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Research Paper

Enhanced recovery after surgery in percutaneous transhepatic cholangioscopic lithotripsy for patients with hepatolithiasis and choledocholithiasis

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ABSTRACT

Background: Percutaneous transhepatic cholangioscopic lithotripsy (PTCSL) provides an effective alternative procedure for the management of complex hepatolithiasis and choledocholithiasis. Enhanced recovery after surgery (ERAS) program is an evidence-based approach that was developed to reduce surgical stress and accelerate postoperative recovery. However, little is known regarding PTCSL in the context of ERAS. The aim of this study was to evaluate the efficacy and safety of PTCSL within ERAS programs.

Patient and methods: The clinical data of patients who underwent PTCSL within ERAS programs consulted at our hospital between November 2017 and November 2022 was retrospectively reviewed. Individualized perioperative ERAS items were evaluated for all patients. The demographics, intraoperative variables, and postoperative outcomes were analyzed.

Results: A total of 43 patients who underwent PTCSL were included in the study. There were 13 men and 30 women aged between 39 and 89 years with an average age of 60 years (60.49 ± 12.37). The stone clearance rate was 77 % after the first operation, and the final clearance rate was 95 %. The incidence of complications in this study is 18.6 % (8/43), including 6 patients with Clavien-Dindo I-II, and 2 patients with Clavien-Dindo III. Pleural effusion, abdominal effusion, infection, bile leakage, and biliary bleeding are the most common complications, however, all patients recovered after aggressive treatment.

Conclusion: PTCSL is a relatively safe, feasible, and efficient method for treating complex hepatolithiasis and choledocholithiasis within ERAS programs. Individualized ERAS entries and precise disease management are required to minimize the occurrence of complications and to provide effective treatment.

Introduction

Hepatolithiasis and choledocholithiasis is a kind of refractory diseases, and the prevalence of hepatolithiasis is more common in East Asian countries than in the Western world [1]. Common bile duct stones are classified as primary or secondary based on the source of the stone, both of which require further treatment. Although the precise incidence and prevalence are not known, it has been reported that there was a rising incidence for both hepatolithiasis [1] and choledocholithiasis [2]. Despite our understanding has improved and surgical treatment modalities have become more diverse, hepatolithiasis and choledocholithiasis are still a complex medical problem faced by surgeons [3].

The primary goal of treating the condition is to reduce the chances of developing cholangitis and stop the progression of biliary cirrhosis [1]. The present-day surgical treatment includes hepatic resection, cholecystectomy with bile duct exploration, choledochojejunostomy, and liver transplantation [4,5]. Besides, endoscopic retrograde cholangiopancreatography (ERCP) also provides an effective way for the treatment of choledocholithiasis. But it is not feasible for all patients because of technical and anatomical reasons, such as duodenal stenosis, altered postsurgical anatomy, or inability to cannulate the papilla [6,7].

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Compared with surgical treatment, PTCSL has great advantages such as less invasive, faster recovery, and repeatability. It could remove or break down biliary stones or other obstructions in the biliary tree. Patients with a high surgical risk, previous abdominal surgery, stone distribution in multiple segments, or those who refuse traditional surgery were also appropriate candidates for PTCSL [8,9].

Enhanced recovery after surgery (ERAS) was first initiated by Prof. Henrik Kehlet in the 1990s for patients undergoing colorectal surgery [10]. Compared with traditional modalities, ERAS programs provide maximum benefits to patients, such as decreased complication rates, accelerated recovery, reduced medical costs, etc. In addition to colorectal surgery, there is accumulating evidence supporting the effectiveness of ERAS in urologic [11], orthopedic [12], thoracic [13], liver [14], pancreatic surgeries [15].

