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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Safety and feasibility of single use cholecystoscopy for guiding laser or mechanical cholelithotripsy, and mechanical cholelithotomy

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PURPOSE

Patients with acute calculus cholecystitis and contraindications to cholecystectomy receive cholecystostomy drainage catheters, many of which remain in place until end of life. This study aims to assess safety, feasibility, and early clinical outcomes of percutaneous cholecystoscopy using the LithoVue endoscope, laser/mechanical cholelithotripsy, and mechanical cholelithotomy for management of symptomatic cholelithiasis.

METHODS

This was a single-institute retrospective analysis of 17 patients with acute calculus cholecystitis who had contraindications to cholecystectomy, underwent cholecystostomy catheter placement between 2015 and 2017, and stone removal between 2017 and 2018. The LithoVue 7.7-9.5 F endoscope was used in combination with laser/mechanical cholelithotripsy, mechanical retrograde, and balloon-assisted anterograde cholelithotomy to remove gallstones and common bile duct stones. Surgical contraindications ranged from cardiopulmonary disease to morbid obesity to neoplastic processes. Timing and number of interventions, as well as technical and clinical successes, were assessed.

RESULTS

The median time interval from cholecystostomy catheter placement to cholelithotripsy was 58 days, after an average of 2 tube exchange procedures. Technical and clinical success were achieved in all patients (stone-free gallbladder and cholecystostomy tube removal). On average, three sessions of cholecystoscopy and laser and mechanical cholelithotripsy were required for complete gallstone extraction. The mean interval time between the first cholelithotripsy session and removal of cholecystostomy was 71.8±60.8 days. There were neither major nor minor procedure-related complications.

CONCLUSION

Percutaneous cholecystoscopy using the LithoVue endoscope, in combination with laser/mechanical cholelithotripsy and mechanical cholelithotomy, is feasible, safe, well-tolerated, and was able to remove the cholecystostomy tube in the patients with contraindication to cholecystectomy.

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Cholelithiasis is a common condition in the Western world, affecting 10%-15% of the population. Of those with the signs and symptoms of biliary colic, 20% experience acute calculous cholecystitis.[1] Although cholecystectomy is the standard of care for acute calculous cholecystitis, percutaneous cholecystostomy placement is considered as first-line treatment in critically ill patients and patients with multiple comorbidities or otherwise poor operative candidates.[2] Cholecystostomy tubes typically remain in place until the gallbladder is removed or the stones are removed, assuming the cystic duct and common bile duct (CBD) are patent. Otherwise, obstruction may reoccur after drain removal in more than 33% of patients with untreated cholelithiasis.[3] Therefore, many of cholecystostomy patients live with the tube for life and are referred to interventional radiologist for cholecystostomy tube maintenance every 2-3 months, primarily to maintain catheter patency.

Various approaches have been developed or attempted for nonsurgical gallbladder stone removal ranging from chemical dissolution to extracorporeal shock wave lithotripsy,

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mechanical, electrohydraulic, ultrasonic or laser lithotripsy, and basket extraction. Recent studies have evaluated direct visualization to aid biliary intervention using endoscopic techniques, with one study using the LithoVue (Boston Scientific), a disposable digital flexible scope originally developed to access the upper urinary tract.[4,5] However, only a few studies have reported management of symptomatic cholelithiasis using percutaneous cholecystoscopy, with technical success rates of around 95% and recurrent cholelithiasis recurrent rate of less than 5%.[6-10]

The aim of this study is to evaluate safety and feasibility of the LithoVue endoscope for diagnostic evaluation and direct visualization during cholelithotripsy and cholelithotomy of the gallbladder, cystic, and CBD, and finally examine effectiveness of the procedure in removing cholecystostomy in these patients.

Methods

Study population

This was a retrospective analysis of patients with acute cholecystitis with or without additional CBD stones who underwent cholecystostomy tube placement due to contraindications for cholecystectomy and who were treated by interventional radiologist at two hospitals of Yale New Haven Health from September 2017 through December 2019. This study was approved by the institutional review board of our institution (IRB ID: 2000025691). Obtaining written informed consent was waived.

Seventeen patients were referred to interventional radiology by the surgery service for cholecystostomy placement and subsequent stone extraction because they were considered as non-surgical candidates. Inclusion criteria were patients with calculus cholecystitis with patent cystic ducts and functional gallbladders but with contraindications to cholecystectomy who underwent cholecystostomy tube placement. Patients who had acalculous cholecystitis or underwent open surgical or laparoscopic cholecystectomy subsequent to cholecystostomy placement were excluded.

