



Standardized Pancreatic Transection in Laparoscopic Distal Pancreatectomy: A Novel Approach to Minimize Postoperative Pancreatic Fistula

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Abstract

Introduction: The incidence of postoperative pancreatic fistula (POPF) after laparoscopic distal pancreatectomy (Lap-DP) remains high. Peri-firing compression (PFC) has been reported to reduce POPF, but techniques have not been standardized.

Methods: From March 2016 to January 2023, 53 consecutive patients (female = 27) with various types of pancreatic neoplasms underwent Lap-DP. All transactions were performed using electrically-powered staplers with a black cartridge. The standardized PFC techniques consisted of three steps: 10min of pre-compression, 5min of cutting, and 5min of post-compression (total cutting time = 20 min). Drain amylase (D-AMY) levels were measured on postoperative days 1, 3, 5, and 7 to evaluate POPF according to the 2016 International Study Group in Pancreatic Surgery (ISGPS) definition update. Postoperative complications were evaluated using the Clavien-Dindo (CD) classification. Preoperative computed tomography (CT) measured preoperative pancreatic thickness at the resection line.

Results: POPF exhibited no biochemical leakage (BL) in 51 patients and grade B in 2 patients. No major complications beyond CD grade IIIb were observed. The mean pancreatic thickness of the stump was 15.4 mm. All patients were discharged approximately 13 days after surgery. Two patients with POPF(B) were characterised by a significantly higher D-AMY of 1POD, more than 30,000 U/ml.

Conclusions: The novel standardized 20-minute PFC techniques using an electrically powered stapler with a black cartridge during Lap-DP may safely and low incidence of POPF in patients with a soft pancreas thickness of up to 29.1 mm. Significantly higher D-AMY in 1POD is characteristic of patients with POPF(B).

Keywords: Postoperative pancreatic fistula, Distal pancreatectomy, Stapling techniques, Peri-firing compression

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Introduction

Postoperative pancreatic fistula (POPF) is the least desired complication after distal pancreatectomy (DP). Recent advances in minimally invasive surgery stapler closure is the most common techniques in Laparoscopic (Lap)-DP, however, the incidence of POPF still remains high ranging from 10% to 30% [1-5]. Risk factors for POPF can be classified into patient- and surgery-related factors [6]. This study focused on surgery-related factors, especially on surgical devices and techniques. Nakamura et al. reported that the prolonged peri-firing compression (PFC) techniques in stapler transection of the pancreas significantly reduced the incidence of clinical POPF in Lap-DP [7], which was confirmed by Ariyathenam et al. [8] and Hirashita et al. [9]. There have been a few reports regarding details of PFC techniques. In this study, we report on our techniques with Lap-DP using fixed surgical devices and techniques for 53 consecutive patients with pancreatic tumors.

Methods

Patients

Our study was a prospective interventional case series from a single center with short-term

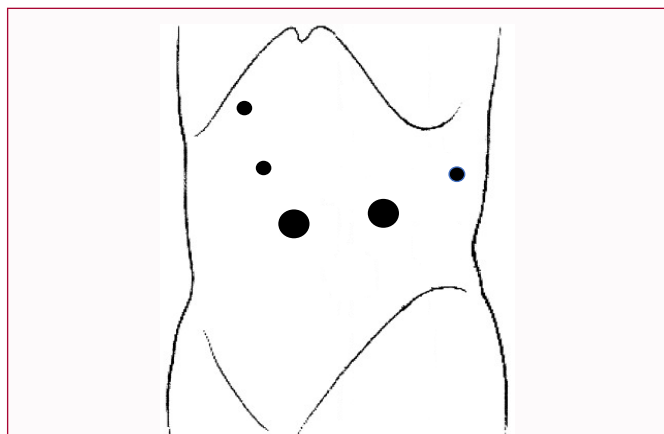


Figure 1: The trocar arrangements.

