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Predictive factors associated with postoperative pancreatic fistula after laparoscopic distal pancreatectomy: a 10-year single-institution experience

Arturo S. Mendoza III[1] · Ho-Seong Han[2] · Soyeon Ahn[3] · Yoo-Seok Yoon[2] · Jai Young Cho[2] · YoungRok Choi[2]

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Abstract
Background Laparoscopic distal pancreatectomy (LDP) is a treatment option for benign and borderline pancreatic tumors. However, pancreatic fistula (PF) remains a significant morbidity, contributing to the length of hospital stay and overall costs. In a consecutive series of 143 patients at a single institution, the predictive factors associated with PF after LDP were identified.
Methods A retrospective study of patients who had undergone LDP between January 2003 and December 2013 was conducted. Patient demographic data and clinicopathological parameters were analyzed to evaluate their correlation with the incidence of PF.
Results Among the 143 patients, the indications for surgery were benign disease in 117 (82 %) and malignant tumors in 26 (18 %). PF occurred in 25 (17 %) patients, 10 (40 %) of whom had clinically significant (grade B) PF. No grade C PF was observed. Multivariable analysis showed that pancreatic thickness was a significant predictive factor for PF ($P < 0.001$). A 12-mm cutoff value was based on the median pancreatic thickness in this series. Pancreatic texture alone was not a significant risk factor ($P = 0.30$); however, it became significant in patients with pancreatic thickness exceeding 12 mm ($P = 0.005$).
Conclusions Pancreatic thickness exceeding 12 mm significantly increases the likelihood of PF after LDP. Pancreatic texture alone is not an independent risk factor for PF, but when combined with a thick parenchyma (>12 mm), a soft pancreas is predictive of PF.

Keywords Distal pancreas · Laparoscopic distal pancreatectomy · Postoperative pancreatic fistula

Distal pancreatectomy is the surgical procedure of choice for left-sided pancreatic lesions, both benign and malignant. Its postoperative mortality rate is currently lower than 3 % [1], but the rate of pancreatic fistula (PF) is still 3–26 % [1–3]. Although many reports have described ways to prevent PF, no precise way to avoid this complication has yet been defined. Similarly, there is no consensus on the management of the pancreatic stump after resection of the distal pancreas.

Laparoscopic distal pancreatectomy (LDP) has gained increasing popularity in recent years, and numerous reports have demonstrated the advantages of LDP as a treatment option for benign and borderline tumors of the body and tail of the pancreas [4, 5]. The laparoscopic approach is reportedly safe and is associated with less blood loss and a rapid recovery [4, 5]. However, the superiority of this technique in preventing PF has not been demonstrated. The fistula rate of LDP is similar to that of open distal pancreatectomy and remains substantial, at up to 21 % [4]. In most cases, transection and occlusion are achieved with an endoscopic linear stapler. Few data are currently available to clarify the risk factors associated with PF in LDP in a large series. Only a few reports have suggested that pancreatic parenchymal thickness is a risk factor for PF [6, 7],

✉ Ho-Seong Han
hanhs@snubh.org

[1] Department of Surgery, University of Santo Tomas Hospital, Manila, Philippines

[2] Department of Surgery, Seoul National University College of Medicine, Seoul National University Bundang Hospital, 166 Gumi-ro, Bundang-gu, Seongam-si, Seoul, Gyeonggi-do 463-707, Korea

[3] Division of Statistics, Medical Research Collaborating Center, Seoul National University Bundang Hospital, Seoul, Korea

but no plausible reason for the high incidence of PF in a thick pancreas has yet been offered.

The aim of this study was to determine the clinicopathological and intraoperative factors that predict PF after LDP with stapled closure at a single high-volume institution.

Methods

Patients

All patients who underwent LDP at Seoul National University Bundang Hospital between January 2003 and December 2013 were reviewed in the study. Of the 151 patients, eight patients were converted to an open procedure and were excluded from the study. Thus, in total, 143 patients were retrospectively investigated in the present study. Patient demographics, intraoperative and pathological parameters were obtained from a prospectively collected database and included sex, age, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, preoperative serum albumin level, estimated blood loss, operative time, pancreatitis, pancreatic texture, pancreatic duct size, pancreatic parenchymal thickness and pathology. In addition, a combined parameter, associating pancreatic texture with parenchymal thickness, was evaluated to determine its relationship to the incidence of PF. Postoperative complications were recorded, with a particular focus on fluid collection and PF.

