin levels count of $>10.0 \times 10^9$/L. Eleven patients had normal total bilirubin levels (<1.2 μmol/L), and 1 had elevated total bilirubin levels levels (>1.2 μmol/L). All 12 patients had aspartate aminotransferase and alanine aminotransferase levels within the normal limits.

Two fellowship-trained interventional radiologists (J.B.S, W.F.B.) with combined 6 years of postgraduate experience served as the primary operators for the lithotripsy. The gallstone size was measured on cross-sectional imaging and confirmed during fluoroscopic cholangiography. Technical success was defined as removal of the entirety of the stone(s) during the procedure. Clinical success was defined as successful removal of the PCT and patient to be symptom-free, as well as image-confirmed gallstone-free after 3 months after removal of the cholecystostomy tube. Adverse events were categorized based on the guidelines set forth by the Society of Interventional Radiology Standards of Practice

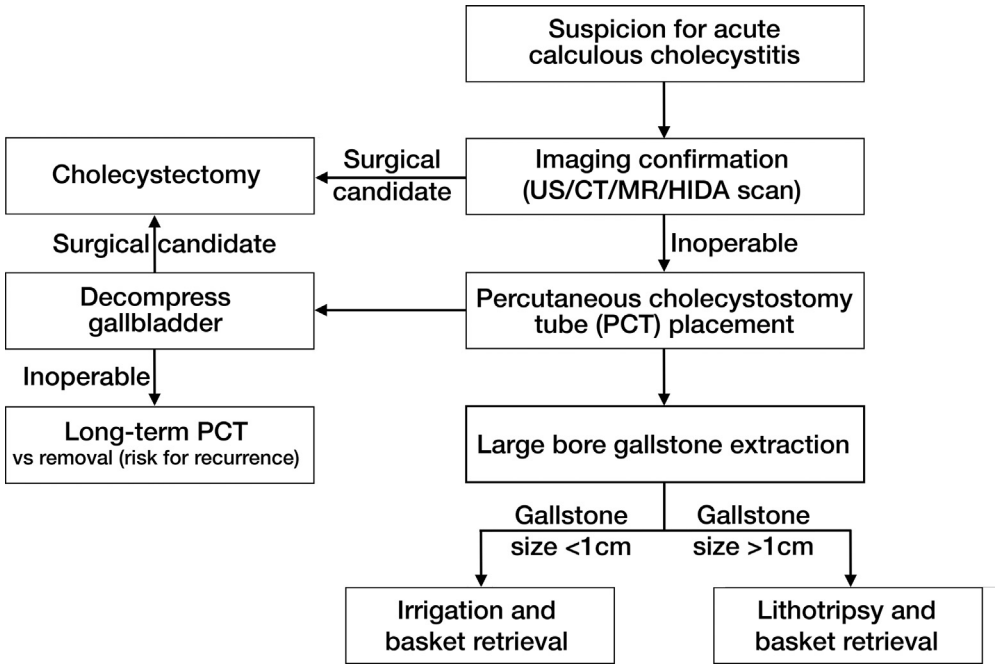

Figure 1. Management algorithm of acute calculous cholecystitis. CT = computed tomography; HIDA = hepatobiliary iminodiacetic acid; MR = magnetic resonance; PCT = percutaneous cholecystostomy tube; US = ultrasound.

Committee (16). Statistical analyzes were performed using SPSS (IBM, Armonk, New York). Descriptive analysis was calculated for all normally distributed categorical variables.

Technique

Initial access to the gallbladder for cholecystostomy tube placement in the setting of cholecystitis was achieved by bedside ultrasound (US) or a combination of US and fluoroscopic guidance in the interventional radiology suite to place an 8- or 10-F catheter. The large-bore gallstone extraction technique was defined as upsize of an indwelling cholecystostomy tube between 2 and 4 weeks after tract maturation to 24-, 28-, or 30-F sheath size or de novo access to the gallbladder with placement of a 24-F sheath for the purpose of stone destruction and extraction. The sheaths used were dependent upon operator preference and included the 24- and 30-F balloon-assisted NephroMax sheaths (Boston Scientific, Marlborough, Massachusetts), 30-F X-Force Balloon Dilation Catheter (BD, Murray Hill, New Jersey), and 28-F Amplatz Renal Dilator Set (Cook Medical, Bloomington, Indiana). All dilation was performed with balloon catheter dilation.

