Reinforced stapler versus ultrasonic dissector for pancreatic transection and stump closure for distal pancreatectomy: A propensity matched analysis

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ABSTRACT

Background: Postoperative pancreatic fistula is the primary contributor to morbidity after distal pancreatectomy. To date, no techniques used for the transection and closure of the pancreatic stump have shown clear superiority over the others. This study aimed to compare the rate of postoperative pancreatic fistula after pancreatic transection conducted with a reinforced stapler versus an ultrasonic dissector after a distal pancreatectomy.

Method: Prospectively collected data of consecutive patients who underwent distal pancreatectomy from 2014 to 2017 were reviewed retrospectively. We included distal pancreatectomies in which pancreatic transection was performed by reinforced stapler or ultrasonic dissector; we excluded extended distal pancreatectomies. To overcome the absence of randomization, we conducted a propensity matching analysis according to risk factors for postoperative pancreatic fistula.

Results: Overall, 200 patients met the inclusion criteria. The reinforced stapler was employed in 108 patients and the ultrasonic dissector in 92 cases. After one-to-one propensity matching, 92 patients were selected from each group. The matched reinforced stapler and ultrasonic dissector cohort had no differences in baselines characteristics except for the mini-invasive approach, which was more common in the ultrasonic dissector group (34% vs 51%, $P = .025$). Overall, 48 patients (26%) developed a postoperative pancreatic fistula, 46 (25%) a grade B postoperative pancreatic fistula, and 2 (1%) a grade C postoperative pancreatic fistula. In the reinforced stapler group, the rate of postoperative pancreatic fistula was 12% ($n = 11$) and in the ultrasonic dissector group 40% ($n = 37$) with a $P < .001$.

Conclusion: The results of this study suggest that the use of reinforced stapler for pancreatic transection decreases the risk of postoperative pancreatic fistula. A randomized trial is required to confirm these preliminary data.

Introduction

Distal pancreatectomy (DP) is a procedure characterized by low mortality, but its morbidity remains high, ranging between 32% and 40%.[1–5] Postoperative pancreatic fistula (POPF) is the primary contributor to morbidity after pancreatic surgery, and its progression may lead to severe complications such as hemorrhage, abdominal abscess, and when not adequately drained, sepsis and death.[1,3,4,6–9] Several risk factors for POPF after DP have been identified, such as high body mass index (BMI), "soft" pancreatic parenchyma, prolonged operative time, and substantial blood loss.[10–14] These factors, however, are mostly nonmodifiable or reflect a challenging operative procedure, with little opportunity to prevent a POPF. For these reasons, most of the efforts in decreasing the POPF rate after DP have been focused on the management of the pancreatic remnant in an attempt to minimize the pancreatic leak after the parenchymal transection. With this aim, several techniques have been proposed, such as the anastomosis of the

pancreatic stump with the stomach or the jejunum, a handsewn closure, pancreatic transection and closure using various devices (such as a mechanical stapler or the ultrasonic dissector), use of fibrin sealant, and use of a "patch" reinforcement using the omentum or falciform ligament.[7,8,15–23] None of these techniques have demonstrated a clear superiority of one technique over the others.[7,8,15–18,20,23]

During the past few years, the use of stapler devices has been adopted increasingly because of the more frequent use of minimally invasive approaches and because of the easy, fast, and reproducible mechanism of action of these staplers. Conversely, several centers, including our institute, have used the ultrasonic dissector during the entire operative procedure, including the pancreatic transection, because of its lesser costs with comparable reported benefits in terms of postoperative morbidity.[14,24,25]

Recently a new category of reinforced staplers (RSs) with an integrated bioabsorbable polyglycolic acid (PGA) felt has been proposed, with preliminary data showing a decrease in the overall incidence and severity of POPF compared with the "bare" stapler.[26] The superiority of this RS with respect to the ultrasonically dissector (US) has not been demonstrated yet.[27] With this study, we aimed to evaluate whether the pancreatic transection with an RS would decrease the incidence of POPF after DP compared with the ultrasonic dissector in a retrospective series matched by risk factors for POPF.