A 12mm trocar was placed in the umbilicus as a camera port. Additionally, a 12-mm trocar placed at the left lateral border of the rectus abdominis muscle, and three 5-mm trocars were placed in the bilateral subcostal areas.

outcomes. Fifty-three consecutive patients (26 males, 27 females) with pancreatic tumors underwent Lap-DP between March 2016 and December 2022. The following clinical characteristics and outcomes were collected from the institutional electronic medical record database: age, sex, body mass index, primary disease, operation time, length of drainage days, and postoperative hospital stay. Morbidity was classified according to the Clavien-Dindo (CD) classification [10,11], and POPF according to the 2016 update of the International Study Group in Pancreatic Surgery (ISGPS) [12]. The pancreas thickness at transection site was measured on preoperative CT with reference to the postoperative CT scan. The thickness of the pancreas was measured five times and the average of the measurements was adopted. Operation time was defined as skin-to-skin time.

Laparoscopic distal pancreatectomy (Lap-DP)

Under general anesthesia, patients were placed in the right semilateral decubitus position. Through an umbilical incision, a 12-mm videoscope trocar was inserted into the peritoneal cavity to establish pneumoperitoneum at 10 mmHg. Additionally, four trocars were placed in the upper abdomen (Figure 1). The greater omentum was incised along the right gastroepiploic vessels using LigaSure™ (Medtronic, Dublin, Ireland) or Harmonic scalpel (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA), and the pancreas and transverse mesocolon were exposed. The splenicocolic and gastrosplenic ligaments were divided. A Nathanson lever retractor (Cook Japan, Tokyo, Japan) or suture fixation of the gastric wall to the abdominal wall was used to expand the field of view such that the gastropancreatic folds were perpendicular to the abdominal wall, exposing the upper edge of the pancreas. Laparoscopic intraoperative ultrasonography was performed to identify the tumor and determine the line of pancreatic transection. Additionally, pancreatic texture was comprehensively assessed by medical history, intraoperative surgeon palpation, and pathological finding. Pancreatic mobilization was performed on Gerota's fascia in cases of borderline malignancies and benign tumors, whereas in cases of malignant lesions it was performed in the layers of the anterior radical antegrade modular pancreatectomy with lymphadenectomy. The splenic artery was dissected prior to pancreatic transection with double Hem-o-Lok clip (Weck Surgical Instruments, Research Triangle Park, NC, USA), while the splenic vein was dissected with the pancreatic parenchyma using the stapler or double Hem-o-Lok individually.

Standardized 20-minute peri-firing compression (PFC) resection techniques

Regardless of pancreas thickness, the Powered Echelon FLEX™ 60 with a black cartridge (Ethicon, Somerville, USA) was utilized for all patients. The stapler was inserted parallel to the surface of the pancreas and perpendicular to the course of the main pancreatic duct, taking great care to avoid damaging the pancreatic capsule (Figure 2).

The standardized PFC techniques consisted of three steps. The first step was pre-compression, which included 5 minutes of compression and 5 minutes of adaptation. The pancreas was directly and gradually compressed for one-step with a stapler for 5 minutes until it was locked (*Step 1*). The stapler was then fired for 5 minutes using the pulse-firing techniques to allow more reliable formation of the B-shape (*Step 2*). We intentionally stopped the blade movement when the stapler blade reached the top for another 5 minutes of adaptation (*Step 3*). This post-compression was performed when the space between the stapler blades was the narrowest. By controlling the time with timers for each step, the transaction was completed in over 20 minutes. If there was bleeding from the transection site, compression hemostasis with hemostatic agent or minimal clipping within three rows of staples was applied.

