Surgery Today (2022) 52:260–267
https://doi.org/10.1007/s00595-021-02344-z

ORIGINAL ARTICLE

Efficacy of the slow firing method using a reinforced triple-row stapler for preventing postoperative pancreatic fistula during laparoscopic distal pancreatectomy

Ippei Matsumoto[1] · Keiko Kamei[1] · Shumpei Satoi[1] · Takaaki Murase[1] · Masataka Matsumoto[1] · Kohei Kawaguchi[1] · Yuta Yoshida[1] · Lee Dongha[1] · Atsushi Takebe[1] · Takuya Nakai[1] · Yoshifumi Takeyama[1]

Received: 9 March 2021 / Accepted: 7 May 2021 / Published online: 28 July 2021

Abstract

Purpose Postoperative pancreatic fistula (POPF) remains the most clinically relevant complication of laparoscopic distal pancreatectomy (LDP). The present study evaluated the efficacy of the "slow firing method" using a reinforced triple-row stapler (Covidien, Tokyo, Japan) during LDP.

Methods This retrospective single-center study included 73 consecutive patients who underwent LDP using the slow firing method. A black cartridge was used in all patients. The primary endpoint was the rate of clinically relevant POPF (CR-POPF) after LDP. Secondary endpoints included perioperative outcomes and factors associated with CR-POPF as well as the correlation between the transection time and thickness of the pancreas.

Results Four patients (5.5%) developed CR-POPF (grade B). Overall morbidity rates, defined as grade ≥ II and ≥ III according to the Clavien-Dindo classification, were 21 and 11%, respectively. The median postoperative hospital stay was 10 days. Preoperative diabetes (13.6 vs. 0.2%, $P=0.044$) and thickness of the pancreas ≥ 15 mm (13.8% vs. 0%, $P=0.006$) were identified as independent risk factors for CR-POPF. The median transection time was 16 (8–29) min.

Conclusion The slow firing method using a reinforced triple-row stapler for pancreatic transection is simple, safe, and effective for preventing CR-POPF after LDP.

Keywords Clinically relevant postoperative pancreatic fistula · Laparoscopic distal pancreatectomy · Postoperative pancreatic fistula · Reinforced stapler · Slow firing method

Abbreviations

CR-POPF	Clinically relevant postoperative pancreatic fistula
DP:	Distal pancreatectomy
ISGPF:	International study group on pancreatic fistula
LDP	Laparoscopic distal pancreatectomy
POPF	Postoperative pancreatic fistula
PDAC	Pancreatic ductal adenocarcinoma
PGA	Polyglycolic acid
POD	Postoperative day

✉ Ippei Matsumoto
ippeimm@gmail.com

[1] Department of Surgery, Kindai University Faculty of Medicine, 377-2 Ohno-higashi, Osakasayama, Osaka 589-8511, Japan

Introduction

Distal pancreatectomy (DP) is performed in patients with a variety of lesions on the left side of the pancreas. With recent advances in laparoscopic techniques, laparoscopic distal pancreatectomy (LDP) is being performed increasingly frequently in select patients with both benign and malignant diseases [1–5]. Postoperative pancreatic fistulas (POPFs) are the most common and clinically relevant postoperative complications of DP, with a reported incidence rate of clinically relevant POPF (CR-POPF) of 10–35% [6, 7]. Different surgical techniques evaluated in randomized controlled trials have failed to reduce POPF rates after DP [8–14]; therefore, an optimal and reliable technique for preventing POPF after DP is yet to be established.

Stapler closure has recently become a standard technique for pancreatic stump closure because of its technical simplicity, especially when performing LDP. Therefore, a safe and effective stapler closure technique should be established to prevent POPF after LDP. A triple-row stapler has become available in recent years. Despite a previous study showing that a triple-row stapler is superior to a double-row stapler in preventing POPF [15], the incidence rate of CR-POPF using triple-row stapler remains as high as 18–57% [15–21]. Recently, a reinforced stapler with bioabsorbable materials was produced. Previous studies have demonstrated that reinforced staplers significantly reduce the incidence of CR-POPF compared with staplers without reinforcement. In 2012, Hamilton et al. [22] demonstrated that pancreatic transection using a triple-row stapler with mesh reinforcement during DP reduced the incidence of CR-POPF by 1.9%. Meanwhile, the efficacy of compression of the pancreas before transection with staplers, the slow parenchymal flattening technique by Okano et al. [23], or prolonged peri-firing compression technique by Nakamura et al. [16], has been reported to prevent CR-POPF after DP. These procedures may work by lowering the risk of pancreatic parenchymal injury when using a stapler.

