Original Article

Percutaneous transhepatic papillary ballooning and extraction for common bile duct stones: a single-center experience

Rongna Hou, Chengzhi Zhang^, Mengyao Song, Zhanguo Sun, Yi Fang, Xinwei Han, Dechao Jiao

Department of Interventional Radiology, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China

Contributions: (I) Conception and design: R Hou; (II) Administrative support: D Jiao; (III) Provision of study materials or patients: D Jiao; (IV) Collection and assembly of data: R Hou, C Zhang, M Song, Z Sun, Y Fang, X Han; (V) Data analysis and interpretation: R Hou, C Zhang, M Song, Z Sun, Y Fang, X Han; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Dechao Jiao, PhD. Department of Interventional Radiology, The First Affiliated Hospital of Zhengzhou University, No. 1 Jianshe East Road, Zhengzhou 450052, China. Email: jiaodechao007@126.com.

Background: At present, some common bile duct stones (CBDSs) cannot be removed by conventional endoscopic treatment. Percutaneous transhepatic papillary ballooning and extraction (PTPBE) is a promising treatment for CBDSs. This study aimed to evaluate the feasibility and efficacy of PTPBE for removing CBDSs.

Methods: From April 2013 to April 2021, 29 patients with CBDSs underwent PTPBE at The First Affiliated Hospital of Zhengzhou University; their clinical data were retrospectively analyzed. The technical success, clinical success, procedure time, radiation dose, 1-year CBDSs recurrence rate, and incidence of early/late complications were recorded, and white blood cell (WBC) counts and alanine aminotransferase (ALT), C-reactive protein (CRP), total bilirubin (TBIL), and carbohydrate antigen-199 (CA-199) levels were compared before the interventional procedure and 1 month later.

Results: The CBDSs were successfully removed in 29 patients (the CBDSs in 20 patients were resolved once, and in 9 patients, they were resolved twice). The mean procedure time and radiation dose were 56.38±13.56 minutes and 732.07±262.23 miligray (mGy), respectively. The technical and clinical success rates were both 100%. The incidence of early complications (including pancreatitis and bile duct bleeding) and late complications (reflux cholangitis) was 10.34% and 3.45%, respectively. The WBC (both $P<0.01$), ALT (both $P<0.01$), CRP (both $P<0.01$), CA-199 (both $P<0.01$), and TBIL (both $P<0.01$) significantly decreased before PTPBE and 1 month later.

Conclusions: PTPBE is a safe and effective alternative solution for elderly patients who cannot undergo or refuse traditional surgical and endoscopic treatments.

Keywords: Common bile duct stones (CBDSs); papillary balloon; stone extraction; interventional radiology

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Introduction

Cholelithiasis, which includes intrahepatic biliary stones, gallbladder stones, common hepatic duct stones, and common bile duct stones (CBDSs), is a common clinical disease (1). Most gallstones have no clinical symptoms and are found only during physical examinations. However, when stones block the opening of the gallbladder duct or the opening of the pancreatic duct or when the ampulla is blocked by CBDS,

^ ORCID: 0000-0002-7367-0334.

some patients may experience recurrent symptoms such as biliary colic, jaundice, or fever. Once the above symptoms occur or if accompanied by cholangitis, biliary obstruction, or biliary pancreatitis, serious disease often leads to severe consequences, even bile duct rupture or septic shock (2,3). At present, the main treatment methods are open common bile duct exploration and stone removal, laparoscopic common bile duct exploration and stone removal, and endoscopic retrograde cholangiopancreatography and stone removal (4,5); open surgery is now considered obsolete (6). Laparoscopic and endoscopic lithotomy involve a minimally invasive treatment mode, which has a wide range of indications. However, some patients have endoscopic contraindications [patients with esophageal and gastric varices, upper gastrointestinal (GI) stenosis, or duodenal diverticulum] or post-GI Roux-en-Y anastomosis, which makes them unable to tolerate anesthesia due to poor cardiopulmonary reserve function or CBDS following previous digestive tract reconstruction surgery (7).

