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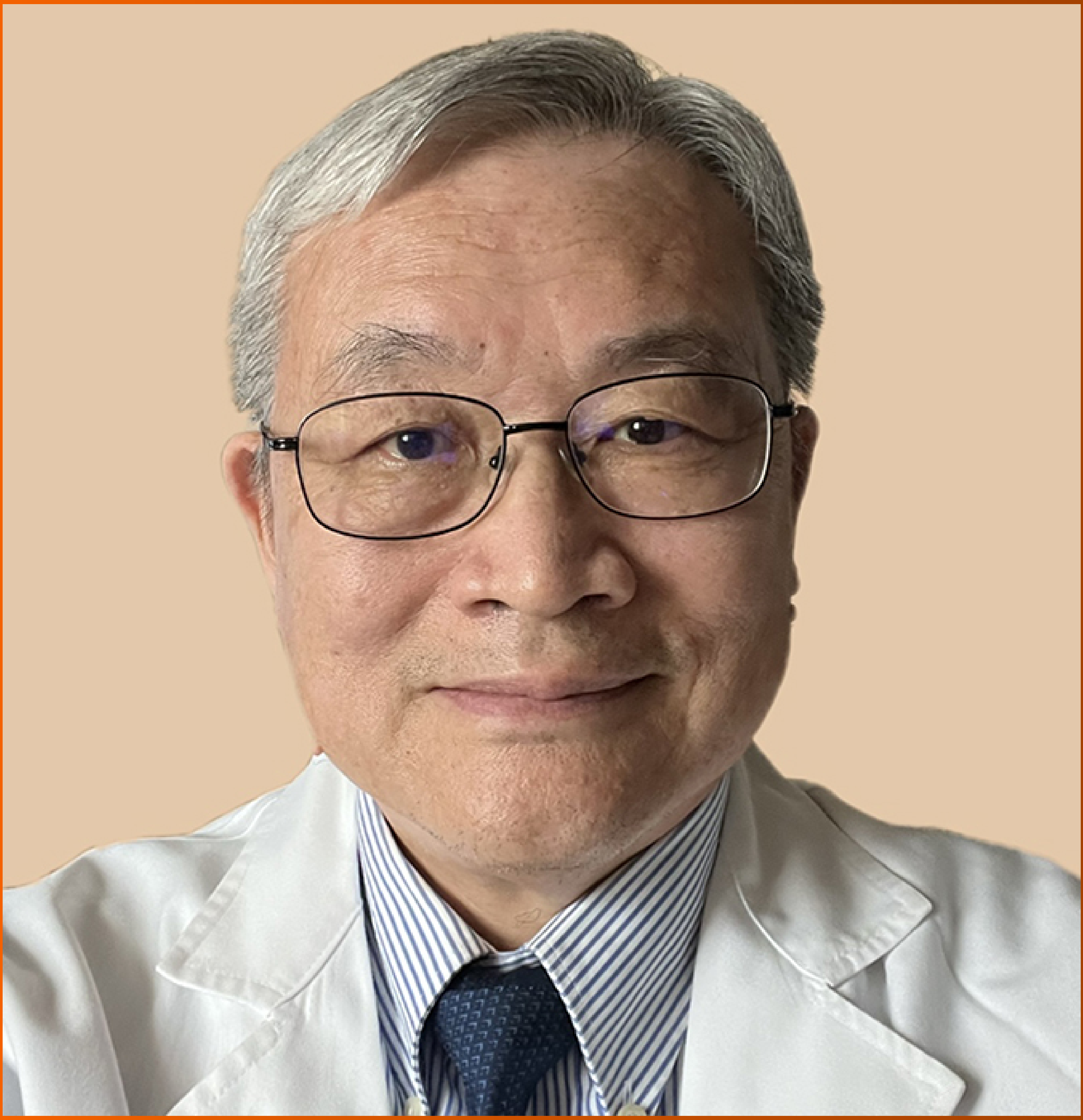

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Contents

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ORIGINAL ARTICLE

Retrospective Study

Three-dimensional visualization technology for guiding one-step percutaneous transhepatic cholangioscopic lithotripsy for the treatment of complex hepatolithiasis

Yong-Qing Ye, Ya-Wen Cao, Rong-Qi Li, En-Ze Li, Lei Yan, Zhao-Wei Ding, Jin-Ming Fan, Ping Wang, Yi-Xiang Wu

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Abstract

BACKGROUND

Biliary stone disease is a highly prevalent condition and a leading cause of hospitalization worldwide. Hepatolithiasis with associated strictures has high residual and recurrence rates after traditional multisession percutaneous transhepatic cholangioscopic lithotripsy (PTCSL).