Postoperative management

A 19 Fr silicone drain (J-VAC drain; Ethicon Endo-Surgery, Johnson & Johnson, Cincinnati, OH, USA) was placed routinely near the stump of the remaining pancreas in all patients. Drain amylase was measured on postoperative days (POD) 1, 3, 5, and 7 to evaluate POPF according to the ISGPS definition. We classified those without POPF as up to BL and those with POPF as B or higher. The AMY of 1 POD was graphed as 1 for 3 POD, 5 POD, and 7 POD. This prophylactic drain was removed on 5 or 7 POD if the drain AMY value showed a downward trend. There was no routine postoperative use of somatostatin analogues or hydrocortisone. CT scan was not routinely performed postoperatively, but only when clinical symptoms or blood tests indicated worsening inflammatory findings. The criteria for discharge were improvement in clinical symptoms, removal of drains and a trend towards reduction in inflammatory data. Postoperative complications were evaluated according to the Clavien-Dindo (CD) classification.

Statistical analysis

Statistical analysis was performed using the JMP for Windows, version 17.2.0 software (SAS Institute Inc., Cary, NC, USA). Data was represented in numbers, percentages, median, and interquartile range. Drain amylase values on 1POD with no POPF or BL and with grade B POPF were compared using the Mann-Whitney U test. The p

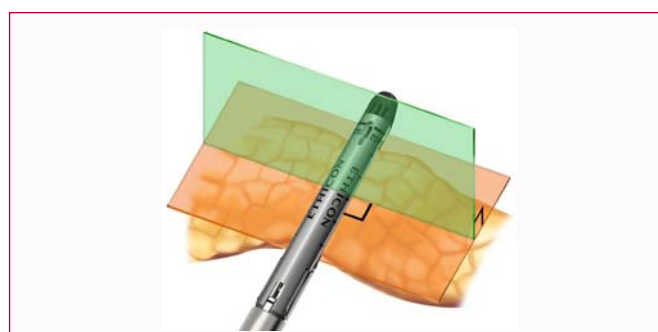


Figure 2: Precautions for staple insertion.

The stapler was inserted parallel and perpendicular to the pancreas surface.

value of <0.05 was considered statistically significant.

Results

The patient demographics are shown in Table 1. Lap-DP included one hand assisted laparoscopic spleen-preserving DP (HALS-SPDP) and two Lap-SPDP. Pancreatic stiffness was soft in 47 patients and hard in six. All patients underwent pancreatic transection with a standardized 20-minute PFC techniques by four surgeons. Figure 3 shows the postoperative drain amylase values in all patients.

Table 1: Patient demographics, pathology, operative details, and outcomes.

Total number of patients, n	53	
Sex, Female, n (%)	27	(50.9)
Age (years), median (IQR)	60.0	(48-69.5)
BMI (kg/m ²), median (IQR)	23.3	(20.7-26.9)
Primary diseases, n (%)		
Intraductal papillary mucinous neoplasms	13	(24.5)
Mucinous cyst neoplasms	11	(20.8)
Pancreatic neuroendocrine neoplasm	7	(13.2)
Solid pseudopapillary neoplasms	6	(11.3)
Pancreatic ductal adenocarcinoma	5	(9.4)
Serous cyst neoplasms	3	(5.7)
Epidermoid	2	(3.8)
Others	6	(11.3)
Operation time (min), median (IQR)	274	(239-329)
Length of drainage days (day), median (IQR)	7	(5-7)
Operations, n		
Lap-DP/HALS-SPDP/Lap-SPDP	49/1/3	
Postoperative hospital stays (day), median (IQR)	11	(10-14)
Clavien-Dindo classification, n (%)		
None+I+II/IIIa/IIIb+IV	49/4/0	(92.5/7.5/0)
POPF grade, n (%)		
None+BL/B/C	51/2/0	(96.2/3.8/0)
Readmission, n (%)	1	(1.9)
Reoperation, n (%)	0	(0)
Pancreatic thickness (mm), Mean (range)	15.4	(7.9-29.1)
Pancreatic stiffness, n (%)		
Soft/Hard	47 / 6	(88.7/12.3)

IQR: Interquartile Range; BMI: Body Mass Index; Lap-DP: Laparoscopic Distal Pancreatectomy; SPDP: Spleen Preserving Distal Pancreatectomy; HALS: Hand-assisted Laparoscopic Surgery; POPF: Post Operative Pancreatic Fistula; BL: Biochemical Leak

