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Original Article

A clinical study of an indwelling nasobiliary duct placed in a trans-abdominal forward direction without cutting the sphincter of Oddi to treat early acute biliary pancreatitis

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Abstract: Background and objective: The retrograde placement of nasal bile ducts in EST operations to deal with acute biliary pancreatitis has become a standard surgical procedure, one recognized by most doctors. However, the operation cuts the sphincter of Oddi, possibly causing sphincter hemorrhage, intestinal leakage, bile leakage, intestinal fluid reflux, and pancreatic juice reflux after surgery. The gallbladder is not removed in this way, so it may recur with pancreatitis and calculus. Meanwhile, the retrograde placement of the nasal bile duct in this way can easily cause a retrograde infection of the bile duct and other problems. We tried to place a nasobiliary drainage without cutting the sphincter of Oddi in a three-scope combination (laparoscope, choledochoscope, and duodenoscope) with surgery for treating acute biliary pancreatitis, and we achieved a good curative effect. The new surgical method can effectively reduce the above complications. Methods: Data were collected from 110 patients with acute biliary pancreatitis who underwent surgery from January 2015 to January 2018. 54 patients underwent new surgical procedures and 56 patients underwent conventional EST surgery. We compared their short-term results. Results: Although the amount of bleeding in the experimental group was higher than it was in the control group, the operation time and the digestive tract symptoms were significantly reduced, the blood amylase and blood lipase were more significantly reduced, and fewer patients suffered from recurrent cholangitis and pancreatitis within one year. Conclusions: In order to reduce the pressure in the bile duct and relieve the symptoms of pancreatitis, it is more effective to place the nasal bile drainage tube in the common bile duct using a laparoscope. Because we did not cut the sphincter of Oddi, the experimental group had fewer digestive tract reactions and a faster recovery, compared with EST combining with nasobiliary drainage. During the one-year follow-up period, the experimental group had a lower recurrence rate of cholangitis and pancreatitis.

Keywords: Biliary pancreatitis, hybrid surgery, duodenal papillotomy, sphincter of oddi, nasobiliary drainage

Introduction

Biliary pancreatitis is a common disease in digestive surgery. Ammori used endoscopic ultrasonography to examine a group of patients with pancreatitis in 2003. The study found that 65% of all patients with pancreatitis had gallstone pancreatitis [1]. For the treatment of this disease, most hospitals in the world have adopted duodenoscope retrograde cholangiopancreatography (ERCP) to remove calculus embedded in the ampulla of Vater at the early stage of acute biliary pancreatitis, and could make bile duct drainage unobstructed through a papillotomy (EST), thus reducing the recurrence rate of cholangitis and pancreatitis [2] and the mortality rate of biliary sepsis [3]. However, due to the retrograde operation from the oral cavity and the intestinal tract to the biliary tract [4], the sphincter of Oddi is cut during the operation. It changes the pressure gradient of the bile and pancreatic ducts, which causes a reflux of the intestinal cavity contents [4], and finally leads to a retrograde infection of the intestinal bacteria [5] soon after surgery. In the long term, the damaged nipples form scars, which l lead to nipple re-stenosis and an obstruction of bile excretion, and then these

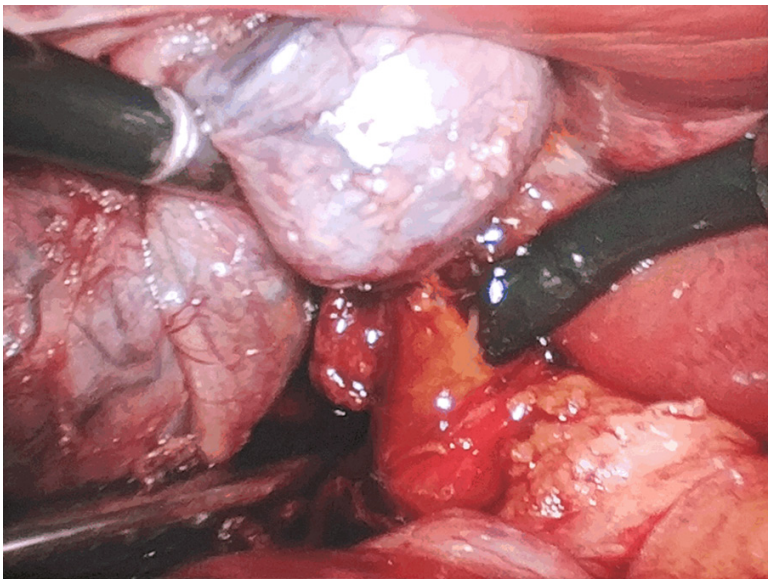

Figure 1. Placing the choledochoscope at the incision of the bile duct until the tip touches the duodenal papilla.

