



# Modified Reinforced Staple Closure Technique Decreases Postoperative Pancreatic Fistula After Distal Pancreatectomy

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## Abstract

Postoperative pancreatic fistula (POPF) is a serious complication that can occur following distal pancreatectomy (DP). Recent studies demonstrated that the use of reinforced staplers with bioabsorbable mesh significantly reduced the incidence of POPF, although the safety and efficacy of this approach remain controversial. Therefore, we originally developed a modified closure technique that combines the use of a reinforced stapler with bioabsorbable mesh with suture closure of the main pancreatic duct. The aim of this study was to determine whether our closure technique is predictive of POPF after DP. Fifty-nine consecutive patients who underwent DP were retrospectively enrolled. Based on the closure technique, we divided the cohort into a suture group (group A;  $n = 39$ ) and a modified closure group (group B;  $n = 20$ ). Using multivariate analysis, surgical closure techniques, including our method, and other well-known POPF risk factors were independently assessed. Multivariate logistic regression analysis identified no pathological fibrosis (odds ratio [OR], 5.41;  $p < 0.01$ ), body mass index ( $> 25 \text{ kg/m}^2$ ) (OR, 3.01;  $p = 0.02$ ), and pancreatic stump closure technique (group A) (OR, 2.04;  $p = 0.01$ ) as independent risk factors for POPF. The present study indicated that our modified closure technique is an additional useful technique to reduce POPF after DP.

**Keywords** Distal pancreatectomy · DP · Pancreatic fistula · POPF · Staple closure

## Introduction

Distal pancreatectomy (DP) is the standard procedure performed for pancreatic diseases located in the body and/or tail of the pancreas, such as pancreatic ductal adenocarcinoma, cystic neoplasm, neuroendocrine neoplasm, and chronic pancreatitis. Recent advances in operative techniques and perioperative management have substantially decreased the postoperative mortality rates to less than 5% [1, 2]. Nevertheless, the postoperative morbidity rate remains high (30–40%), even in high-volume centers. Postoperative pancreatic fistula (POPF) is the most common major complication of DP, with a frequency ranging from 2 to 20% [3, 4]. POPF is associated with

numerous further complications, such as intra-abdominal abscesses, wound infection, sepsis, electrolyte imbalance, malabsorption, and hemorrhage, and with a dramatic increase in healthcare resource utilization. Therefore, reducing the rate of POPF has been an important but challenging goal for pancreatic surgeons.

Several risk factors for the development of clinically relevant POPF after DP have been defined and subsequently validated: patient-related factors, including older patients, male sex, high body mass index (BMI), history of diabetes, and preoperative low serum albumin level; pancreas-related factors, including pancreatic texture, thick pancreatic stump ( $> 12 \text{ mm}$ ), and malignant pathology; and surgery-related factors, including greater operation time, greater blood loss, blood transfusion, splenectomy, and the surgical closure technique for managing the pancreatic remnant [5–7].

In particular, the surgical closure technique is considered one of the most relevant risk factors for fistula formation. Several closure techniques have been introduced for pancreatic remnants in an attempt to reduce POPF [8–13]. These include hand-sewn suture closure, transection and closure using various stapling devices, a combination of staple closure and reinforcement of the stump with sutures or a seromuscular

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patch, pancreatic enteric anastomosis, and the use of fibrin sealants. However, no technique has been able to reduce fistula rates reproducibly, and none has been identified as being consistently superior to the others [14].

Recently, a reinforced stapler with bioabsorbable mesh was produced to provide additional support for the tissue at the resection line by overlaying the staple line with reinforcement [15–18]. Several studies demonstrated that reinforced staplers significantly reduced the incidence of pancreatic fistula compared with stapler closure without reinforcement, although its add-on effect on the reduction of POPF did not yield satisfactory outcomes. To solve this problem, we originally developed a modified closure technique that combines a reinforced stapler with bioabsorbable mesh with suture closure of the main pancreatic duct (MPD).

In this study, univariate and multivariate analyses were performed to identify potential risk factors for POPF, with special emphasis on the developed closure technique by comparing various patient-, pancreas-, and surgery-related factors in a retrospective cohort.

