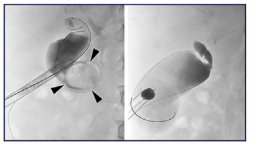

Safety and Effectiveness of Large-Bore Percutaneous Cholangioscopy–Assisted Gallstone Retrieval for Inoperable Calculous Cholecystitis: A Multi-Institutional Retrospective Study

John B. Smirniotopoulos, MD, Neil Jain, DO, Matthew Lamberti, MD, Daniel Marchalik, MD, Timothy McClure, MD, and William Browne, MD

ABSTRACT

Purpose: To evaluate the safety and effectiveness of large-bore percutaneous biliary access techniques for cholangioscopy-assisted gallstone extraction in patients with a history of acute calculous cholecystitis who are poor surgical candidates.

Materials and Methods: A retrospective analysis was conducted on patients who underwent percutaneous cholangioscopy for gallstone extraction using large-bore access (24 or 30 F) at 2 large academic centers from September 2020 and August 2022. Technical success, procedure duration, fluoroscopy time, immediate postprocedural symptom reduction, 3-month symptom-free outcomes, and adverse events (AEs) were assessed.

Results: Thirty consecutive patients were included. Gallstone removal in a single cholangioscopy session was successful in 93.3% of cases. Large-bore access facilitated the removal of gallstones ranging from 0.5 to 4 cm in diameter, with mean procedure and fluoroscopy times of 105.4 minutes and 21.7 minutes, respectively. All patients who presented for 3-month follow-up remained symptom-free without gallstone recurrence on imaging. The overall AE rate was 6.7%, one Grade 2 and one Grade 3 based on the Society of Interventional Radiology (SIR) AE grading system, both managed successfully, leading to patient discharge home.

Conclusions: Large-bore percutaneous biliary access for cholangioscopy-assisted gallstone extraction is a safe and effective technique for managing symptomatic cholelithiasis in poor surgical candidates.

ABBREVIATIONS

ACC = acute calculous cholecystitis, FDA = U.S. Food and Drug Administration, IR = interventional radiology, PCT = percutaneous cholecystostomy tube, PTCS = percutaneous cholangioscopy, US = ultrasound

Acute cholecystitis is most often caused by cystic duct obstruction and subsequent gallbladder inflammation in the setting of cholelithiasis (1). The current standard of care for acute calculous cholecystitis (ACC) is medical management and surgery, either urgently or delayed depending on timeline of clinical presentation. However, some patients with ACC are precluded from definitive surgical management in the setting of certain contraindications, such as multiple prior surgical interventions, severe cirrhosis, severe cardiopulmonary disease, and bleeding disorders (2). In nonoperative candidates, the preferred treatment for ACC is urgent or emergent decompression of the biliary system with a percutaneous cholecystostomy tube (PCT) placed by interventional radiologists.

PCT placement is a safe and highly effective temporizing intervention for such patients, with up to 91% of patients achieving successful resolution of ACC (3). Although the ultimate goal of PCT is to stabilize and medically optimize the patient for eventual cholecystectomy, certain comorbidities may persistently preclude surgical intervention. The rate of recurrent cholecystitis in this population is reported to be between 14% and 41% after cholecystostomy tube removal in the setting of a patent cystic duct with persistent cholelithiasis, with rates likely higher in patients with acute-onset chronic cholecystitis (4,5).

Percutaneous cholangioscopy (PTCS) and gallstone extraction has been gaining momentum in the field of interventional radiology (IR) in response to the need for

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RESEARCH HIGHLIGHTS

- Large 24–French and 30-F access was safe and effective to allow percutaneous, cholangioscopy-assisted gallstone removal in high-risk patients with calculous cholecystitis.
- A large-bore access track may be safely tamponaded with a 14-F cholecystostomy tube.
- No recurrent stones or cholecystitis was observed 3 months after cholecystostomy tube removal.