Methods

Study design

Approval for data collection and analysis for this study was obtained from our institutional review board. Prospectively collected data of consecutive patients who underwent open or minimally invasive DP from January 2014 to January 2017 with pancreatic transection performed by RS or UD were reviewed retrospectively. Exclusion criteria were age younger than 18 years, pancreatic transection performed with other techniques, and extended DPs in which pancreatic transection has been performed to the right of the superior mesenteric vein or portal vein junction. We decided to exclude these procedures because of the greater risk of complications, such as bleeding, the possibility of developing a biliary leak, and the greater thickness of pancreatic parenchyma at this level than at the pancreatic neck.

To overcome the absence of randomization, we performed a propensity matching analysis according to specific, preoperative and intraoperative variables associated with the development of POPF after DP, including BMI, intraoperative blood loss, and operative time (Fig 1).[10] Although pancreatic texture has been widely recognized as a risk factor for POPF, it was not included in the matching analysis because of the difficulty to classify the pancreatic texture in patients receiving the minimally invasive approach.

The primary end point of this study was the evaluation of the POPF rate. Secondary outcomes evaluated were the rate of biochemical leak (BL),[28] postpancreatectomy hemorrhage (PPH),[29] abdominal collection, pulmonary complication, interventional drainage (ID), reoperation, intensive care unit (ICU) admission, hospital readmission within 1 month from the operation, duration of hospital stay, and 30-day inhospital mortality rate.

Operative procedure

Open DP was performed for cases of malignant neoplasms, and the minimally invasive approach with or without splenic preservation was reserved for patients with selected benign tumors. Video-laparoscopic and robotic-assisted DP were carried out as
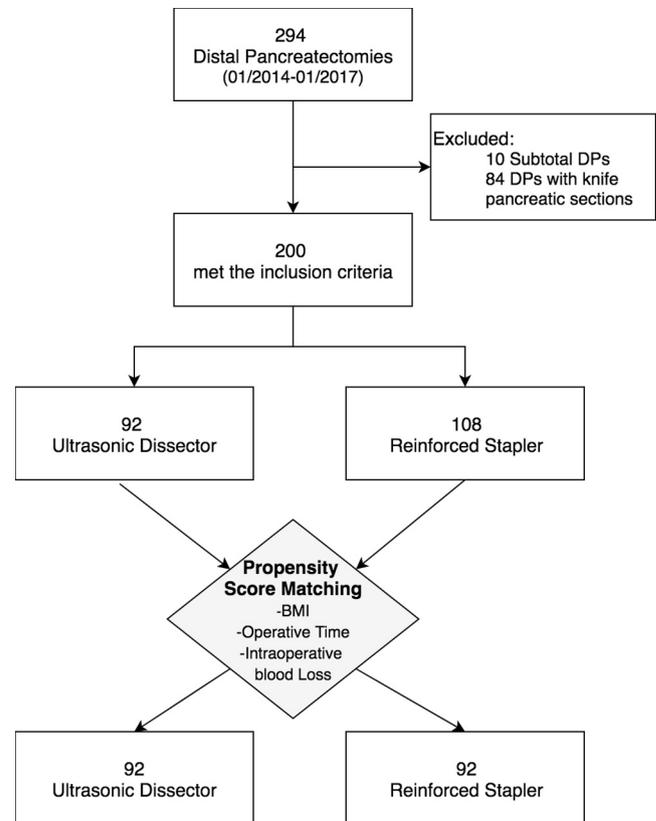

Fig 1. Flowchart summarizing the study design.

described elsewhere by our group.[19,30] In both groups, the pancreas was transected at the level of the pancreatic neck, and the choice to transect with UD and RS was performed according to the surgeon preference. In the RS group, pancreaatic transection was performed with a triple row stapler reinforced with a PGA felt (NEOVEIL Endo GIA Reinforced Reload with Tri-Staple Technology 60 mm, COVIDIEN, North Haven, CT, USA), using the purple (3 mm) or the black (4 mm) cartridge according to surgeon judgment regarding the thickness at the pancreatic transection line. Before the parenchyma was cut, it was compressed directly with the stapler for about 2 to 3 minutes and then released slowly after the transection. In the UD group, the pancreas was transected using the ultrasonic dissector (HARMONIC, Johnson & Johnson Medical, Ethicon, Tokyo, Japan) at the lowest vibration level for the full duration of the pancreatic dissection. In both techniques, no additional sutures were placed into the pancreatic stump or the main pancreatic duct. At the end of the DP, at least 1 silicone drain was placed close to the pancreatic remnant.