Main points

- Percutaneous cholecystoscopy using the LithoVue endoscope is safe and effective in patients with acute cholecystitis that are poor surgical candidates.
- Laser/mechanical cholelithotripsy and mechanical retrograde/anterograde cholelithotomy are well tolerated using existing cholecystostomy access.
- Cholelithotripsy and cholelithotomy with percutaneous cholecystoscopy can play a role in eventual cholecystostomy tube removal.

Imaging

The diagnosis of acute calculous cholecystitis was established in each patient prior to cholecystostomy tube placement. All patients had undergone an ultrasound scan of the right upper quadrant, as a preliminary evaluation. Gallbladder size and distension were examined in 3 planes. Gallbladder wall thickening was defined as wall thickness greater than 3 mm on transverse view. The lumen was examined for sludge, stones, and polyps. A sonographic description of the gallbladder calculi including the presence of acoustic shadowing, echogenicity, shape, and contours was documented. The presence or absence of pericholecystic fluid was assessed. Sonographic Murphy's sign was assessed by the sonographer. Further examinations using HIDA scan, computed tomography scanning, or magnetic resonance imaging were performed if the diagnosis of acute cholecystitis was ambiguous.

Preprocedural medication

All procedures were performed by two interventional radiologists specializing in biliary system interventions (T.S. and I.L., with 9 and 8 years of experience, respectively). An intravenous broad-spectrum antibiotic, typically weight-based dose of Piperacillin and Tazobactam (Zosyn®, Pfizer Inc.), was administered prior to both the percutaneous cholecystostomy and stone removal procedures per operator's preference, unless the patient was allergic to these antibiotics or was already on an antibiotic regimen. Sedation regimen during stone extraction was left to the discretion of the attending anesthesiologist but most procedures were performed under moderate to deep sedation, without the need for intubation (none was performed under general anesthesia).

Cholecystostomy

All interventions described were performed in one of our interventional radiology suites. Access into the gallbladder was obtained via percutaneous transhepatic gallbladder puncture with a 21-gauge Chiba needle (Cook Med. LLC.) under ultrasound guidance. A 6 French (F) AccuStick introducer set (Boston Scientific) was used for dilation of the access track followed by the placement of an 8 F or 10 F locking loop drain. In most cases, a proper cholecystogram/cholangiogram was not performed at the time of initial cholecystostomy placement, in order to avoid overdistension of the gallbladder.

Upsizing the access track

Appropriateness of patient for cholecystoscopy, cholelithotripsy, and cholelithotomy was assessed through a multidisciplinary review with surgery, gastroenterology, and interventional radiology. Our interventional radiologists discussed treatment options and consented each patient, then the treatment plan was confirmed. During this phase of our biliary endoscopy program development, our de novo drain pathway was as follows: the percutaneous cholecystostomy catheter was upsized to a 14 F pigtail catheter after a minimum period of 4 weeks of initial placement to allow easier transition to the 16 F size access required for cholecystoscopy. The biliary endoscopy was subsequently carried out 2 weeks after the tube upsize. Prior to starting our biliary endoscopy program, we had patients who waited for longer periods of time without any specific plans for lithotripsy or tube removal due to case backlog. These patients had an 8 F tube placed initially which was eventually upsized to 16 F as discussed above.

Cholecystoscopy

The technical details of percutaneous cholecystoscopy and cholelithotripsy have been described previously.[11] A single-use LithoVue endoscope (Boston Scientific) was used in this study (Figure 1). The percutaneous tract was typically upsized depending on the stone size (Figure 2a) to accommodate a 16 F peel-away sheath (Figure 2b) (Cook Medical), through which the endoscope was advanced and used for stone management by 5 interventional radiologists, including 2 with Holmium laser privileges. The technical specifications of LithoVue endoscope include tip diameter 7.7 F, shaft diameter 9.5 F, working channel diameter 3.6 F, and deflection (up/down) of 270°/270°. The scope was connected to either its own proprietary

