Original Article

Decreased pancreatic leakage rate in the application of a measurable variable-diameter pancreatic duct catheter in laparoscopic pancreaticoduodenectomy

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Background: Pancreatic leakage remains one of the most serious complications after laparoscopic pancreaticoduodenectomy (LPD). At present, most medical centers use local materials for the common pancreatic duct catheters required for pancreaticoenterostomy. However, there is a lack of a measurable and variable-diameter pancreatic duct catheter. Recently, a measurable variable-diameter pancreatic duct catheter was developed to remedy the limitation of the common pancreatic duct catheters. This study sought to evaluate its preventive effect on pancreatic leakage in LPD.

Methods: A total of 202 patients who underwent LPD using the Hong's single-stitch method from January 2021 to April 2022 were included in the study. Patients were divided into the 2 groups: the variable-diameter group (n=111) and the normal group (n=91) according to the application of different pancreatic duct catheters. Patient characteristics and perioperative data, including operation time, pancreatic fistula rate, postoperative bleeding rate and postoperative length of stay in the two groups were collected and analyzed. The Chi-square test was used to compare the differences between the groups in relation to the categorical variables.

Results: Among the 202 patients, there were 123 males and 79 females, with an average age of 58.79±7.89 years (range, 15–79 years), and an average body mass index (BMI) of 23.55±4.25 kg/m^2. There were no statistically significant differences between the variable-diameter group and the normal group in terms of age, sex, BMI, operation time, intraoperative blood loss, preoperative bilirubin, and pancreatic texture (P>0.05). The pancreatic fistula rate (2.70% *vs.* 9.89%) and postoperative median length of stay (15 *vs.* 16 days) of the variable-diameter group was significantly lower than that of the normal group.

Conclusions: The measurable variable-diameter pancreatic duct catheter could decrease the pancreatic fistula rate and postoperative median length of stay in the application of laparoscopic duodenectomy.

Keywords: Pancreaticoduodenectomy; laparoscopy; pancreatic leakage

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Introduction

There are 2 steps for laparoscopic pancreaticoduodenectomy (LPD) (1); that is, excision and reconstruction. Pancreaticojejunostomy is the most important concern in reconstruction, as the leakage of pancreaticointestinal anastomosis is one of the most serious complications after LPD and has an incidence rate of 5–25% (2-4). Pancreaticointestinal anastomosis leakage may lead to

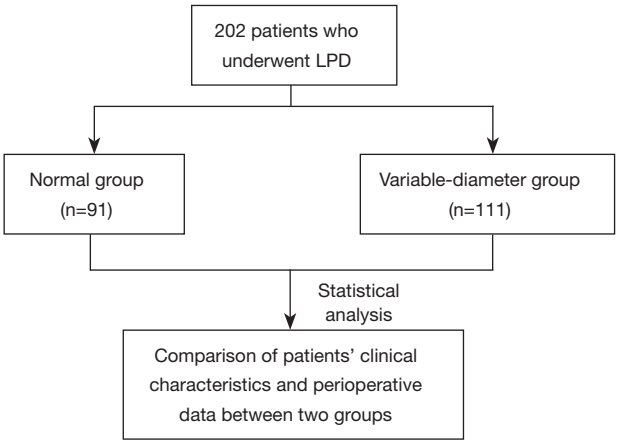


Figure 1 A study design. LPD, laparoscopic pancreaticoduodenectomy.

secondary complications, such as postoperative bleeding and abdominal infection, which is one of the main causes of perioperative death (5). Thus, experts and scholars in China have long been exploring and innovating methods for pancreaticojejunostomy, which include Chen's technique (6,7), implantation (8), and the Hong's single-stitch method (9). A previous report on the innovation in pancreaticojejunostomy has further promoted the popularization and development of LPD (10).

In 2017, our team began to explore the use of the Hong's single-stitch method in pancreaticojejunostomy. The Hong's single-stitch method was developed by Professor Defei Hong, and has achieved good results in the clinical practice of LPD (11,12). During the application of the Hong's single-stitch method, we found that a pancreatic duct catheter was needed to drain pancreatic fluid into the jejunum. However, the common pancreatic duct catheters currently in clinical use have poor versatility. Pancreatic duct catheters are based on a single model with a fixed diameter, and the depth of placement into the pancreatic duct cannot be measured when such catheters are used. Thus, Professor Jianhua Liu developed a measurable variable-diameter pancreatic duct catheter and applied for a patent. This measurable variable-diameter pancreatic duct catheter has diameter changes from thin to thick and is marked with scales. It can be adapted to the different pancreatic duct diameters encountered in clinical practice, and can accurately determine the depth of the catheter stent inserted into the pancreas.