Data collection

Demographic, radiologic, operative, pathologic, and postoperative data were recorded in a prospective database and included the following: (1) preoperative characteristics, such as as BMI, neoadjuvant therapy, the thickness of the pancreatic neck measured at the preoperative computed tomography; (2) intraoperative characteristics, such as the operative approach, vascular resection, multiorgan resection, duration of operation, blood loss, and need for transfusion; (3) pathologic characteristics of the tumor; and (4) postoperative outcomes as POPF, biochemical leak, postpancreatectomy hemorrhage, abdominal collection, pulmonary complication, and death, as well as the need for operative re-

Table I
Baseline, intraoperative, and pathology characteristics of study population

Characteristic	All (n = 200)	All patients (n = 200)			Matched patients (n = 184)		
		Ultrasonic dissector (n = 92)	Reinforced stapler (n = 108)	P	Ultrasonic dissector (n = 92)	Reinforced stapler (n = 92)	P
Age, years, median (IQR)	58 (74–69)	55 (46–67)	60 (47–70)	.335	55 (46–67)	58 (46–68)	.638
Male, number (%)	87 (44)	38 (41)	49 (45)	.571	38 (41)	53 (58)	1.000
BMI > 25, number (%)	103 (52)	56 (61)	47 (44)	.016	56 (61)	47 (51)	.235
Neoadjuvant therapy, number (%)	17 (9)	6 (7)	11 (10)	.449	6 (7)	9 (10)	.591
Pancreas thickness, mm, median (IQR)	16 (13–20)	15 (13–20)	16 (12–20)	.821	15 (13–20)	17 (13–20)	.513
Minimally invasive procedure, number (%)	84 (42)	47 (51)	37 (34)	.021	47 (51)	31 (34)	.025
Spleen preserving, number (%)	23 (12)	14 (15)	9 (8)	.181	14 (15)	9 (10)	.373
Vascular resection, number (%)	11 (6)	5 (5)	6 (6)	1.000	5 (5)	4 (4)	1.000
Multiorgan resection, number (%)	23 (12)	10 (11)	13 (12)	.828	10 (11)	9 (10)	1.000
Duration of surgery, minutes, median (IQR)	242 (200–300)	248 (196–309)	240 (201–299)	.962	248 (196–309)	240 (195–289)	.622
Blood loss, number (%)				.045			.509
≤200	125 (62.5)	66 (72)	59 (55)		66 (72)	59 (64)	
200–500	61 (30.5)	22 (24)	39 (36)		22 (24)	29 (32)	
>500	14 (7)	4 (4)	10 (9)		4 (4)	4 (4)	
Pathology, number (%)				.312			.332
PDAC	51 (25.5)	19 (20.7)	32 (29.6)		19 (20.7)	27 (29.3)	
PanNET	63 (31.5)	29 (31.5)	34 (31.5)		29 (31.5)	29 (31.5)	
Cystic Neoplasm	50 (25)	29 (31.5)	21 (19.4)		29 (31.5)	18 (19.6)	
IPMN	14 (7)	7 (7.6)	7 (6.5)		7 (7.6)	5 (5.4)	
Renal carcinoma metastasis	5 (2.5)	1 (1.1)	4 (3.7)		1 (1.1)	3 (3.3)	
Other	17 (8.5)	7 (7.6)	10 (9.3)		7 (7.6)	10 (10.9)	

IPMN, intraductal papillary mucinous neoplasia; IQR, interquartile range; PanNET, pancreatic neuroendocrine tumor; PDAC, pancreatic adenocarcinoma.

exploration, interventional drainage, ICU management, and hospital readmission. The data were collected for the duration of the hospitalization and after discharge up to 30 days from the operation. Pancreatic neoplasms were classified according to the World Health Organization classification of the exocrine and endocrine neoplasms of the pancreas.[31] Postoperative complications were graded according to the Clavien–Dindo classification.[32] The POPF was defined according to the 2016 International Study Group of Pancreatic Surgeons definition and classification.[28]

Statistical analysis

The one-to-one matching analysis between the RS and the UD groups was performed to minimize bias attributable to the nonrandom allocation of the device among patients. Patients were matched using a logistic regression model including risk factors for POPF after DP. The propensity score summarizes covariates in a single variable that was included in the analyses of outcomes across the two groups. Each patient in the RS group was matched with a patient who underwent transection with UD with the nearest estimated propensity score to obtain a uniform distribution of the covariates between groups.

