

## Three level risk assessment for pancreatic fistula formation after distal pancreatectomy with a strategy for prevention

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### ABSTRACT

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**Background:** Distal pancreatectomy (DP) has a high post-operative morbidity predominantly due to pancreatic fistula though the mortality is very low. Data on distal pancreatectomy was reviewed to analyse the risk factors that contribute to this morbidity.

**Methods:** Thirty three patients underwent distal pancreatectomy with sutured closure of the remnant, over a 5-year period between May 2006 and April 2011. Pancreatic fistula (PF) was defined according to the International Study Group on Pancreatic Fistula definition. Patient and surgical risk factors were subdivided as those reflecting a poorer pre-morbid status, those associated with increased complexity of surgery and those related to pancreas gland and were analyzed for incidence of pancreatic fistula.

**Results:** Indications for DP included 16 (51.5%) pancreatic tumours, 13 (39.4%) chronic pancreatitis and 3 (9.1%) trauma. Spleen was preserved in 12 patients (36.4 %). There was no mortality while the morbidity rate was 45.5% (n=15). Incidence of pancreatic fistula was 30.3% (n=10); eight were grade A (80%) and two were grade C (20%). Incidence of clinically significant pancreatic fistulae was 6.1%. PF was significantly more common if the pancreatic duct was not identified ( $p=0.024$ ) was significantly less with extensive peri-pancreatic adhesions ( $p=0.036$ ).

**Conclusions:** Identification and ligation of main pancreatic duct can help reduce the incidence of pancreatic fistulae. The identification of patients at high risk of developing a PF helps to implement prevention strategies.

**KEYWORDS:** distal pancreatectomy, pancreatic fistula, intra-abdominal abscess, suture method, complications

### Introduction

Distal pancreatectomy (DP) continues to remain a procedure with high morbidity though advances in operative technique and peri-operative care of patients have resulted in low mortality.<sup>1-3</sup> Pancreatic fistula (PF) is the most frequent complication occurring in 11 to 31% cases.<sup>1-9</sup> Factors

predisposing to morbidity have been studied but poorly characterized. Factors described are method of closure of the pancreatic remnant, splenectomy, high BMI, malnutrition, primary disease, texture, degree of fibrosis etc.<sup>1-9</sup> Identification of patients at high risk of developing a PF allows surgeons to

identify and implement prevention strategies to select patients with potential risk factors who will benefit the most.<sup>9</sup> The aim of this study was to classify and analyse risk factors predictive of post-operative pancreatic fistulae in patients undergoing distal pancreatectomy with sutured closure of the pancreatic remnant and to propose simple measures to reduce their incidence.

## Methods

### Data collection

The present analysis included a retrospective review of in-patient data collected prospectively for a total of 33 patients undergoing distal pancreatectomy over a 5-year period between May 2006 and April 2011. Information regarding age, sex, pre-operative evaluation, indication for distal pancreatectomy, concomitant splenectomy or other additional procedures, texture of pancreatic parenchyma (graded as soft vs. firm by the surgeon), location of pancreatic transection (neck vs. body), identification and closure of the main pancreatic duct, operative time, blood loss, peri-operative transfusion and post-operative outcome, was gathered. There were 17 males and 16 females with a median age of 33 years (range 11 to 68 years). The indications for surgery included 16 patients with pancreatic tumours, 13 patients with chronic pancreatitis and 3 with trauma. Twenty one patients underwent distal pancreatectomy with splenectomy and twelve patients underwent spleen preserving distal pancreatectomy. The patient demographics and indications for surgery are summarized in **Table 1**.

**Table 1: Patient characteristics and indications for distal pancreatectomy**

	Total (n=33)
<b>Demographics</b>	
• Male	17(51.5%)
• Female	16(48.5%)
• Median age (range)	33(11-68)
<b>Indication</b>	
• Pancreatic tumours	17(51.5%)
• Serous cystadenoma	2
• Mucinous cystadenoma	6
• Solid pseudopapillary neoplasm	3
• Neuroendocrine tumour	5
• Intraductal papillary mucinous tumour	1
Chronic pancreatitis	13(39.4%)
Trauma	3(9.1%)

### Standard treatment protocols

All patients underwent contrast-enhanced abdominal computed

tomography (CECT) or magnetic resonance imaging with cholangiopancreatography (MRCP) as the standard pre-operative investigation along with blood tests. The pre-operative risk was graded according to the American Society of Anesthesiologists (ASA) classification. All patients received prophylactic antibiotics peri-operatively together with a daily dose of subcutaneous low molecular weight heparin. No patients received prophylactic subcutaneous octreotide. Peri-operative and post-operative pain management included epidural anaesthesia in all patients. After the operation, patients were transferred to the intensive care unit overnight. Nasogastric suction tubes were placed during the operation and routinely removed on the first post-operative day. All patients were started on early diet. One drainage tube was routinely placed in close proximity to the pancreatic remnant during the operation and was removed after 3 days depending on the volume and content. All complications were recorded prospectively in the database.

