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Method Article

Stented Versus Non-Stented Pancreaticogastrostomy after Pancreaticoduodenectomy

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1. Abstract

1.1. Background: After pancreaticoduodenectomy (PD), pancreatic leakage is the most frequent and serious complication. The use of pancreatic duct stenting for pancreaticogastrostomy (PG) in PD remains controversial. This study aimed to evaluate the effectiveness of stenting when fashioning a PG to prevent pancreatic leakage after PD.

1.2. Design: A retrospective study.

1.3. Methods: Eighty-five consecutive patients undergoing PG were divided into three groups: externally stented (n=25), internally stented (n=23), and non-stented (n=37). All pancreatic anastomoses were performed in one layer using an invagination method between the pancreatic remnant and posterior gastric wall, with or without pancreatic duct stents. The three groups were compared regarding pancreatic leakage, morbidity, mortality, and surgical risks, including associated clinical and radiological parameters.

1.4. Results: All patients' operative time and blood loss were 410 ± 115 min and 745 ± 225 ml, respectively. The postoperative morbidity was 25.8%, and no mortality was recorded. The overall rates of pancreatic leakage (grades A, B, and C) were 16.0% in the externally stented group, 13.0% in the internally stented group, and 10.8% in the non-stented group. However, the median postoperative hospital stay was significantly shorter in the non-stent group than in the two stented groups. Regarding the rate of postoperative pancreatic fistula (POPF), no significant differences were observed in the stents used in the soft and hard pancreas group; however, patients with a soft pancreas exhibited a higher rate of pancreatic leakage than those with a hard pancreas (18.7% vs. 5.4%, P<0.01).

1.5. Conclusions: Pancreatic duct stenting in the PG did not decrease the frequency or severity of POPF. However, the non-stent method reduced the duration of postoperative hospitalization and

nursing care for patients.

2. Background

Postoperative pancreatic fistula (POPF) is one of the most frequent and severe complications of pancreaticoduodenectomy (PD) [1,2]. With advances in pancreatic surgeries to prevent pancreatic leakage, considerable efforts have been expended by the surgical community. Some groups have reported the effectiveness of pancreaticogastrostomy (PG) for anastomosis of the pancreatic stump in preventing fistula formation in PD [3,4,5]. Furthermore, surgeons have revealed that the texture of the pancreas is a critical factor in determining the incidence of POPF [6,7]. Therefore, the use of pancreatic duct stenting to reduce POPF after PD is considered an attractive strategy. A stent is a small tube placed in a duct or passageway to maintain patency and facilitate fluid flow. The use of a stent in PG may depend on various factors, including the specific circumstances of the patient and the surgeon's preference. Several randomized controlled trials (RCTs) have compared pancreatic drainage (external or internal stenting) and no pancreatic drainage, with the former showing a slightly lower POPF rate [8,9,10]. However, recent prospective randomized studies have not confirmed which procedure is better for reconstructing the remnant pancreas [11,12,13]. In contrast, discordant results reporting no utility of external or internal stents have been reported in the literature [14]. Furthermore, to our knowledge, these studies were conducted in patients who underwent pancreaticojejunostomy (PJ) after PD. To date, no meta-analyses have compared the efficacy of pancreatic stents in PG. Therefore, this retrospective study aimed to clarify the role of transanastomotic pancreatic duct stenting in reducing POPF in PG after PD by comparing the occurrence rates of POPF and postoperative complications among external, internal, and non-stent patients.

3. Methodology

Between 2000 and 2018, a surgical team performed conventional subtotal stomach-preserving pancreatoduodenectomy (SSPPD) on 85 consecutive patients. The patients undergoing PG were divided into three groups: externally stented (n=25), internally stented (n=23), and non-stented (n=37). All pancreatic anastomoses were performed using the invagination method in one layer between the pancreatic remnant and the posterior gastric wall, with or without pancreatic duct stents. The stents were used according to the surgeon's preference.

All pancreatic anastomoses were performed in one layer between the pancreatic remnant and the posterior gastric wall using invagination techniques. Using a wound protector for anastomosis on PG was another modification to our procedure. Following PG, antecolic reconstruction and setting were performed using the Billroth I technique. All PD procedures were performed or overseen by two surgeons. Patients who underwent multiple visceral pancreatic resections were excluded.