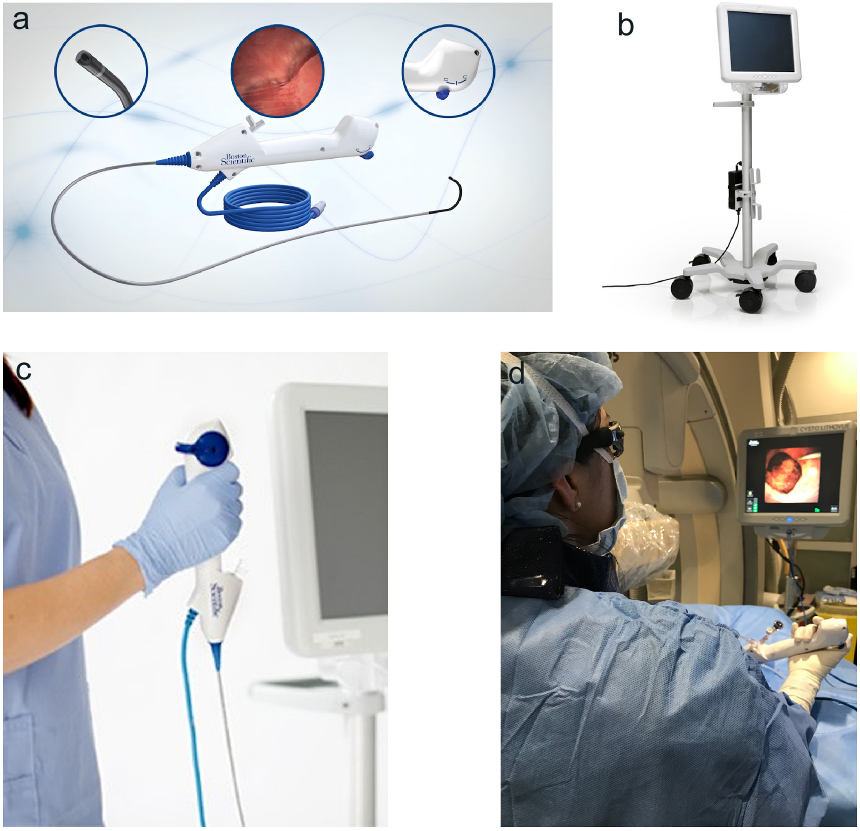

Figure 1. a-d. The components of the LithoVue scope system (Boston Scientific: www.bostonscientific.com). (**a**) A detailed view of the LithoVue scope. (**b**) An all-in-one, touchscreen PC includes the monitor, image processor, and controller. (**c**) The scope and the stand-alone PC unit together. (**d**) A real-life picture of the LithoVue scope system in our interventional radiology suite.

monitor or to another color digital monitor in the room.

Laser/mechanical lithotripsy and retrograde/anterograde stone retrieval

Laser lithotripsy (Figure 2c-2e) was performed using Lumenis Pulse Laser 30H (Lumenis Ltd.) 30 Watt laser source attached to a 365 nm fiber (Flexiva™ High Power Single-Use Laser Fiber, Boston Scientific). Mechanical lithotripsy using nitinol baskets (Boston Scientific) under direct visualization was perfromed.

For retrograde stone retrieval, retrieval baskets were used either directly through the peel-away sheath or through the scope (Figure 2f and 2g). Anterograde sweep to the CBD and small bowel (Figure 2h) was performed using 5 F Fogarty balloons (Edwards Lifesciences). Figure 3 shows pictures of stones from 2 different patients who underwent a single session of cholecystoscopy, cholelithotripsy, and cholelithotomy, while Figure 4 demonstrates a single stone from a patient who underwent multiple sessions of cholecystoscopy, cholelithotripsy, and cholelithotomy. At the end of each session, a 0.035-inch short Amplatz wire was advanced through the existing peel away sheath, and the sheath was exchanged for a 16 F pigtail cholecystostomy tube.

Cholecystostomy removal

A follow-up cholangiography was typically performed a week after the stone extraction procedure, followed by a clamping trial for up to 1 week, if the gallbladder, cystic duct, and CBD were found to be stone-free and patent. The cholecystostomy catheter was removed if the patient tolerated the clamping trial without complication. Cholecystoscopy, lithotripsy, and stone extraction procedure were repeated if there were residual gallstones.

Statistical analysis

Statistical analysis and data management were performed using SPSS statistical software version 22.0 (IBM Co.). The visibility was assessed with a subjective assessment of the image quality. The technical success was defined as performance required maneuvers to access all predetermined areas in the gallbladder and cystic duct, as well as CBD and common hepatic duct in one case, expressed by interventional radiologists at the end of the procedures. Clinical success was defined as removal of all stones. Mean ± standard deviation (SD) was used to present quantitative data, and number (%) were used to show qualitative data. Complications and recurrence-free survival were calculated based on the time of intervention to date of a recurrence or complication. A student t test was used to evaluate whether there was a difference in number of cholecystostomy tube exchange sessions between patients who underwent cholecystostomy prior to percutaneous endoscopy in simultaneous or staged fashion (prior to the introduction of our biliary endoscopy program). The probability value less than .05 was considered significant.