In 2016, the ERAS Society published the first guideline for perioperative care in liver surgery to add to existing ERAS guidelines regarding other surgical specialties [14]. However, the treatment of hepatolithiasis and choledocholithiasis is a major and challenging procedure both for doctors and patients. It is questionable whether ERAS principles applied in liver surgery can be truly extrapolated to PTCSL. On the other hand, curative management of hepatolithiasis and choledocholithiasis is difficult due to the complex biliary anatomy and large stone burden. In the current study, we retrospectively analyzed the clinical data of patients who underwent PTCSL within our implemented ERAS programs. We present our experience in treating challenging biliary stones with PTCSL and explore the safety and efficacy of PTCSL within ERAS.

Materials and methods

Patients

Forty-three patients with complete clinical information within the ERAS programs, who underwent PTCSL in our center from November 2017 to November 2022 were enrolled in this study. After approved by Ethics Committee of the Third Affiliated Hospital of Sun Yat-sen University (Guangdong province, China), all patients included in this study were informed well about the procedure. An informed written consent was obtained from each patient. All the information obtained was used only for scientific research.

All of the included patients were diagnosed with intrahepatic or extrahepatic cholelithiasis based on medical history and imaging examinations, such as ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance cholangiography (MRCP), with liver function preoperatively assessed as Child-Pugh A or B grades. Patients with severe biliary tract infection, multiple biliary strictures, hepatic lobe atrophy or combined with carcinoma were excluded. Besides, patients with cardiac, brain, lung, kidney, or other functional abnormalities who could not tolerate the operation, or patients refused to surgery treatment, patients refused to ERAS program were also excluded.

Preoperative assessment

After admission, all patients were examined by routine blood test, coagulation function, infectious disease screening, liver and kidney function, electrocardiogram, X-ray radiography in chest. Patients with other concomitant diseases were estimated by relevant specialists and got it under control as soon as possible. The location of calculi was determined according to ultrasound and radiographic examination. All patients were routinely evaluated for their tolerance to general anesthesia by anesthesiologists and confirmed as ASA (American Society of Anesthesiologists) grades I or II. All patients were educated before surgery to get a basic knowledge of PTCSL and ERAS. Routine preparation before hepatobiliary operation was also made for all the patients.

Percutaneous transhepatic cholangial drainage (PTCD) and PTCSL

Real-time ultrasound-guided PTCD was performed intraoperatively (one-step approach) or preoperatively (two-step approach) for all patients. Two-step approach was applied for patients with biliary obstruction, pancreatitis or biliary infection. The point and path of the puncture were confirmed both by surgeons and sonographers according to the preoperative planning to facilitate the subsequent PTCSL. Once a successful puncturing was performed, a guidewire (Arrow Medical, USA) was placed into the bile duct system. The percutaneous tract was immediately expanded with expanders (Kangyibo Medical, China) from 8-Fr to16-Fr or 18-Fr, step-by-step, until the bile duct could hold a 16-Fr or 18-Fr protective sheath (one-step approach). For two-step approach, an 8-Fr pig tail catheter (Cook Medical) was first inserted into the target bile duct for biliary external drainage. Around 1 week after PTCD, the sinus was dilated to allow passage of the cholangioscope as the same way as the one-step approach.

After the sheath was implanted, the rigid cholangioscopic (Wolf nephroscope) or flexible cholangioscopic (Olympus Corporation, Japan) was used to reach the targeted bile duct through the sheath, while saline was continuously infused with an adjustable pressure pump. The whole biliary tree was explored and the size and number of calculi as well as biliary tract abnormal lesion or stricture was also determined. Various methods were used to facilitate stone removal. Simple and small calculi could be lavaged out through the operating sheath. Mechanical lithotripsy (ML) using a retrieval basket, alligator leaf forceps or balloon catheter was applied for difficult calculi. The larger recalcitrant stones need fragmentation prior to removal. With the aid of pneumatic ballistic crusher or electrohydraulic lithotripsy, we disintegrate the calculi into small pieces and powder, then the shattered calculi were flushed out with warm saline by a “rapid biliary lavage” procedure. Meanwhile, there was continuous saline irrigation to avoid damaging the bile duct. The flow rate was non-constant, which was usually slow, so as to have a clear vision. While the total volume should be controlled within 3000–6000 mL to avoid water poisoning. All surgical operations were performed by experienced chief physicians. Finally, a 14-Fr or 16-Fr shortened nasogastric tube was inserted through the protective sheath as the external biliary drainage catheter, and ropivacaine wound infiltration was routinely administered.