AIM

To study one-step PTCSL using the percutaneous transhepatic one-step biliary fistulation (PTOBF) technique guided by three-dimensional (3D) visualization.

METHODS

This was a retrospective, single-center study analyzing, 140 patients who, between October 2016 and October 2023, underwent one-step PTCSL for hepatolithiasis. The patients were divided into two groups: The 3D-PTOBF group and the PTOBF group. Stone clearance on choledochoscopy, complications, and long-term clearance and recurrence rates were assessed.

RESULTS

Age, total bilirubin, direct bilirubin, Child-Pugh class, and stone location were similar between the 2 groups, but there was a significant difference in bile duct strictures, with biliary strictures more common in the 3D-PTOBF group (P = 0.001). The median follow-up time was 55.0 (55.0, 512.0) days. The immediate stone clearance ratio (88.6% *vs* 27.1%, P = 0.000) and stricture resolution ratio (97.1% *vs* 78.6%, P = 0.001) in the 3D-PTOBF group were significantly greater than those in the PTOBF group. Postoperative complication (8.6% *vs* 41.4%, P = 0.000) and stone recurrence rates (7.1% *vs* 38.6%, P = 0.000) were significantly lower in the 3D-PTOBF group.

CONCLUSION

Three-dimensional visualization helps make one-step PTCSL a safe, effective, and promising treatment for patients with complicated primary hepatolithiasis. The perioperative and long-term outcomes are satisfactory for patients with complicated primary hepatolithiasis. This minimally invasive method has the potential to be used as a substitute for hepatobiliary surgery.

Key Words: Hepatolithiasis; One-step percutaneous transhepatic cholangioscopic lithotripsy; Biliary disease; Three-dimensional visualization; Clinical efficacy

Core Tip: Hepatolithiasis is a clinical benign biliary tract disease with a high incidence and a leading cause of hospitalization, seriously affecting the quality of life of patients. However, current treatment modalities have not achieved good curative effects, with high rates of stone and stenosis retention and recurrence. In the present study we introduce a new technology that one-step percutaneous transhepatic cholangioscopic lithotripsy using the percutaneous transhepatic one-step biliary fistulation (PTOBF) technique guided by three-dimensional (3D) visualization technology. And we performed a randomized trial to assess the efficacy and safety of 3D-PTOBF in the treatment of patients with hepatolithiasis. We found that 3D-PTOBF offered significant improvement of immediate stone clearance ratio and stricture resolution ratio. 3D-PTOBF as a safe, effective, and promising treatment for patients with complicated primary hepatolithiasis.

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INTRODUCTION

Hepatolithiasis, a common benign biliary tract disease in East Asia, is the presence of gallstones (calculi) in the biliary ducts of the liver. According to statistics, hepatolithiasis accounts for 20% to 45% of patients who undergo surgery for gallstones[1-4]. Women have a lifetime risk of developing gallstones approaching 25%[5]. Gallstones can cause several clinical symptoms, such as biliary colic and jaundice, and some may be lethal. If left untreated, this causes bile flow stagnation, recurrent cholangitis, liver parenchymal destruction, and, eventually, secondary biliary cirrhosis or cholangiocarcinoma[6].

Stone removal is the primary method for treating clinical symptoms. Current treatments for hepatolithiasis include surgical resection of affected liver segments, laparoscopic surgery, endoscopic retrograde cholangiopancreatography, and percutaneous transhepatic cholangioscopy lithotripsy (PTCSL). Surgical intervention is preferred when possible, but many patients are ineligible due to multiple recurring surgeries, comorbidities, or anatomical factors[7]. In traditional PTCSL surgery, an external biliary fistula must be gradually dilated over 2-3 weeks prior to lithotripsy using serial fascial dilators[8]. This method is associated with longer hospitalization, a high recurrence rate, and a high rate of calculus reoperation[9].