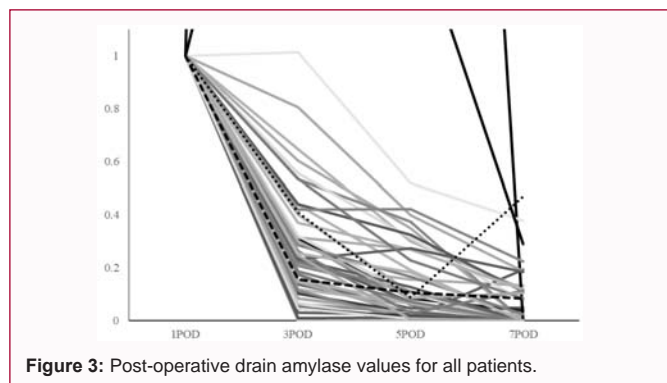


Figure 3: Post-operative drain amylase values for all patients.

Table 2: Comparison of D-AMY on 1 POD between patients with no POPF or BL and with grade B.

	n	Mean	Standard Error	95% CI	P value / U value
POPF(-)	51	8137	1117.9	5892-10381	P=0.0236 / U=0.6065
POPF(+)	2	33002	5645.2	21669-44335	

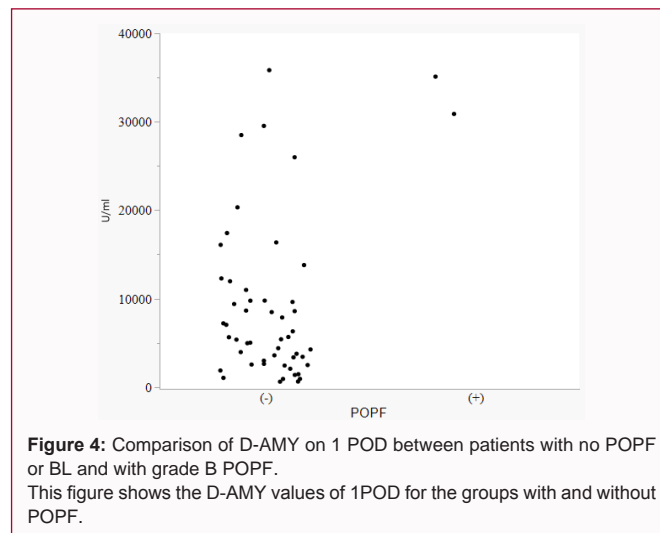


Figure 4: Comparison of D-AMY on 1 POD between patients with no POPF or BL and with grade B POPF. This figure shows the D-AMY values of 1POD for the groups with and without POPF.

patients (3.8%) developed grade B POPF, but none developed grade C. These patients with grade B POPF were clinically nonrelevant and improved only with prophylactic drain replacement. The remaining 51 patients (96.2 %) had no POPF or BL. Two patients showed an upward trend from POD1 to POD3 of 17.2-fold and 2.7-fold respectively, but a downward trend from 3POD to 7POD and no POPF. One patient with grade B POPF trended upward from 5 to 7 POD. The other patient showed a decreasing trend in D-AMY from 1 to 7 POD. CT scan was performed due to a persistent inflammatory response, followed by replacement of the drain. Two patients with grade B POPF had significantly higher drain amylase values of more than 30000 U/L at 1 POD (Figure 4, Table 2). The remaining 51 patients had their prophylactic drains removed within a week. All patients had no serious complications greater than CD classification grade IIIb. 30-day readmission and reoperation rate were 1.9% and 0%, respectively. The mean stump thickness was 15.4 mm, and the maximum was 29.1 mm. The average postoperative hospital stay was 13.1 days.