ERAS

The multidisciplinary ERAS protocol, which was based on consensus between our surgeons, anesthetists, physiotherapists, dieticians, and nurses, was implemented for all participating patients (Table 1). Preoperative counseling and patient education about the necessity of ERAS and suggestions about rehabilitation time of each stage were introduced to each patient in detail. Nutritional risk screening and assessment was based on the form Nutritional Risk Screening 2002 (NRS-2002). Patients with high nutrition risk ($\geq$3 points) should receive nutritional supplements prior to surgery. Other risk factors that affect recovery, such as smoking and drinking, were advised to quit, stop, and begin physical exercises according to their physical status.

Diet administration and fluid management were referred to the relevant literature and made appropriate adjustments. Every patient consumes only clear liquid drinks 2 h prior to surgery and should be fasting from solid food for 6 h. Laryngeal mask anesthesia was routinely implemented by an experienced anesthesiologist. Prophylactic antibiotics should be administered before the skin incision for patients without preoperative infection. Every step of PTCSL is designed to minimize patient trauma, so as intraoperative anesthesia management and patient care. After the entire operation, the wound is immediately infiltrated with long-acting local anesthetic ropivacaine. Gastric tube and urine catheter were not routinely indwelled in surgery. Multimodal approaches for preventing postoperative nausea, vomiting, and postoperative analgesia were also used. Early mobilization was encouraged

Table 1
Items of ERAS for percutaneous transhepatic cholangioscopic lithotripsy.

Preoperative	Intraoperative	Postoperative
1. counseling and education 2. nutrition screening 3. previous disease control 4. physical exercises 5.improve respiratory function 6. glycemic control 7. VTE assessment 8. no infusion unless necessary 9. no bowel preparation 10. minimal fasting 11. avoidance of preanesthetic medications 12. oral celecoxib (200 mg) 6 h prior to surgery 13. no special skin preparation 14. accurate surgical planning	1. cefmetazole (2 g, 30 min) before surgery 2. omeprazole (40 mg) before surgery 3. laryngeal mask anesthesia 4. temperature monitoring 5. body warming device 6. stretch sock for high risk VTE patients 7. minimally invasive surgery 8. operation time <3 h 9. rinse warm saline <6 L 10. multimodal lithotripsy 11.methylprednisolone intravenous (40 mg) 12. no routine gastric tube 13. no routine urinary catheter 14. immediate ultrasound examine after operation 15. ropivacaine infiltrates the wound	1. early mobilization 2. multimodal analgesia 3. chewing gum for stimulation bowel movement 4. fluid diet when fully awake 5. nutritional support 6. limited intravenous fluid 7. first 24 h fluid balance 8. nausea and vomiting prophylaxis 9. removal gastric tube and urinary catheter on day 1 10. low molecular weight heparin when necessary 11. stop antibiotics unless infection 12. biliary irrigation when necessary 13. discharge when met criteria

for all patients and a liquid diet was restored 6 h after surgery. The patient was discharged 3–5 days after the operation, and the biliary drainage tube was removed during outpatient follow-up.

Definition of complications

The Clavien-Dindo system is used for grading postoperative complications. Surgery-related complications included pleural and abdominal effusion, infection, bile leakage, postoperative pancreatitis, bleeding, retained stones and stone recurrence. Bleeding was defined as perihepatic hematoma or significant bleeding requiring transfusion of blood or angiographic intervention. Infection was diagnosed by a fever of >38 °C, leukocytosis (white blood cell count $>10^{*}10^{9}$/ L), bacteremia, cholangitis, intra-abdominal infection, pulmonary infection, and wound infection. Complete stone clearance means no residual stones or isolated small stones at the edge of the intrahepatic bile duct on postoperative ultrasound, CT, MR, or MRCP review. The immediate clearance rate (within 1 week) and final clearance rate (half a year) was also calculated, stone recurrence was determined by postoperative imaging data. Complications that required intervention or were life threatening were regarded as major complications.