STUDY DETAILS

Study type: Retrospective, observational, descriptive study

Level of evidence: 4 (SIR-D)

definitive treatment management for these patients. Techniques such as PTCS-assisted gallstone irrigation, basket retrieval, electrohydraulic lithotripsy, laser lithotripsy, and ultrasonic wave lithotripsy have granted interventional radiologists the capabilities to percutaneously remove gallstones through an existing cholecystostomy access without the need for surgery. These techniques have demonstrated effectiveness in the literature, with the rates of recurrent sequelae of gallstone disease after intervention reported to be as low as 10%–21% (3,6,7).

There is limited evidence in the available literature demonstrating the optimal sheath size for cannulating the cutaneobiliary tract in preparation for stone extraction. The selection is often based on operator preference and is often limited to cholangioscope diameter, with many interventionalists opting to use a sheath size of 12–14 F as a procedural standard. However, this size of sheath size may limit efficiency of stone removal for larger cholelithiasis (>1 cm) or a gallbladder with numerous stones, necessitating repeat interventions. In 2023, Smirniotopoulos et al (7) demonstrated advantages of the large sheath size in a retrospective study of 12 patients undergoing dual-energy lithotripsy. An advantage of large lumen access is that 24- and 30-F sheaths accommodate larger instruments such as a rigid nephroscope used as an off-label tool to support dual-energy lithotripsy. Additionally, the larger sheath allows for rapid irrigation and clearance of multitude of small stones (7). However, this study was limited to only patients undergoing dual-energy lithotripsy with a small sample size.

In order to address these issues, this study aimed to evaluate the safety and effectiveness of large-bore (24- and 30-F sheath) access for percutaneous gallstone extraction for nonsurgical candidates with calculous cholecystitis.

MATERIALS AND METHODS

A retrospective multi-institutional study was performed with approval from the MedStar Washington Hospital Center and Weill Cornell Medicine institutional review boards at 2 academic centers. Patients who underwent PTCS-assisted large-bore (24–30 F) gallstone extraction for calculous cholecystitis between September 2020 and August 2022 were reviewed for inclusion in this study. Thirty patients with history of ACC or mixed ACC and cholangitis who underwent this large-bore access technique to remove gallstones percutaneously were identified. Each patient chart was examined for demographics, including age, sex, ethnicity, and race. Inclusion criteria included all patients who underwent percutaneous large-bore gallstone retrieval. Exclusion criteria included patients who underwent cholangioscopy-assisted gallstone removal with a sheath size of <24 F.

Two fellowship-trained interventional radiologists (J.B.S., W.B.) served as the primary operators for percutaneous large-bore cholangioscopy–assisted gallstone retrieval. Additional parameters included procedural technical data and clinical data, including details of clinical presentation, mean hospital length of stay, and postprocedural symptom reduction. Gallstone size was measured on preprocedural cross-sectional imaging and during cholangiography. Technical success was defined as the removal of all visualized stones during a single procedure. Clinical success was defined as patients being symptom-free as well as imaging-confirmed gallstone-free 3 months or longer after removal of the cholecystostomy tube. All adverse events (AEs) were categorized on the basis of the guidelines set forth by the Society of Interventional Radiology (SIR) Standards of Practice Committee (8). Statistical analysis was performed using SPSS version 26 (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 acute cholecystitis was achieved by bedside ultrasound (US) or a combination of US and fluoroscopic guidance in the interventional radiology suite to place an 8-F or 10-F catheter. Based on the gallstone size on the initial cholangiogram, large-bore gallstone extraction was presented as a treatment option for these patients. Large-bore gallstone extraction technique was defined as upsize of an indwelling cholecystostomy tube between 2 and 4 weeks after tract maturation to 24-F or 30-F sheath size, or de novo access to the gallbladder with placement of a 24-F or 30-F sheath for the purpose of stone destruction and extraction. The sheath used was dependent upon operator preference, including 24-F and 30-F balloon-assisted sheaths (Nephromax; Boston Scientific, Marlborough, Massachusetts), 30-F balloon dilation catheter (X-Force; BD, Murray Hill, New Jersey), and dilator set (Amplatz Renal Dilator Set; Cook Medical, Bloomington, Indiana) in conjunction with either a 10-mm or 10-mm × 40-mm balloon catheter (Conquest; BD) for balloon-assisted tract dilation. All dilations was performed with balloon dilation over a 0.035-inch × 145-cm Amplatz wire