In this study, we conducted a retrospective comparative analysis of the relevant clinical data of 91 patients who underwent LPD with a common pancreatic duct catheter and 111 patients who underwent LPD with measurable variable-diameter pancreatic duct catheter at the Department of Hepatobiliary Surgery, The Second Hospital of Hebei Medical University, from January 2021 to April 2022, to evaluate the preventive effect on pancreatic leakage of the measurable variable-diameter pancreatic duct catheter in LPD. We present the following article in accordance with the STROBE reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-22-478/rc).

Methods

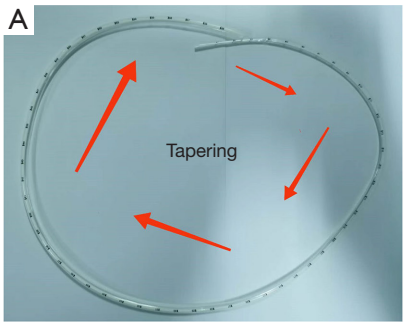
Patients and study design

As illustrated in *Figure 1*, a retrospective analysis was performed from January 2021 to April 2022 using data from The Second Hospital of Hebei Medical University from the liver surgical team, which used the Hong's single-stitch method to perform pancreatic duct jejunum anastomosis. All the eligible patients were diagnosed with periampullary tumors or benign masses by preoperative liver function tests, tumor marker tests, ultrasonography, contrast-enhanced computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography-CT, endoscopic ultrasonography, and duodenoscopy biopsy, and there were no signs of distant metastasis of the tumor. Patients who met all these inclusion criteria were eligible for LPD surgery. Based on the type of catheter used for the pancreaticojejunostomy, the patients who received LPD surgery were divided into the following 2 groups: (I) the normal group; and (II) the variable-diameter group. The patients' clinical characteristics and perioperative data were collected and compared between these two groups. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of The Second Hospital of Hebei Medical University (No. 2020-R325), and the requirement of individual consent for this retrospective analysis was waived.

Surgical procedure

Each patient was placed in a supine position and intubated under general anesthesia. First, a laparoscopy was performed on the abdominal cavity and pelvis to exclude distant metastasis. After excision using a routine surgical

A



B

Reference diameter and perimeter at scale mark, mm								
Scale	5	10	15	20	25	40	50	60
Diameter	1.5	1.6	1.7	1.8	2.0	3.5	3.8	4
Perimeter	4.7	5.0	5.3	5.6	6.2	11	11.9	12.5

Figure 2 Measurable variable-diameter pancreatic duct catheter (A) and the corresponding numerical table for the measurable variable-diameter pancreatic duct catheter (B).

procedure, the specimen was placed in a bag, and an incision of approximately 5 cm was made under the xiphoid process of the upper abdomen. The specimen was removed, and pneumoperitoneum was re-established. After the abdominal cavity was rinsed, the digestive tract was reconstructed using Child's method (13). For all of the patients who underwent pancreaticojejunostomy, the Hong's single-stitch method was adopted. The specific procedures were as follows:

(I) The neck of the pancreas was separated vertically with an ultrasonic knife, the pancreatic duct was cut with sharp scissors, and for the bleeding points, hemostasis was performed by electrocoagulation or suture. The broken end of the pancreas was dissociated by 1 cm. After identifying the pancreatic duct, a common pancreatic duct catheter or measurable variable-diameter pancreatic duct catheter (see *Figure 2A*,*2B*) was inserted. A 4-0 absorbable suture was introduced from the ventral side of the pancreas through the anterior and posterior walls of the pancreatic duct catheter (see *Figure 3A*). The suture was threaded out from the dorsal side of the pancreas, knotted, and fixed beside the pancreatic duct catheter with a margin >5 mm.

(II) At a jejunal loop, an ultrasonic knife was applied to the mesentery edge for a full thickness bowel wall incision and perforation, with the diameter of the pore approximately equal to that of the pancreatic duct catheter. A purse-string suture was placed around the pore with a 4-0 absorbable suture without knotting (see *Figure 3B*).