In the 1960s, Mondet *et al.* (8) first explored the use of balloon dilation catheters or stone removal baskets to treat CBDSs. Subsequently, similar techniques were reported by multiple centers, with a high success rate (9-11). In theory, percutaneous puncture can quickly reduce the pressure on the bile duct and can also be used to push stones in the bile duct through an anterograde approach (12,13). The current study mainly summarizes the clinical experience from our center to develop the knowledge of the percutaneous transhepatic papillary ballooning and extraction (PTPBE) and to evaluate the feasibility and efficacy of PTPBE for removing CBDSs in clinical practice, especially for elderly patients who cannot undergo or refuse traditional surgical and endoscopic treatments. We present this article in accordance with the STROBE reporting checklist (available at https://qims.amegroups.com/article/view/10.21037/qims-24-325/rc).

Methods

General information

From April 2013 to April 2021, 29 patients with CBDSs underwent PTPBE at The First Affiliated Hospital of Zhengzhou University; their clinical data were retrospectively analyzed. The inclusion criteria were as follows: (I) clear diagnosis of CBDS; (II) maximum stone diameter ≤2 cm; (III) endoscopic treatments failure; (IV) high risk of airway intubation anesthesia; (V) enough cardiopulmonary function to tolerate intravenous analgesia and local anesthesia; (VI) obstructive jaundice related with CBDS. The exclusion criteria were as follows: (I) severe coagulation dysfunction such as prothrombin time (PT) ≥25 seconds, platelet count (PLT) $\leq 30\times10^9$/L; (II) previous history of recurrent duodenal papilla ulcers; (III) no suitable percutaneous transhepatic puncture access. The outcomes/endpoints of the analysis were the technical and clinical success, early and late complications, and the white blood cell (WBC), alanine aminotransferase (ALT), C-reactive protein (CRP), carbohydrate antigen-199 (CA-199) and total bilirubin (TBIL) levels. The complications were classified according to the Clavien-Dindo classification (14). This retrospective study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of The First Affiliated Hospital of Zhengzhou University (No. 2021-ky-259). The requirement for individual consent for this retrospective analysis was waived.

Procedures

Satisfactory pain control was achieved by intravenous infusion of 50 mL of a mixture of deszocin (10 mg) and dexmedetomidine hydrochloride (400 μg) (4 mL/h) by a pump. The patient was placed prone on the digital subtraction angiography (DSA) examination table (Artis Zeego; Siemens, Erlangen, Germany). All the operations were completed under the guidance of DSA and ultrasound. After disinfection, local anesthesia was applied with 2% lidocaine (5–10 mL), the dilated perihepatic biliary branch was successfully punctured by the Seldinger technique using a percutaneous transhepatic cholangiography (PTC) puncture set (Cook, Bloomington, IN, USA), and a contrast agent (300 mg/I/100 mL; Hengrui, Jiangsu, China) was injected to determine the biliary tree information and the CBDS location. A 0.018-inch platinum guide wire was introduced through the 21 G puncture needle, and a 6F sheath (23 cm in length; Termo, Tokyo, Japan) was used to establish percutaneous access. A 0.035-inch guide wire and 5F Kumpe catheter (Cook, USA) were manipulated together into the duodenum, and the 0.035-inch strength guide wire was exchanged to establish the following manipulation access. According to the CBDS size, a 12–18 mm balloon (Boston Scientific, Marlborough, MA, USA) dilation catheter was used to locate the area across the ampulla, and a pressure pump (Tuoren, Beijing, China) was used to dilate the stenosis (with a pressure of 8 atm, each dilation lasting for 30–60 s with an interval of 60 s). The basic principle of choosing a balloon is that the chosen balloon should be 10–15% larger than the maximum diameter of the