Recent technological advances have enabled modifications, such as percutaneous transhepatic one-step biliary fistulation (PTOBF) combined with the rigid choledochoscopy technique, for optimizing the PTCSL procedure[10,11]. One-step PTCSL using the PTOBF technique enables the clearing of intrahepatic stones and the resolution of strictures. Ultrasound (US) images cannot directly reveal the three-dimensional spatial relationships of calculi, bile ducts and blood vessels. Thus, it is difficult to obtain their exact anatomical locations, which will influence the precision of the operation.Furthermore, the choledochoscope can only acquire the local abdominal information of the patient while the corresponding global abdominal information is a little different from the preoperative two-dimensional (2D) computed tomography (CT) image.

In recent years, 3D visualization technology has been employed to assist in making surgical decisions involving liver resection[12-15]. With the assistance of 3D visualization, the liver anatomy, the morphological structure of the intrahepatic duct system, the location of liver lesions, and the spatial relationship with adjacent liver vessels can be displayed visually and clearly from any angle[14]; this can prevent the excessive resection of liver tissues, maximally maintain functional liver tissues, and aid in the development of individualized surgical plans[16].

The purpose of this study was to introduce a detailed protocol and assess the long-term outcomes of the application of 3D visualization technology in one-step PTCSL for the treatment of complex hepatolithiasis patients with biliary strictures.

MATERIALS AND METHODS

Study design and participants

This retrospective study included 140 patients with complex hepatolithiasis from October 2016 to October 2023 at The First Affiliated Hospital of Guangzhou Medical University. A total of 140 patients underwent one-step PTCSL with or without 3D visualization. All patients provided written informed consent for participation in these procedures. Data were gathered for all patients. For further evaluation, the patients were divided into two groups, the 3D-PTCSL group (n = 70) and the PTCSL group (n = 70), who were subsequently compared. This study was approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou Medical University, No. 09, 2017.

3D model reconstruction

CT data were reconstructed in sections with the IQQA-3D Digital Medicine Central Server. Important anatomical structures on the CT images, such as intrahepatic biliary ducts, calculi, and intrahepatic vessels, were extracted *via* segmentation, and 3D models were generated by the surface rendering algorithm. The spatial distribution of the intrahepatic duct system and the relationship between lesions and surrounding tissues from different perspectives could be observed in the reconstructed model, which can be exported as a standard template library. In the 3D reconstruction model, the anatomical features of the tissue structure, stone distribution, bile duct stricture, malformation, and vascular arrangement were identified by magnifying, deleting, rotating, and transparentizing the patient's organs (Figure 1).

Surgical procedure

All procedures were performed under general anesthesia by an experienced biliary surgeon. The one-step PTOBF technique was utilized as follows (Figures 2 and 3, Video).

Preoperative planning: Important preoperative evaluation data, including the location of intrahepatic stones and strictures, the degree of stricture, the biliary anatomy, and the relationship between the vasculature and biliary system, were collected. The preoperative assessment tools include US, CT, magnetic resonance imaging (MRI) or magnetic resonance cholangiopancreatography, and 3D visualization.

Three-dimensional visualization and US-guided puncture: According to preoperative planning, target biliary tract puncture was performed using an 18G needle and a 0.035-inch hydrophilic guidewire under real-time intraoperative US and 3D-model guidance. The patients were encouraged to hold their breath for 2 minutes during puncture to minimize interference.

Establishing channel: After successful biliary puncture, the sinuses were expanded with serial fascial dilators from 8 Fr to 14 Fr. A 14 Fr sheath was passed over the guidewire to establish the channel for the rigid choledochoscope.

Choledochoscopic stone removal: Small stones were flushed out with a "wash and suction" procedure. Larger stones were removed by using a basket, a clamp, or electrohydraulic shock wave lithotripsy.

Managing anastomotic strictures: Choledochoscopy and cholangiography were used to confirm the degree and location of the anastomotic stricture. A membranous stricture with a thin fibrous layer was designated as a mildly anastomotic stricture and could be expanded with a 16 Fr or 18 Fr dilator. A scar-like stricture of the bile duct was designated a severe anastomotic stricture. These could be dilated by flushing with mannitol solution, inserting a 40-W electric knife to cut the open stricture, and/or employing a 4, 6 or 8 mm balloon dilatation catheter.

Supporting drainage tube insertion: A 14 Fr drainage tube was placed into each hepatolithiasis patient at the end of the procedure. If the patient had strictures, a 16- or 18-Fr supporting drainage tube had to be placed across them. The drainage tubes were exchanged every 2-3 months and removed 6 to 9 months after percutaneous transhepatic cholangioscopy, when the strictures were resolved on the last endoscopic intervention.