Statistical analysis

Statistical analysis was performed with SPSS 22.0 (IBM, Armonk, NY, USA). Data are presented as the mean ± standard deviation (SD) or median. The counting data are expressed as component ratio or rate (%).

Results

Baseline characteristics and preoperative data

Among the 43 recruited patients, there were 13 men and 30 women aged between 39 and 89 years with an average age of 60 years (60.49 ± 12.37). The baseline characteristics of patients are shown in Table 2. Thirteen cases with a history of anemia and two patients received blood transfusion before surgery to accelerate postoperative recovery. When admitted, nine patients had a biliary infection and fever and underwent PTCD immediately. Eighteen patients had complex stones that involved both intrahepatic hepatolithiasis and choledocholithiasis. The majority of patients (40, 93 %) had a history of abdominal surgery, of which 39 cases with a history of biliary tract surgery. Seventeen patients had undergone more than two times operation and two patients received endoscopic retrograde cholangiopancreatography (ERCP) treatment.

Table 2
The baseline characteristics and preoperative parameters for included patients.

Characteristics	Patients (n = 43)
Sex	
Male	13
Female	30
Past history	
Hypertension	8
Diabetes	6
Cirrhosis	15
Anemia	13
Mild	9
Moderate	4
Child-Pugh score	
Grade A	33
Grade B	10
Location of stone	
left lobe	5
Right lobe	2
Bilateral	8
Common bile duct	7
Common bile duct + Left lobe	3
Common bile duct + Right lobe	10
Common bile duct + Left lobe + Right lobe	5
Anastomotic calculi	3
Stone condition	
Primary	14
Recurrent	29
Previous abdominal surgery	
Cholecystectomy	15
Choledocholithotomy	18
Choledochojejunostomy	5
Hepaticresection	3
Hepaticresection + cholecystectomy	2
Hepaticresection + choledocholithotomy	12
ERCP	2
ASA grade	
I	21
II	22

Intraoperative data

All of the 43 patients in this study underwent intraoperative ultrasound-guided bile duct dilation with a 100 % success rate. The whole procedure of one-step approach PTCSL is presented in Fig. 1. The red rubber ring on the expander was used to mark the depth that needs to be inserted during the dilation. Paraffin oil was applied to reduce additional trauma during puncture and successful puncture would be indicated by smooth bile aspiration after removing the puncture needle core. The percutaneous location and operation approach depended on the patient's condition. Most patients [21] had their biliary stones successfully removed through the large channel (18F) by mechanical lithotripsy. Seven patients (7/43, 16 %) required a second operation to remove stones. Two patients experienced a third times operation, and one patient underwent a fourth times surgery. (Table 3). The operation time ranges from 45 min to 180 min, with an average time of 106.4 ± 36.2 min. Intraoperative bleeding ranged from 20 mL to 400 mL, with an average bleeding of 75.8 ± 51.6 mL. Two patients experienced intraoperative significant bleeding and required blood transfusions.