complications such as cholangitis and pancreatitis occur repeatedly [6]. However, after laparoscopic cholecystectomy (the cystic duct is not disconnected for the time being), we will complete the choledocholithotomy and nasobiliary duct placement from the cystic duct stump approach at the same time. Because the operation adopts the physiological channels of the cystic duct, the common bile duct, the nipple, and the intestinal cavity to place the nasal bile duct in the abdominal forward direction, it is very easy to pass through the duodenal papilla without an incision in the papilla. The method described here avoids dirty intestinal fluid from being brought into the biliary tract by the nasobiliary duct, so it reduces the risk of retrograde bacterial contamination. The technique doesn't involve making a tiny incision in the duodenal papilla, so it saves sphincter of Oddi function and avoids all kinds of complications from an incision of the papilla.

Materials and methods

This is a retrospective study. This study has been IRB approved by the institution, and all the patients signed informed consents before their operations.

Patients

We retrospectively analyzed the clinical data of 110 patients with an acute biliary pancreatitis in the Second People's Hospital of Chengdu from January 2015 to June 2018, including preoperative, intraoperative, postoperative, and follow-up data. The inclusion criteria for the patients with acute biliary pancreatitis were based on Tenner and Folsh's approach; (1) The patient had an elevated blood amylase and blood lipase; (2) Color Doppler Ultrasound and MRCP confirmed gallbladder and bile duct stones; (3) CT showed an inflamed pancreas; (4) The patient was within 24 hours of the onset of abdominal pain; (5) The patient had no absolute surgical contraindications. During this period, a hybrid operation was performed on 54 patients and EST was performed on 56 patients.

Hybrid group surgery methods

Surgical procedures: 1, Laparoscopic and choledochoscopic combined surgical method: First, we performed a laparoscopic cholecystectomy and a laparoscopic common bile duct exploration. Second, we used choledochoscopy to remove common bile duct stones and ensured that there were no residual stones in the bile duct using intraoperative cholangiography. 2, Placing the nasal bile duct in the abdomen: (1) We placed a choledochoscope at the incision of the bile duct until the tip touched the duodenal papilla (**Figure 1**). (2) The 4F ureteral catheter was pushed to the underside of the duodenal papilla using the Pliers channel of the choledochoscope (**Figure 2**). (3) The assistant removed the choledochoscope after holding the ureteral catheter with laparoscopic forceps (**Figure 3**). (4) We used a 4-0 absorbable thread to sew the soft nasal bile duct and the tough ureteral catheter twice, making sure the nasal bile duct does not slip during the advancing process (**Figure 4**). The second surgeon used an extraction basket to clamp the ureteral catheter, which went through the duodenal papilla (**Figure 5**). (5) The second surgeon continued to pull the ureteral catheter and nasobiliary out of the mouth using the duodenoscope (**Figure 6**). (6) We fixed the nasal

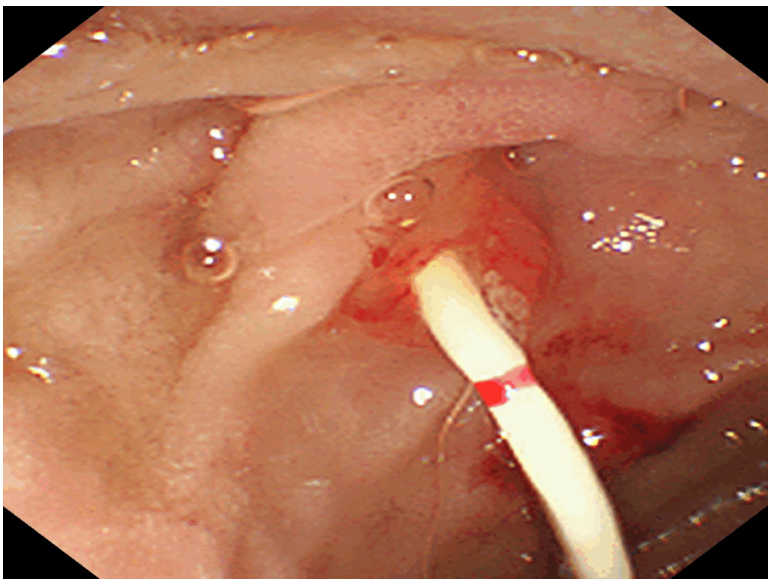

Figure 2. The ureter catheter has reached the intestinal cavity through the sphincter of Oddi.