Pancreatic characteristics

Contrast-enhanced dynamic multi-detector CT (MDCT) scans were obtained pre- and postoperatively for each patient. The postoperative CT was obtained at 5–7 days after the operation in all patients to assess any postoperative morbidity, including fluid collection and PF. The pancreatic parenchymal phase, which distinguishes the pancreatic parenchyma from the adjacent tissue, was used. The preoperative MDCT axial image was used to measure the pancreatic thickness at the transection line, which was compared with the equivalent image on postoperative MDCT (Fig. 1). The texture of the pancreatic parenchyma was defined as either soft or hard based on the surgeon's judgment.

Pancreatic transection

All pancreatic resections were performed by the standardized techniques in our institution [8]. Endoscopic linear stapler was used for parenchymal transections. The type or color of cartridge used was determined prior to transection

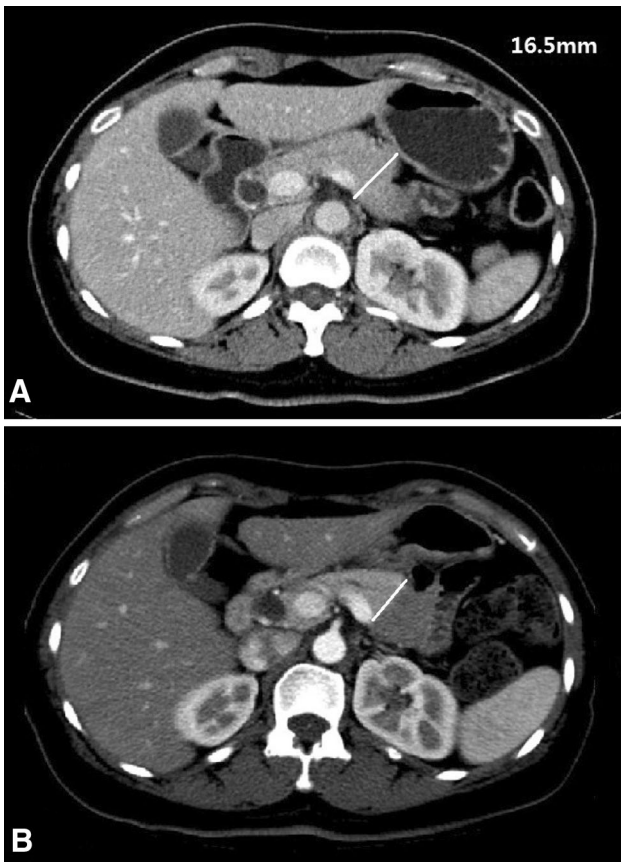

Fig. 1 Preoperative (**A**) and postoperative (**B**) MDCT images to measure pancreatic parenchymal thickness. The thickness of the cutting line (*white line*) was measured based on transection line of the postoperative image

depending on the pancreatic texture and thickness. Although it is a subjective way of assessment, the tactile response of the instrument allows the surgeon to determine a soft or hard pancreas. For a hard pancreas, usually the green (thick) cartridge was utilized, and the white (vascular) cartridge was used for a soft pancreas. The slow parenchymal flattening technique [9] was used when transecting the pancreas. Additional ligation of pancreatic duct was not performed.

Evaluation of PF

Upon completion of the procedure, one Jackson–Pratt drain was routinely placed near the stump of the remnant pancreas and was removed when the drainage fluid was clear and no pancreatic fistula was present. The fluid from the drain and the serum amylase levels were recorded on postoperative days 1, 3, 5 and 7. Oral feeding was generally commenced on postoperative day 1 and continued thereafter. Conservative management of PF was attempted whenever possible as the first-line treatment. When

significant fluid collection was observed on CT scan, percutaneous catheter drainage was performed.