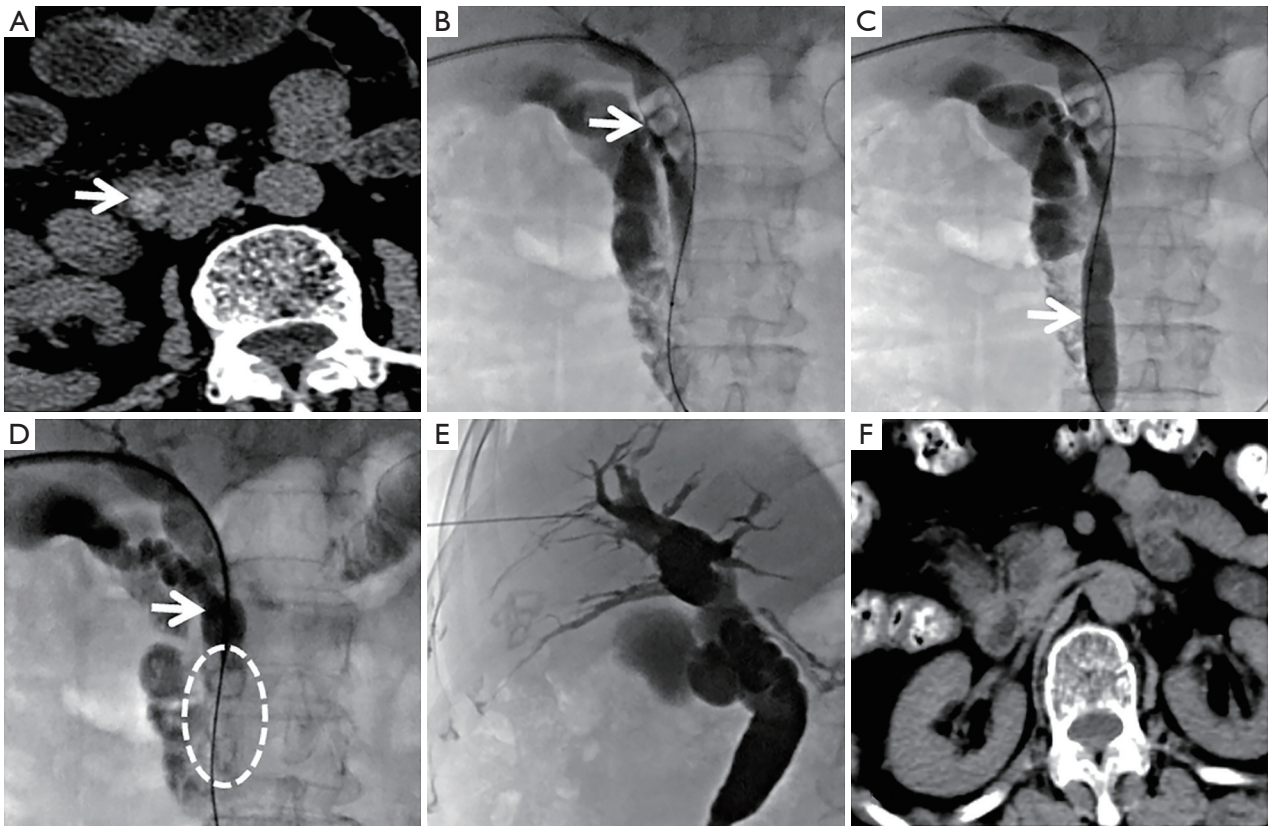

Figure 1 A 75-year-old female with epigastric pain accompanied by jaundice. (A) Preoperative CT revealed multiple high-density stones in the bile duct (arrow); (B) intraoperative puncture of the bile duct revealed 3 stones (arrow) in the common bile duct, with a maximum diameter of 1.3 cm; (C) 14 mm × 4 cm balloon dilating Vatter ampulla; (D) Fogarty balloon (arrow) filled up to 1.4–1.6 cm above the stone, allowing the stone (white circle) to be gradually pushed into the duodenum under fluoroscopy; (E) postoperative angiography showed that the stones in the bile duct had disappeared; (F) no high-density stones were found in the bile duct 3 days after surgery. CT, computed tomography.

stone measured under fluoroscopy. The main consideration for this selection is the occurrence of retractive stenosis after balloon dilation of the ampulla.

A Fogarty balloon (Microtech., Nanjing, China) was used to expand the area above the CBDS to an appropriate size, after which the CBDS was pushed into the duodenum under real-time fluoroscopy. An 8.5-F external drainage tube was used to drain the bile duct when there was no obvious CBDS under cholangiography. Cholangiography was performed again to recheck the residual CBDS after 3 days, and if necessary, PTPBE was performed again. The treatment plan for a 75-year-old patient with epigastric pain and jaundice is shown in *Figure 1*. It was generally recommended to remove the biliary drainage tube 1 month later after confirmation of no stones via computed tomography (CT) and ultrasound examinations.