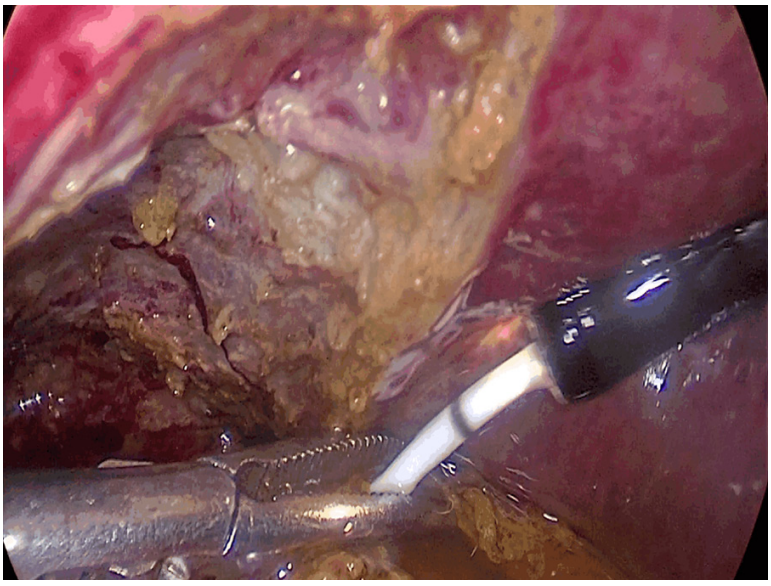

Figure 3. The choledochoscope was removed after holding the ureteral catheter with laparoscopic forceps.

bile duct on the cheek when the end of the nasal bile duct was 15 cm away from the bile duct incision. (7) We placed the remaining nasobiliary duct into the common bile duct and sutured the common bile duct. (Annotation: The nasal bile duct is soft, so it is very difficult for us to send it into the duodenal lumen through the sphincter of Oddi. It was necessary to use a ureteral catheter as a guide).

EST group surgery methods

The methods of operation for ERCP, EST, and the nasobiliary drainage are described in references 7 and 8 [7, 8].

Clinical information

The following conditions were compared between the two groups: 1. Preoperative data: preoperative gender, age, diameter of the bile duct, white blood cells, liver function, bilirubin, blood amylase and lipase, and the bedside index score of severity in acute pancreatitis (BISAP score). 2. Intraoperative data: operation time, intraoperative blood loss. 3. Postoperative data: liver function, bilirubin, blood amylase and lipase. 4. Postoperative conditions: gastrointestinal symptoms (including nausea, vomiting, diarrhea), abdominal relief time, biliary pain leakage, biliary bleeding, number of relapses of cholangitis and pancreatitis within 1 year after surgery.

Statistical analyses

The statistical analyses in this study were performed with SPASS 19. In analyses and comparisons of preoperative covariates and clinical parameters. The authors used numbers to express the classified data, including the preoperative BISAP score, gender, postoperative bile leakage, postoperative digestive tract reaction, recurrent cholangitis, and recurrent pancreatitis, and the authors used a chi-squared test to verify these variables, and $P<0.05$ is statistically significant. The authors used the mean standard deviation to represent the continuous data of the approximate positive distribution: age, preoperative white blood cell number, preoperative ALT, preoperative AST, preoperative