Based on the available evidence, we developed a slow firing method with reinforced triple-row stapler during LDP. The present study evaluated the efficacy of this technique.

Materials and methods

Patient population and study design

From June 2014 to October 2020, 79 patients underwent LDP at Kindai University Hospital. Demographic information, perioperative parameters, and outcomes obtained from prospectively accumulated data were retrospectively reviewed. Although pancreatic transection was attempted using the slow firing method with a triple-row stapler during LDP in all patients, pancreatic transection was converted to the hand-sewn procedure in six patients because of a positive margin on the intraoperative frozen section ($n = 3$), stapling failure with severe damage to the pancreatic parenchyma ($n = 2$), and conversion to open surgery ($n = 1$). Excluding these patients, 73 patients who underwent LDP with pancreatic transection using the slow firing method were included in this study.

The diameter of the main pancreatic duct and the thickness of the pancreas at the resection site were estimated and measured by preoperative multidetector row computed tomography (CT) with 1-mm thickness based on the distance from the left edge of the portal vein measured intraoperatively. The time taken to transect the pancreas (transection time) was measured by video review.

The primary endpoint was the rate of CR-POPF after LDP. Secondary endpoints included perioperative outcomes and factors associated with CR-POPF as well as the correlation between the transection time and thickness of the pancreas.

Written informed consent was obtained from all patients before surgery according to the rules and regulations of our institution. This study was performed in accordance with the principles of the Declaration of Helsinki. The Ethics Review Committee of Kindai University Faculty of Medicine approved this study (No. 31093).

Surgical principles and procedures

Our surgical principles and procedures for LDP have been described previously [1, 24]. In brief, for pancreatic ductal adenocarcinomas (PDAC), indications for LDP were based on the Yonsei criteria [25] as follows: tumors confined to the pancreas, an intact posterior pancreatic fascial layer, and tumors located more than 1–2 cm from the celiac axis. We excluded patients with tumor invasion to the portal vein and to other organs except to the spleen; those who had undergone gastrectomy and those with a history of severe acute pancreatitis were also excluded.

We performed D2 lymph node dissection for malignant disease. LDPs with splenectomy were performed if there was potential lymph node metastasis of the pancreatic neoplasm, and/or technical difficulty in dissecting the distal pancreas from the splenic vessels. Spleen-preserving LDPs were attempted to preserve the splenic artery and vein. Spleen preservation while sacrificing the splenic vessels (Warshaw technique) was performed when tumor dissection from the splenic vessels was difficult intraoperatively.

Slow firing method with a reinforced stapler for pancreatic transection

Intraoperative ultrasonography was performed to determine the transection line of the pancreas. Pancreatic transection was performed using a triple-row stapler with polyglycolic acid (PGA) (Endo GIA Reinforced Reload with Tri-Staple™ Technology, Covidien, Tokyo, Japan). The black cartridge, which allowed a post-fire staple height of between 4.0 and 5.0 mm, was used in all cases. The slow firing method was performed as follows: the pancreas was slowly compressed with the stapler at the transection site, and the jaws of the stapler were closed for 1–3 min. After closing the jaws, the pancreas was compressed for another 3 min. For pancreatic transection, the pancreas was fired for 1 cm according to the scale (1 cm increments) on the jaw and kept compressed for at least 1 min. The pancreas was then fired for another 1 cm and kept compressed for at least another 1 min. The firing was completed by repeating the maneuver. The pancreas was kept compressed for further 1–3 min or more after firing. The duration of each instance of compression was determined by the surgeon according to the intraoperative findings of the pancreas, such as thickness and hardness.

Definition of postoperative complications

POPF was defined by the classification system of the International Study Group on Pancreatic Fistula (ISGPF) [26]. An amylase level in the drained fluid on the third postoperative day (POD) that was > threefold the serum amylase level was defined as biochemical leak, grade B, or grade C according to the ISGPF clinical criteria. CR-POPF was defined as grade B or C POPF. Postoperative complications were evaluated using a modified Clavien grading system [27].