Definition and follow-up

Technical success was defined as successful removal of CBDS. Clinical success was defined as cholelithiasis relief and a decrease in TBIL of more than 50% within 2 weeks compared with that observed before treatment. The radiation dose was collected via the monitoring system of the DSA. The WBC count and ALT, CRP, TBIL, and CA-199 levels were compared before treatment and at 1 week and 1 month after treatment. Complications were evaluated according to the Society of Interventional Radiology (SIR) Standards of Practice Committee classification on percutaneous hepatobiliary interventions (15). Minor complications were defined as no therapy and no consequence (grade 1) or overnight observation only, no therapy, or no consequence (grade 2). Major complications

Table 1 Patient characteristics

Characteristics	Value
Total number	29
Age (years), mean ± SD	68.86±10.17
Sex, n (%)	
Male	16 (55.17)
Female	13 (44.83)
Clinical symptoms, n (%)	
Abdominal pain with jaundice	14 (48.28)
Jaundice with fever	15 (51.72)
Common bile duct stone number, n (%)	
Single (n=1)	13 (44.83)
Multiple (n≥2)	16 (55.17)
Max diameter of biliary stone (cm), mean ± SD (range)	1.37±0.29 (0.80–2.00)
BMI (kg/m^2), mean ± SD (range)	27.53±4.29 (18.10–36.20)
The causes of choosing PTPBE, n (%)	
Risk of intubation anesthesia	12 (41.38)
Endoscopic failure (gastric varices/ duodenal diverticulum)	2/3 (17.24)
Surgical treatment failure	4 (13.79)
Patient preference	8 (27.59)
Procedure time (min), mean ± SD (range)	56.38±13.56 (32.10–86.60)
Diameter of balloon (mm), n (%)	
<16	13 (44.83)
≥16	16 (55.17)
Radiation dose (mGy), mean ± SD (range)	732.07±262.23 (355.50–1,279.20)

SD, standard deviation; BMI, body mass index; PTPBE, percutaneous transhepatic papillary balloon and extraction; mGy, miligray.

were defined as those requiring therapy and hospitalization (48 hours, grade 3), permanent adverse sequelae (grade 4), or death (grade 5). All patients were followed up for at least 1 year to observe the stone recurrence rate.

Statistical analysis

All the statistical analyses were performed using the software SPSS 26.0 (IBM Corp., Armonk, NY, USA). Numerical variables were presented as n (%). The Shapiro-Wilk test was used to check the normal distribution of the data. Continuous data were presented as the mean ± standard deviation. We used paired *t*-tests for the same indices before and after the procedure in the same patient. P values <0.05 were considered to indicate statistical significance.

Table 2 Clinical outcomes

Outcomes	Value
Technical success, %	100
Clinical success, %	100
Number of stone extraction, n (%)	
First	25 (86.21)
Second	4 (13.79)
Early complications, n (%)	
Pancreatitis (grade 2)	1 (3.45)
Bile duct bleeding (grade 2 and grade 3)	2 (6.90)
Hospitalization time (day), mean ± SD	7.97±1.86
Stone recurrence rate 1 year, %	10.34

SD, standard deviation.

Results

A total of 29 patients (16 men and 13 women) with a median age of 68.86±10.17 years were included in this retrospective study. The clinical symptoms were abdominal pain with jaundice (n=14) and jaundice with fever (n=15), and the maximum diameter of the biliary stones was 1.37±0.29 cm. More detailed information is listed in *Table 1*.