Statistical analysis

Statistical analysis was performed using R version 3.4.1. Categorical variables are expressed as frequencies and percentages. Continuous variables are expressed as the mean ± SD or median (range). P values < 0.05 were considered to

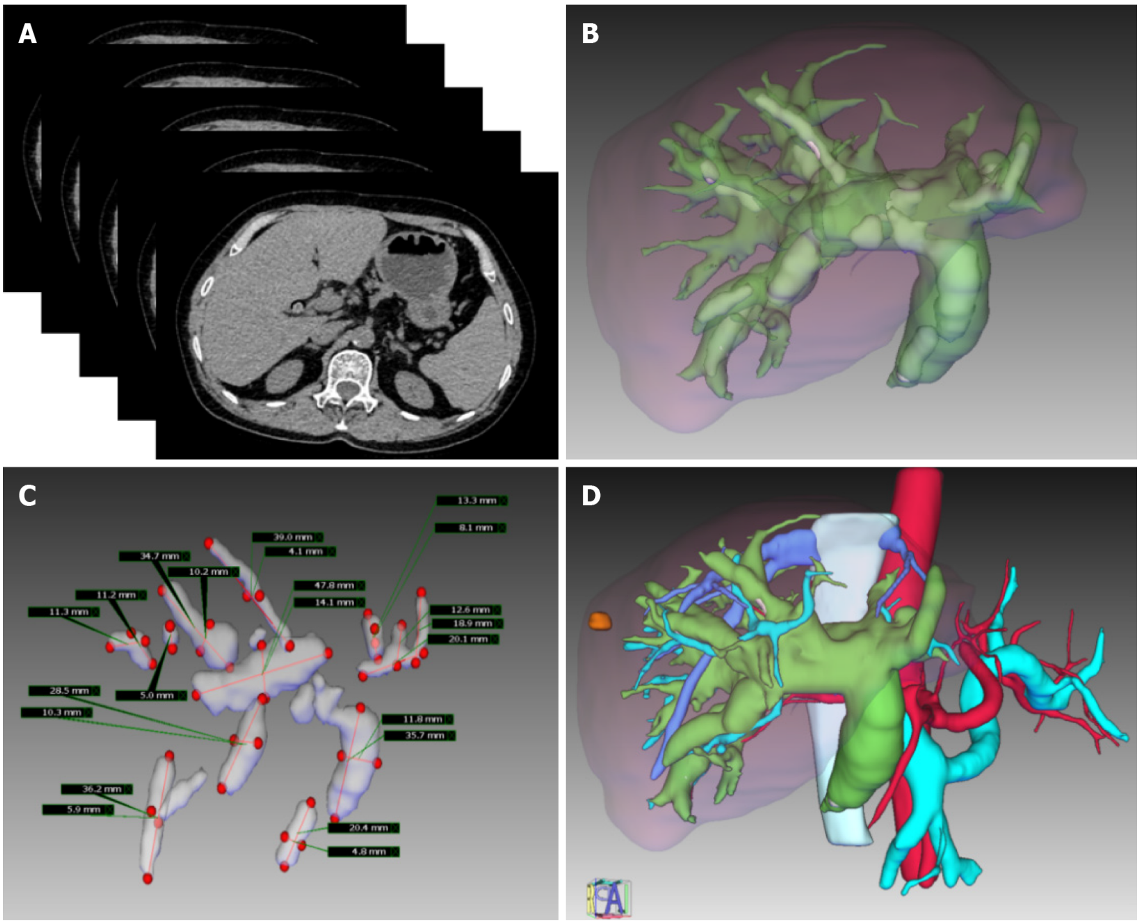

Figure 1 Details of the liver reconstruction model. A: Iterative computed tomography images; B: The bile duct system involves the clearly visible hepatic bile duct segments, and the hepatolithiasis is labeled in yellow; C: Reconstruction of the location and size of the hepatolithiasis; D: A complete liver reconstruction model with intrahepatic bile duct stones.