Treatment outcomes

Ten patients presented stone residual after the first operation, thus, the immediate clearance rate was 77 %. The average time interval between the second operation and the first operation is 15.6 ± 8.0 days,

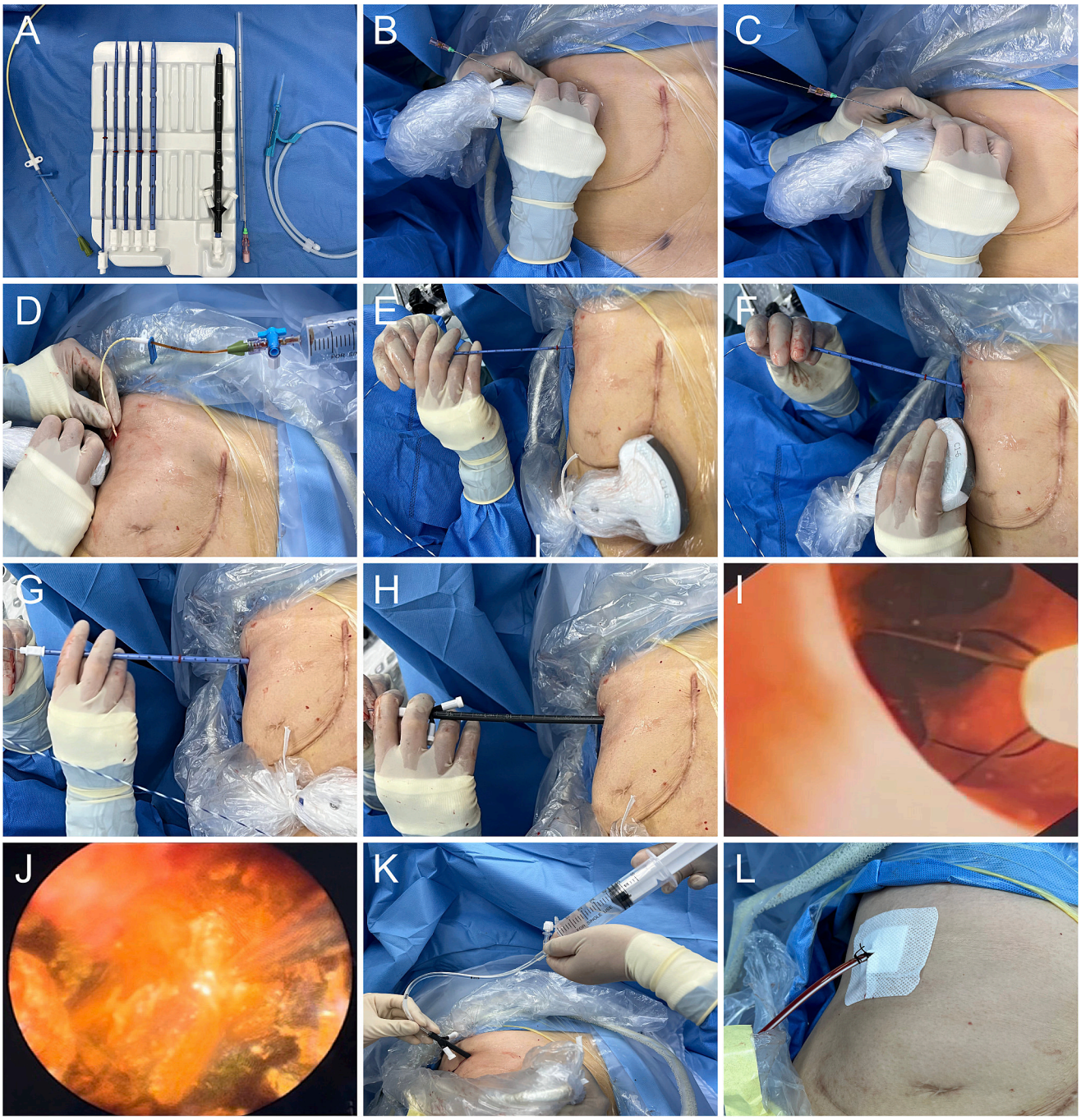

Fig. 1. The procedure of one-step approach of percutaneous transhepatic cholangioscopic lithotripsy. (A) Required materials: central venous catheter and its guidewire, expanders, 18-gauge puncture needle, (B) Intraoperative ultrasound-guided bile duct puncture, (C) Place the guidewire along the puncture needle tube, (D) Insert central venous catheter along the guidewire and dilate the biliary tract with saline, (E, F, G) Replace with zebra guidewire and sequentially dilate the biliary tract, (H) Surgical operating channel made by the protective sheath, (I) Removing biliary calculus with the stone extraction basket, (J) Shattering the biliary calculus with pneumatic ballistic crusher, (K, L) Placement of bile drainage tube through protective sheath and correct its position in the biliary system.