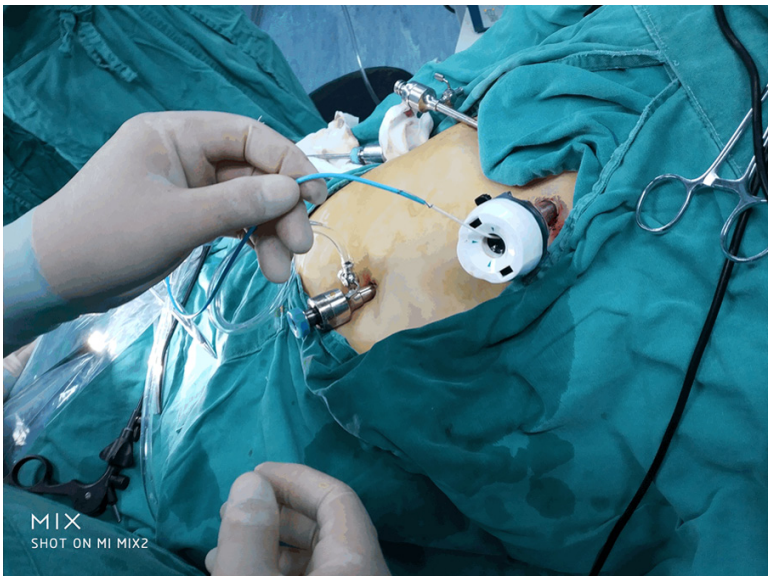

Figure 4. Suture and ligate at the front end of the nasobiliary and the end of the ureteral catheter.

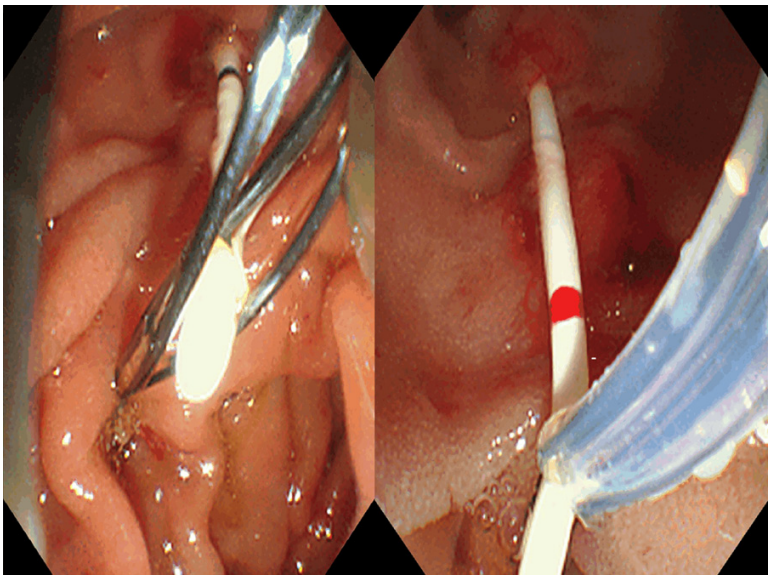

Figure 5. The extraction basket clamps the ureteral catheter.

AMY, preoperative LPS, operation time, surgical hemorrhage, pain relief time, postoperative ALT, postoperative AST, postoperative TBIL, postoperative DBIL, and we used a t test on these continuous variables, $P<0.05$ is statistically significant. We used the median (25%, and 75% quartile range) to represent the continuous data of a non-normal distribution: bile duct diameter, preoperative TBIL, preoperative DBIL, postoperative AMY and postoperative LPS, and we adopted the Mann-Whitney U rank sum test, $P<0.05$ is statistically significant.

Results

The patients' characteristics are shown in **Tables 1** and **2**. There were no significant differences in the preoperative bedside BISAP scores, gender, age, diameter of the bile duct, white blood cells (WBC), alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, blood amylase and lipase (AMY and LPS) ($P>0.05$). During the study, all the patients successfully completed the operation and there were no deaths during the perioperative period. There were no significant differences between the two groups in terms of postoperative ALT, AST, bilirubin, relief time of the abdominal pain, and biliary leakage ($P>0.05$) (**Table 3**). The experimental group had more bleeding than the control group (24.41±4.45 ml vs. 13.29±3.71 ml, $P=0.00$) (**Table 3**). The operation time was shorter in the experimental group than it was in the control group (108.20±9.02 min vs. 113.02±10.04 min, $P<0.05$). The postoperative blood amylase and lipase were lower in the control group (AMY: 52.00 U/L [31.75-105.25] U/L vs. 62.50 U/L [45.00-136.75 U/L]; LPS: 122. 00 U/L [58.00-286.00 U/L] vs. 217.00 U/L [91.25-554.25 U/L], $P<0.05$) (**Table 3**). There were fewer patients with gastrointestinal symptoms (including nausea, vomiting, and diarrhea) in the experimental group ($P<0.05$) (**Table 4**). There were 2 cases of duodenal papillae bleeding and 1 case of duodenal fistula in the control group. Three patients were infected with *E. coli* in the bile, and all of them came from the control group. The experimental group had fewer patients with recurrent pancreatitis and cholangitis during the one-year follow-up period (**Table 4**).