(III) One end of the 3-0 double-needle vascular suture was placed into the abdominal cavity, and the other end was left outside the body by a trocar. A continuous suture of the jejunal seromuscular layer and ventral pancreas was performed from the foot side to the cephalic side using 1 end of the 3-0 double-needle vascular suture. The needle was introduced from the jejunal seromuscular layer and was placed so that it exited from the pancreas side after 4–5 stitches, with an interval between stitches of 0.5–1 cm. The pancreatic duct catheter was inserted into the intestinal canal, and the purse-string suture from Step 2 was knotted. An assistant inserted a double-needle vascular suture into the abdominal cavity by the same trocar (with the vascular suture partially left outside the body to avoid having an intraperitoneal vascular suture that was too long to operate on) and placed a continuous suture of the jejunal seromuscular layer and ventral pancreas from the foot side to the cephalic side. Generally, the needle was introduced from the pancreas side and exited from the jejunal seromuscular layer after 4–5 stitches, with an interval of 0.5–1 cm between stitches depending on the width of the pancreas (see *Figure 3C*). The needles were then removed at both ends of the vascular suture, and the 2 ends at the upper margin of pancreaticointestinal anastomosis were knotted. The remaining vascular suture was cut at the lower margin of pancreaticointestinal anastomosis to a suitable length and was slowly tightened, and was then knotted to complete the anastomosis (see *Figure 3D*).

(IV) End-to-end continuous suturing was used for bilioenteric anastomosis, and side-to-side anastomosis was used for gastrointestinal anastomosis.

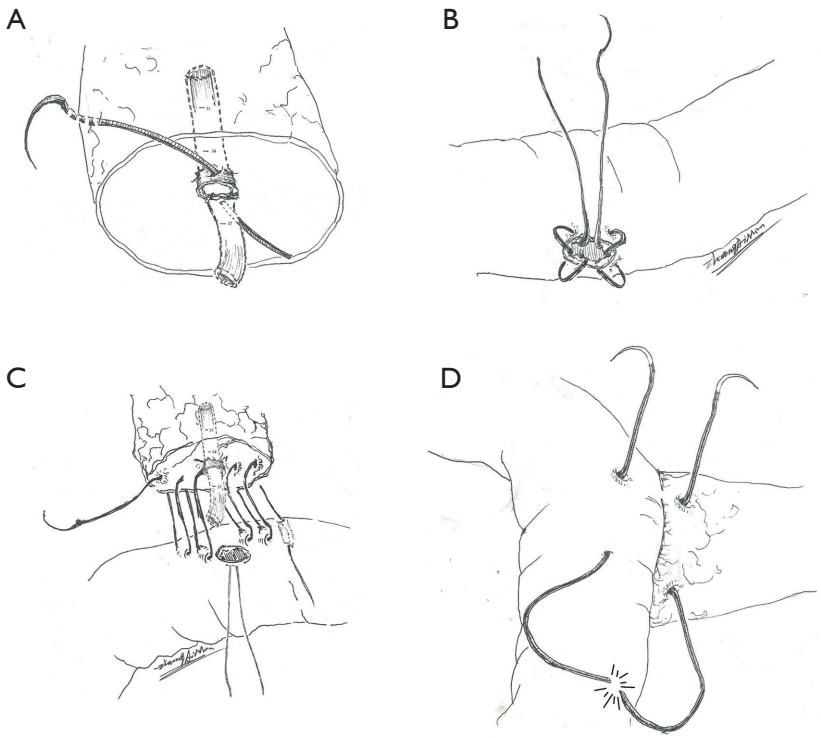


Figure 3 Key surgical procedures of the Hong's single-stitch method for pancreaticojejunostomy. (A) Fixing the pancreatic duct catheter. (B) Purse suture at the jejunal perforation position. (C) Continuous suture of the jejunal seromuscular layer and pancreatic stump. (D) The knotting of the sutures at the upper and lower edges of the pancreaticojejunostomy, respectively.

Postoperative management

The patients abstained from water in the early postoperative period. The gastric tube was removed after 24 hours of drainage, flatulence, and defecation. After the gastric tube was removed, the patients then tried liquid foods. A routine proton pump inhibitor was administered to protect the gastric mucosa, and the patients also received symptomatic treatments to prevent infections, liver protection, phlegm reduction, hypoproteinemia correction, and nutritional support. After surgery, the patency and drainage of each drainage tube and the amylase content of relevant drainage fluid were checked every day. The highest amylase content of the drainage fluid in the drainage tubes was taken as the amylase value of the patient's postoperative drainage fluid. The approaches adopted to diagnose and grade pancreatic fistulas (14), diagnose biliary fistulas (15), diagnose gastric emptying disorders (16), and diagnose postoperative hemorrhages (17) have been described previously.