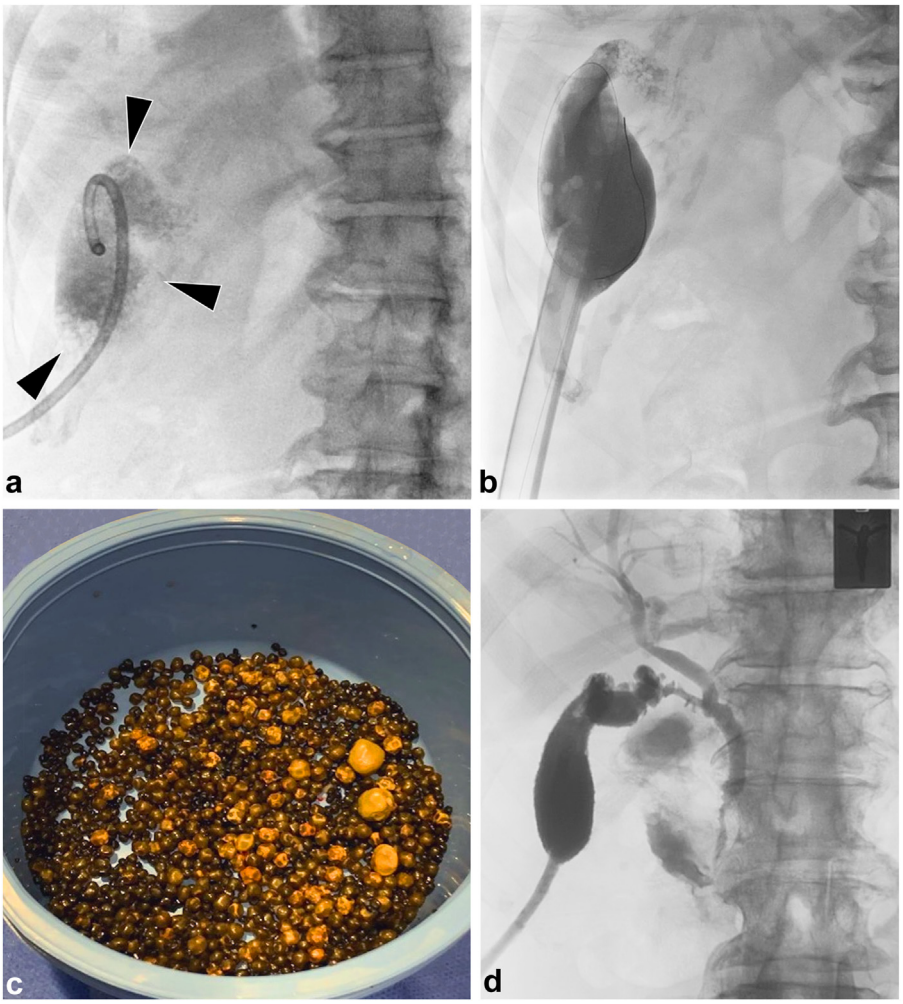

Figure 1. **(a)** Fluoroscopic image of cholelithiasis with a multitude of small stones (arrowheads) and an indwelling cholecystostomy tube. **(b)** A 30-F X-Force sheath in place midprocedure with cholangiography demonstrated decreased stone burden in the gallbladder. **(c)** Stones retrieved. **(d)** Final cholangiography with a 14-F cholecystostomy tube in place demonstrated clearance of stones, patency of the cystic and intra- and extrahepatic bile ducts, and adequate tamponade of the track without extravasation.

with either a 0.018- or 0.035-inch safety wire in the gallbladder lumen, secured to the operative field.