Statistical analyses

Categorical variables were presented as proportions, and continuous variables were presented as medians and ranges. The significance of differences in distributions of values was tested using the Shapiro–Wilk statistic. Comparisons between two groups were performed using the Mann–Whitney *U* test. Proportions were compared using the chi-square test or Fisher's exact test when the expected value in any of the cell of the contingency table was below 5. A multivariate logistic regression analysis was performed to identify preoperative risk factors for CR-POPF. Statistical significance was defined as $P < 0.05$. All analyses were performed using the JMP software program, version 15.0 for Macintosh (SAS Institute, Inc., Cary, NC, USA).

Results

Patient characteristics and operative data

The study population comprised 22 males and 51 females, with a median age of 67 (18–89) years. Approximately 26% ($n = 19$) had PDAC (Table 1). Other indications for LDP were neuroendocrine neoplasms ($n = 19$), intraductal papillary mucinous neoplasms ($n = 12$), mucinous neoplasms ($n = 7$), solid pseudopapillary neoplasms ($n = 4$), and others ($n = 19$). The median thickness of the pancreas at the transection line was 14 (7–31) mm.

The operative data are shown in Table 2. Spleen-preserving LDP was performed in 23 (32%) patients. The median operation and pancreas transection times were 314 (158–582) and 16 (8–29) min, respectively. There were no cases of stapling line hemorrhaging that required suturing or clipping for hemostasis.

Rate of CR-POPF and other postoperative outcomes

Four patients (5.5%) developed POPF grade B, but none of the patients developed POPF grade C. Other postoperative outcomes are shown in Table 2. There was no mortality. The overall morbidity rates defined as grade ≥ II and ≥ III according to the Clavien–Dindo classification were 21 and 11%, respectively. The median length of postoperative hospital stay was 10 (4–113) days.

The comparison of patient characteristics and perioperative outcomes in patients with or without CR-POPF

We compared patient characteristics and perioperative outcomes in patients with CR-POPF and those without CR-POPF (Tables 1 and 2). The pancreas at the transection line was significantly thicker in the patients with CR-POPF than in those without CR-POPF (please check this carefully) (18 vs. 13 mm, $P = 0.039$). Although not statistically significant, the incidence of preoperative diabetes tended to be higher in the patients with CR-POPF than in those without CR-POPF [please check this carefully] (75 vs. 28%, $P = 0.080$). There was no significant difference in patient characteristics or other preoperative factors between the two groups. There were also no significant differences in operative factors, including type of operation, combined resection of other organs, operation time, pancreatic transection time, pancreatic texture, blood loss, blood transfusion, and conversion to open surgery, between the groups.

Regarding morbidity, other than CR-POPF, there was no marked difference in the morbidity rates between the two groups, and none of the patients in either group developed grade ≥ IV complications. The time to oral intake (5 vs. 3 days, $P = 0.034$), and the length of postoperative hospital stay (29 vs. 10 days, $P = 0.002$) were significantly longer in the patients with CR-POPF than in those without CR-POPF (please check this carefully).

Preoperative risk factors associated with CR-POPF

To identify independent preoperative risk factors for CR-POPF, a multivariate logistic regression analysis was performed. Preoperative diabetes (13.6 vs. 0.2%, $P = 0.044$) and a thickness of the pancreas ≥ 15 mm (13.8 vs. 0%, $P = 0.006$) were identified as independent preoperative risk factors for CR-POPF (Table 3).