Image guidance was used, including fluoroscopy in combination with direct visualization via cholangioscopy using a disposable cholangioscope (SpyGlass Discover; Boston Scientific) and/or a rigid nephroscope (Storz MIP-L; Storz, Tuttlingen, Germany) to directly visualize the target stones (Fig 2a–d). The SpyGlass Discover was used in instances where basket retrieval was required and direct visualization of the cystic and common bile ducts was necessary to remove smaller stones. The ShockPulse-SE, featuring a dual action ultrasound and ballistic/mechanical mechanism, was utilized in all procedures via placement through the Storz MIP-L rigid nephroscope. Following direct visualization of the cholelithiasis, gallstone destruction was performed using the lithotripter, which allowed for simultaneous destruction of the stone and removal via high-power suction. Because the nephroscope and lithotripter combination at both institutions required at least a 24-F system for appropriate implementation, this was the smallest access sheath placed. Successful eradication of cholelithiasis and determination of a patent gallbladder lumen were confirmed with direct visualization using cholangioscopy, as well as fluoroscopic cholangiography, which was also used to evaluate patency of the cystic and common bile ducts (Fig 3a, b). The accesses were closed using a 14-F pigtail cholecystostomy tube or a 12-F internal/external biliary catheter if transcholecystic access to the duodenum was achieved depending upon operator discretion. A purse-string silk suture was then placed to approximate the skin around the tube, which was left to a gravity drainage bag.

RESULTS

Eleven patients had cholecystostomy tubes in place before the lithotripsy procedure, whereas 1 patient had a de novo access to the gallbladder with upsize to a 24-F sheath. This patient's access was obtained in the setting of medically managed chronic calculous cholecystitis, and after discussion with the patient and surgical service, elective percutaneous cholelithotomy was chosen. Eleven patients had transhepatic access, and 1 patient had transperitoneal access. The mean initial percutaneous biliary tube insertion

Table 1. Patient Demographic Characteristics

Demographic characteristic	Value of characterestic
Total no. of patients, n (%)	12 (100)
Mean age, y (range)	74.6 (52–94)
Female sex, n (%)	6 (50)
Race, n (%)	
White	7 (58)
Black or African American	3 (25)
Asian	2 (17)

Table 2. Preoperative Laboratory Findings

Laboratory findings	Number of patients
White blood cell count ($\times 10^9$/L), n (%)	
<10	11 (92)
>10	1 (8)
Aspartate aminotransferase (U/L), n (%)	
<48	12 (100)
>48	0 (0)
Alanine aminotransferase (U/L), n (%)	
<55	12 (100)
>55	0 (0)
Total bilirubin level (μmol/L), n (%)	
<1.2	11 (92)
>1.2	1 (8)

to percutaneous lithotripsy time was 172.3 days (SD, 244.3 days; median, 62.5 days; range, 0–722 days), with the longer time attributed to lack of this procedure being available to the patient at the time of initial cholecystostomy tube placement.

Technical procedural outcomes are shown in Table 3. The mean procedure time was 111.5 minutes (SD, 55.8 minutes; median, 108 minutes; range, 56–227 minutes) with a mean fluoroscopy time of 19.2 minutes (SD, 13.5 minutes; median, 17.7 minutes; range, 3.5–44.9 minutes). Longer procedural and fluoroscopy times were attributed to the learning curve of cholangioscopy, as well as the 2 cases in which transcholecystitic access to the duodenum was achieved, and fragments from the stones were removed using the cholangioscope.

There were no major procedure-related adverse events including death related to the procedure. According to the Society of Interventional Radiology (SIR) standard classification of adverse events, 2 patients had Grade 1 mild adverse events, which included a small perforation of the gallbladder and intraperitoneal spillage of the contrast, without subsequent hospitalization or prolonged infection. One patient had a Grade 3 severe adverse event, which included biliary colic and sepsis approximately 3 days after gallstone extraction. This patient was subsequently admitted to the intensive care unit and required a prolonged hospital stay of 24 days. All outpatients were kept in the hospital for a minimum 23-hour observation after stone extraction to monitor for signs of infection and for pain control. The mean length of hospital stay after the procedure was 3.4 days (SD, 7.3 days; median, 1 day; range, 0–24 days). Of note, 1 patient had a prolonged stay in the hospital because of sepsis, whereas another patient had social issues and other ongoing unrelated medical concerns that required prolonged hospitalization.