The three groups were compared regarding pancreatic leakage, morbidity, mortality, and surgical risks, including associated clinical and radiological parameters. Furthermore, preoperative clinical and demographic information, as well as operative factors such as operative time, blood loss, transfusion volume, tumor size, pancreatic depth, pancreatic duct diameter, pancreatic texture, amylase levels in the drainage fluid and serum, postoperative course, and complications, were retrospectively collected using patients' files and operative records. Subsequently, all patients were divided into two groups because the subgroup analyses were based on whether the pancreatic texture was soft or hard. A hard pancreas was defined as a dilated main pancreatic duct (>3.0 mm) with histological fibrosis. Surgical risks and clinical and radiological characteristics associated with POPF were compared between the soft and hard groups. According to the International Study Group on Pancreatic Fistula guidelines [15], a pancreatic fistula is defined as drainage of any detectable fluid on or after postoperative day 3, with an amylase content exceeding three times the serum amylase activity. Postoperative complications were recorded and graded according to the Dindo-Clavien classification system [16].

4. Surgical Technique

Once SSPPD was completed, an anterior gastrostomy was performed, and the distance between different planes was calculated until adequate tension was achieved. An Alexis wound retractor (Applied Medical, Rancho Santa Margarita, CA, USA) was introduced and secured through the anterior layer of the stomach. After wound retractor insertion, mild tension was generated in the posterior layer of the stomach to facilitate PG anastomosis. A transverse gastrostomy was performed on the posterior wall of the stomach, aligning with two-thirds of the diameter of the pancreatic stump. The anterior and posterior margins of the pancreas were fastened 2

using PDS-II (Ethicone, Cincinnati, OH, USA) sutures (5-0). The pancreas was invaginated into the stomach by at least 2-3 cm to control the entire anastomotic rim. The duct 5 cm from the internal pancreatic duct, a proximal 2 cm of 6 Fr silicone catheter with multiple side pores, and one small hump (MD-41515; Sumitomo Bakelite, Tokyo, Japan) were inserted into the main pancreatic duct. Three centimeters from the distal side, the stent was placed in the gastric cavity. Catheter migration was prevented using an anchoring stitch that secured the stump of the pancreatic duct using a single absorbable suture. Alternatively, in the external stent method, the external stent exited through the anterior portion of the stomach and was externalized through a stab incision in the anterior abdominal wall. A nasogastric tube was inserted to avoid direct contact with the anastomoses. The Billroth I technique performed gastrojejunostomy through the anterior gastric aperture between the distal gastric stump and end of the jejunum using a 25 or 28 G PC-EEA (Ethicone, London, United Kingdom). The anterior gastric wall opening was then closed using a linear gastrointestinal stapler to complete the PG anastomosis. Hepaticojejunostomy was performed on the distal 20 cm to the gastroenterostomy site via end-to-side with or without a stent, and digestive continuity was reconstructed. Fibrin glue was used around the anastomotic site to prevent leakage in almost all the patients.

5. Perioperative Management

All patients were administered intraoperative and postoperative broad-spectrum antibiotics for 72 h after the operation to prevent infection. Amylase levels in the serum and drainage fluid were measured on postoperative days 3, 5, and 7 to confirm the absence of POPF. If no complications were evident, the intra-abdominal drains were removed between postoperative days 5–7. In cases of severe complications like clinically relevant (CR)-POPF or abdominal abscess, intra-abdominal drains and antibiotics were continued until inflammation resolved. In all cases, the external stent tube was removed one month after surgery, regardless of the presence of POPF.

6. Statistical Analysis

The mean \pm standard deviation was used to express the data. Statistical Package for Social Science for Windows (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The chi-squared test and Student's t-test were used to compare patient characteristics and intraoperative and postoperative variables between the POPF and non-POPF groups. Univariate and multivariate logistic analyses were used to identify the independent variables for POPF development. Statistical significance was set at P < 0.05.