and the clearance rate was 90 % (39/43). After requiring another operation, forty-one patients had their biliary tract stones cleared successfully with a final clearance rate of 95 %. The representative cases of stone clearance were shown in the CT and cholangiography. (Fig. 2). The two patients with retained stone were reluctant to receive further treatment because they had no symptoms. All included patients were followed up for a period that ranged from 12 to 72 months, and no patient was diagnosed with a recurrence of calculus. The postoperative hospital stay ranged from 4 days to 16 days, with an average hospital stay 6.1 ± 2.0 days. More than two weeks after surgery, after confirming there were no residual stones through cholangiography and other examinations, the drainage tube was removed. One patient's biliary drainage tube prolapsed unexpectedly, and the average time for drainage tube removal in remaining patients was 17.6 ± 4.8 days.

Complications of PTCSL

There were no unexpected readmission cases or perioperative mortality patients in this study. The complications are shown in Table 4. Pleural effusion occurred in two patients with the right puncture

Table 3
The important index of the intraoperative data.

Operation approach	Patients (n = 43)
One-step	22
Two-step	23
Percutaneous location	
Right	34
Left	7
Bilateral	2
Operation frequency	
1	33
2	7
≥3	3
Expanded tract	
16-Fr	11
18-Fr	46
Lithotomy method	
Saline irrigation	9
Mechanical lithotripsy	21
Pneumatic ballistic crusher	11
Electrohydraulic lithotripsy	16

approach, one case with mild reactive pleural effusion and recovered after conserved therapy, and the other patient with moderate pleural effusion accompanied by pulmonary infection required thoracic puncture and drainage treatment. There was no fistula injury or biliary stricture after surgery and during follow-up, although one patient with drainage tube shedding. One patient presented mild biliary leakage and peritoneal effusion, which improved after interventional treatment. No patient developed abdominal infection, wound infection, or bacteremia. Three patients experienced intraoperative bleeding, and two patients recovered after hemostasis, blood transfusion, and other treatments. One patient with massive hemorrhage of the biliary tract appeared with a biliary portal vein fistula and finally experienced microwave ablation treatment. The incidence of complications in this study is 18.6 % (8/43), including 6 patients with Clavien-Dindo I-II, and 2 patients with Clavien-Dindo III.

Discussion

Recently, the ERAS program has been widely applied in surgical areas and there was a growing number of published studies of ERAS programs in liver surgery [16,17]. Although several benefits of the ERAS program have been covered, few studies have examined biliary calculi surgery in the context of ERAS programs. After comparing holmium laser lithotripsy with choledochoscopic mechanical lithotripsy for multiple intrahepatic calculi, Wang C et al. reported that coledocholithotomy combined with holmium laser lithotripsy could be well coupled to the ERAS program to relieve surgical stress and accelerate postoperative recovery [18]. For patients undergoing laparoscopic common bile duct exploration, Li G et al. indicated that ERAS can reduce the postoperative stress response and postoperative complications, promote rehabilitation and shorten the length of postoperative hospital stay [19]. In the current study, the high stone clearance rate and the limited complication incidence showed that PTCSL is safe, feasible for treating hepatolithiasis and choledocholithiasis within ERAS programs.

PTCSL is a useful technique to remove hepatolithiasis and choledocholithiasis because of its direct visualization of bile duct stones. The core element of the procedure is to establish a percutaneous operating channel through the intrahepatic bile ducts. It opens up a new way to treat complex biliary stones, achieving the purpose of minimally invasive and protecting liver function [9]. Patients with complicated cholelithiasis, and failed ERCP are good candidates for bile duct stone removal with PTCS [7].