The discharge indicators included the following: stable vital signs, free movement, no complications that required continued hospitalization, a normal body temperature, no signs of infection, normal food intake and defecation, and imaging findings indicating no obvious abnormality in the abdominal cavity.

The preoperative, intraoperative, and postoperative data, and the pathological results of the patients were organized and summarized, and the postoperative complications were recorded in real time.

Statistical analysis

SPSS (version 21.0) was used for the statistical analysis. The Chi-square test or Fisher's exact test was used to compare the differences between the groups in relation to the categorical variables. Student's *t*-test or the Wilcoxon rank-sum test was used to compare differences between two groups in relation to the continuous variables, depending on whether the data analyzed were normally distributed. A two-sided P value <0.05 was considered statistically significant.

Table 1 Patient characteristics

Events	All (n=202)	Variable-diameter group (n=111)	Normal catheter group (n=91)	P value
Sex				0.293
Male	123 (60.89%)	62 (55.86%)	61 (67.03%)	
Female	79 (39.11%)	49 (44.14%)	30 (32.97%)	
Age (years, mean ± SEM)	58.79±7.89	59.34±8.90	58.12±6.44	0.275
BMI (kg/m^2, mean ± SEM)	23.55±4.25	23.75±3.99	23.23±4.68	0.394
Combined underlying diseases	113 (55.94%)	59 (53.15%)	54 (59.34%)	0.378
Hypertension	39 (19.31%)	23 (20.72%)	16 (17.58%)	0.574
Coronary heart disease	24 (11.88%)	10 (9.01%)	14 (15.38%)	0.164
Type 2 diabetes	37 (18.32%)	16 (14.41%)	21 (23.08%)	0.113
Hepatitis	13 (6.44%)	10 (9.01%)	3 (3.30%)	0.100

BMI, body mass index; SEM, the standard error of the mean.

Results

Patient characteristics

A total of 202 eligible patients (123 male and 79 female) were enrolled in this study, and the patient characteristics are summarized in *Table 1*. The patients had an average age of 58.79±7.89 years (range, 15–79 years) and an average body mass index (BMI) was 23.55±4.25 kg/m^2. In terms of the preoperative complications, 24 patients had coronary heart disease, 39 had hypertension, 37 had diabetes, and 13 had a history of abdominal surgery. Among the jaundice patients, 6 underwent endoscopic nasobiliary drainage and 15 underwent percutaneous transhepatic bile duct drainage before surgery to reduce jaundice. Based on the type of catheter used for pancreaticojejunostomy, the 202 patients were divided into the following 2 groups: (I) the normal group (n=91), who underwent intestinal anastomosis with a normal pancreatic duct catheter; and (II) the variable-diameter group (n=111) who underwent intestinal anastomosis with a measurable variable-diameter pancreatic duct catheter.

The clinical characteristics between the 2 groups were compared, and no statistically significant differences were found in terms of age, sex, BMI, or combined underlying diseases (P>0.05; see *Table 1*).

The pancreatic fistula rate in the variable-diameter catheter group was significantly lower than that in the normal catheter group

The patients' perioperative data are shown in *Table 2*. The differences in the perioperative data between these 2 groups were compared, and no statistically significant differences were found in terms of preoperative bilirubin, the proportion of preoperative jaundice reduction, the operation time, intraoperative blood loss, pancreatic texture, biliary fistulas, postoperative bleeding, or disorders of gastric emptying (P>0.05; see *Table 2*). For both groups, the biliary fistulas healed spontaneously after conservative treatment. In the normal catheter group, 5 patients had delayed gastric emptying, including 3 Grade B patients and 2 Grade C patients. In the variable-diameter catheter group, 7 patients had delayed gastric emptying in, including 6 Grade B patients and 1 Grade C patient. For both groups, gastrointestinal decompression, the prolongation of the time of gastric intubation, and the provision of parenteral nutrition support, gastric motility therapy, and psychotherapy improved all the relevant symptoms, and the patients were all discharged successfully. In the normal catheter group, 2 patients suffered from gastrointestinal bleeding and 2 patients suffered from abdominal bleeding after surgery; the bleeding sites were the mesenteric root