Table 1 Patient characteristics and results of a univariate analysis of preoperative factors associated with CR-POPF

	Total (%) ($N=73$)	No CR-POPF ($N=69$)	CR-POPF ($N=4$)	*P* value
Sex				
Male	22 (30)	20 (29)	2 (50)	0.393
Female	51 (70)	49 (71)	2 (50)	
Age [years; median (range)]	67 (18–89)	67 (18–89)	71 (55–74)	0.536
ASA score				
I	21 (29)	20 (29)	1 (25)	0.720
II	47 (64)	44 (64)	3 (75)	
III	5 (7)	5 (7)	0 (0)	
Body mass index [kg/m^2; median (range)]	21.5 (15.0–31.5)	21.5 (15.0–31.5)	25.1 (21.1–25.4)	0.137
Diabetes				
No	51 (70)	50 (72)	1 (25)	0.080
Yes	22 (30)	19 (28)	3 (75)	
Previous abdominal surgery				
No	53 (73)	51 (74)	2 (50)	0.323
Yes	20 (27)	18 (26)	2 (50)	
Disease				
PDAC	19 (26)	17 (25)	2 (50)	0.461
NEN	19 (26)	18 (26)	1 (25)	
IPMN	12 (16)	12 (17)	0 (0)	
MCN	7 (10)	6 (9)	1 (25)	
SPN	4 (5)	4 (6)	0 (0)	
Others	12 (16)	12 (17)	0 (0)	
Lesion size [mm; median (range)]	21 (3–90)	21 (3–90)	23 (10–33)	0.929
Lesion site				
Body	11 (15)	10 (14)	1 (25)	0.487
Tail	62 (85)	59 (86)	3 (75)	
Diameter of the main pancreatic duct [mm; median (range)]	2 (1–8)	2 (1–8)	3 (1–4)	0.408
Thickness of the pancreas [mm; median (range)]	14 (7–31)	13 (7–31)	18 (15–18)	0.039

CR-POPF clinically relevant postoperative pancreatic fistula, *ASA* American Society of Anesthesiologists, *PDAC* pancreatic ductal adenocarcinoma, NEN neuroendocrine neoplasm, *IPMN* intraductal papillary mucinous neoplasm, *MCN* mucinous cystic neoplasm, *SPN* solid-pseudopapillary neoplasm

The comparison of patient characteristics and perioperative outcomes between the patients with and without CR-POPF who had a thick pancreas (≥ 15 mm)

According to the results concerning risk factors for CR-POPF, we compared patient characteristics and perioperative outcomes among patients with thick pancreas (≥ 15 mm) (Supplemental Tables 1 and 2). Preoperative diabetes was significantly more frequent in the patients with CR-POPF than in those without CR-POPF [please check this carefully] (75 vs. 20%, $P=0.0312$). However, no significant variables that affect CR-POPF were found among other patient characteristics or perioperative outcomes between the two groups.

Correlation between the transection time and thickness of the pancreas

Video reviews for the measurement of pancreatic transection were available in 67 of 73 cases. Figure 1 shows the correlation between the transection time and the thickness of the pancreas. The transection time was correlated with the thickness of the pancreas ($R^2=0.023$, $P<0.0001$). The median transection time was 16 (8–29) min (Table 2).