7. Results

Patient characteristics and surgical diagnoses of the three groups are summarized in Table. This study included 55 males and 30 females. The average age was 72.8 ± 8.4 years, ranging from 43-86 years. Pancreatic cancer was the most common disease (n=33),

followed by extrahepatic biliary cancer (n=27), ampullary cancer (n=12), intraductal papillary mucinous neoplasm (IPMN) (n=10), endocrine tumors (n=2), and chronic pancreatitis (n=1) (Table 1). No significant differences were observed regarding age, sex ratio, BMI, comorbidities, presence of preoperative biliary drainage, and ASA classification among the three groups. (Table 2) shows the intraoperative variables for patients in the three groups. Operative time and blood loss in all patients were 410±115 min and 745±225 ml, respectively. No significant differences were observed in the operative time, blood loss, transfusion volume, or use of fibrin glue. Furthermore, no significant differences were observed in morphological factors of the pancreas, such as texture, pancreatic duct size, and tumor size. The postoperative morbidity was 25.8%, and no mortality was recorded. Notably, the incidence of POPF did not differ significantly among the three groups. Overall, 11 patients (12.9%) experienced POPF among all groups, with rates of 16.0%, 13.0%, and 10.8% in the externally stented, internally stented, and non-stented groups, respectively (p=0.77). The CR-POPF rates were 8.0%, 4.3%, and 5.4% in the externally stented, internally stented, and non-stented groups, respectively (p=0.60).

Twenty-one (24.7%) patients experienced postoperative complications. Two patients experienced bleeding, one from the cut surface of the pancreatic stump and the other from an aneurysm of the gastroduodenal artery stump, which was treated using gastroscopy and interventional radiology. Other complications that were more than Clavien-Dindo classification II included intra-abdominal abscess in five (5.9%), delayed stomach emptying in six (7.1%), wound infection in five (5.9%), and significant ascites in two (2.4%) patients, although all were treated conservatively with nutritional assistance and antibiotic treatment. No statistically significant differences in the rates of postoperative complications were observed among the three groups. Two cases of pneumonia and three of arrhythmias had pulmonary and cardiac consequences, respectively. No stent-related complications or bile leakage was observed in any patient.

The mean postoperative hospital stay was significantly shorter in the non-stented group than in the two stented groups $(23.5\pm8.9 \text{ days})$ in a non-stented group vs 29.5±5.5 days in the externally stented group and 26.4±10.5 days in the internally stented group, P<0.05 (Table 3). However, the rate of pancreatic leakage in patients with a soft pancreas was higher than that in patients with a hard pancreas (18.7% vs. 5.4%, P<0.01). Furthermore, intraoperative factors such as operation time, blood loss, stump thickness, and use of pancreatic stents, except for the texture of the pancreas, were not significantly associated with the development of POPF in the univariate and multivariate analyses. Multiple analyses revealed that pancreatic tissue texture and diameter of the pancreatic duct were the only independent risk factors for POPF (odds ratio, 0.55 (0.21-0.91) P< 0.03 and 0.42 (0.02-0.84) P<0.02, respectively). Therefore, subgroup analyses were performed for the pancreatic texture regarding the occurrence of POPF. In 48 patients with soft pancreatic texture, POPF occurred in 23.1%, 21.4%, and 14.4% of the externally stented, internally stented, and non-stented groups, respectively (Table 4a). No significant differences were observed in the POPF rates among the three groups with soft pancreatic textures. In 37 patients with a hard pancreatic texture, the incidence of POPF was low, with rates of 8.3%, 0%, and 6.3% in the externally stented, internally stented, and non-stented groups, respectively, showing no significant differences (Table 4b).

Preoperative parameter	External stent (n=25)	Internal stent (n=23)	No stent (n=37)
Age (years)	70±15	73±12	72±13
Sex ratio (M:F)	12:13	17:6	26:11
BMI (kg/m2)	22±3.5	21±2.1	22±3.1
Comorbidities	16 (64.0%)	12 (52.1%)	20 (54.0%)
Preoperative biliary drainage	18 (72.0%)	16 (69.6%)	27 (73.0%)
ASA classification			
	9 (36.0%)	9 (39.1%)	10 (27.0%)
2	14 (56.0%)	12 (52.2%)	22 (59.5%)
	20 (8.0%)	2 (8.7%)	5 (13.5%)
Operative indication			
Ductal adenocarcinoma	9 (36.0%)	8 (34.8%)	16 (43.2%)
IPMN	3 (12.0%)	3 (8.1%)	4 (10.8%)
chronic pancreatitis	2 (8.0%)	1 (4.3%)	0
Bile duct carcinoma	7 (28.0%)	6 (26.0%)	14 (37.8%)
Ampullary adenocarcinoma	4 (16.0%)	5 (21.8%)	3 (8.2%)