Table 2 Patient perioperative data

Events	All (n=202)	Variable-diameter group (n=111)	Normal catheter group (n=91)	P value
Total bilirubin 1 d before surgery [μmol/L, median (Q1, Q3)]	78.50 (43.16, 112.71)	73.05 (38.53, 117.81)	81.88 (46.63, 109.82)	0.549
Preoperative jaundice reduction	21 (10.40%)	13 (11.71%)	8 (8.79%)	0.499
Operation time (min, mean ± SEM)	313.75±69.56	318.85±64.00	307.54±75.69	0.251
Intraoperative blood loss [mL, median (Q1, Q3)]	400 (100, 600)	300 (100, 500)	400 (100, 600)	0.09
Pancreatic texture				0.422
Soft	143 (70.79%)	76 (68.47%)	67 (73.63%)	
Hard	59 (29.21%)	35 (31.53%)	24 (26.37%)	
Pancreatic fistula	12 (5.94%)	3 (2.70%)	9 (9.89%)	0.032
Biliary fistula	10 (4.95%)	6 (5.41%)	4 (4.40%)	0.742
Postoperative bleeding	7 (3.47%)	3 (2.70%)	4 (4.40%)	0.513
Disorders of gastric emptying (gastroparesis)	12 (5.94%)	7 (6.31%)	5 (5.50%)	0.808
Postoperative length of stay (d), median (Q1, Q3)	15 (13, 18)	15 (12, 17)	16 (13, 19)	0.005

SEM, the standard error of the mean.

vessels and the broken end arterioles of the pancreas. In the variable-diameter catheter group, 3 patients suffered from intraperitoneal hemorrhages after surgery, but postoperative pancreatic fistulas were not considered. The exploratory laparotomies indicated that the pancreaticointestinal anastomoses had healed well. Bleeding points were found in all 3 cases (1 in the gastric stump and 1 in the mesentery of the small intestine) and hemostasis was successful. These 3 patients were discharged successfully after the re-operations.

Notably, the pancreatic fistula rate of the variable-diameter catheter group was significantly lower than that of the normal catheter group (2.70% *vs.* 9.89%, P=0.032). In the normal catheter group, 6 patients had Grade B pancreatic fistulas and 3 patients had Grade C pancreatic fistulas. In the variable-diameter catheter group, 3 patients had Grade B pancreatic fistulas, but no patients had Grade C pancreatic fistulas. The postoperative length of stay in the variable-diameter catheter group was less than that in the normal group (15 *vs.* 16 days), and the difference was statistically significant (P=0.005). There were no deaths in either group.

Discussion

The Hong's single-stitch method was invented by Professor Defei Hong, and has been applied in several centers in China, and all of the surgeries have achieved good results (11,12). Based on Hong's single-stitch method, our team formed our own views on the location of jejunal perforation, insertion and fixation of pancreatic duct catheter and purse string suture (9). There are two main purposes for inserting pancreatic duct catheter: one is to drain pancreatic juice, and another is to promote the formation of artificial fistula between pancreatic duct and jejunum along the pancreatic duct catheter. However, at present, most medical centers use local materials for the common pancreatic duct catheters required for pancreaticoenterostomy, such as scalp needles with appropriate diameters, sputum suction tubes, and anesthesia pump extension tubes (18). Thus, there is a lack of dedicated pancreatic duct catheter.

Thus, 2 problems arise in clinical work: (I) the local pancreatic duct catheter does not accurately match the diameter of the pancreatic duct; thus, the catheter with the closest size to the pancreas duct has to be selected; and (II) most of the stent catheter surfaces have no scales, and

thus it is impossible to accurately measure the implantation depth during the operation. To address these issues, Professor Jianhua Liu developed a measurable variable-diameter pancreatic duct catheter to replace the original ordinary pancreatic duct catheter (see *Figure 2A*,*2B*). This measurable variable-diameter pancreatic duct catheter is marked with scales, its diameter changes from thin to thick, and it can be adapted to the different pancreatic duct diameters encountered in clinical practice. Further, the specific position of the tube body scale corresponds to the fixed value of the tube diameter so that the thickness of the pancreatic duct can be accurately measured during the operation, and the depth of the catheter stent inserted into the pancreas can be accurately determined.