The method for cholelithiasis removal was dependent upon size and number of stones. Additionally, transcystic duct internal/external access was obtained in patients with concern for stone migration to the cystic and common bile ducts as well as to provide increased stability for sheath upsize, particularly in those with transperitoneal rather than transhepatic access. Transcystic access was determined on the basis of operator preference. Typically, if many small gallstones were noted on preprocedural imaging, transcystic access was obtained to balloon sweep forward through the cystic duct and common bile duct. Additionally, if there was concern for access stability, transcystic guidewire access was obtained to allow for secure advancement of a large access sheath.

For patients with a large number of stones <5 mm in diameter, as determined on preprocedural cross-sectional imaging and/or cholangiogram by the operator, a dual catheter irrigation technique was used with a Single Action Pumping System (Boston Scientific) connected to a reverse curve catheter and a 5.5-F balloon catheter (Fogarty; Edwards Lifesciences, Santa Ana, California). The 2 catheters were inserted through the sheath into the gallbladder lumen (not over a wire), and aggressive irrigation was performed through the reverse curve catheter while simultaneously retracting the partially inflated balloon catheter through the sheath to provide suction and sweep removal of stones. This was repeated until no stones were observed from the sheath, at which point direct visualization with a cholangioscope (Spyglass Discover; Boston Scientific) was used to identify any residual stones in the gallbladder lumen, and retrieved with 12- or 16-mm–diameter nitinol baskets (Zero Tip; Boston Scientific). After cholangioscopy and fluoroscopic cholangiography demonstrated a patent gallbladder lumen, the sheath was removed and a 14-F cholecystostomy tube was pursestring sutured and left to gravity drainage (Fig 1a–d).

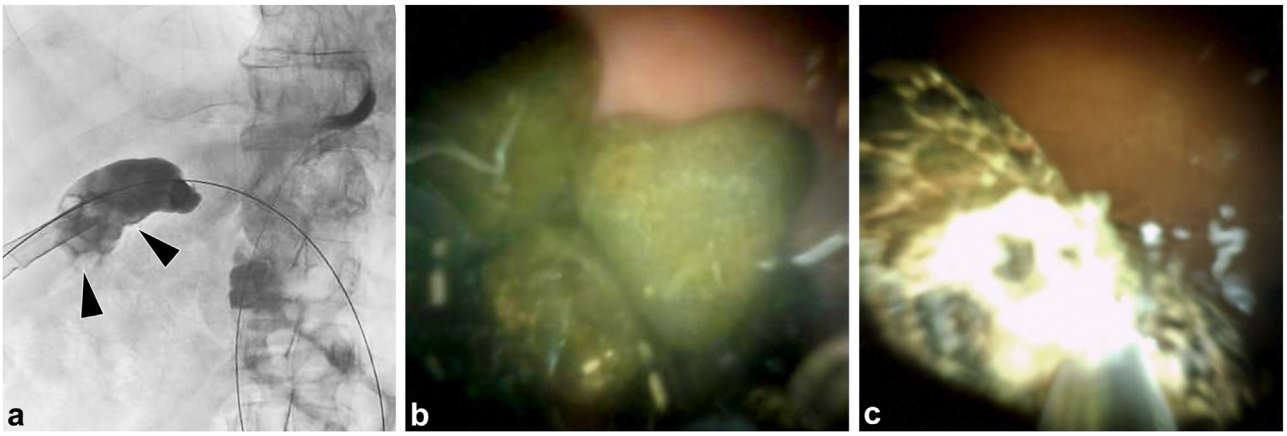

Figure 2. (a) Cholangiography with a 24-F Nephromax sheath in place and a safety wire traversing the cystic and common bile ducts showed multiple, moderate-sized faceted stones (arrowheads). **(b)** Cholangioscopic confirmation of cholelithiasis and faceted stones. **(c)** Basket retrieval of the stone using a 16-mm Zero Tip nitinol basket.