Table 2 Operative data and postoperative outcomes

	Total (%) (*N* = 73)	No CR-POPF (*N* = 69)	CR-POPF (*N* = 4)	*P* value
Type of resection planned				
LDP with splenectomy	50 (68)	46 (67)	4 (100)	0.301
Spleen-preserving LDP	23 (32)	23 (33)	0 (0)	
Type of resection performed				
LDP with splenectomy	52 (71)	48 (70)	4 (100)	0.318
Spleen-preserving LDP	21 (29)	21 (30)	0 (0)	
Combined resection of other organs				
No	60 (82)	56 (81)	4 (100)	0.237
Yes	13 (18)	13 (19)	0 (0)	
Operation time [minutes; median (range)]	314 (158–582)	311 (158–582)	335 (284–408)	0.370
Transection time of the pancreas (min)	16 (8–29)	16 (8–29)	24 (20–27)	0.063
Pancreatic texture				
Soft	66 (90)	62 (90)	4 (100)	0.362
Hard	7 (10)	7 (10)	0 (0)	
Staple line hemorrhaging				
No	73 (100)	69 (100)	4 (100)	1.000
Yes	0 (0)	0 (0)	0 (0)	
Blood loss [mL; median (range)]	50 (5–3.202)	50 (5–1.146)	225 (5–3.202)	0.199
Blood transfusion				
No	67 (92)	64 (93)	3 (75)	0.296
Yes	6 (8)	5 (7)	1 (25)	
Conversion to open surgery				
No	70 (96)	67 (97)	3 (75)	0.120
Yes	3 (4)	2 (3)	1 (25)	
Mortality	0 (0)	0 (0)	0 (0)	1.000
Morbidity (Clavien-Dindo classification)				
None or I	58 (79)	58 (84)	0 (0)	< 0.001
II	7 (10)	7 (10)	0 (0)	
IIIa	6 (8)	2 (3)	4 (100)	
IIIb	2 (3)	2 (3)	0 (0)	
IV	0 (0)	0 (0)	0 (0)	
V	0 (0)	0 (0)	0 (0)	
Intra-abdominal abscess	6 (8)	5 (7)	1 (25)	0.296
Chylous ascites	2 (3)	2 (3)	0 (0)	1.000
Delayed gastric emptying	1 (1)	1 (1)	0 (0)	1.000
Postoperative hemorrhaging	1 (1)	1 (1)	0 (0)	1.000
Wound infection	1 (1)	1 (1)	0 (0)	1.000
Portal thrombosis	1 (1)	1 (1)	0 (0)	1.000
Pancreatic pseudocyst	1 (1)	1 (1)	0 (0)	1.000
Other complications	4 (5)	3 (4)	1 (25)	0.206
Reoperation				
No	71 (97)	67 (97)	4 (100)	0.633
Yes	2 (3)	2 (3)	0 (0)	
Oral intake [POD; median (range)]	3 (2–15)	3 (2–9)	5 (3–15)	0.034
Hospital stay [POD; median (range)]	10 (4–113)	10 (4 -101)	29 (23–113)	0.002
Readmission				
No	71 (97)	67 (97)	4 (100)	0.633
Yes	2 (3)	2 (3)	0 (0)	

CR-*POPF* clinically relevant postoperative pancreatic fistula, *LDP* laparoscopic distal pancreatectomy, *POD* postoperative day

Table 3 Results of a multivariate analysis of preoperative risk factors for CR-POPF after LDP

	CR-POPF	*P* value
Diabetes		
No	1/51(0.2%)	0.044
Yes	3/22(13.6%)	
Thickness of the pancreas		
< 15 mm	0/44(0%)	0.006
≥ 15 mm	4/29(13.8%)	

CR-*POPF* clinically relevant postoperative pancreatic fistula, *LDP* laparoscopic distal pancreatectomy

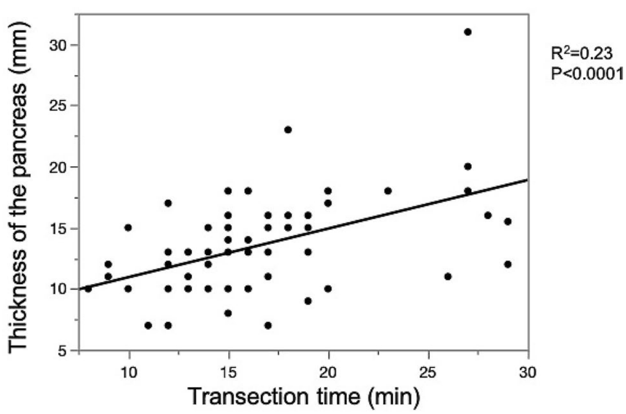

Fig. 1 Correlation between the transection time and the thickness of the pancreas. The transection time was associated with the thickness of the pancreas (R^2 = 0.023, P < 0.0001)

Discussion

We demonstrated that the slow firing method using reinforced staplers was useful in preventing CR-POPF in LDP. The rate of CR-POPF was 5.5%, and our method is simple and easy to perform. To our knowledge, this is the first report to analyze the correlation between transection time and pancreatic thickness in detail. Since Hamilton et al. [22] reported a CR-POPF rate of only 1.9% using a reinforced triple-row stapler, two prospective multicenter studies have been conducted. Kawai et al. [28] conducted a multicenter single-arm prospective study to evaluate the safety and efficacy of the same stapler in our study. They reported that CR-POPF occurred in 13 (12.4%) of 105 patients. Subsequently, Kondo et al. [29] reported the results of a multicenter randomized controlled study that compared a reinforced stapler with a bare stapler during DP (HisCO-07 Trial). They also used the same staplers as those used in our study. The results revealed no significant difference in the incidence of CR-POPF between the reinforced stapler and bare stapler groups (16.3 vs. 27.1%, P = 0.15). However, the authors acknowledged that the sample sizes were too small to draw definitive conclusions. Recently, using a propensity score-matched analysis to evaluate the usefulness of reinforced stapler (same as the one in our study), Pulvirenti et al. [30] reported a 12% incidence of CR-POPF. Furthermore, a recent meta-analysis showed that the risk of CR-POPF using PGA was significantly lower than that without PGA after DP [31]. With increasing evidence in recent years, we believe that the reinforced stapler is effective in reducing the occurrence of CR-POPF after DP.