It has been reported that approximately 10–15 % of intractable biliary stones are difficult to extract with conventional stone retrieval methods [20]. The complex anatomical structure of the intrahepatic bile ducts and the limitation of the angle of choledochoscopic operation also increase the difficulty for completely removing the whole stones. To reduce surgical trauma, the percutaneous location and puncture path should be carefully designed to overcome the angular limitations of the biliary tract. Besides, multimodal lithotripsy methods including mechanical, pneumatic ballistic crusher, and electrohydraulic were applied in this study. Despite this, ten patients (23 %) required another operation to remove stones. This fact is not only based on patient factors but

Table 4
Periprocedural complications associated with PTCSL.

Postoperative complications	Patients (n = 43)
Reactive pleural effusion	1
Peritoneal effusion + bile leakage	1
Minor intraoperative bleeding	1
Massive hemorrhage of the biliary tract	2
Drainage tube shedding	1
Pulmonary infection+ reactive pleural effusion	1
Cholangitis	1

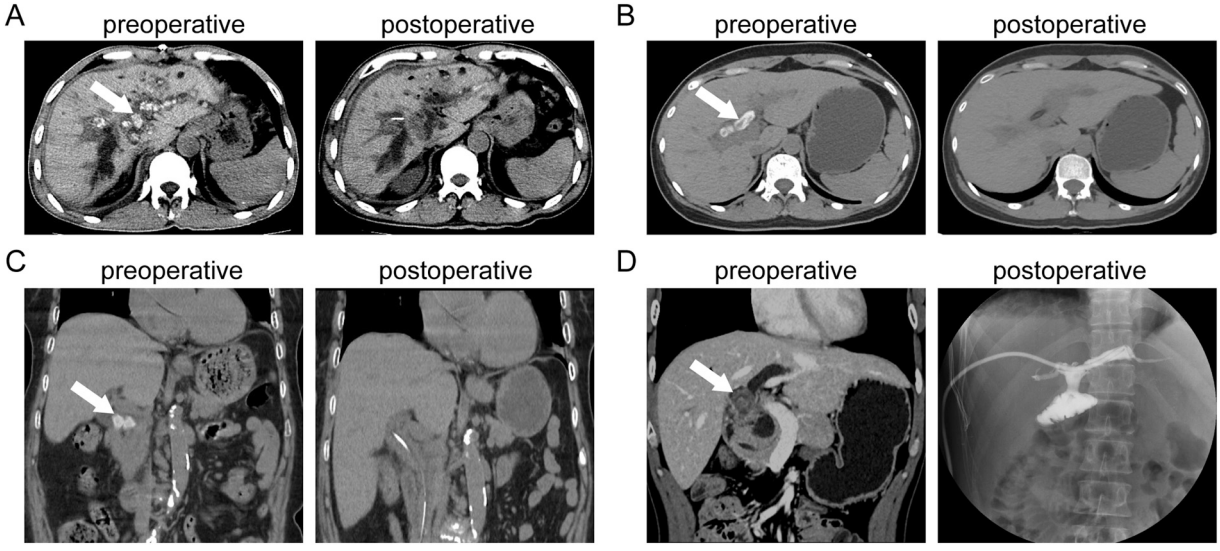

Fig. 2. Comparison of CT images before and after percutaneous transhepatic cholangioscopic lithotripsy. (A) Bilateral Hepatolithiasis, (B) Right intrahepatic bile duct stones, (C) Choledocholithiasis, (D) Anastomotic calculi. White arrows indicate the location of the stones.

also on stone factors. Most of re-operation cases have a large number or size of stones, and the basic conditions make it impossible for a long-time operation and irrigation too much saline.