## Materials and Methods

### Patients

We retrospectively evaluated 59 consecutive patients who underwent DP at the Tsukuba Medical Center Hospital, Tsukuba, Japan, between January 2007 and May 2018. The ethics committee of the Tsukuba Medical Center Hospital approved this study. Until December 2015, we routinely performed a hand-sewn suture closure technique for pancreatic stump closure. Since January 2016, we have employed our modified closure technique to combine the use of a reinforcing stapler with hand-sewn sutures. Therefore, we divided the cohort into a suture group (group A;  $n = 39$ ) and a modified closure group (group B;  $n = 20$ ) based on the pancreatic stump closure technique.

The following patient characteristics were compared between the two groups: age, sex ratio, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of diabetes, preoperative serum albumin level, and primary disease. Because these factors can also influence the incidence of POPF, we collected additional data regarding splenectomy, pancreatic texture, thickness of the pancreatic stump, and perioperative outcomes, including operating time, intraoperative blood loss, and intraoperative blood transfusion [4–7, 19, 20]. We defined the pancreatic texture and the thickness of the pancreatic stump according to the intraoperative findings or the pathologic status of the pancreatic parenchyma.

### Patient-, Pancreas-, and Surgery-Related POPF Risk Factors

In addition to these modified closure techniques, we analyzed the relationship between the POPF and previously reported POPF risk factors, including patient-, pancreas-, and surgery-related factors, in different treatment phases. Cut-off values for each categorical or continuous value were defined according to previously reported values or an ROC curve analysis [4–7, 19, 20].

Several risk factors for the development of clinically relevant POPF have been defined and subsequently validated: patient-related risk factors, including elder patient, male sex, high BMI, high ASA score, history of diabetes, and low preoperative serum albumin level; pancreas-related factors, including pancreatic pathological fibrosis, thickness of the pancreatic stump ( $>12$  mm), and malignant pathology; and surgery-related factors, including greater operation time, greater blood loss, blood transfusion, and splenectomy. POPF was defined in accordance with the guidelines of the International Study Group on Pancreatic Fistula [21]. The incidence of POPF was also defined as grade B or C POPF.

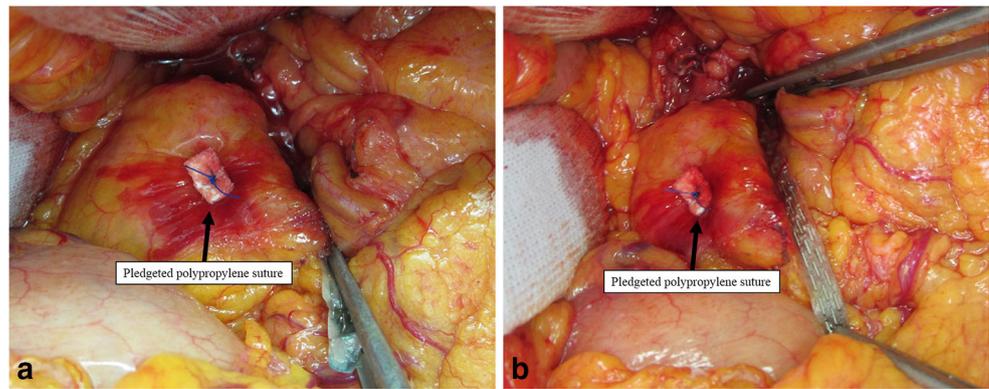
### Surgical Procedures

The reinforced stapler with bioabsorbable materials used in this study was a linear stapling device with preattached polyglycolic acid (PGA) felt (Endo GIA™ Reinforced Reload with Tri-Staple™; black reload; 60-mm long; Medtronic plc, Dublin, Ireland). This stapler was used in conjunction with a reinforcing sheet of Neoveil® (Gunze, Kyoto, Japan). The material structure of Neoveil® consists of PGA. Previous studies have already reported that the use of a linear stapling device with preattached PGA felt for pancreatic stump closure during DP was feasible and significantly suppressed POPF [15, 16]. Furthermore, gentle prefiring compression of the pancreatic parenchyma has been reported to decrease the incidence of POPF after DP [22]. The pancreatic parenchyma was slowly compressed with forceps and staplers at the site of resection for a period of 10 min before transection of the pancreatic parenchyma. The staplers were not released immediately after firing, and their jaws were held shut for 10 min.