Our study also identified the thickness of the pancreas and preoperative diabetes as independent risk factors for CR-POPF. These results are similar to those reported in previous studies [15, 17–20, 32]. Many studies have shown that a thick pancreas is a risk factor for CR-POPF when using a stapler for pancreas transection during DP [15, 17–20, 32]. Tissue tears or inadequate stapling of the pancreatic parenchyma might occur easily during transection of a thick pancreas. The efficacy of the slow parenchymal flattening technique or prolonged peri-firing compression technique for reducing the incidence of tissue tears or inadequate stapling has been reported [16, 23]. In addition, we hypothesized that it is important and effective to take one's time during pancreatic transection with slow firing. The median transection time was 16 min (8–29 min). However, the transection time was associated with the thickness of the pancreas (R^2 = 0.023, P < 0.0001), with a thick pancreas being transected more slowly than a thin pancreas. In addition, there may be a discrepancy between the value of the pancreas thickness evaluated based on preoperative CT and the actual value determined during the operation. Unfortunately, neither the actual data on the thickness nor the objective data on the hardness of the pancreas were available. Zimmitti et al. [33], in a video review analysis, found pancreatic capsule disruption and/or staple line bleeding to be risk factors for CR-POPF after LDP. In their study, the rate of CR-POPF was 21%, and the median pre-firing compression time was 75 s (20–246 s). Kawai et al. [28] also reported that staple line bleeding was an independent risk factor for CR-POPF while using the same stapler in our study. Despite these studies reporting staple line bleeding as an independent risk factor for CR-POPF, there were no patients with stapler bleeding that require intraoperative sutures in our study. Gentle and slow pancreatic transection in our method might be associated with secure and complete sealing of the stapler line. However, as described in the methods section, 2 (2.5%) of 79 patients had stapling failure with severe damage to the pancreatic parenchyma, and the procedure was converted to hand-sewn closure via small laparotomy. Of note, these pancreases were thick and hard, as we previously described [24]. The results were comparable to those of a prospective multicenter study by Kawai et al. [28], which reported that the rate of severe stapling failure was 2.9%. Inadequate stapling with severe damage to the pancreatic parenchyma at the stapling site can occur, especially in a thick and hard pancreas. Further improvement of the stapler device is warranted for such cases. It is important to have a reliable hand-sewn technique available for cases of stapling failure.

In our study, we used a black cartridge, which allowed a post-fire staple height of 4.0–5.0 mm in all cases. Although several recent studies focusing on optimal stapler cartridge selection according to the thickness of the pancreas have been reported, no suitable cartridge for thicker pancreases has yet been proposed [18–20]. Furthermore, in addition to pancreatic thickness, the fibrosis, hardness, and fatty infiltration may also affect the development of CR-POPF.

Several limitations associated with the present study warrant mention. Although the CR-POPF rate was low, this was a single-center retrospective study without a control group and with a relatively small sample size; therefore, it is difficult to reach a definitive conclusion. Despite these limitations, the strength of this study was based on the inclusion of only LDP cases (not open DP) with a coherent procedure using the same stapler and cartridge, in contrast to most previous studies that included various types of operations (laparoscopic and open DPs), staplers, and cartridge. In this regard, we believe that our results are reliable, with few technical biases. Furthermore, the CR-POPF rate of 5.5% was the lowest among recently reported studies [28–30].

In conclusion, the slow firing method with a reinforced triple-row stapler is simple, safe, and effective for preventing CR-POPF after LDP. A prospective multicenter randomized controlled study is required to confirm the efficacy of this method.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00595-021-02344-z.

Funding No grant support was provided for this study.

Declarations

Conflict of interest The authors have no conflicts of interest to disclose.

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