Discussion

In the present study, our novel standardized 20-minute PFC techniques based on slow compression and firing used an electrically powered stapler with a black cartridge was safe and achieved a low POPF for soft or hard pancreas thickness of within 29.1 mm. Drainage amylase levels were as high as >30,000 U/L at 1 POD in patients with grade B POPF. A postoperative hospital stay of 13.1 days was a valid length of stay given a 30-day readmission rate of 1.9%, a CD classification greater than IIIb of 0% and a grade C POPF of 0%.

There have been few reports with over 15 patients using pre- or post-compression for at least one minute; besides, the PFC techniques and devices used were varied (Table 3) [7-9,13-16]. In these reports, incidence of B/C POPF ranges from 0 to 12.4%, lower than previous non-PFC reports [1]. Pre- and post-compression times varied, whereas our 20-minute PFC techniques were the longest standardized

Table 3: Summary of previously published studies on pancreatic transection using peri-firing compression (PFC): studies with ≥ 15 cases and PFC application for ≥ 1 minute.

	Operation	No. of Patients	Stapler type	Stapler drive	Cartridge type	Reinforced	Pre-compression (min)	Post-compression (min)	POPF B/C n, (%)
Okano et al. [*]	Open	22	Echelon	M	GL	-	5	2	1 (4.5)
Nakamura et al. [†]	Lap	17	Echelon	M	GN	-	3	2	1 (5.9)
Nakamura et al. [‡]	Lap	42	Echelon	M	GN	-	3	2	3 (7.1)
Ariyathenam et al. [§]	Lap	20	Endo-GIA	M	GN/WH	-	3	1	0
Kawai et al.	Lap/Open	20/85	Endo-GIA	N/D	PL/BK	+	5	1	13 (12.4)
Hirashita et al. [¶]	Lap/Open	27-Oct	Endo-GIA	M	BL/GN/PL	-	8 □	2	2 (5.3)
Matsumoto et al. ^{††}	Lap	73	Endo-GIA	N/D	BK	+	4-6	1-3	4 (5.5)
Our study	Lap	53	Echelon	P	BK	-	10	5	2 (3.8)

Lap: Laparoscopic; M: Manual; P: Powered; GL: Gold; GN: Green; WH: White; PL: Purple; BK: Black; BL: Blue; N/D: Not Described

*: [13], †: [7], ‡: [14], §: [8], ||: [15], ¶: [9], □: Compression with an intestinal clamp for 5 minutes followed by compression with a linear stapler for 3 minutes, ††: [16]

pancreatic transection time using stapler. In addition, this is the first study to perform fixed devices and techniques for all pancreatic transections. The stapler we selected featured electrical power, parallel compression, gripping during firing, and the longest closed staple leg. Moreover, the techniques we performed featured pre- and post-compression and pulse firing under the time management. Recent advances in stapling technology have the potential to improve patient outcomes; however, effective utilization of these technologies remains a critical issue.

An electrically powered stapler was first introduced in 2010 by Medtronic (Minneapolis, MN, USA), followed by Ethicon (Johnson & Johnson, New Brunswick, NJ) in 2011. No reports have investigated whether a manual stapler or a powered stapler is better for pancreatic transection. In the field of video-assisted thoracic surgery (VATS), powered stapler group had a shorter hospital stay, lower total hospital costs, lower rates of hemostasis complications and postoperative air leaks [17,18]. We speculate that the advantage of the powered stapler may be lack of distal tip movement and reduced trauma to the parenchyma adjacent to the staple line. The pancreas is a less resilient parenchymal organ than the lungs, so unintentional shaking or anterior slippage during stapling can easily result in pancreatic capsular and parenchymal injury [19,20]. This stapler employed is a hinged jaw stapler; however, both jaws close as parallel as possible, and the pinched tissue has difficulty moving during firing with grip-surface technology.