Definition of PF

A postoperative PF was defined as a drain output of any measurable volume on or after the third postoperative day, with amylase content greater than three times the normal serum value either in the operatively placed drain or upon percutaneous insertion of a drainage catheter for postoperative fluid collection. The grading system for a postoperative PF was based on the International Study Group of Pancreatic Fistula (grades A, B and C) [10]. In this study, no grade C fistula was observed. In patients with grade B fistula, the drain was repositioned or a percutaneous drainage catheter was inserted.

Statistical analysis

All statistical analyses were performed using STATA software 13 (Stata Statistical Software: Release 13. StataCorp LP, College Station, TX). All data were summarized as mean ± standard deviation or median (interquartile range) for continuous variables or as frequency and percent for categorical variables. A univariable analysis was performed with a Student's *t* test for continuous variables and the χ^2 test for categorical variables to identify confounding variables for the development of PF. Potential confounding variables were detected in the univariable analysis at the significance level of 0.2 and were included in the multivariable analysis. A separate univariable analysis for patients with clinical PF (grade B) was performed. Two multivariable logistic regressions were examined to determine independent predictive factors for PF as well as to investigate whether the combined parameter would be an independent predictive factor as well. For each variable, the odds ratio (OR) and the 95 % confidence interval (CI) were determined. A $P < 0.05$ was considered statistically significant.

Results

Patient characteristics and surgical factors

Of the 143 patients included, 58 were men and 85 were women. The mean age at the time of surgery was 57 years. The main indication for LDP was pancreatic tumor, of which 117 cases (82 %) were benign and 26 cases (18 %) were malignant. Of the benign tumors, intraductal papillary mucinous neoplasm was most common (26, 18 %), followed by solid pseudopapillary neoplasm (23, 16 %) and mucinous cystadenoma (22, 15 %). Pancreatic ductal adenocarcinoma (17, 12 %) was the most frequent single entity among the malignant tumors. The indications for surgery are summarized in Table 1. The mean overall operating time was 236 ± 91.6 min. The median pancreatic thickness among the 143 patients was 12.3 mm (IQR 9.2–19.7 mm), and the mean thickness was 12.7 ± 2.1 mm. Splenectomy was performed in 68 cases (48 %). Multivisceral resection (including the colon, kidney and adrenal gland) was necessary in three patients (2 %). The patient characteristics and surgical factors are presented in Table 2.

Pancreatic fistula

Twenty-five patients (17 %) developed PF, of whom 15 (60 %) had subclinical PF (grade A) and the remaining 10 (40 %) had clinical PF (grade B). No grade C PF was identified in this patient cohort (Table 2). Radiological intervention was required by all 10 patients with grade B PF, but no patient required reoperation. The characteristics of the patients with and without PF were compared to identify the risk factors for PF in all patients (Table 3).

Risk factors for PF

Univariable analysis showed that the pancreas were significantly thicker (16.1 ± 1.8 mm) in patients who developed PF in general (grade A and B) than in those without PF (11.9 ± 1.3 mm) ($P = 0.001$; Table 3). The other variables analyzed did not differ significantly between the two groups. We then further analyzed the risk factors for clinical PF (grade B), for which pancreatic thickness was also an independent predictive factor (OR 12.2, 95 % CI 1.5–99.7, $P = 0.019$; Table 4). All the potential variables

Table 1 Indication for laparoscopic distal pancreatectomy (LDP)

Indications for surgery	No. of patients (%)
Benign	117 (82)
Malignant	26 (18)
Intraductal papillary neoplasm	26 (18)
Solid pseudopapillary neoplasm	23 (16)
Mucinous cystadenoma	22 (15)
Neuroendocrine tumor	18 (13)
Ductal adenocarcinoma	17 (12)
Serous cystadenoma	14 (10)
Solid mucinous adenoma	6 (4)
Mucinous cystadenocarcinoma	5 (4)
Oligocystic adenoma	3 (2)
Renal cell cancer	3 (2)
Others	6 (4)

Categorical data are *n* (%)

Table 2 Demographic and clinicopathologic characteristics of patients ($n = 143$)