Results

The mean and standard deviation of the patients' age was 76.8 ± 14.3 years, mainly male patients (76.50%). Prior endoscopic retrograde cholangiopancreatography was attempted in 2 patients, successfully removing CBD stones in 1 patient, though the patient presented with recurrent CBD stones, and resulting in pancreatitis in another patient. Demographic characteristics of the study patients are presented in Table 1. The mean time intervals from diagnosis of cholecystitis to cholecystostomy placement, cholecystostomy placement to first session of cholecystoscopy, first to last session of cholecystoscopy, and last session of cholecystoscopy to cholecystostomy removal were shown in Figure 5.

Gallbladder lumen and gallstones were successfully visualized in all cases. Technical and clinical success were achieved in all sessions and all patients, except one patient who was transferred to hospice after the first cholecystoscopy session due to underlying diseases unrelated to the gallbladder. The mean length of cholecystoscopy and cholelithotripsy sessions was 127.85 ± 40.93 minutes.

The median number of cholecystoscopy, cholelithotripsy, and cholelithotomy sessions was 2 (range: 1-4). The median number of cholecystostomy exchanges between initial tube placement and first cholecystoscopy was 6 (range: 1-12). The number of cholecystostomy tube exchange sessions was significantly lower in patients who underwent cholecystostomy tube placement after the introduction of the