Continuous variables were reported as median and interquartile range (IQR). Comparative analysis between groups was conducted using the χ^2 or Fisher exact tests for categorical variables, and the Mann–Whitney U test was used for continuous variables. Data were analyzed using the Statistical Package for the Social Sciences 24.0 for Windows (SPSS, Inc, Chicago, IL, USA).

Results

In the study period, 200 patients who had undergone DP met the inclusion criteria (Fig 1). Among these, in 108 patients, the pancreas was transected using the RS, and in 92, the UD was used. The 2 populations had several differences in clinical and intraoperative characteristics (Table I). After the one-to-one propensity matching, 92 pairs of patients were selected from each group (Fig 1), and on univariate analysis, no differences were found between groups in terms of demographic, clinical characteristic, and
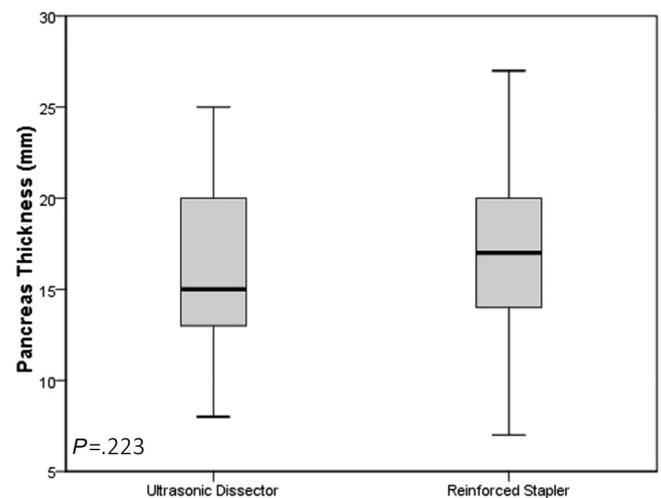
Fig 2. Box-and-whisker plot. Distribution of pancreatic thickness at the neck estimated based on the preoperative, cross-sectional imaging and grouped according to the technique of pancreatic transection. The middle of the box represents the median value, the extremity of the plots the minimum and maximum value.

tumor pathology (Table I). Also, the estimated pancreatic thickness at the pancreas neck was similar among the RS and UD cohort (P = .223; Fig 2), as were the rate of vascular and multiorgan resection, the duration of operation, and the blood loss (Table I). Only the rate of patients who underwent a minimally invasive approach was different between the cohorts, being more common in the UD group (UD 51% vs RS 34%, P = .025). Significant differences were observed for each group according to different periods, (P < .001; Fig 3) and according to the surgeon who performed the procedure (P < .001).

Primary end point

Overall, 48 patients (26%) developed a POPF. Of those, 46 (25%) had a grade B and 2 (1%) a grade C fistula. Comparing the 2 groups,
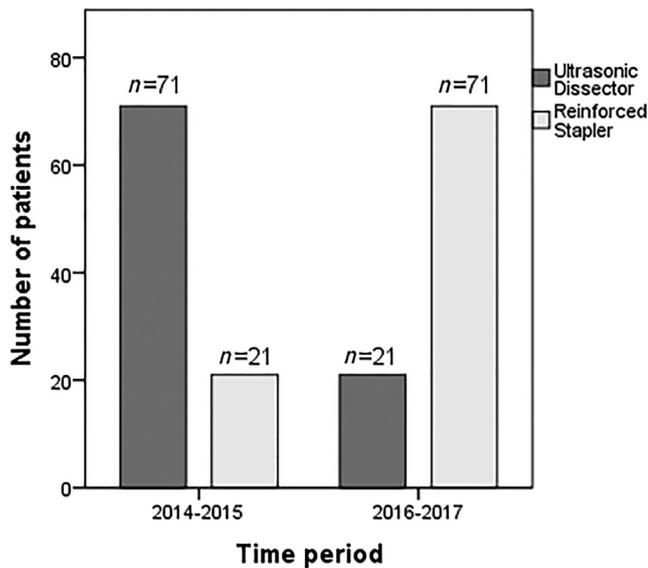
Fig 3. Use of ultrasonic dissector and reinforced stapler during the study period.

the rate of POPF was less in the RS group than in the UD group (12% vs 40%; $P < .001$). No grade C fistula was observed in the RS group (Table II).