In addition to the use of the reinforced stapler, we appended hand-sewn suturing of the MPD. We first detected the MPD 10 mm away from the staple line using intraoperative ultrasonic guidance. Next, a 3–0 one-quarter-circle curved needle was used to penetrate the full thickness of the pancreatic parenchyma and bind the MPD to the posterior wall. Finally, a pledgeted polypropylene suture was horizontally placed on the pancreatic anterior wall (Fig. 1a, b).

In the hand-sewn suture closure technique, the remnant of the pancreatic stump was cut and closed with 4–0 or 5–0

**Fig. 1 a, b** Intraoperative findings in distal pancreatectomy. The pancreas was closed using the reinforced stapler with bioabsorbable mesh. A pledgeted polypropylene suture was horizontally placed on the pancreatic anterior wall (arrow)



monofilament interrupted single sutures or U-sutures in a “fish-mouth” fashion [23]. The MPD on resected pancreatic surface was manually ligated. Two drainage tubes were placed superiorly and inferiorly to the pancreatic stump. All surgical procedures were performed under the supervision of one or two senior pancreatic surgeons.

### Perioperative Management

The management of the drains and checking of the amylase levels in the drainage fluid were standardized in this study. The drain was inserted until at least postoperative day (POD) 3 and was removed by POD 5 if the drainage fluid was clear and both pancreatic fistula and bacterial contamination were absent. The amylase levels in the drainage fluid were routinely measured on POD 1 and 3 in all patients with DP. Prophylactic octreotide to prevent pancreatic fistula was not administered in this study. All patients received prophylactic antibiotic either intraoperatively or for 1 or 2 days postoperatively.

### Statistical Analyses

Correlations with patient background data were analyzed using a  $\chi^2$  test or Fisher’s exact test, as appropriate. For the multivariate analysis, a multiple logistic regression analysis yielding odds ratios and 95% confidence intervals (CIs) was used to identify risk factors for POPF (with  $p$  values  $< 0.05$ ). Statistical analyses were performed using a statistical analysis software package (SPSS Statistics, version 21; IBM, Armonk, NY, USA), and  $p$  values  $< 0.05$  were considered significant.

## Results

### Patient Backgrounds

The backgrounds of the patients in the two groups are presented in Table 1. Significant differences were observed between the two groups with regard to operating time ( $p < 0.01$ ),

intraoperative blood loss ( $p = 0.02$ ), and intraoperative blood transfusion ( $p < 0.01$ ).

### Univariate analyses for POPF risk factors in different treatment phases (Table 2)

In terms of patient-related risk factors, BMI (high, 13 (45%) vs. low, 3 (10%),  $p < 0.01$ ) and history of diabetes (yes, 7 (64%) vs. no, 9 (19%),  $p = 0.01$ ) showed significant differences with respect to incidence of POPF.

In terms of pancreas-related risk factors, pathological fibrosis (yes, 10 (20%) vs. no, 6 (60%),  $p < 0.01$ ) and thickness of the pancreatic stump ( $> 12$  mm, 12 (39%) vs.  $< 12$  mm, 4 (14%),  $p = 0.03$ ) showed significant differences with respect to the incidence of POPF.

In terms of surgery-related risk factors, operating time ( $> 212$  min, 11 (39%) vs.  $< 212$  min, 5 (16%),  $p = 0.04$ ), intraoperative blood loss volume ( $> 238$  g, 12 (44%) vs.  $< 212$  g, 4 (13%),  $p = 0.03$ ), and type of pancreatic stump closure technique (group A, 14 (36%) vs. group B, 2 (10%),  $p = 0.03$ ) showed significant differences with respect to the incidence of POPF.

### Multivariate analysis (Table 3)

Multivariate logistic regression analysis only identified no pathological fibrosis (odds ratio [OR], 5.41;  $p < 0.01$ ), BMI ( $> 25$  kg/m<sup>2</sup>) (OR, 3.01;  $p = 0.02$ ), and pancreatic stump closure technique (group A) (OR, 2.04;  $p = 0.01$ ) as independent risk factors for POPF.