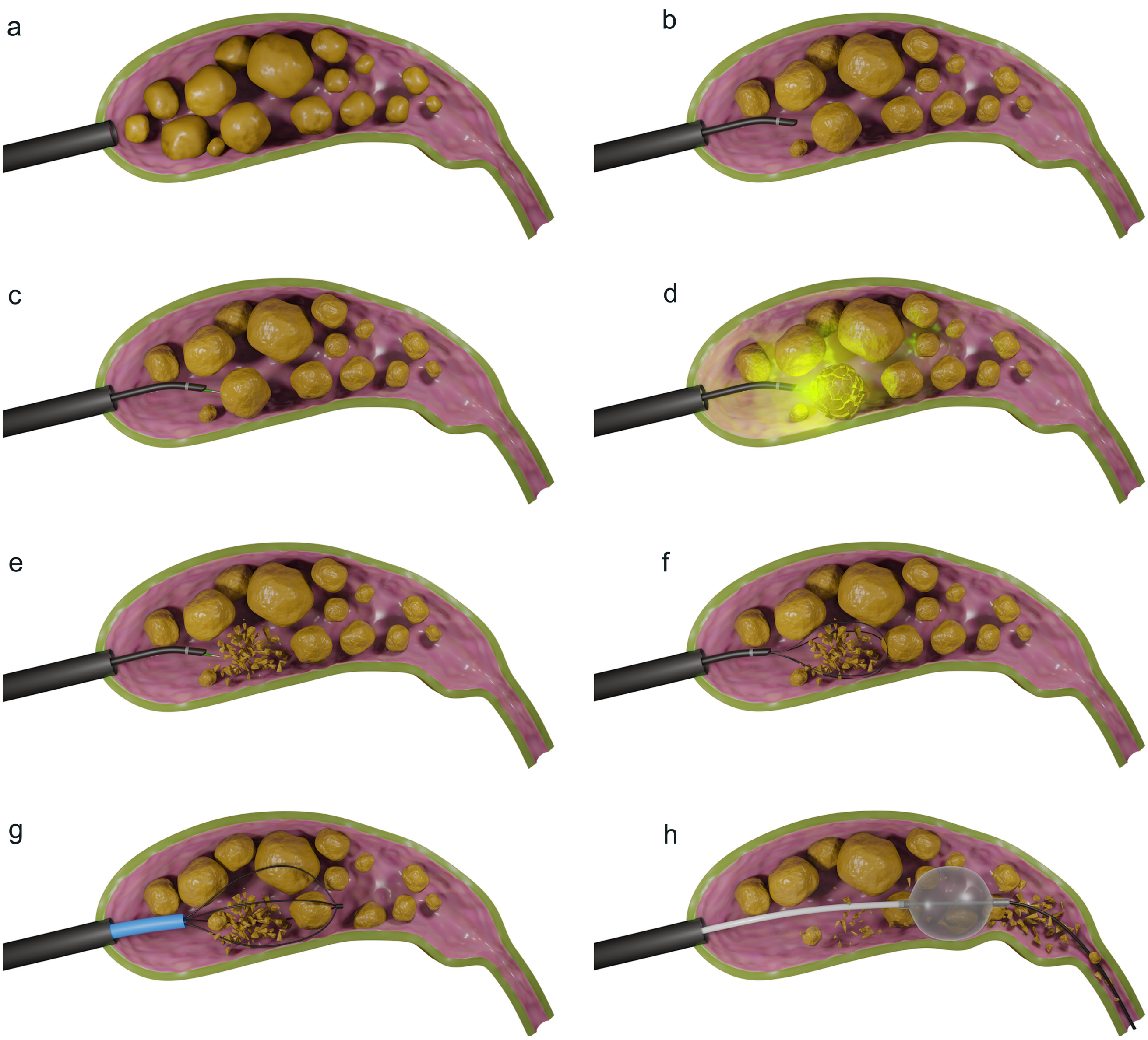

Figure 2. a-h. Schematic picture demonstrating different steps of upsizing, cholecystoscopy, laser cholelithotripsy, and mechanical cholelithotomy. **(a)** Cholecystostomy is exchanged for a Peel-Away sheath. **(b)** The LithoVue scope is advanced into the gallbladder lumen through the Peel-Away sheath. **(c)** The laser fiber is advanced through the scope's work channel and parked against target stone. **(d, e)** Lithotripsy is performed. **(f, g)** Mechanical cholelithotomy (retrograde retrieval) is performed using a through the scope basket **(f)** or independent baskets **(g)**. **(h)** Anterograde sweep of stones and stone fragments into the cystic duct and common bile duct using a balloon.

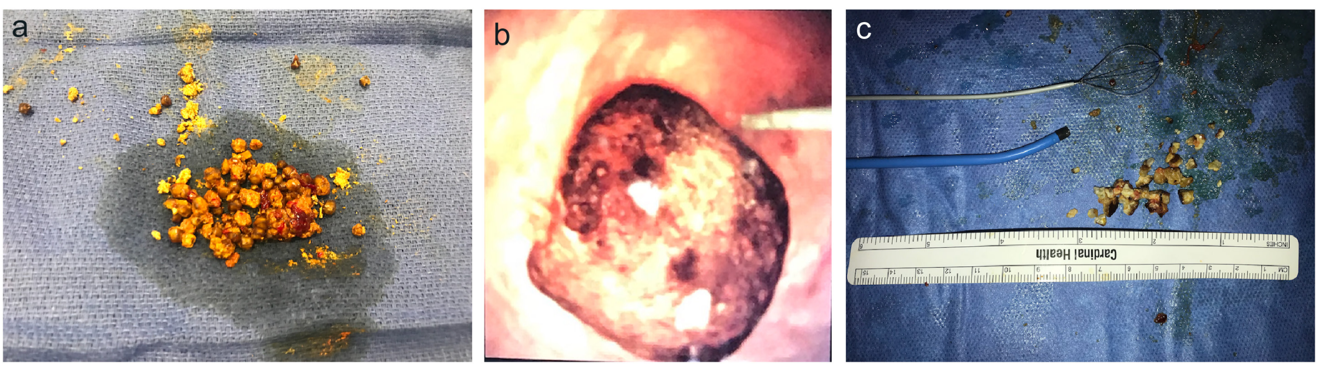

Figure 3. a-c. Different types of stones were retrieved from 2 patients who underwent only single session of cholecystoscopy and cholelithotomy. **(a)** Multiple small cholesterol stones were retrieved from a patient during a single session. **(b)** Cholecystoscopy picture of a single large mixed type gallstone before retrieval. **(c)** Fragments of the same stone after cholelithotripsy and cholelithotomy during a single session.