Variable	Value
Sex	
Men	58 (41 %)
Women	85 (59 %)
Age (years)	57 ± 15.3
BMI (kg/m^2)	22.7 ± 3.5
ASA score	
1	65 (46 %)
2	73 (51 %)
3	5 (4 %)
4	0 (0 %)
Preoperative serum albumin (mg/dL)	4.3 ± 0.3
Estimated blood loss (mL)	334 ± 276.9
Operative time (min)	236 ± 91.6
Pancreatitis	
Yes	10 (7 %)
No	133 (93 %)
Pancreatic texture	
Hard	59 (41 %)
Soft	84 (59 %)
Pancreatic duct size (mm)	2.8 ± 0.8
Pancreatic parenchymal thickness (mm), mean ± SD	12.7 ± 2.1
Pancreatic parenchymal thickness (mm) median (IQR)	12.3 (9.2, 19.7)
Operative procedure	
LDP + splenectomy	68 (48 %)
Spleen-preserving LDP	72 (50 %)
LDP + splenectomy + additional procedure	3 (2 %)
Postoperative fluid collection	24 (17 %)
Postoperative pancreatic fistula	
Grade A	15 (11 %)
Grade B	10 (7 %)
Grade C	0 (0 %)

Categorical data are *n* (%); continuous data are mean ± SD or median (IQR)

were examined in a multivariable analysis, which included age, preoperative albumin, pancreatic duct size, pancreatic thickness and the combined parameter. Pancreatic thickness was a significant predictive factor for PF in the first model of multivariable analysis (OR 4.5, 95 % CI 2.5–24.2, $P < 0.001$; Table 5). On the second multivariable analysis model, the combined parameter was collapsed into three levels due to rare event of PF when combining pancreatic texture and a thin pancreas. The thick and soft combination was particularly significant in this analysis (OR 22.3, 95 % CI 2.6–193.8, $P = 0.005$; Table 6).

A box plot showed the distribution of pancreatic thickness according to the group of patients by PF grade (Fig. 2). A median thickness of 12.3 mm was observed in this series, which was used as the cutoff value. Only one patient with a thin pancreatic remnant (<12 mm) developed PF, whereas most of the patients who developed PF had a thick pancreatic remnant (>12 mm).

Discussion

Our increasing experience with laparoscopic surgery has meant that increasing numbers of LDP procedures have been performed at our institution in the past decade. With greater surgical experience and technical refinement, the indications for LDP have widened to include borderline and early malignant tumors of the pancreatic body and tail [11]. However, despite the advantages of laparoscopic surgery, including the better visualization and exposure of the pancreas and adjacent vessels, PF remains an ongoing problem, with an occurrence rate similar to that for open

Table 3 Factors associated with PF (grades A and B) after LDP

Variable	No PF ($n = 118$)	With PF ($n = 25$)	P
Sex			0.217
Male	50 (42 %)	8 (32 %)	
Female	68 (58 %)	17 (68 %)	
Age (years)			0.105
>70	23 (19 %)	2 (8 %)	
<70	95 (81 %)	23 (92 %)	
BMI			0.86
<22	52 (44 %)	7 (28 %)	
>22	66 (56 %)	18 (72 %)	
Preoperative albumin (mg/dL)	4.3 ± 0.3	4.4 ± 0.3	0.115
Estimated blood loss (mL)	325 ± 242	383 ± 401	0.344
Operative time (min)	237 ± 96.3	229 ± 66.5	0.687
Pancreatic texture			0.203
Hard	49 (42 %)	10 (40 %)	
Soft	69 (58 %)	15 (60 %)	
Pancreatic duct size (mm)	2.9 ± 0.8	2.6 ± 0.7	0.146
Pancreatic thickness (mm)	11.9 ± 1.26	16.1 ± 1.8	*0.001*
Pathology			0.24
Malignancy	25 (21 %)	1 (4 %)	
Benign	93 (79 %)	24 (96 %)	
Operative procedure			0.454
LDP + splenectomy	63 (53 %)	5 (20 %)	
Spleen-preserving LDP	53 (45 %)	19 (76 %)	
LDP + additional resection	2 (2 %)	1 (4 %)	
Pancreatitis			0.786
Yes	9 (8 %)	1 (4 %)	
No	109 (92 %)	24 (96 %)	
Combined parameter (thickness and texture)			*<0.001*
Thin + hard	30 (25 %)	0 (0 %)	
Thin + soft	38 (32 %)	1 (4 %)	
Thick + hard	21 (15 %)	8 (32 %)	
Thick + soft	29 (25 %)	16 (64 %)	

Categorical data are n (%); continuous data are mean ± SD

$P < 0.05$ is statistically significant

surgery. This morbidity can lead to postoperative fluid collection, abscess and even fatality when inappropriately treated. Retrospective studies have reported incidences of clinically significant PF ranging from 3 % to 26 % [12–15]. In the present study, the overall rate of PF was 17 % (25/143), and the incidence of clinically significant PF was 7 % (10/143), which does not deviate significantly from the incidence reported in the literature [16–18].