## Discussion

In the present study, we found that our modified closure technique significantly reduced the incidence of POPF compared with the suture closure technique. Furthermore, our multivariate analysis indicated that the pancreatic stump closure technique was a risk factor for POPF, in addition to no pancreatic fibrosis and BMI ( $> 25$  kg/m<sup>2</sup>). Therefore, we concluded that

**Table 1** Patient characteristics

Factors	Group A (n = 39)	Group B (n = 20)	p value
Age	58 (34–86)	59 (39–82)	0.31
Sex ratio (male:female)	20: 19	11:9	0.24
BMI (kg/m <sup>2</sup> )	23.7 ± 2.25	22.6 ± 2.16	0.54
ASA score (1–4)	1 (1–3)	1 (1–3)	0.56
History of diabetes	7 (18%)	4 (20%)	0.72
Preoperative serum albumin level (mg/dL)	4.0 ± 0.67	3.8 ± 1.12	0.32
Primary disease			
Pancreatic cancer	18 (46%)	9 (23%)	
IPMN	6 (15%)	4 (20%)	
MCN	5 (13%)	2 (10%)	
SCN	3 (7.6%)	2 (10%)	0.51
NET	3 (7.6%)	2 (10%)	
Pancreatitis	2	(5.1%)	0
Others	2 (5.1%)	1 (5%)	
Splenectomy	31 (80%)	17 (85%)	0.81
Pancreas texture (hard:soft)	32:7	17:3	0.32
Thickness of pancreatic stump (mm)	21 ± 3.23	18 ± 3.18	0.52
Operating time (minutes)	223 ± 65.5	182 ± 43.2	< 0.01*
Intraoperative blood loss (g)	311 ± 192	205 ± 81	0.02*
Intraoperative blood transfusion	4	1	< 0.01*

BMI, body mass index; ASA, American Society of Anesthesiology; IPMN, intraductal papillary mucinous neoplasm; MCN, mucinous cystic neoplasm; SCN, serous cystic neoplasm; NET, neuroendocrine tumor

\* $p < 0.05$

our modified closure technique is an additional useful technique to reduce POPF after DP.

Recent technical advances in safely performing laparoscopic DP for benign and/or malignant pathology have led to the use of staple devices becoming a more common method of transection [20, 24]. The published DISPACT trial demonstrated in a randomized, controlled fashion that stapled closure is as safe as hand-sewn suturing of the pancreatic stump [14]. The rationale for reinforcing the stapled closure with mesh was initially based on the successful reduction of leaks achieved in other areas of surgery, including lung reduction and gastric bypass [25, 26]. In terms of pancreatic resection, Kurahara et al. and Hamilton et al. reported that mesh reinforcement of the pancreatic stump decreased POPF after DP [17, 27]. Subsequently, a randomized controlled trial (RCT) reported that reinforced staplers significantly reduced clinically relevant POPF after DP [18, 28]. Meanwhile, a meta-analysis regarding the efficacy of reinforced staplers in DP concluded that no significant difference regarding clinically relevant POPF was observed between stapler closure with and without reinforcement [23, 29]. Therefore, the safety and efficacy of using reinforced staplers with bioabsorbable materials for DP remain controversial.

Questions regarding the mechanisms by which our modified closure technique significantly reduced the incidence of POPF compared with suture closure remain unanswered. One

possible reason is that our modified closure technique improved perioperative outcomes, which are well-known POPF risk factors [4–7]. Although the hand-sewn suturing closure technique has the assumed advantage of the easy identification, access, and separate ligation of the MPD, it is time consuming and technically not feasible on the soft, fragile pancreatic parenchyma. We assumed that the routine use of the staple device could contribute to both the standardization of surgical procedures and a reduction in the time required for procedures. In fact, our modified closure group showed a positive correlation with surgery-related POPF risk factors, including operating time ( $p < 0.01$ ), intraoperative blood loss ( $p = 0.02$ ), and intraoperative blood transfusion ( $p < 0.01$ ) (see Table 1).

In addition, we assumed that the incidence of POPF after DP partially resulted from MPD stapling errors at the pancreatic stump. Previously, an appropriate combination of stapler cartridge size and thickness of the pancreatic parenchyma was reported to be one of the important considerations during staple closures [15, 30]. Kawai et al. previously reported that a pancreas thickness greater than 12 mm significantly increased POPF after DP using stapler closure [31]. Shorter staple height may cause laceration or dehiscence of hard or thick pancreatic parenchyma. Conversely, a taller staple height may inadequately seal the pancreatic parenchyma, including the MPD, and result in leakage or bleeding from the pancreatic stump.