The clinical procedural outcomes are detailed in Table 4. The mean time from percutaneous ShockPulse lithotripsy to cholecystostomy tube removal was 35 days (SD, 8.6 days; median, 35 days; range, 17–45 days) in 11 of 12 patients. One patient was unable to have the tube removed because he died of COVID-19 complications at a later date after lithotripsy. The remaining 11 patients were confirmed to be gallstone-free and symptom-free on US (n = 10) and computed tomography (n = 1) 3 months after cholecystostomy tube removal.

DISCUSSION

In this study, lithotripsy was demonstrated to be reasonably safe and effective in treating gallstones of >1 cm. The technique for percutaneous cholangioscopy-assisted lithotripsy varies among operators, although 24- and 30-F sheaths are required to allow the advancement of the lithotripter device and nephroscope. Regardless of the technique from operators from different institutions, the technical success rate in this study remained 100%. There was no significant variability in the procedural time between institutions, with the mean time approximately 50 minutes faster than that in the single institution study by Patel et al (15), likely attributable to progression of comfort using the device over the 2-year period of evaluation. There was 1 SIR Grade 3 procedure-related adverse event. This patient had multiple comorbid conditions, including Class III obesity and immobility, and developed sepsis approximately 3 days after the procedure but was successfully treated and discharged 25 days later. Two patients had SIR Grade I adverse events, which included a small perforation of the gallbladder and intraperitoneal spillage of the contrast, respectively. Patel et al (15) demonstrated an 85% primary technical success rate in a group of 13 patients who underwent electrohydraulic and ultrasonic lithotripsy for symptomatic cholelithiasis. Two patients in their cohort experienced major adverse events, which included a death. The presence of a high technical success rate in the current cohort is a promising finding with respect to the safety of this procedure, especially given the prevalence of medical comorbidities inherent to the population.

Similar to the study by Patel et al (15), all patients in this study were symptom-free after the procedure, with a median of 1 day for postprocedural monitoring. Compared with a mean of 151 days for the length of time between the initial PCT placement and stone retrieval in the study by Patel et al (15), this study demonstrated a longer interval between the 2 procedures by approximately 20 days. This difference can be attributed to the COVID-19 pandemic and reallocation of hospital resources. Additionally, the large-bore stone retrieval program was only recently offered at both