Table 1: Patients characteristics with or without trans anastomotic pancreatic duct stenting

Table 2: Intraoperative variables for all patients

Preoperative parameter	External stent (n=25)	Internal stent (n=23)	No stent (n=37)
Operative time (min)	435±75	405±138	418±110
Blood loss (ml)	805±205	905±250	680±214
Patients transfused (%)	3 (12.0%)	5 (21.7%)	8 (21.6%)
Use of fibrin glue	23 (92.0%)	21 (91.3%)	35 (94.1%)
Tumor size (cm)	3.5±1.1	3.8±2.1	3.6±1.6
Texture of pancreas			
Soft	14 (56.0%)	13 (56.5%)	20 (54.1%)
Hard	11 (44.0%)	10 (43.5%)	17 (45.9%)
Pancreatic duct size (mm)	3.5±1.1	3.2±1.2	3.0±1.5

Table 3: Postoperative outcomes of all patients

	External stent (n=25)	Internal stent (n=23)	No stent (n=37)
Pancreatic leakage	4 (16.0%)	3 (13.0%)	4 (10.8%)
Grade A	2 (8.0%)	2 (8.7%)	2 (5.4%)
Grade B	1 (4.0%)	1 (4.3%)	1 (2.7%)
Grade C	1 (4.0%)	0	1 (2.7%)
Mortality	0	0	0
Bile leakage	0	0	0
Intraoperative bleeding	0	0	0
Reoperation	0	0	0
Postoperative length of stay (days)	29.5±5.5	26.4±10.5	23.5±8.9
		P<0.01	

Table 4a: Postoperative pancreatic leakage for patients with soft pancreas

	External stent (n=13)	Internal stent (n=14)	No stent (n=21)
Grade A	1 (7.7%)	2 (14.3%)	1 (4.8%)
Grade B	1 (7.7%)	1 (7.1%)	1 (4.8%)
Grade C	1 (7.7%)	0 (0%)	1 (4.8%)
No	10 (76.9%)	11 (78.6%)	18 (85.6%)

Table 4b: Postoperative pancreatic leakage for patients with hard pancreas

	External stent (n=12)	Internal stent (n=9)	No stent (n=16)
Grade A	1 (8.3%)	0 (0%)	1 (6.2%)
Grade B	0 (0%)	0 (0%)	0 (0%)
Grade C	0 (0%)	0 (0%)	0 (0%)
No	11 (91.7%)	9 (100%)	15 (93.8%)

8. Discussion

Our results showed that neither external nor internal stents were associated with statistically significant differences in the occurrence of POPF compared to no stents in the PG after PD. Our results showed no significant differences in the other postoperative complications among the three groups. However, the hospital stay in the non-stent group was significantly shorter than that in the externally stented group. Moreover, the subgroup analyses in our study based on the texture of the pancreas showed no advantages or disadvantages of the stent used in the soft and hard pancreas groups. However, POPF occurrence rates were significantly higher in the soft pancreas group than in the hard pancreas group. From a surgical perspective, stents may be used in PG to prevent postoperative complications for several reasons [17,18].

Provide Support: A stent can help support the connection between the pancreas and stomach and maintain the lumen, particularly in cases with concerns about premature anastomosis closure.

Prevent Leakage: A stent can help prevent the leakage of pancreatic fluids from the anastomosis site; thereby, reducing the risk of complications such as infection or abscess formation.

Facilitate Drainage: A stent can aid the drainage of pancreatic

secretions into the stomach, which is important in patients with certain pancreatic conditions.

However, do stents in the PG have disadvantages? Disadvantages of stent use other than stent migration remain to be discussed. Using a stent in a PG may have potential drawbacks or disadvantages. Some disadvantages of using a stent in this procedure include the following: [17,18]

Migration: Stents can sometimes move from their intended positions, potentially leading to complications or requiring additional procedures to reposition or remove the stent.