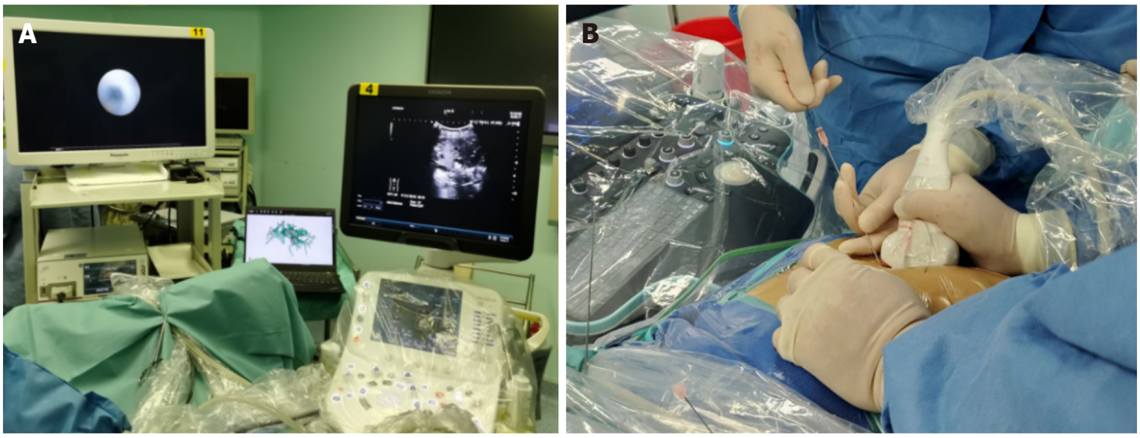

Figure 2 Three-dimensional model combined with real-time B-ultrasonic navigation. A: Combination of three-dimensional reconstruction and B-ultrasound for guiding one-step percutaneous transhepatic cholangioscopic lithotripsy (PTCSL); B: Using the percutaneous transhepatic one-step biliary fistulation technique for one-step PTCSL.

indicate statistical significance.