Among all 29 patients, CBDSs were successfully removed (in 20 patients, the CBDSs were resolved once, and in 9 patients, they were resolved twice). The clinical outcomes are listed in *Table 2*. The technical and clinical success rates were both 100%. The general condition of the patient with complication grade 3 was stabilized after the administration of systemic supportive therapy, application of hemostatic drugs and anti-infection. The mean radiation dose and procedure time were 732.07±262.23 miligray (mGy) and 56.38±13.56 minutes, respectively. The mean hospitalization time was 7.97 (range, 6–14) days. Early complications were as follows: pancreatitis (grade 2) in 3.45% (1/29) and bile duct bleeding (including grade 2 and grade 3) in 6.90% (2/29). Late complications included reflux cholangitis 3.45%

Table 3 Comparison of biochemical indicators

Characteristics	Pretreatment	1 week later	1 month later	P_1 value	P_2 value
WBC ($\times10^{12}$/L)	11.15±2.51	7.18±2.02	6.17±1.43	<0.01	<0.01
ALT (U/L)	91.68±34.63	47.21±13.42	34.92±4.99	<0.01	<0.01
TBIL (μmol/L)	139.55±33.21	47.27±10.57	29.92±5.20	<0.01	<0.01
CRP (mg/L)	62.00±23.35	50.17±45.10	13.79±6.11	<0.01	<0.01
CA-199 (U/mL)	274.31±138.24	100.82±42.77	35.45±12.09	<0.01	<0.01

Numerical data are expressed as the mean ± standard deviation. P_1, comparison between 1-week post-operation and pre-operation; P_2, comparison between 1-month post-operation and pre-operation. WBC, white blood cell; ALT, alanine aminotransferase; TBIL, total bilirubin; CRP, C-reactive protein; CA-199, carbohydrate antigen-199.

(1/29). The 1-year CBDS recurrence rate was 10.34% (3/29). The WBC, ALT, CRP, TBIL, and CA-199 levels before and after treatment are shown in *Table 3*, and all the changes were significant (P<0.05).

Discussion

Choledocholithiasis is a common and frequent disease in clinical practice and is prone to obstructive jaundice accompanied by biliary infections and biliary colic as common acute abdominal conditions (16,17). Endoscopic sphincterotomy (EST) leads to disruption of some papillary sphincter functions and a high incidence of postoperative reflux cholangitis (18). Although endoscopic papillary balloon dilatation (EPBD) has the advantages of preventing complications such as bleeding and perforation and preserving the function of the duodenal papillary sphincter (19), in patients with diverticular papillae, flat papillae, and lower bile duct stenosis, treatment fails due to difficulty in passing through the papillae (20). It has been reported that laparoscopic exploration of the common bile duct (LCBDE) should be the first choice for younger patients with choledocholithiasis, with the advantage of avoiding papillotomy and allowing simultaneous cholecystectomy (21).

In this study, PTPBE can be seen as an extension of the PTCD procedure. It is different from EPBD and EST in terms of access and stone extraction, but it can achieve similar therapeutic outcomes and success rates, and it is easier to pass through the narrow choledochal segments that cannot be passed by EST or ERCP. Reflux cholangitis is avoided and the function of the papillary sphincter is preserved by using balloon dilatation of the duodenal papilla to open the stone extraction pathway. It is especially preferable for older patients with choledocholithiasis who have failed endoscopic treatment and cannot afford the risk of general anesthesia. This study shows that PTPBE can also clarify the location, size, and number of stones, and intraoperative fluoroscopy can directly observe balloon dilatation of the duodenal papilla and evaluate stone extraction in a timely manner; PTPBE is very intuitive, clear, and real.

In 1981, Centola *et al.* (10) reported the successful treatment of a patient with choledocholithiasis with the first case of PTPBE. In 2012, Ozcan *et al.* (11) reported 261 cases of percutaneous transhepatic balloon dilation (PTBD) for the treatment of choledocholithiasis, with a technical success rate of 95.70% and a complication rate of 6.80%. Subsequently, Li *et al.* (22) retrospectively analyzed 68 patients with CBDS treated by PTPBE, and the technical success, complication, and 1-year recurrence rates were 100%, 14.7%, and 14.7%, respectively. Liu *et al.* (23) reported the largest cohort of 360 patients who underwent PTPBE in 2021, and the technical success and complication rates were 99% and 4%, respectively. More details about PTPBE therapy in recent years are listed chronologically in *Table 4*. A total of 25 patients in our study underwent 1-time stone removal using this technique, and 4 patients underwent 2 interventional surgeries. Our results are encouraging, with the technical success, early/late complication rate, and 1-year recurrence rate of stones being 100%, 10.34%/3.45%, and 10.34%, respectively. These findings align with previous studies and confirm the feasibility and safety of PTPBE, particularly for elderly patients.