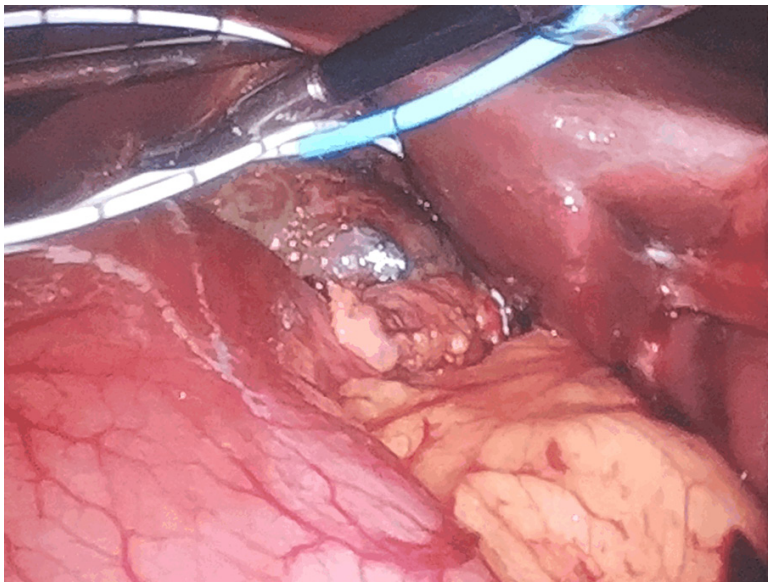

Figure 6. The ureter catheter guided the nasobiliary duct through the common bile duct into the intestinal tract and out of the mouth.

Table 1. Preoperative bedside BISAP scores of the two groups

Bedside BISAP scores	Test group (cases)	Control group (cases)
1 point	28	26
2 point	18	17
3 point	7	10
4 point	1	3
5 point	0	0
X^2	1.596	
P	0.660	

Discussion

EST has the advantages of less pain, a quick recovery, it's no restricted by adhesion around the bile duct, and it's easily tolerated by the frail elderly [9]. This technique has been widely used in many hospitals since Karwai first publicized it in 1974. However, with the progress of minimally invasive surgery, its drawbacks have also been noticed by more and more clinicians: First, surgeons cut the sphincter of Oddi to remove the bile duct stones in EST, which causes complications such as hemorrhage, intestinal fistula, biliary fistula and pancreatic fistula [10]; in this study, two patients in the control group developed sphincter hemorrhage, and one patient developed a small bowel fistula, which was caused by the operation. In contrast, the experimental group avoided these complications by retaining the intact sphincter of Oddi. EST reversely placed the nasal bile duct from the oral cavity to the biliary tract. It caused a reflux of intestinal juice and pancreatic juice [11], aggravating gastrointestinal symptoms such as nausea, vomiting, and diarrhea [11]. Second, the bile of three of the control patients contained *E. coli*, which was considered to be caused by the operation of the reverse placement of the nasobiliary. There was no infection in the experimental group, which proved that an anterograde placed nasobiliary can effectively reduce biliary infection. Third, in the study, 13 patients and 14 patients with recurrent cholangitis and pancreatitis were included in the study. There were only 4 cases of recurrent cholangitis and 5 cases recurrent pancreatitis in the experimental group. The difference between the two groups was statistically significant ($P<0.05$). This result is caused by inflammatory spasticity after EST, scar hyperplasia of the sphincters after EST, and not removing the gallbladder in EST. The former had been confirmed by Tarnasky's study of measuring the pressure around the sphincter of Oddi [12] in 1997. The report illustrates that inflammatory sphincter and scar hyperplasia can lead to a significant increase in the recurrence rate of cholangitis and pancreatitis. Regarding the latter, we removed the gallbladder during the first hospitalization to reduce the recurrence of biliary pancreatitis, which was recommended by the American Gastroenterology Association (AGA). AGA pointed that in patients with biliary pancreatitis who do not have their gallbladders removed during the first hospitalization, the probability of re-inducing acute pancreatitis is 29%-63% [13]. There are two main reasons for recurrence: first, the secretion of the pancreas is regulated by cholecystokinin and a cholecystokinin releasing peptide [14]; second, the small stones in the gallbladder slide downward, which can lead to an obstruction of the pancreaticobiliary junction and cause pancreatitis [15]. Therefore, we believe that the removal of