The measurable variable-diameter pancreatic duct catheter has 2 main advantages. First, because the diameter of the catheter can be measured from thin to thick, the process of inserting the catheter into the pancreatic duct is much smoother. It is more suitable for the anatomical morphology of the pancreatic duct and can be inserted deeper. In the past, if the diameter of the non-variable pancreatic duct catheter matches the diameter of the pancreatic duct at the end of the pancreas fracture, it is difficult for the duct to be inserted deep enough because the closer it is to the tail of the pancreas, the thinner the pancreatic duct. Consequently, the following 2 issues often arise: (I) the diameter of the non-variable pancreatic duct catheter is difficult to intubate to an effective depth, so it can easily fall off; and (II) after forced insertion, it can be too tight, which may affect the secretion function of some pancreatic duct branches, resulting in pancreatitis. Conversely, if a pancreatic duct catheter with a diameter smaller than the diameter of the broken pancreatic duct is selected, there is a gap, which increases the risk of leakage. The use of the measurable variable-diameter pancreatic duct catheter can cut out the corresponding stent section on the measurable variable-diameter pancreatic duct according to the specific pancreatic duct diameter during the operation, which effectively solves these problems.

Second, in relation to measurability, the diameter of the pancreatic duct and the depth of the pancreatic duct insertion can be measured. Indeed, the diameter of the pancreatic duct can be measured directly using the measurable variable-diameter pancreatic duct catheter in the operation. When the measurable variable-diameter pancreatic duct catheter is perfectly matched with the pancreatic duct, the accurate value of the pancreatic duct diameter can be obtained by reading out the marked value on the pancreatic duct catheter. Currently, the diameter of the pancreatic duct is measured by preoperative CT and MRI, but the broken end of the pancreas selected during pancreaticoenterostomy surgery is not necessarily the thickest part of the pancreatic duct (19). Thus, an accurate measurement is still needed.

When selecting a suitable pancreatic duct catheter, the thinner end can be inserted into the pancreatic duct first. After determining the insertable depth and diameter of the pancreatic duct, a pancreatic duct catheter with a suitable diameter and length can be selected for insertion (20). The depth of insertion into the pancreatic duct can also be measured. Due to the magnification effect and visual deception effect of laparoscopy, it is often difficult to judge the length of the catheter inserted into the pancreas during surgery, and sometimes, it must even be pulled out and reinserted after visual inspection. A catheter with a variable-diameter can be used to measure the pancreatic duct, which completely solves this problem, as it has a marked scale on its surface and can be used to accurately measure the length of the inserted pancreatic duct, which makes the operation more accurate and improves the operation efficiency.

The length of the pancreatic duct of patients at our center is generally approximately 10 cm, and the depth of the pancreatic duct is approximately 4–5 cm. If the depth is <3 cm, the probability of prolapse shortly after surgery is high, and the intestinal segment is approximately 5 cm. If it is too long, it will not be conducive to endoscopic operation. Additionally, there is the possibility of missing the intestinal wall or encountering resistance in the intestinal wall in the intestinal cavity, which leads to an increase in the pancreatic duct pressure and pancreatic juice leakage. To address this issue, our team injects water into the intestine before inserting the pancreatic duct catheter into the intestine for lubrication. If pancreaticoenterostomy is performed by laparotomy, the length of the pancreatic duct in the intestinal segment can be 6–7 cm.

Among the indices that may affect the occurrence of postoperative pancreatic leakage in the 2 groups, there were no significant differences in 3 of the items; that is, the softness and hardness of the pancreas texture, the preoperative total bilirubin, and whether it is necessary to reduce jaundice before surgery (21). However, the number of Grade B and Grade C pancreatic fistulas in the variable-diameter group was lower than that in the normal group, and there was no significant difference in the incidence of pancreatic leakage between the 2 groups, which shows that the measurable variable-diameter pancreatic duct catheter

reduces the occurrence of pancreatic leakage compared to the normal pancreatic duct catheter.

This study had some limitations. First, the sample size of the cohort was limited, and thus it is necessary to further expand the sample size. Second, this was a single-center retrospective study, and clinical randomized controlled studies need to be conducted to improve the relevant experimental conclusions. Third, strict follow-up should be carried out to observe the incidence of long-term complications after surgery.

Conclusions

Compared to the pancreatic duct catheter commonly used in clinical practice, the measurable variable-diameter pancreatic duct catheter has 2 advantages. First, it has a variable diameter. Second, it is measurable. Thus, it can better meet the needs of precise surgery. It could also decrease the pancreatic fistula rate and postoperative median length of stay in laparoscopic duodenectomy, and it is worthy of further clinical application and research.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://gs.amegroups.com/article/view/10.21037/gs-22-478/rc

Data Sharing Statement: Available at https://gs.amegroups.com/article/view/10.21037/gs-22-478/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://gs.amegroups.com/article/view/10.21037/gs-22-478/coif). The authors have no 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of The Second Hospital of Hebei Medical University (No. 2020-R325), and the requirement of individual consent for this retrospective analysis was waived.

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