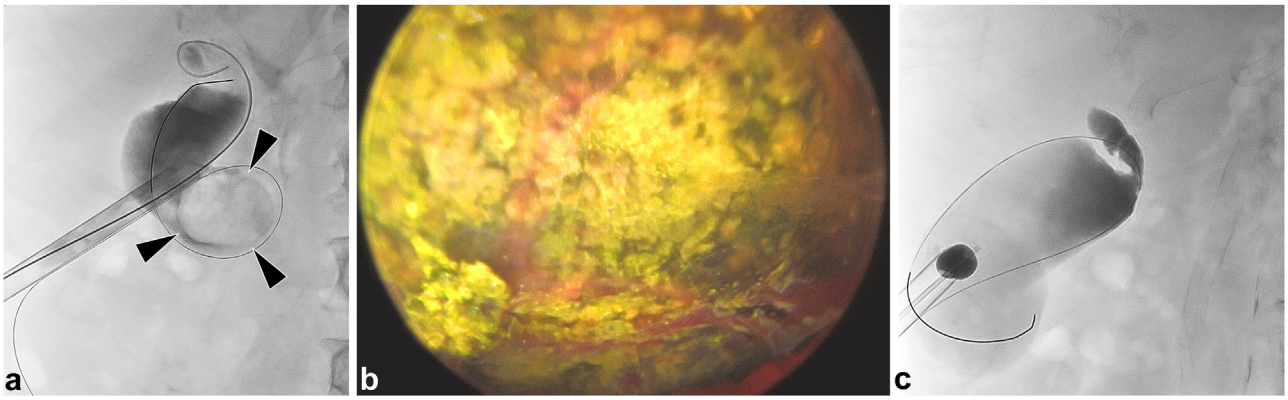

Figure 3. (a) Cholangiography through a 24-F Nephromax sheath demonstrated a large stone (arrowheads). The cystic duct was noted to be patent. **(b)** Cholangioscopic confirmation of the large stone. **(c)** Postlithotripsy and fragment retrieval cholangiography demonstrated a clear gallbladder lumen. The cystic duct was noted to be no longer patent, likely due to transient edema and spasm incurred during the procedure.

Patients who presented with stones between 5 mm and 1 cm in diameter were treated with cholangioscopy-assisted basket retrieval and/or laser lithotripsy using thulium laser (Soltive; Olympus, Center Valley, Pennsylvania) (Fig 2a–c). In patients with stones larger than 1 cm, a Storz MIP-L rigid nephroscope (Karl Storz, El Segundo, California) was used for cholangioscopy and fragmentation was performed with a lithotriptor (Shockpulse-SE; Olympus) for eradication of the cholelithiasis. A patent gallbladder lumen was 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–c).

RESULTS

Thirty patients (mean age, 73.3 years; range, 35–94 years; 17 men and 13 women) underwent large-bore sheath (24–30 F) cholangioscopy–assisted gallstone extraction. Twenty-eight patients had prior cholecystostomy access for 3–6 weeks prior to gallstone extraction to ensure tract maturation, and 2 patients had de novo access on the date of cholangioscopy. Twenty-five patients had transhepatic access, and 5 patients had transperitoneal access (Table 1).

Mean procedure time was 105.4 minutes (SD ± 42.5), and mean fluoroscopy time was 21.7 minutes (SD ± 13.9). Twenty-one patients received general endotracheal intubation for the procedure, and 9 patients received monitored anesthesia care. The Spyglass Discover cholangioscope was used in all cases to visualize the gallstones within the gallbladder and cystic duct. Of these 30 patients, 13 were upsized to a maximum 24 F using a Nephromax sheath, and lithotripsy was used to fragmentize solitary gallstones >1 cm in size in 16 patients. Seventeen cases were upsized to a maximum 30-F sheath, and a combination of irrigation and baskets was used for the retrieval of several small stones measuring <1 cm. Transcystic duct access was obtained in 17 patients during primary cholangioscopy (Table 2).