There are several variations in the technique used to close the pancreatic stump. Many attempts have been made to reduce the incidence of PF, but until now the superiority of any particular closure technique has not been convincingly demonstrated. Seromuscular patches, individual pancreatic duct ligation, the application of fibrin glue or mesh and stapler reinforcement have been used to minimize the occurrence of PF [4, 19–23]. The slow parenchymal flattening technique while using a linear stapler, proposed by Okano et al., is one procedure proposed to reduce the occurrence of PF. However, the incidence rates have not changed significantly despite these methods.

Numerous predictive factors for PF have been reported in previous studies [3, 10, 12, 14], including the patient's age, parenchymal texture and pancreatitis [3, 5, 12, 14, 15]. However, most of these factors cannot be controlled by the surgeon performing LDP. Few studies have investigated the use of the linear stapler as the cause of PF. A multicenter trial, the DISPACT trial [24], proposed that stapler closure does not significantly reduce the incidence of PF after DP compared with hand-sewn closure (stapler 32 % vs hand sewn 28 %).

Table 4 Factors associated with clinical PF (grade B) after LDP

Variables	OR	95 % CI	*P*
Gender	1.11	0.29–4.11	0.884
Age	0.98	0.94–1.03	0.586
BMI	1.15	0.95–1.40	0.134
ASA score	1.94	0.62–6.08	0.252
Preoperative serum albumin (mg/dL)	1.63	0.22–11.7	0.626
Estimated blood loss	1	0.99–1.00	0.801
Operative time	1	0.99–1.00	0.461
Pancreatitis	1.01	0.11–8.75	0.986
Pancreatic texture	6.58	084–55.8	0.07
Pancreatic duct size	0.63	0.25–1.56	0.317
Pancreatic thickness	12.24	1.50–99.7	*0.019*
Tumor size	0.88	0.65–1.18	0.386
Pathology	1	NE	NE
Combined parameter			
Thin	1	NE	NE
Thick + hard	3.23	0.19–54.0	0.413
Thick +soft	18.75	2.24–156.8	*0.007*

CI confidence interval, *OR* odds ratio, *NE* no event

$P < 0.05$ is statistically significant

Table 5 Multivariable analysis of risk factor for PF (model 1)

Variables	OR	95 % CI	*P*
Age	0.1	0.9–1.1	0.697
Preoperative albumin	7.8	0–360	0.627
Pancreatic duct size	0.5	0.1–3.3	0.584
Pancreatic thickness	4.5	2.5–24.2	<0.001

CI confidence interval, *OR* odds ratio

Table 6 Multivariable analysis of risk factor for PF (model 2)

Variables	OR	95 % CI	*P*
Age	0.99	0.95–1.05	0.968
Preoperative albumin	1.64	0.94–1.05	0.665
Pancreatic duct size	0.47	0.15–1.41	0.176
Combined parameter			
Thin	1	Ref	Ref
Thick + hard texture	2.59	0.15–45.27	0.513
Thick + soft texture	22.27	2.56–193.84	*0.005*

CI confidence interval, *OR* odds ratio, *ref* reference

$P < 0.05$ is statistically significant

In this study, we found that a pancreatic thickness exceeding 12 mm was a significant risk factor for PF when a linear stapler was used for pancreatic transection. Three