Nonetheless, our study has several limitations, including its retrospective design, single-center experience, small sample size, short follow-up period, and lack of control studies involving surgical and endoscopic treatments.

The single center experience of PTPBE is summarized as follows: (I) usually puncture of peripheral dilated bile ducts of the liver reduces the damage to intrahepatic blood

Table 4 Recent published papers on PTPBE

Year	Author/country	Study design	Sample	Male/female	Max. stone diameter (mm)	Balloon diameter (mm)	Technical success (%)	TBIL changes (μmol/L) (pretreatment/posttreatment)	Complications (%)	1-year biliary stone recurrence (%)
2011 (24)	Szulman C/Argentina	RS	300	123/177	18	6–20	96.00	NA	0	0
2012 (11)	Ozcan N/Turkey	RS	261	138/123	40	8–12	95.70	NA	6.80	NA
2013 (22)	Li YL/China	RS	68	39/29	22	8	100	159.00/14.00	14.70	14.70
2015 (25)	Han JY/Korea	PS	11	7/4	13.7	13.5	100	NA	0	NA
2018 (3)	Liu B/China	RS	17	10/7	>20	22	94.10	169.00/16.10	5.90	0
2018 (26)	Wang W/China	RS	18	8/10	>20	10–22	88.89	NA	0	5.56
2021 (23)	Liu B/China	RS	360	163/197	>15	NA	99.00	27.80/19.30	4.00	0.56
2022 (27)	Shim DJ/Korea	RS	123	62/61	31	6–18	96.00	NA	21.14	NA
2024 (28)	Wang ZX/China	RS	48	25/23	>15	NA	95.80	NA	14.60	NA

PTPBE, percutaneous transhepatic papillary balloon and extraction; TBIL, total bilirubin; RS, retrospective study; PS, prospective study; NA, not available.

vessels and the occurrence of biliary vascular fistula. (II) The angle of puncture through the common bile duct is recommended to be more than 120 degrees, so that the resistance of introducing interventional instruments such as balloons in the later stage will be significantly reduced. (III) The balloon diameter to dilate the sphincter of Oddi is recommended to be equal to or slightly larger than the maximum diameter of the stone by 10%; the sphincter of Oddi should be gradually and intermittently dilated to avoid serious fiber tear, and the maximum recommended diameter is within 18 mm. (IV) If the stone is too large, it can be pushed into the duodenum after lithotripsy, and an external drainage tube can be placed routinely to reduce the pressure in the bile duct and reduce the incidence of postoperative pancreatitis and cholangitis. (V) Intravenous anesthesia is recommended for this operation; it is appropriate for anesthesiologists to work together because the pain caused by balloon dilation of Oddi sphincter is relatively serious; and some patients may even experience biliary-cardiac reflex, whereas local anesthesia combined with intravenous anesthesia can obtain satisfactory analgesic effects and improved patient comfort. (VI) Percutaneous transhepatic puncture may lead to bile duct bleeding, balloon dilation may cause pancreatitis, and intestinal mucosal bleeding may occur during stone pushing. Therefore, drugs such as somatostatin and octreotide acetate can be used to prevent GI bleeding and pancreatitis before surgery. (VII) Fine intraoperative procedures are helpful for reducing the incidence of pancreatitis. After the operation, changes in vital signs were closely monitored, and routine blood test results, liver and kidney function, blood biochemistry and blood and urine amylase levels were regularly reviewed.

Conclusions

As a minimally invasive, efficient, and safe treatment for CBDSs, PTPBE not only improves the therapeutic efficacy of choledocholithiasis and reduces the complication rate and recurrence rate, but also provides more treatment choices for high-risk populations such as elderly patients. With the continuous progress of medical technology and the accumulation of clinical experience, PTPBE has been more widely used and developed. In the future, we look forward to seeing more research and clinical practice on PTPBE, contributing more power to the treatment of CBDSs.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-24-325/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-24-325/coif). All authors report that this study was funded by the Henan Province Science and Technology Research Project (No. 232102311132). The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This retrospective study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of The First Affiliated Hospital of Zhengzhou University (No. 2021-ky-259). The requirement for individual consent for this retrospective analysis was waived.

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