There was a 93.3% technical success rate of removal of all visualized stones in the first session of

Table 1. Patient Demographics

Demographics	Values
Total patients, n	30
Age (y), mean (range)	73.3 (34–94)
Female sex, n (%)	13 (43.3)
Race, n (%)	
White	16 (53.3)
Black or African American	11 (36.7)
Other	3 (10)

Table 2. Procedural Data

Procedural data	Values
Transhepatic access	25/30
Transperitoneal access	5/30
Transcystic duct access	17/30
24-F access	13/30
30-F access	17/30
Procedure time (min), mean ± SD	105.4 ± 42.5
Fluoroscopy time (min), mean ± SD	21.7 ± 13.9

cholangioscopy with no major procedure-related adverse events, and 2 patients required a second cholangioscopy procedure to remove residual stones measuring <1 cm. Furthermore, 93.3% of patients were symptom- and pain-free immediately after the procedure. Median hospital stay was 1 day after procedure for elective outpatients, noting that 2 procedures were performed for inpatients as living with a chronic cholecystostomy tube was determined to be a barrier to discharge. Mean time from first cholangioscopy and stone removal to successful removal of the PCT was 37 days (SD ± 25.3; Table 3).

There were 2 notable AEs observed in 2 patients. A moderate grade 2 adverse event of subcutaneous abscess was found in 1 patient 2 weeks after his initial cholangioscopy, requiring placement of a drainage catheter as an elective outpatient procedure. Both the catheter and cholecystostomy tube were successfully removed 30 days after cholangioscopy, without recurrent abscess or cholecystitis on follow-up imaging. A severe grade 3 adverse event was noted in 1 patient who developed sepsis and encephalopathy, requiring prolonged hospitalization. The sepsis resolved with appropriate antibiotics, and the patient's cholecystostomy tube was successfully removed 45 days after initial cholangioscopy.

Twenty-eight of the 30 patients received 3-month follow-up imaging and clinic visits after removal of their tubes, which demonstrated no recurrent stone formation. Furthermore, patients remained symptom-free without cholecystitis or cholangitis. One patient passed away during an inpatient admission related to coronavirus disease 2019, and a second patient was lost to follow-up (Table 3).

Table 3. Clinical Procedural Outcomes

Clinical procedural outcomes	Values
Postprocedural length of stay (d), median (range)	1 (0–25)
Postprocedural length of stay (d), mean ± SD	2.6 ± 6.4
Symptom-free after procedure, n (%)	28 (93.3)
Symptom-free at 3 mo, n (%)	28 (100)*
Lithotripsy to biliary tube removal time (d), median (range)	36 (15–119)*
Lithotripsy to biliary tube removal time (d), mean ± SD	37 ± 25*

*One patient was unable to have their tube removed as he passed away from coronavirus disease 2019–related symptoms separate from the extraction, and 1 patient was lost to follow-up. The sample size for the mean extraction to biliary tube removal time and 3-month symptom evaluation calculation was 28 patients.

DISCUSSION

PTCS has gained interest in the field of IR as a minimally invasive modality to visualize the biliary system and provide guidance in removing biliary stones for patients who have a history of calculous cholecystitis but are unable to undergo a cholecystectomy. The current U.S. Food and Drug Administration (FDA)–approved cholangioscope, Spyglass Discover, is often advanced into the system using a 10-, 11-, or 12-F system to aid in stone removal. Although effective, this can require multiple cholangioscopy events for a patient to eradicate large stones (>1 cm) or multiple small stones. This study demonstrated the safety and effectiveness of large-bore (24 and 30 F) percutaneous biliary access techniques for cholangioscopy-assisted gallstone extraction for management of cholelithiasis in poor surgical candidates with history of ACC, possibly reducing the number of overall procedures required to achieve gallstone and eventual cholecystostomy tube removal. The technical success of gallbladder and common bile duct gallstone retrieval in a single session of cholangioscopy was 93.3% between 2 large academic centers. Immediate postprocedural symptom reduction was achieved in the majority of patients, and 3-month symptom-free outcomes were achieved in 100% of patients who presented for follow-up (28 of 30 patients) without redevelopment of cholelithiasis on imaging.

Using a large access of 24 or 30 F allowed operators to remove gallstones ranging from 0.5 to 4 cm in diameter in a shorter mean procedure (105.4 minutes) and fluoroscopy time (21.7 minutes) than observed in previous studies in cholangioscopy-guided gallstone extraction. For example, Patel et al (9) reported a mean procedure and fluoroscopy time of 164 minutes and 30 minutes, respectively, in a series of 13 patients. Additionally, these findings are comparable with patient outcomes observed in alternative procedures for biliary stone disease that are performed by other specialists.