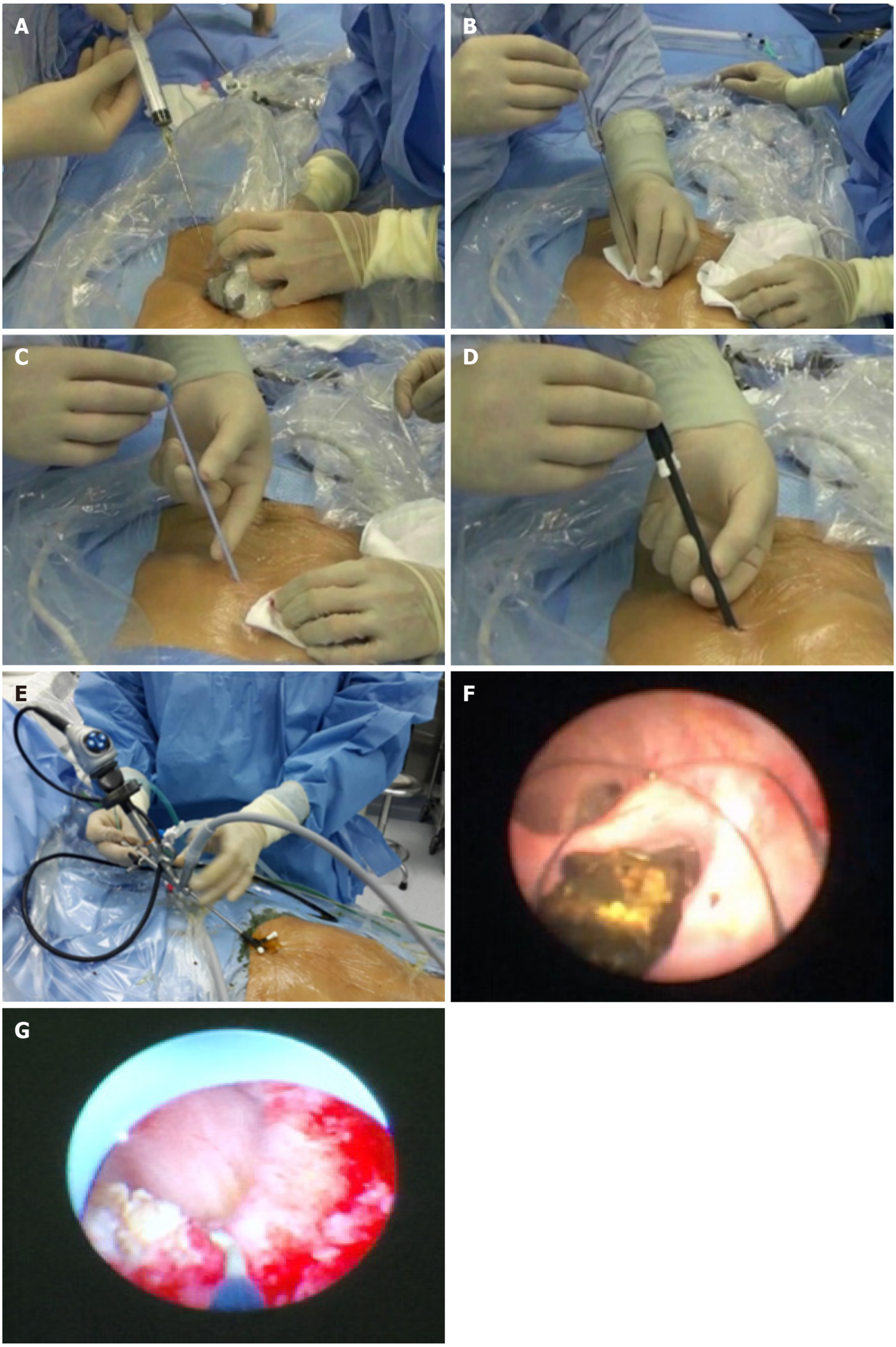

Figure 3 One-step percutaneous transhepatic cholangioscopic lithotripsy using the percutaneous transhepatic one-step biliary fistulation technique. A: Ultrasound-guided puncture; B: Guidewire insertion; C: Fistula dilation D: Sheath insertion; E: Rigid choledochoscope exploration; F: Stone clearance; G: Stricture resolution using an electric knife.

RESULTS

Baseline characteristics of the patients

From October 2016 to October 2022, 140 patients who underwent one-step PTCSL for hepatolithiasis with biliary stricture were eligible and included in the study. There were 54 male and 86 female patients, and the mean age was 19.1 ± 11.4 years. The operation-related data, including age, sex, total bilirubin, direct bilirubin, alanine aminotransferase, Child-Pugh class, stone, and stricture location, were similar between the 2 groups. There was a significant difference in bile duct strictures, with biliary strictures more common in the 3D-PTOBF group (35.7% *vs* 7.1%, P = 0.001). A comparison of the specific characteristics of the three groups is listed in Table 1.

Perioperative outcomes

The intraoperative data of the 2 groups are shown in Table 2. The immediate stone clearance ratio in the 3D-PTOBF group was significantly greater than that in the PTOBF group after analysis (88.6% *vs* 27.1%, P = 0.000). The postoperative complication rate were significantly lower in the 3D-PTOBF group (8.6% *vs* 41.4%, P = 0.000). No significant differences were found between the groups in terms of the operation time and intraoperative blood loss.

Long-term results

The patients were followed up for a period that ranged between 55 and 512 days (mean 55 days). The stricture resolution ratio (97.1% *vs* 78.6%, P = 0.001) in the 3D-PTOBF group was significantly better than that in the PTOBF group after analysis. The stone recurrence rate (7.1% *vs* 38.6%, P = 0.000) was significantly lower in the 3D-PTOBF group. The final total stone clearance rates were 77.1% (3D-PTOBF) and 78.6% (PTOBF). The reoperation rates were 1.4% (3D-PTOBF) and 12.9% (PTOBF) (Table 3).

DISCUSSION

This study demonstrated that 3D-guided one-step PTCSL using PTOBF is highly effective and safe for the treatment of hepatolithiasis patients with associated biliary strictures. The procedure achieved an immediate stone clearance ratio of 88.6%, a final total stone clearance rate of 77.1%, a stricture resolution rate of 97.1%, a postoperative complication rate of 8.6%, and a stone recurrence rate of 7.1% over a median follow-up period of 55.0 (55.0, 512.0) days.

In one-step PTCSL, 3D visualization of the hepatobiliary tract is carried out beforehand to design an appropriate preoperative plan *via* preoperative CT imaging, in which the calculi and bile duct stricture can be visually located[17]. According to the preoperative plan, percutaneous transhepatic cholangiography is performed intraoperatively under real-time US navigation, and the sinus tract is expanded to an appropriate diameter (16-18 Fr). Then, a protective sheath is used to ensure that biliary endoscopic surgery can be continued immediately without waiting for full recovery of the sinus tissue. This approach significantly shortens the operation and treatment times. Due to the convenience of the operation, multiple punctures can be made in a single operation to create multiple stone-extracting channels, which significantly enhances the success rate of stone extraction[18,19]. This approach is especially suitable when primary intrahepatic bile duct stones are distributed in a diffuse manner. In this case, one stone-extracting channel is not sufficient to clear all the stones.