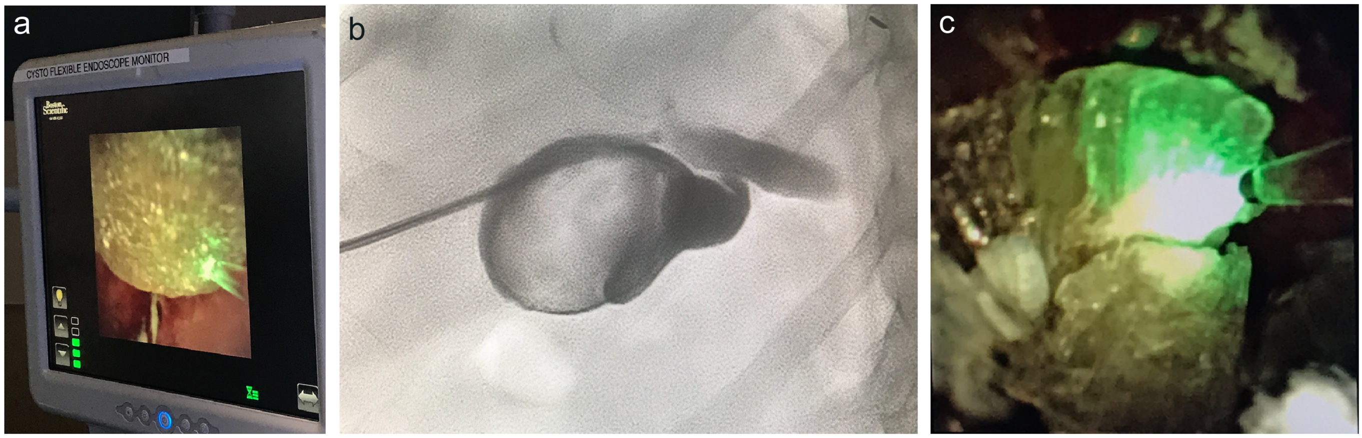

Figure 4. a-c. A single large crystalized stone required multiple sessions of cholecystoscopy, cholelithotripsy, and cholelithotomy. **(a)** Cholecystoscopy shows a large colorless crystallized stone in the gallbladder, corresponding to the large stone seen on the cholecystogram under fluoroscopy **(b)**. **(c)** Laser lithotripsy of the stone is demonstrated.

Table 1. Patient characteristics

Age (mean ± SD, range)	76.8 ± 14.3 (35-90)
Sex (M : F)	13 : 4
Comorbidities	
Cardiovascular disease	10/17 (59%)
Diabetes mellitus	6/17 (35%)
Respiratory	7/17 (41%)
Obesity	3/17 (18%)
Stroke	2/17 (12%)
Malignancy	1/17 (6%)
ASA classification	
4	11/17 (65%)
5	6/17 (35%)

SD, standard deviation; M, male; F, female; ASA, American Society of Anesthesiologists.

endoscopy-assisted gallstone management program compared to who had cholecystostomy tube placement prior to this (4.8 ± 2.2 vs. 9.0 ± 3.4 times, $P = .008$). The median number of laser and mechanical cholelithotripsy was 1 (range: 0-4) and 3 (range: 1-6), respectively. The median number of retrograde stone retrieval was 2 (range: 0-2) and 1 (range: 0-2) for anterograde stone retrieval. One patient needed retrograde hepatic ductal cholangioscopy to remove intrahepatic bile duct stones.

The mean interval time between the first cholelithotripsy session and removal of cholecystostomy was 71 days. There was no procedure-related major and minor complications, except for self-limited oozing within the gallbladder during procedure, primarily in patients who were on anticoagulation. No hospitalization or blood transfusions were required following any session of cholecystoscopy, cholelithotripsy, and cholelithotomy. Figure 6 shows our treatment and intervention paradigm for this study and that the interval between placement of the cholecystostomy and cholecystoscopy has been steadily decreasing in our institution since starting our biliary endoscopy program.

Discussion

Our findings showed that percutaneous cholecystoscopy using LithoVue endoscope can assist cholelithotripsy and cholelithotomy in patients with cholecystostomy tubes placed for acute calculous cholecystitis. Complete clinical and technical success was achieved in each patient with no complications aside from minor, self-limited oozing within the gallbladder, primarily in patients who were continued on anticoagulation. In addition, all patients were able to undergo cholecystostomy tube removal without recurrent episode/symptoms in the mean follow-up period of 48 weeks, except 1 patient who was transferred to a hospice center for palliative care. Upon launching our biliary endoscopy program, we saw shorter wait times for intervention and eventual tube removal.