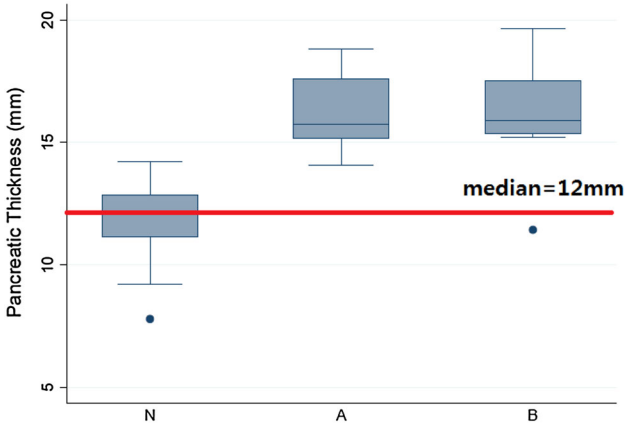

Fig. 2 *Box plot* showing the distribution of thickness according to the group of patients by PF grade; grade A (A), B (B) and no PF (N). *Box* represents the 25th and 75th percentiles of the thickness in each group of patients, and the outliers were marked as *points* (*dot*)

previous retrospective studies have reported a relationship between pancreatic thickness and the occurrence of PF [6, 9, 25]. Stapler transection and occlusion during LDP are simple and effective methods of closing the pancreatic stump [5, 26]. The most important issue when using this method is to avoid tissue injury and tearing of the pancreatic capsule. Because a linear stapler was used for the transection and occlusion of the pancreatic remnant in all LDP performed in this study, it can be presumed that closure may be unsatisfactory when the parenchymal thickness exceeds 12 mm. The cause of this phenomenon was not identified and is beyond the scope of this study. However, most reports speculate that a thick pancreas is more likely to be crushed during the procedure, causing the parenchyma to tear when it is compressed by the stapler [25]. Other reports have also suggested that staplers cannot be fully approximated in thick pancreatic parenchyma leading to incomplete sealing. However, no study has yet tested these hypotheses. If a thick pancreas increases the risk of PF, it may be necessary to perform additional procedures to ensure better sealing of the pancreatic remnant when an endoscopic linear stapler is used. The application of additional running sutures may be helpful. Several reports have also recommended individual ligation of the pancreatic ducts [27].

The importance of the pancreatic parenchymal thickness has been examined in only a few studies [6, 9, 25]. In this study, we selected 12 mm as the cutoff value because this was the median thickness in our series of patients. Identifying a thick pancreas preoperatively from an axial MDCT image would advantage the surgeon in two ways. It would allow him/her to anticipate a higher risk of postoperative PF and to consider additional procedures to reinforce the pancreatic stump, as discussed above. Although measuring

the parenchymal thickness is not routine practice at most institutions, the preoperative measurement of this parameter may provide the surgeon with useful information.

In contrast, pancreatic texture has previously been reported to be a risk factor for PF [2, 9]. Although it is a very subjective variable, the surgeon can distinguish a hard pancreas from a soft pancreas by the tactile response of the instrument. However, whether a hard or soft parenchymal texture is more susceptible to PF is controversial. Numerous reports have shown that a fibrotic or hard pancreas is more likely to develop PF when a linear stapler is used [9]. However, in our study, pancreatic parenchymal texture alone was not an independent risk factor for PF. Interestingly, when pancreatic thickness was combined with parenchymal texture, a soft and thick pancreas significantly predicted PF, contrary to other reports. Although pancreatic texture alone was not a significant risk factor for PF, a soft thick pancreas may increase the likelihood of PF.

A drawback of this study is the non-uniformity of the type of stapler cartridge used among patients. Although the size of cartridge used (white or green) depended on the pancreatic texture assessed intraoperatively, there was no strict guideline on which type of cartridge to use. A uniform type of cartridge for a particular pancreatic texture and thickness would significantly improve the accuracy of the findings.

In conclusion, PF continues to be a significant challenge to surgeons. In our series, a pancreatic thickness of more than 12 mm indicated a higher risk of PF than a thickness of less than 12 mm. Therefore, preoperative measurement of the pancreatic parenchymal thickness may be useful for predicting the occurrence of postoperative PF and may be useful for the surgeon when considering the need to reinforce stump closure.

This study also demonstrates that pancreatic texture alone is not a risk factor for postoperative PF. However, when combined with a thick pancreas, a soft parenchymal texture was a significant risk factor for this complication. A randomized clinical trial to confirm these findings is warranted.

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