As for the compression, Okano et al. first described the importance about slow parenchymal flattening compression for preventing destruction of the pancreatic capsule and parenchyma [13]. Nakamura et al. systematized this method as PFC and demonstrated its effectiveness in reducing POPF and shortening postoperative hospital stay after Lap-DP [7]. An experimental study in porcine pancreases using a novel force-fluorescence measurement system has demonstrated that slow compression and firing are important in preventing POPF [19]. Additionally, Matsuzawa et al. reported in porcine stomachs that pre-compression and slow firing are essential techniques to avoid serosal injury when using an electrically powered stapler [21]. The purpose of the one-step pre-compression with stapler is to remove fluid from inside the pancreas at the resection line to the surrounding area, whereas the purpose of the pulse firing and post-compression is to make the B-shape more reliable and to prevent tension at the transection site due to sudden fluid return.

Several studies have also investigated the relationship between the

pancreatic thickness and stapler height, such as the Echelon 60 stapler with a gold cartridge [13,22] or with a green cartridge (2.0 mm) [7]. Kim et al. calculated the compression ratio by dividing the pancreatic thickness by the closed stapler height and reported that gold cartridge performed better when the pancreatic thickness was less than 12 mm [23]. Sugimoto et al. also defined as the ratio of the stapler height at closure to the stump thickness, reported that the risk of POPF was low when the compression index was 0.16 or less [24]. Kang et al. reported that using a gold cartridge for pancreatic thickness < 13 mm may help reduce BL, whereas a green or black cartridge is recommended for pancreatic thickness > 13 mm [25]. These reports suggest that a higher stapler height should be selected for thicker pancreas. On this basis, our results indicate that only the stapler with the highest stapler leg may be sufficient to achieve optimal outcomes. Further studies are required to determine the optimal devices and techniques for the morphology and stiffness of the pancreas.

Our study attempted to standardize PFC devices and techniques, but some limitations remain as a prospective pilot study. Mainly, our study is a consecutive single-center case series demonstrating that the PFC techniques, with consistent application and standardization of both techniques and devices, effectively reduces the incidence of POPF in Lap-DP. Despite being a single-center study, it provides a basis for wider research and highlights the potential for standardization of techniques to improve patient outcomes in minimally invasive surgery. Larger studies are needed to validate these results, as are randomized clinical trials to establish the benefits of this approach over non-PFC resection. Second, most patients enrolled in the study had benign or borderline lesions. Therefore, most were soft pancreas up to 29.1 mm thickness. Considering that POPF is more likely to occur in soft pancreases, the 3.8% incidence of grade B and no grade C POPF observed in this study is acceptable. Third, two patients with grade B POPF were clinically nonrelevant and required drainage for more than three weeks with prophylactic drain exchange. These two patients were close to BL in the 2016 ISGPS definition update.

Conclusion

The 20-minute PFC techniques are devised from the concept of stapler transection of the pancreas as much as possible due to its fragile characteristics. Using standardized surgical instruments and techniques, characterized by the 10 minutes pre-compression, 5 minutes pulse firing cutting, and 5 minutes post-compression, demonstrated low-grade B/C POPF while minimizing the risk of surgical complications. In the group with grade B POPF, drain

amylase on 1 POD were significantly higher. However, further prospective comparative studies are necessary to validate these findings and determine their broader applicability.

Author' Contributions

All authors contributed to the study conception and design. Acquisition of the data was performed by HS. Analysis and interpretation of data were performed by HS, YS, and NS. The first draft was written by HS. Critical revision of manuscript was performed by all authors. All authors read and approved of the final manuscript.

Statements and Declarations

Funding: The authors did not receive support from any organization for the submitted work.

Competing interests: All authors meet the criteria for authorship in the Consensus Statement on Journal Authorship. There are no conflicts of interest.

Ethics approval: All procedures performed in our study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Central Ethics Committee for Clinical Research of Jichi Medical University (Shimotsuke, Japan). (No. A21-064).

Informed consent: Informed consent was obtained for surgical procedure prior to their participation.

Data availability: Raw data were generated at Jichi Medical University (Shimotsuke, Japan). Derived data supporting the findings of this study are available from the corresponding author HS on request.

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