Many patients with acute cholecystitis and contraindications to surgery live with a cholecystostomy tube till end of life. Having an indwelling catheter not only limits the patients' activity but also impacts quality of life, as it requires daily flushing, drainage bag maintenance, and routine exchanges every 8-12 weeks. In addition, there are possible complications including tube dislodgment or obstruction, track infection, or granulation tissue formation. Studies have shown recurrent cholecystitis in 21%-33% of patients after cholecystostomy tube removal[3,12] when cholelithiasis is not adequately addressed. Altogether, cholecystostomy care can be very challenging and costly. Therefore, cholecystostomy removal as soon as possible would not only improve quality of life but also could reduce long-term costs.

Percutaneous endoscopic procedures have been gaining popularity within the interventional radiology community with promising recent results.[6,13] Percutaneous cholangioscopy aids successful removal of gallbladder and biliary stones in 80%-100% of cases.[14] Similarly, cholecystoscopy can provide benefit for patients with indwelling cholecystostomy catheters in setting of acute calculus cholecystitis. Some authors argue that percutaneous approach might be more advantageous compared to traditional endoscopic methods (i.e., cholangioscopy), as preservation of the biliary sphincter is linked to reduced long-term

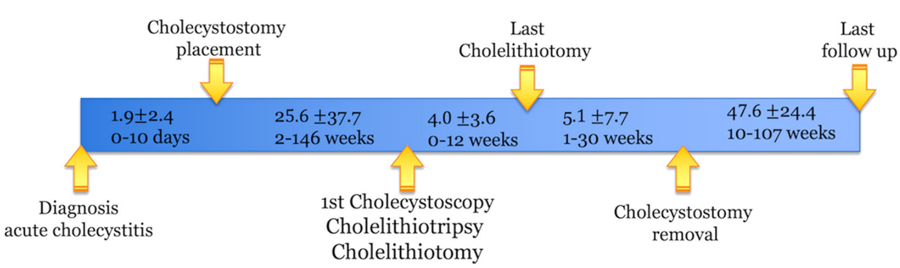

Figure 5. Time interval between different procedures in our study.

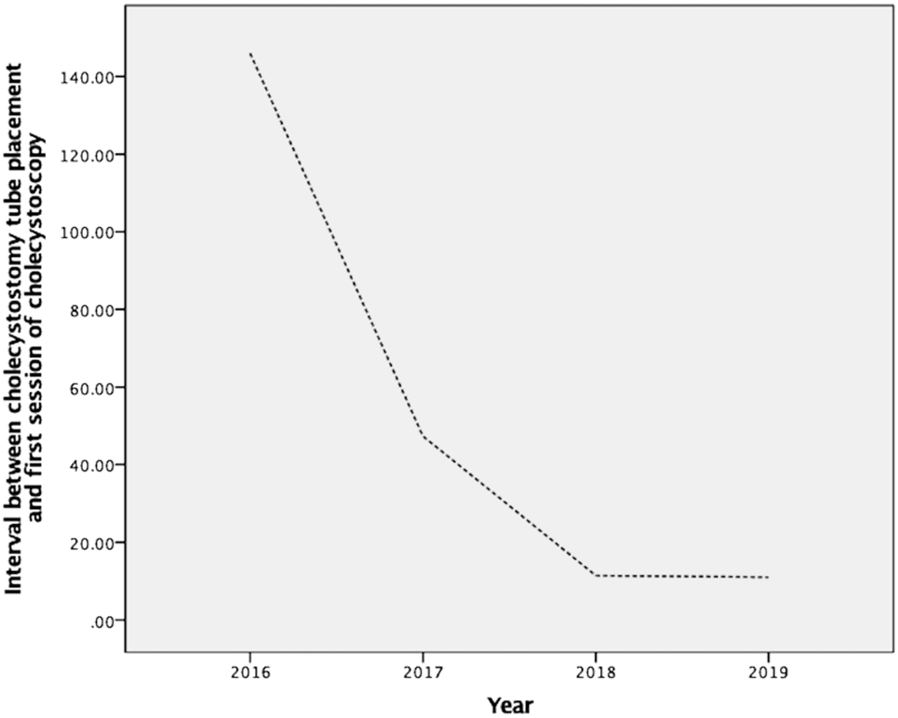

Figure 6. Interval between cholecystostomy tube placement and first session of cholecystoscopy according to years. There has been decrease in interval between the cholecystostomy placement and first cholecystoscopy session since 2016.