Secondary end points

Overall, BL occurred in 26 patients (14%), 16 patients (17%) in the RS group, and 10 (11%) in the UD group ($P = .290$). Among operative complications, the development of an abdominal collection was the most frequent, occurring in 65 patients (35%). These collections required ID in only 11 cases (6%). Between the 2 groups, there were no differences in terms of abdominal collections, need for ID placement of a drain, and abdominal or pulmonary complications (Table II). The duration of stay was similar between RS and UD ($P = .498$). We observed 1 postoperative death that occurred in the RS group. This patient was an 80-year-old woman with multiple comorbidities and a history of several abdominal operations for gastric cancer and renal cell carcinoma. She had a DP for a neuro-endocrine tumor and developed early pancreatitis of the pancreatic remnant followed by bowel perforation, sepsis, and disseminated intravascular coagulation. She eventually died on postoperative day

22. Overall, 15 patients (8%) underwent operative reoperation (Table II). The most common cause was bleeding that occurred in 9 of 15 patients. Other causes were intestinal perforation (4 of 15) and bowel obstruction (2 of 15).

Discussion

The surgical management of the pancreatic stump after DP has been widely debated in the literature for years, whereas the majority of comparative studies failed to prove the superiority of one technique over the other.[7,8,15,18,33]

In this study, we compared the rate of pancreatic fistula after DP, using the RS or the UD for the pancreatic transection in two retrospective matched cohorts. We observed that the use of RS was associated with a decrease in the rate of POPF by 28%, with a 26% decrease in grade B POPF. The development of pancreatic fistula after DP is believed to be a consequence of the pancreatic juice leaking from secondary ducts rather than a leak from an unsealed main pancreatic duct. Both the RS and the UD have the advantage of promoting the sealing of both the main and the secondary ducts at the same time; however, the RS employed in this study was also reinforced with a preloaded PGA felt that might have contributed in decreasing the rate of POPF in the RS cohort. A randomized clinical trial[34] has already shown that wrapping the pancreatic stump with a PGA mesh also decreases the rate of POPF. Similar results have been also reported by Hamilton et al[35] in a randomized trial, where the addition of a mesh buttress reinforcement on the pancreatic stump was associated with a decrease in B- or C- grade POPF compared with the use of the bare stapler alone. Finally, the RS used in this study has a triple-row staple line that might have further contributed to decreasing the rate of POPF. In a retrospective study, Sugimoto et al[36] observed that the triple-row stapler was associated with lesser rates of POPF compared with the double-row staplers. In the present study, however, we compared two completely different technologies, and it was therefore not possible to establish whether the decrease in the rate of POPF was related to the triple-row sewing mechanism, to the reinforced material, or to their combination. Also, the technique used during the stapler closure seems relevant to allow the proper tissue compression and help to avoid the development of a POPF. Several authors[3,37] have suggested that firing of the stapler immediately after application without a gentle, slow increase in the compression during application might be harmful, potentially promoting the development of POPF by crushing and tearing the pancreatic parenchyma at the edge of the stump. Therefore, Nakamura et al[37] suggest flattening

Table II
Outcomes of matched patients who underwent pancreas transection and closure with ultrasonic dissector and reinforced stapler