**Table 2** POPF risk factors at different treatment phases

Parameter	Cut-off value	No. of patient	None and grades A POPF	Grades B and C POPF	<i>p</i> value
Patient-related risk factors					
Age					
High	60	30	21	9	0.42
Low		29	22	7	
Sex					
Male		31	23	8	0.62
Female		28	20	8	
BMI (kg/m <sup>2</sup> )					
High	25	29	16	13	< 0.01*
Low		30	27	3	
ASA score (1–4)					
High	2	31	23	8	0.26
Low		28	20	8	
History of diabetes					
Yes		11	4	7	0.01
No		48	39	9	
Preoperative albumin level (mg/dL)					
High	3.5	28	19	9	0.08
Low		31	22	9	
Pancreas-related risk factors					
Pathological fibrosis					
Yes		49	39	10	< 0.01*
No		10	4	6	
Thickness of pancreatic stump (mm)					
High	12	31	19	12	0.03
Low		28	24	4	
Malignant pathology					
Yes		31	22	9	0.31
No		28	21	7	
Surgery-related risk factors					
Operating time (min)					
High	212	28	17	11	0.04
Low		31	26	5	
Intraoperative blood loss volume (g)					
High	238	27	15	12	0.03
Low		32	28	4	
Intraoperative blood transfusion					
Yes		5	3	2	0.49
No		54	40	14	
Splenectomy					
Yes		50	37	13	0.33
No		9	6	3	
Pancreatic stump closure technique					
Group A		39	25	14	0.03
Group B		20	18	2	

POPF, postoperative pancreatic fistula; BMI, body mass index; ASA, American Society of Anesthesiology

\**p* < 0.05

**Table 3** Multivariate analyses of POPF risk factors

Parameter	Odds ratio	95% CI	<i>p</i> value
BMI (> 25 kg/m <sup>2</sup> )	3.01	1.27–5.62	0.02*
History of diabetes	1.01	0.61–1.65	0.98
No pathological fibrosis	5.41	2.20–8.22	< 0.01*
Thickness of pancreatic stump (> 12 mm)	0.97	0.34–2.78	0.96
Operating time (> 212 min)	0.74	0.35–1.44	0.31
Intraoperative blood loss volume (> 238 g)	0.79	0.42–1.56	0.15
Pancreatic stump closure technique (group A)	2.04	1.02–3.59	0.01*

CI, confidence interval; BMI, body mass index

\**p* < 0.05

To overcome MPD stapling errors, we originally added the hand-sewn MPD ligation to the staple closure method. A previous report indicated that ligation of the MPD contributed to a reduction in POPF after DP [32]. In fact, our multivariate analysis indicated that the pancreatic stump closure technique was a strong risk factor for POPF (OR, 2.04; Table 3).

Our modified closure technique has several difficulties that must be addressed. First, both the thickness and softness of the pancreas should be taken into consideration simultaneously for the safe compression of the pancreatic parenchyma using staplers. In our multivariate analysis, soft pancreas texture without pathological fibrosis was the strongest risk factor for POPF (OR, 5.41; Table 3). Hirashita et al. suggested that gentle prefiring compression of the pancreatic parenchyma could contribute to a reduction in the occurrence of POPF after DP [22]. Kleeff et al. reported that mechanical stapling could crush the soft pancreatic parenchyma, thus leading to the subsequent leakage of pancreatic juice from the branch pancreatic duct and later resulting in POPF [5]. Therefore, the mechanical jaw of the stapler should be closed gently, and the pancreas should be cut slowly to avoid causing any tissue damage. Furthermore, the stapler should not be released immediately after firing. Second, hand-sewn suturing of the MPD may cause laceration or dehiscence of hard or thick pancreatic parenchyma. Therefore, the MPD ligation technique was required to perform gentle ligation according to the texture or thickness of the pancreatic parenchyma.

## Conclusion

We propose that our modified closure technique combining the use of a reinforced stapler with bioabsorbable mesh with suture closure of the MPD is an additional useful technique for reducing POPF after DP. The present study has several limitations. Because this study was a retrospective, single-center study with a relatively small patient cohort, these results will need to be prospectively confirmed by additional multicenter, large-scale studies. A randomized controlled study would be the most effective way to evaluate the impact of our modified

closure technique combining the use of a reinforced stapler with bioabsorbable mesh with suture closure of the MPD compared with that of staplers without suture closure.

## Compliance with Ethical Standards

The ethics committee of the Tsukuba Medical Center Hospital approved this study.

**Conflict of Interest** The authors declare that they have no conflicts of interest.

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