Although PTCSL is a minimally invasive procedure, postoperative complications are always present. It can be generally divided into non-infectious (bleeding, bile leakage, pleural effusion, or abdominal effusion) and infectious complications (cholangitis, pancreatitis, pneumonia, or bacteremia). It has been reported that complications occur most commonly during initial access and tract dilation, the cholangioscopy itself is less risky when performed by an experienced clinician [8]. Oh HC et al. also reported that the incidence of complication was nearly twice as high for the initial access and subsequent tract dilation (12.8 %) in comparison with tract maturation and cholangioscopy sessions (6.9 %) [21]. To reduce complication risk, traditional PTCSL and a two-step approach should be applied, which allow the percutaneous transhepatic tracts to mature and gradually dilate. In the current study, 23 patients underwent a two-step approach by experienced sonographers and surgeons with a lower complication rate (3/23, 13 %). Besides, real-time ultrasound-guided and the protective sheath during operation effectively decrease the risk of iatrogenic injury.

Overall complication rates have been reported to range from 5 %–54 %, with an average rate of approximately 20 %–22 % [8,22]. In the present study, complications occur in 18 % of patients, mainly reactive pleural effusion and bleeding, both of which were noninfectious. The incidence of infectious complications in this study was 4.7 %, which can be attributed to the fact that more than half of patients underwent preoperative biliary drainage and a two-step surgical approach. Appropriate biliary drainage reduces biliary tract pressure, especially for patients with infection before operation. Bleeding involved both during tract dilation and cholangioscopic lithotripsy, it ranges from minor bleeding that stops on its own to significant bleeding that may require blood transfusion or intervention. Once biliary bleeding occurs, the location and cause of bleeding must first be determined. Biliary tract flushing with norepinephrine and ice-cold saline and clamping the drainage tube is an effective way to control bleeding. For vascular biliary fistula formed during tract dilation, a thicker drainage tube can be used to compress the percutaneous tract and clamp it to stop bleeding. In this current study, massive hemorrhage of the biliary tract occurred in two patients, but the bleeding stopped after aggressive treatment. Reactive pleural effusion all occurred in patients with the right puncture approach (right intercostal space), and it was well controlled after active treatment.

Complications have a greater impact on patient's clinical course and prolong the length of hospitalization. There were 6 patients with Clavien-Dindo I-II, and 2 patients with Clavien-Dindo III. Patients with severe complications recovered smoothly with aggressive and timely postoperative management. Thus, the average postoperative hospital stay was 6.1 days, which was slightly lower than reported in the literature [23]. The recurrence rate is another important consideration for evaluating treatment. One of the most important factors associated with recurrence is cholelithiasis combined with bile duct strictures [24]. There were no cases of recurrence in this study, the main reason is related to the initial case selection, hepatectomy is recommended for most patients with intrahepatic stones and biliary strictures [4].

While the results are encouraging, there are some limitations in this study. Firstly, this was a retrospective study for patients undergoing PTCSL within ERAS, and selection bias that may impact the results was inevitable. Secondly, the sample size is too small. Therefore, more patients should be recruited in our further research to validate our results. Finally, some patients in this study lacked long-term follow-up data that may impact the results.

In conclusion, our results suggest that PTCSL is an effective approach for treating complex hepatolithiasis and choledocholithiasis within ERAS programs. Although there are several types of postoperative complications, timely and appropriate treatment can reduce the risk of complications. Further prospective studies are needed to provide high-level evidence for verifying our conclusion.

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Ethical approval

This study complies with the Declaration of Helsinki and was approved by Ethics Committee of The Third Affiliated Hospital of Sun Yat-Sen University (Ref: [2023] 02–356). Written informed consent was obtained from all of the included patients.

CRediT authorship contribution statement

Peng Zhang: Writing – original draft, Methodology, Investigation. **Xi Dang:** Writing – original draft, Software. **Xiaojie Li:** Writing – original draft, Data curation. **Bo Liu:** Writing – review & editing, Writing – original draft, Conceptualization. **Qingliang Wang:** Writing – review & editing, Writing – original draft, Data curation.

Declaration of competing interest

The authors declare no conflict of interest.

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