Previous 2D plane structure generated based on B-US, CT or MRI medical images is very different from the 3D bile duct tree structure. Limited spatial information of 2D structure makes it difficult for determining the spatial locations of the stones, therefore leading to high surgical risk and low efficiency of stone removal. The results of this study are comparable to those of prior studies showing immediate clearance rates of 41%-46% with traditional multisession PTCSL [20]. This reflects the technical complexity of clearing all stones in a single setting from the intrahepatic biliary tree. The limited spatial information available in 2D makes it difficult to determine the spatial locations of the stones, leading to high surgical risk and low stone removal efficiency. However, with 3D visualization technology and adjunctive techniques such as biliary stenting and saline irrigation, the immediate stone clearance ratio in the 3D-PTOBF group was 88.6% (62/70). Three-dimensional visualization can promote one-step PTCSL with a preoperative simulated operation plan, intraoperative digitization of the patient's anatomy, and a predetermined diagnosis.

The long-term recurrence rate of 7.1% (5/70) in our study is also lower than the 15%-40% reported in the literature[21-23]. This may be attributed to the complete initial stone clearance and prolonged biliary stenting performed to prevent stricture recurrence in our patients. Our surgeons employ a rigid choledochoscope to treat stenosed bile ducts and leave an 18 Fr drainage tube in the distal end of the stenosed bile ducts for 6-9 months[11]. Bacterial biofilms and bile sludge cause blockage and restenosis of the bile ducts, so the drainage tubes need to be replaced every 3 months.

The postoperative complication rates were significantly lower in the 3D-PTOBF group than in the PTOBF group (8.6% *vs* 41.4%, P = 0.000). The perioperative complication rate of traditional multisession PTCSL is between 15% and 23%. Complex and dangerous situations that may occur in the actual operation can be simulated and estimated by 3D visualization technology prior to the procedure. It is highly important to compare the advantages and disadvantages of different surgical plans through simulation, as this can aid in developing reasonable individual surgical plans and preoperative demonstrations for the patients.

Our study adds to the limited data on the long-term efficacy of one-step PTCSL. Fang *et al*[24] described 3D visualization technology for treating hepatolithiasis patients in 2013. Yang *et al*[20] first described the PTOBF technique in 2013 [20]. However, these studies focused only on immediate outcomes. Our long-term follow-up provides evidence that 3D-guided one-step PTCSL is beneficial and effective for treating complex hepatolithiasis.

Table 1 Comparison of the preoperative data between the two groups, *n* (%)

Variables	3D-PTOBF (*n* = 70)	PTOBF (*n* = 70)	*P* value
Age (year)	50.5 ± 17.3	49.0 ± 17.2	0.608
Sex			
Male	24 (34.3)	30 (42.9)	0.298
Female	46 (65.7)	40 (57.1)	
TBIL (mmol/L)	33.9 ± 32.9	30.8 ± 33.6	0.581
DBIL (mmol/L)	13.3 ± 18.1	13.4 ± 20.3	0.990
ALT (U/L)	59.9 ± 61.7	56.5 ± 57.0	0.791
γ-GGT (U/L)	210.6 ± 262.2	238.0 ± 236.3	0.517
ALB (g/L)	39.3 ± 6.4	37.6 ± 5.8	0.105
PT (second)	14.2 ± 4.5	13.5 ± 1.0	0.174
Child-Pugh score			
Grade A	67 (95.7)	58 (82.9)	0.014
Grade B	3 (4.3)	12 (17.1)	
Stone location			
S1	1 (1.4)	2 (2.9)	0.559
S2	9 (12.9)	12 (17.1)	0.478
S3	11 (15.7)	13 (18.6)	0.654
S4	17 (24.3)	23 (32.9)	0.262
S5	4 (5.7)	5 (7.1)	0.730
S6	12 (17.1)	12 (17.1)	1.0
S7	8 (11.4)	16 (22.9)	0.137
S8	12 (17.1)	17 (24.3)	0.297
Common bile duct	23 (32.9)	13 (18.6)	0.053
Biliary stricture Location			
S1	0	0	1.0
S2	1 (1.4)	8 (11.4)	0.008
S3	8 (11.4)	12 (17.1)	0.334
S4	14 (20.0)	14 (20.0)	1.0
S5	4 (5.7)	6 (8.5)	0.512
S6	11 (15.7)	6 (8.5)	0.196
S7	6 (8.6)	3 (4.2)	0.301
S8	7 (10.0)	8 (11.4)	0.785
Bilio-enteric anastomosis	12 (17.1)	21 (30.0)	0.073
Common bile duct	25 (35.7)	5 (7.1)	0.001