Outcome	All (n = 184)	Ultrasonic dissector (n = 92)	Reinforced stapler (n = 92)	P
Pancreatic fistula, number (%)	48 (26)	37 (40)	11 (12)	< .001
Pancreatic fistula grade, number (%)				
Grade B	46 (25)	35 (38)	11 (12)	< .001
Grade C	2 (1)	2 (2)	0 (0)	.497
Biochemical leak, number (%)	26 (14)	10 (11)	16 (17)	.290
PPH, number (%)	22 (12)	14 (15)	8 (9)	.256
Abdominal collection, number (%)	65 (35)	39 (42)	26 (28)	.064
Interventional drainage, number (%)	11 (6)	8 (9)	3 (3)	.212
Reoperation, number (%)	15 (8)	11 (12)	4 (4)	.103
Pulmonary complication, number (%)	47 (26)	26 (28)	21 (23)	.499
ICU admission, number (%)	18 (10)	8 (9)	10 (11)	.805
30-day mortality, number (%)	1 (0.5)	0 (0)	1 (1)	1.000
Readmission, number (%)	17 (9)	7 (8)	10 (11)	.612
Duration of stay, median (IQR), days	8 (7-12)	9 (6-14)	8 (7-13)	.498
Clavien-Dindo ≥3, number (%)	29 (16)	19 (21)	10 (11)	.104

IQR, interquartile range; PPH, postpancreatectomy hemorrhage.

the pancreatic parenchyma during the procedure to promote the sealing of the pancreatic surface to minimize parenchymal injury. According to this technique, we gradually compressed the pancreatic neck with the stapler for about 2 to 3 minutes. We then cut the parenchyma and released the device slowly.

Only two other studies have evaluated the use of RS for DP with small cohorts and contradictory results. In a retrospective study, Karabicak et al[27] compared the rate of POPF in 36 cases of DP performed by RS and 89 by UD with the pancreatic duct closed with a transfixing suture. Although the authors found no decrease in the rate of POPF in the RS group compared with UD, a second study by Yamashita et al[26] showed that the RS decreased the rate of B or C POPF compared with the bare stapler, but it was not clear whether the cohorts were balanced for POPF risk factors.

Regarding the secondary outcomes, we observed in the RS group a lesser rate of abdominal collections, need for interventional drainage, and reoperations than patients in the UD group, but our study was underpowered to achieve any statistical validity (power is ranging between 40% and 51%), and we estimated the need of a minimum of 490 patients to confirm these differences with a power 80%, an α of 0.05, and a β of 0.2). In addition, despite the decrease in the rate of POPF, we were not able to demonstrate a decrease in hospital duration of stay in the RS group. We can explain this finding by the fact that, in our institution, the duration of stay is not a reliable parameter of opertive outcomes because the duration of stay is influenced by many external factors. Indeed, our hospital is a high-volume center for pancreatic surgery that serves patients from throughout Italy. In this setting, patients are often kept in the hospital for a greater time postoperatively when they are unable to travel far or need to be seen back in the clinic in the very near future. Other centers have pointed out this issue recently, and the time to functional recovery after an operation has been proposed as a more objective outcome measure than hospital stay.[38]

Our study has several limitations. First, patients were not allocated randomly to 1 technique or the other. Although the 2 groups were well matched for risk factors for POPFs, other uncounted or unrecognized variables may have contributed to our results. For example, the pancreatic texture was not included as a matching variable because it could not be evaluated accurately during the minimally invasive procedures (42%). No DP was performed for chronic pancreatitis. Thus it is reasonable to assume that most of the patients in this cohort had a soft pancreatic texture. In addition, minimally invasive procedures were not equally distributed between the cohorts. Although the operative approach is not believed to be associated with the development of a POPF,[38] we performed a subgroup analysis that confirmed the decrease in POPFs in the RS group and also in the minimally invasive cohort (data not presented). Also, the pancreatic thickness was measured on preoperative, cross-sectional imaging at the pancreatic neck, and a discrepancy with the reported data and the actual thickness on the site of transection was possible. Finally, possible biases are represented by the fact that patient allocation varied over time, and the use of the device was chosen according to surgeon preference. Indeed, a surgeon's perception of better outcomes in terms of the prevention of POPFs, using the RS contributed to an increased use of this device over time, advocating a deeper analysis that led to the results presented in this study.

In conclusion, we found that the RS decreased the risk of POPF after a DP and should be preferred to a UD for pancreatic transection. A randomized prospective trial comparing outcomes and costs regarding different techniques is currently ongoing at our institution to confirm these data.

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