Obstruction: In some cases, the stent itself may become blocked, impeding the flow of pancreatic secretions and potentially leading to complications.

Infection Risk: The risk of infection associated with foreign objects is low; however, it still exists.

Inflammatory Response: A stent can cause an inflammatory reaction in the surrounding tissues, although this is relatively rare.

Tissue Irritation or Injury: The stent may cause irritation or injury to the contacted tissues. However, this condition is uncommon and typically managed by a surgical team.

Potential Need for Removal: In some cases, the stent may later need removal, necessitating an additional procedure.

Cost: Using a stent can increase the overall cost of the procedure due to the expense of the stent and the potential need for additional interventions.

In many institutions, pancreatic duct stents have been routinely used, which was influenced by several reports [19,20,21] showing that POPF rates in the PJ after PD were reduced compared to no stent use. For example, in RCTs [22,23], retrospective studies and meta-analyses have demonstrated the superiority of external stents over no stents. Internal stent utilization in some small-sized studies has effectively decreased rates of POPF [24,25]. However, the opposite results showed no differences in POPF rates, which were also observed in external and internal stents compared to no stent [26,27,28]. Current evidence is insufficient to determine the effectiveness of stent use. Furthermore, little attention has been paid to comparing external and internal stent use, and more consensus is required regarding their superiority. Some RCTs [29,30,31] have controversially reported both the efficacy and non-efficacy of external versus internal stents in preventing POPF.

According to a recent literature search conducted in 2017, Zhang et al. [32] reported similar results in three RCTs. They indicated that neither method had any obvious advantages or disadvantages in subgroup analyses based on the texture of the pancreas. In 2022, Guo et al. [33] conducted a meta-analysis of 847 patients to evaluate the effectiveness of pancreatic stents for POPF in PD. They revealed that pancreatic duct stents did not reduce the risk of POPF and other complications after PD compared to no stents, although external stents were associated with a reduced POPF rate compared to no stents. In 2016, Dong et al. [34] conducted a systematic review incorporating eight trials with 1018 participants to determine whether using stents is beneficial and, if so, whether internal or external stenting, with or without replacement, is preferable. They found no evidence that stents lead to a lower fistula risk than no stents. They also found no evidence of a difference between the use of internal and external stents. Therefore, the safety and efficacy of drainage types in preventing and reducing POPF in the PJ after PD remain controversial.

The critical point discussed in our study was the efficacy of pancreatic stents in PG using an invagination method. However, this remains an unsettled question as only a few studies have been conducted [35]. The incidence of POPF in the PG between duct-to-mucosa anastomosis and invagination is uncertain. External stenting can reduce POPF by decreasing the amount of pancreatic juice and intraluminal pressure in duct-to-mucosa anastomoses [36]. However, such methods are considered unnecessary in invagination procedures that maintain the lumen of the pancreatic duct. Uncertain factors, such as pancreatic texture, patient's physical condition, and surgeons' preferences for anastomosis, should be initially unified in RCTs; however, this is extremely difficult. Notably, although potential drawbacks are associated with employing a stent in PG [37,38], the decision to use one relies on a thorough evaluation of the individual patient's medical condition and specific details of the surgical procedure. The benefits of using a stent, such as providing support and preventing leakage, must be weighed against the potential risks and drawbacks. A decision should be made by the surgical team in consultation with the patient. Therefore, more extensive multicenter randomized prospective clinical trials are needed to verify the effectiveness of external duct stenting compared to internal or non-stenting in preventing and treating POPF at different levels of PG risk.

9. Conclusion

Our data showed a 12.9% POPF rate and 25.8% morbidity. Pancreatic duct stenting in PG tends to increase the rate of pancreatic leakage and hospital stay. Compared to 'ordinary' PG, our 'open' method provides excellent visualization of the intragastric cavity and, consequently, more accurate performance of the anastomoses. In the subgroup analysis of the differences in pancreatic texture, pancreatic duct stenting did not significantly change the rate of pancreatic leakage. However, the rate of pancreatic leakage in patients with a soft pancreas was considerably higher than in those with a hard pancreas. In conclusion, routine pancreatic duct stenting was not associated with a decrease in the pancreatic leakage rate of the PG after PD.

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