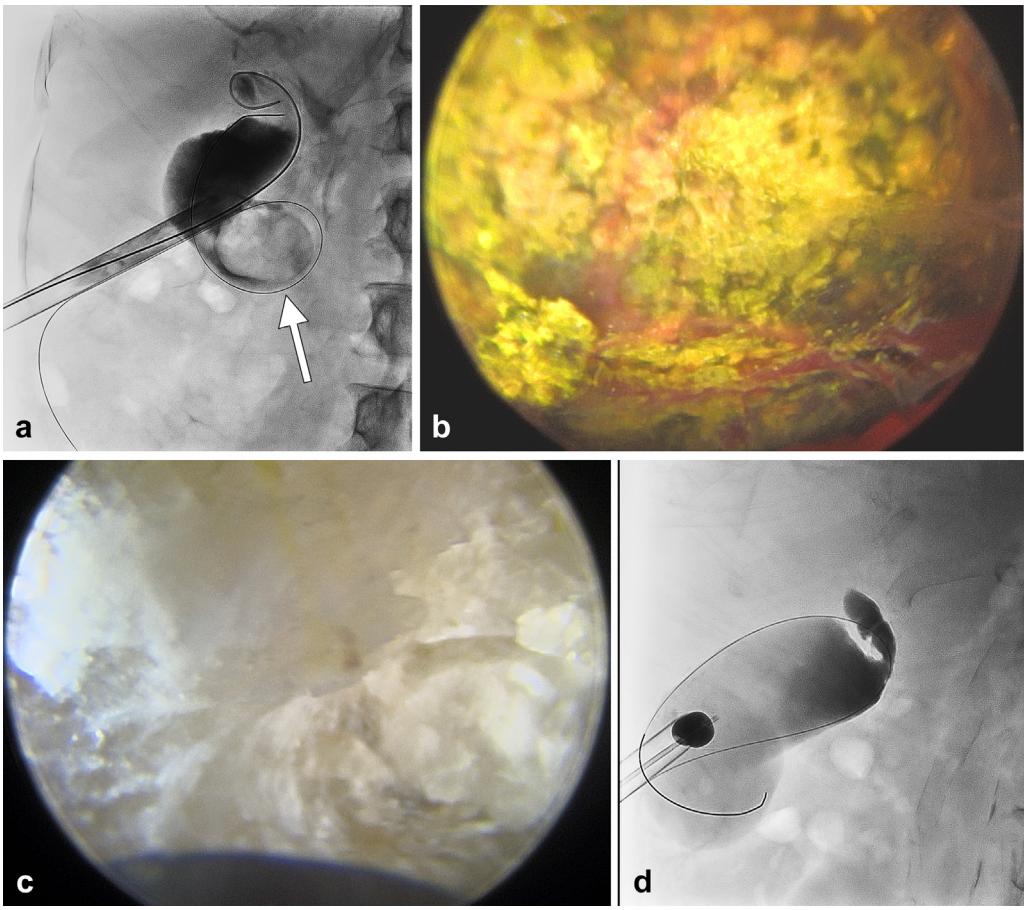

Figure 2. (a) Initial cholangiogram with a 24-F sheath in the gallbladder lumen demonstrated a large, solitary gallstone (arrow). A 0.018-inch nitinol wire was kept as a safety wire. **(b)** Direct visualization of the gallstone through the nephroscope. **(c)** Partially resolved cholelithiasis after lithotripsy, with the lithotripter partially visible at the inferior margin of the image. **(d)** Balloon-occluded completion cholangiography using a 5.5-F Fogarty catheter through the sheath demonstrated complete clearance of the stone.

institutions. Hence, several patients were living with a chronic cholecystostomy tube before being offered lithotripsy. Similarly, the extended length of time between the initial stone retrieval and tube removal in this study was due to a combination of the COVID-19 pandemic limiting room availability and logistics of patient scheduling. Many patients traveled great distances for their gallstone extraction and had limitations in returning to interventional radiology for the follow-up.

Multiple devices, such as EHL, are advantageous in destruction of bile salt stones (19). However, EHL may require multiple procedures and probes to achieve complete destruction and removal of these cholelithiases, especially cholesterol-based stones. Additionally, high frequency EHL is maximized at 2,000 Hz, limiting stone destruction (20). Dual mechanism ultrasound and ballistic/mechanical lithotripsy is more robust and advantageous in this setting because only 1 procedure is required to fragment stones and there is no limitation in effectiveness for stone composition.

Dual mechanism lithotripsy is an alternative tool in the fast-growing field of percutaneous cholangioscopy to remove gallstones with a size of >1 cm. Patients who are poor surgical candidates commonly have cholecystostomy tubes for a prolonged period of time, and these drains can have a marked impact on quality of life. Additionally, the cholecystostomy tube may intermittently become blocked or dislodged, which may require repeat procedures and possible readmission to the hospital (17–19). Furthermore, in the presence of cholestasis, the rate of recurrent cholecystitis is reported to be anywhere between 14% and 41% after cholecystostomy tube removal, despite cystic and common bile duct patency at the time of removal, with rates likely higher in patients with acute or chronic cholecystitis (10). Also, in a patient population already physically unable to tolerate surgery, this vulnerability to repeat infection comes with additional morbidity and mortality because of increased prevalence of pre-existing conditions in this population (6). Percutaneous extraction of gallstones is gaining momentum as a method of treatment for high-risk surgical patients, ultimately bridging them to eventual tube removal (10–14). Although this provides an avenue of treatment previously