Table 2. Preoperative data of the two groups

Characteristics	Test group (n=54)	Control group (n=56)	Statistical value	P
Sex (male/female)	22/32	25/31	0.171	0.679
Age (years)	54.13±14.99	58.91±18.94	1.464	0.146
Bile duct diameter (cm)	0.6 (0.4-1.0)	0.6 (0.3-0.8)	0.858	0.391
WBC (10^9/L)	11.60±4.43	10.54±4.12	1.304	0.195
ALT (U/L)	280.61±127.55	282.84±135.96	0.089	0.930
AST (U/L)	191.35±111.86	208.04±118.10	0.760	0.449
TBIL (umol/L)	44.40 (38.60-54.15)	43.80 (38.17-62.35)	0.057	0.955
DBIL (umol/L)	29.60 (25.30-35.42)	29.70 (24.85-39.45)	0.087	0.931
AMY (U/L)	760.44±511.04	902.68±539.78	1.418	0.159
LPS (U/L)	1532.13±1007.09	1728.16±1077.71	0.985	0.327

Table 3. Comparative study of the intraoperative and postoperative data

Characteristics	Test group (n=54)	Control group (n=56)	Statistical value	P
Operation time (min)	108.20±9.02	113.02±10.04	2.641	0.010
Bleeding (ml)	24.41±4.45	13.29±3.71	14.242	0.000
relief time of Pain (d)	2.78±0.64	2.76±0.63	0.157	0.875
ALT (U/L)	118.80±89.17	144.30±99.86	1.411	0.161
AST (U/L)	67.17±54.68	85.00±60.61	1.618	0.109
TBIL (umol/L)	21.06±8.03	23.93±11.43	1.518	0.132
DBIL (umol/L)	12.96±6.88	15.75±9.29	1.783	0.077
AMY (U/L)	52.00 (31.75-105.25)	62.50 (45.00-136.75)	2.099	0.036
LPS (U/L)	122.00 (58.00-286.00)	217.00 (91.25-554.25)	2.317	0.021

Table 4. Comparative study of the postoperative complications (perioperative and follow-up within 1 year)

Group	Biliary leakage	Digestive symptoms	Cholangitis (recurrence)	Pancreatitis (recurrence)
Test group (cases)	2	6	4	5
Control group (cases)	4	15	13	14
X^2	0.631	4.373	5.257	4.767
P	0.427	0.037	0.022	0.029

the gallbladder can reduce the recurrence of pancreatitis to some extent.

The ampulla often appears with an iatrogenic inflammatory edema after being surgically treated for biliary pancreatitis. The inflammatory edema can cause a biliary obstruction again at the peak of the edema (2-5 days after surgery) [16, 17]. Therefore, it is especially important to place the nasobiliary drainage to maintain an unobstructed bile duct post operation. We disposed acute biliary pancreatitis using the hybrid surgery model; that is, we combined laparoscopy, choledochoscopy, and duodenoscopy to achieve the cholecystectomy, cholangiolithotomy, and nasobiliary drainage at the same time. Compared with the procedure of reversely placing the nasal bile duct in EST, this new solution not only solved the problem of biliary drainage, but it also completed the cholecystectomy and kept the integrity of the sphincter of Oddi during the same operative period. This surgical method reduced the recurrence rate of postoperative pancreatitis and postoperative cholangitis and reduced the postoperative reverse flow intestinal juice and pancreatic juice. It avoided the risk of small bowel fistula, biliary fistula, pancreatic fistula, sphincter of Oddi bleeding, inflammatory spasm, and cicatricial hyperplasia of the ampulla after EST. In addition, we placed the nasobiliary from the biliary tract to small intestine instead of placing it from small intestine to biliary tract in EST, so it reduced the risk of intestinal pathogen retrograde infection.

Conclusions

This study confirmed that it is feasible, effective, and safe to indwell a nasobiliary duct without cutting the sphincter of Oddi during early

acute biliary pancreatitis using the hybrid surgery mode. And it has certain advantages over the placement of the nasobiliary in EST. This operation can be further explored as a new way to treat early acute pancreatitis.

Disclosure of conflict of interest

None.

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