For example, in peroral endoscopic cholangioscopy, a systemic review and meta-analysis performed by gastroenterologists demonstrated an estimated 88% stone clearance

rate across a compilation of patients from 49 studies (10). Laparoscopic cholecystectomy has reported technical success rates of 95% in the literature with approximately 5% requiring conversion to open cholecystectomy (11). Additionally, the most common adverse events of laparoscopic cholecystectomy are conversion to open cholecystectomy, bile leak, bile duct injury, and mortality (12). Therefore, data from the present study suggest that large-bore PTCS-guided gallstone extraction is a similarly effective alternative therapy for biliary stone disease compared with the standard of care, particularly in patients who are poor surgical candidates or failed peroral endoscopic retrograde cholangiopancreatography management.

Previous studies (13) have described major procedure-related AEs related to percutaneous biliary interventions, including hemobilia, ductal injury, cholangitis, and biliary sepsis, particularly in the setting of intraductal manipulations such as cholangioscopy and electrohydraulic lithotripsy. An incidence rate of severe AEs related to percutaneous cholangioscopic interventions has been reported up to 8.2% in a series of 364 patients (13). There are compelling data that these AEs can be limited by allowing adequate time for track maturity prior to instrumentation through the cutaneobiliary tract; however, many operators may be wary of a presumed increase in AE rates associated with the large-bore access techniques described in this study. These data found 2 AEs related to large-bore percutaneous gallstone extraction, including 1 patient who developed a postprocedural superficial abscess requiring 6-F superficial drainage catheter placement and a second patient who developed sepsis requiring prolonged hospitalization. The overall AE rate for patients who underwent large-bore cholangioscopic interventions in this study was 6.7%, with these patients recovering from their adverse events with no further sequelae as noted at 3-month follow-up after removal of their cholecystostomy tubes. There was no mortality related to the intervention.

Given the mean age (73.3 years) and comorbidities present in this patient demographic, this study suggests that AE rates associated with large-bore cutaneobiliary access are comparable with the outcomes observed in the current standard-of-care interventions for cholelithiasis. Patel et al (9) reported a 15% AE rate in their series of 13 patients who underwent cholangioscopic gallstone removal with access sheath sizes ranging from 14 to 24 F. A retrospective review of AEs of laparoscopic cholecystectomy in patients >70 years of age demonstrated a 14.7% intraprocedural AE rate requiring conversion to open cholecystectomy (14). The postoperative AE rate in the same age demographic was 13.2%, which is comparable with the outcomes observed in this patient demographic. Moreover, these data demonstrate a median hospital stay of 1 day after procedure, which may be superior to the length of stay observed in patients who undergo surgical intervention, with a study (15) of elderly patients undergoing laparoscopic cholecystectomy reporting a mean length of stay of 2–4 days after procedure.

This study aimed to increase awareness among the community of IR regarding the utility of large-bore percutaneous biliary access for the conduction of cholangioscopy-guided biliary interventions. A 24- or 30-F biliary access does not appear to increase risk of AEs and may demonstrate the benefit of shorter procedure and fluoroscopy times. Moreover, it demonstrates an opportunity for interventional radiologists to offer patients definitive treatment for gallstone disease without the need for long-term cholecystostomy management.

There are several limitations of this study, including the retrospective design, small sample size, difference in techniques and experience among operators at multiple institutions, and selection bias from 2 tertiary centers. Moreover, this study lacks objective measurements of long-term treatment outcomes, such as rate of recurrence of gallstone-related sequelae or standardized metrics to evaluate subjective symptom improvement in patients who underwent the procedure.

Large-bore image-guided percutaneous biliary access for cholangioscopy-assisted gallstone extraction has been demonstrated to be a safe and effective treatment technique for managing cholelithiasis in patients who are poor surgical candidates. This method provides outcomes comparable with those achieved with current percutaneous gallstone extraction methods using smaller bore access while potentially offering advantages such as reduced procedure duration and decreased fluoroscopy time.

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