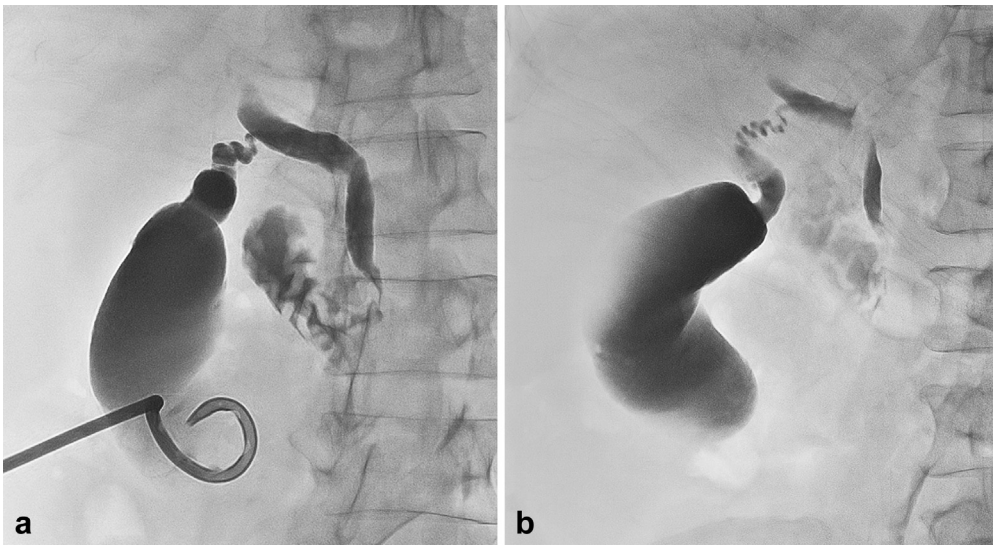

Figure 3. (a) Follow-up cholangiography via a 14-F cholecystostomy tube 2weeks after gallstone extraction demonstrated a patent cystic duct with contrast medium freely flowing into the duodenum. **(b)** After removal of the cholecystostomy tube, there was no evidence of residual stone, peritoneal leak, or obstruction of the cystic or common bile ducts.

Table 3. Technical Procedural Outcomes

Technical and procedural outcomes	Procedure values
Gallstone size range, cm	1.2–4.0
Mean initial biliary tube insertion to lithotripsy time, d (range)	172.3 (0–722)
Stone removal, n (%)	12 (100)
Type of anesthesia, n (%)	
General anesthesia	11 (91)
Moderate sedation	1 (9)
Mean procedure time, min	116.9
Mean fluoroscopy time, min	19.2
SIR classification of adverse events, n (%)	
Grade 1	2 (16)
Grade 2	0 (0)
Grade 3	1 (8)
Grade 4	0 (0)
Grade 5	0 (0)

SIR = Society of Interventional Radiology.

Table 4. Clinical Procedural Outcomes

Clinical outcomes evaluated	Clinical outcome values
Median postprocedural length of stay, d	1
Symptom-free after the procedure, n (%)	12 (100)
3-mo symptom-free, n (%)	11 (100)*
Mean lithotripsy to biliary tube removal time, d (range)	35 (17–45)*

*One patient was unable to have their tube removed because he died of COVID-19–related complications unrelated to lithotripsy. The sample size for mean lithotripsy to biliary tube removal time and 3-month symptom evaluation calculation was 11 patients.

underutilized, there are size limitations regarding which stones can safely be retrieved percutaneously. Percutaneous cholangioscopy-assisted lithotripsy has been demonstrated to be a safe and effective intervention to aid the retrieval of large gallstones in patients who are unable to tolerate surgery.

The limitations of this study include the retrospective design, small sample population, difference in techniques among physicians at multiple institutions, selection bias from 2 tertiary centers, and short-term follow-up. This study followed patients only 3 months after cholecystostomy tube removal, whereas a prior study (15) followed their patients for approximately 3 years. A concern for percutaneous treatment of gallstones is the risk of recurrent cholelithiasis formation and subsequent cholecystitis (18). The risk of recurrent cholecystitis after cholecystostomy removal without gallstone retrieval can be as high as approximately 40%, whereas subsequent percutaneous retrieval appears to be associated with significantly lower rates of recurrent biliary pathology (10–15). This discrepancy emphasizes the need for percutaneous treatment options for patient stones of all sizes. Whether a history of previous lumen-occupying stones requiring fragmentation portends a future risk of large gallstones necessitating percutaneous treatment is a question of particular interest to the population described in this study, and a continued follow-up of this cohort will help further characterize the long-term benefit of percutaneous gallstone lithotripsy and removal.

In conclusion, the results of the current report in conjunction with previous studies suggest that PCT placement paired with interval percutaneous gallstone removal with or without lithotripsy, depending on stone size, is associated with high rates of technical success and symptom resolution.

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