TBIL: Total bilirubin; DBIL: Direct bilirubin; ALT: Alanine aminotransferase; γ-GGT: Gamma-glutamyl transpeptidase; ALB: Albumin; PT: Prothrombin time; 3D: Three-dimensional; PTOBF: Percutaneouas transhepatic one-step biliary fistulation.

Clinically, choledochoscopy can only be performed until maturation of the sinus tract at least 1 week following percutaneous biliary drainage[25]. The one-step approach avoids incremental fistula dilation and reduces overall hospitalization times. We introduced 3D visualization into the one-step PTCSL technique to further show that the reconstructed 3D model can be used to localize lesions with submillimeter accuracy and can therefore contribute to planning an accurate puncture route before surgery and guide the puncture and stone extraction operations during surgery.

Table 2 Patient outcomes, *n* (%)

Variables	3D-PTOBF (*n* = 70)	PTOBF (*n* = 70)	*P* value
Operation time (minute)	55.2 ± 34.0	59.8 ± 37.8	0.448
Intraoperative blood loss (mL)	26.5 ± 52.1	16.4 ± 13.4	0.117
Immediate stone clearance ratio	62 (88.6)	19 (27.1)	0.000[a]
Complications	6 (8.6)	29 (41.4)	0.000[a]
Hemobilia	1 (1.4)	2 (2.9)	0.559
Pulmonary infection	2 (2.9)	4 (5.7)	0.384
Cholangitis	2 (2.9)	14 (20.0)	0.001
Pleural effusion	1 (1.4)	9 (12.9)	0.009

[a]$P < 0.001$.
3D: Three-dimensional; PTOBF: Percutaneous transhepatic one-step biliary fistulation.

Table 3 Long-term results, *n* (%)

Variables	3D-PTOBF (*n* = 70)	PTOBF (*n* = 70)	*P* value
Follow-up time	498.0 ± 373.5	1031.3 ± 573.0	0.000[a]
Final stone clearance ratio	54 (77.1)	55 (78.6)	0.839
Stricture resolution ratio	68 (97.1)	55 (78.6)	0.001
Number of operations	3.0 ± 1.5	2.9 ± 1.8	0.535
Stone recurrence	5 (7.1)	27 (38.6)	0.000[a]
Reoperation rate	1 (1.4)	9 (12.9)	0.009
Late complications	9 (12.9)	9 (12.9)	1.0
Cholangitis	8 (11.4)	7 (10.0)	0.785
Liver failure	1 (1.4)	2 (2.9)	0.559

[a]$P < 0.001$.
3D: Three-dimensional; PTOBF: Percutaneous transhepatic one-step biliary fistulation.

There were still some limitations in this study. This was a single-center study with a limited number of patients; hence, there was some inevitable selection bias between the groups that may have impacted the results.

CONCLUSION

This study confirmed that one-step PTCSL guided by 3D visualization can be used to safely puncture the biliary tract and effectively remove stones, improving the treatment of patients with complicated primary hepatolithiasis. The perioperative and long-term outcomes for these complicated primary hepatolithiasis patients were satisfactory.

FOOTNOTES

Author contributions: Wang P, Li RQ and Ye YQ conceptualized and designed the research; Li EZ, Ding ZW, Fan JM screened patients and acquired clinical data; Cao YW, Wu YX collected blood specimen and performed data analysis; Ye YQ and Cao YW wrote the paper; All the authors have read and approved the final manuscript. Cao YW proposed, designed and conducted data analysis and prepared the first draft of the manuscript. Ye YQ was responsible for patient screening, enrollment, collection of clinical data and blood specimens. Both authors have made crucial and indispensable contributions towards the completion of the project and thus qualified as the co-first authors of the paper.

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