complications.[15] Percutaneous access for cholelithotripsy, cholelithotomy, and even biliary stenting in addition to cholangioscopy is well studied,[16] with initial reports showing cholecystoscopy with reusable scopes to be safe and effective in the treatment of acute calculous cholecystitis in poor surgical candidates.[7,8] However, this method has not been widely adopted due to concerns of bleeding or liver parenchymal disruption during dilatation of percutaneous access, cost of procedure, and lack of access to endoscopic suite/equipment.[7] One study from 2018 reported successful percutaneous cholecystoscopy in a small subset of patients (4.3%) to aid stone removal.[9] Today, interventional radiologists are embracing the use of endoscopic technique more than ever. This cost-effective and streamlined approach could easily be adopted to not only assist percutaneous interventions including cholelithotripsy and cholelithotomy but also expedite cholecystostomy tube removal. Using this method to directly visualize internal structures would overall reduce cost (even after taking into account the cost of endoscopy and lithotripsy equipment) and possibly decrease the cumulative radiation dose related to tube exchanges.[17]

While cholangioscopy and cholecystoscopy are exciting procedures for interventional radiologists, management of acute cholecystitis especially in patients with contraindications to cholecystectomy requires a coordinated multi-disciplinary approach. With an increase in cholecystostomy referrals,[17] interventional radiologists have more reason to be a part of the conversation. Increasing evidence behind endoscopic procedures and percutaneous biliary interventions provides interventional radiologists with more tools to treat calculous cholecystitis in this vulnerable population. As medicine becomes more efficient and cost-focused, reducing time for patients to be cholecystostomy-free becomes paramount. Percutaneous cholecystoscopy with cholelithotripsy and/or cholelithotomy offers an effective treatment of symptomatic calculous cholecystitis through an already existing access site. This technique has the potential to reduce number of separate procedures, related complications, hospitalizations, and significantly improve quality of life. For this reason, the tentative plan for these procedures should be discussed with the surgery service during initial consult for cholecystostomy placement.

In this study, the LithoVue flexible scope (outer diameter 9.5 F) was used instead of larger bore rigid scopes (such as the 22.5 F Olympus or 26 F Storz Medical scopes). To our knowledge there has not been any studies comparing outcomes in hepatobiliary endoscopy of flexible and rigid scopes. In gastroenterology literature, flexible endoscopy was shown to be safe and effective under local anesthesia and sedation without in-patient hospitalization.[18] Rigid endoscopy provides a wider operating lumen, allowing for utilization of multiple instruments but requires general anesthesia.[18] Our results show safety and efficacy of using a small flexible disposable endoscope without the need for anesthesia or additional hospitalization due to cholecystoscopy and lithotomy/lithotripsy. Other interventional radiology practices have documented the use of similar ureteroscopes (i.e., the Storz 7.5 F ureteroscope) in biliary endoscopy,[19] which can be manipulated much like a catheter adding to the comfort level for most interventional radiologists to perform these procedures. Although our study is the first to explore the use of a disposable scope for biliary intervention, benefits of using a LithoVue ureteroscope is also presented in endourological literature. The LithoVue scope has been shown to have the best deflection capability and lowest image distortion among both single-use and reusable scopes.[20] In addition, the scope we chose was shown to have similar visualization and maneuverability as higher-end reusable scopes.[20] One study[21] showed that cumulative costs of 28 procedures using a reusable ureteroscope (UFR-V for example) would cost approximately $50 000, while that using LithoVue ureteroscopes for a similar number of procedures would amount to less than $35 000 as each scope costs $1200.

There were a few limitations to our study. We did not compare single-use to reusable scopes for feasibility, safety, and effectiveness due to the higher overall cost of reusable scopes. In this cohort of patients, we have reported much longer mean tube indwelling times than in previously reported studies of percutaneous cholecystostomy (mean of 243 days compared to 64-89 days reported in prior studies).[9,22] This is largely due to the inclusion of patients who had been on long-term cholecystostomy prior to initiating our cholecystoscopy program. Also, unlike the previously reported studies, we chose to exclude patients who underwent an eventual cholecystectomy. Finally, limitations of the disposable endoscope when treating larger stones might have increased the number of required sessions and added to the catheter indwelling time. With greater acceptance, we expect this procedure to be performed in a timelier fashion, with reduction in the interval between cholecystostomy tube placement and cholecystoscopic intervention, resulting in shorter catheter indwelling times. We suggest planning for future prospective studies for a larger group of patients, and to additionally investigate its impact on the quality-of-life and long-term outcomes.

In conclusion, percutaneous cholecystoscopy using the LithoVue scope was safe and effective for successful laser/mechanical cholelithotripsy, mechanical cholelithotomy, and eventual cholecystostomy tube removal.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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