### Operative procedure

All resections were performed by open laparotomy. The standard procedure was distal pancreatectomy with splenectomy and spleen-preserving distal pancreatectomy with preservation of the splenic vessels in cases of benign lesions. The pancreas was transected with a cautery/harmonic, followed by identification of the main pancreatic duct and cannulation of the pancreatic duct to check for obstruction. The transection was considered as located at the neck when performed at the level of the portal vein/superior mesenteric trunk, and as located at the body when performed to the left of it. Closure of the pancreatic duct using single stitches of 4-0 or 5-0 PDS was performed if the duct was identified. The parenchyma was then closed using single interrupted stitches of 4-0 or 5-0 PDS. All procedures were performed by the same surgical team and the same single technique of suture closure of the pancreatic remnant was used in all cases. All patients had one closed drain placed near the transected end. Fibrin glue was never used.

### Definition of pancreatic fistula

Patients were categorized based on the definitions of the International Study Group on Pancreatic Fistula (ISGPF). The incidence of biochemical leakage (regarded as grade A) was defined as any measurable output on, or after, the 3<sup>rd</sup>

postoperative day from an operatively positioned abdominal drain and displaying pancreatic amylase more than three times the upper serum reference value. Clinically significant pancreatic fistula was a fistula that was symptomatic (grade B) or a fistula with severe clinical sequelae or requiring any therapeutic intervention (grade C).

### *Management of persistent pancreatic fistula*

Treatment of pancreatic fistula was to ensure adequate drainage of the contents. In general, drains were left in place, or (in the case of early drain removal) interventional drains were placed. Antibiotics were started as per culture sensitivities. Oral intake was not stopped. ERCP was not used for the treatment of pancreatic fistulae. Somatostatin analogues were not used.

### *Risk factor subgroups for pancreatic fistulae*

Incidence of PF according to factors classified as those reflecting a poorer pre-morbid status (age >50 years, Hb <10 gm%, creatinine >1.1, serum albumin <3.5, ASA status >2), those associated with increased complexity of surgery (spleen preservation, presence of extensive peri-pancreatic adhesions, operative time >180 min, blood loss >250 ml, need for blood transfusions) and those related to pancreas gland (indication / pathology, texture of parenchyma, location of transection and elective ligation of the main duct) were analyzed.

### *Statistical analysis*

All data were reported as mean  $\pm$  standard deviations (SD) and/or medians. The data were analyzed using SPSS 12.01 statistical package for Windows. Univariate analyses were conducted using Pearson's Chi-square test with correction for continuity and multivariate analyses were performed with multiple logistic regression analyses. The relative risk was described by the estimated odds ratio (OR) with a 95% confidence interval. Two-sided p values were computed and considered statistically significant at  $p < 0.05$ .

## **Results**

There was no post-operative mortality while the morbidity rate was 45.5% (n=15) which included all patients with any one complication including: pancreatic fistula, wound infection, intra-abdominal abscess, and intra-abdominal haemorrhage. Ten

patients (30.3%) developed pancreatic fistulae. Eight fistulae (80%) were Grade A and two, Grade C (20%). Two patients (6.1%) developed clinically significant pancreatic fistulae (Grade B/C). Wound infection occurred in seven patients (21.2%), intra-abdominal abscess in six patients (18.2%) and intra-abdominal haemorrhage in one (3%). None of patients required a reoperation. The median operative time was 230 min (range: 180-300 min). The median amount of blood loss was 300 ml (50-500 ml). The median length of post-operative hospital stay was 8 days (range: 5-10 days). The post-operative results are showed in **Table 2**.

Among factors reflecting poorer pre-morbid status, pancreatic fistula was significantly more common in patients aged >50 years occurring in 4 of 5 (80%) of these patients compared to 6 of 22 (27%) patients <50 years ( $p=0.036$ ). Other factors analysed included presence of co-morbidities, ASA grade >2, Hb <10 gm%, serum creatinine >1.1 and serum albumin <3.5 gm, which showed higher number of fistulae but the difference was not statistically significant (**Table 3**).

Among factors associated with increased complexity of surgery pancreatic fistula was significantly less common in patients with extensive peri-pancreatic adhesions occurring in 1 of 14 (7.1%) patients compared to 9 of 19 (47.4%) of these patients with no adhesions ( $p=0.036$ ). Other factors analysed included, extent of resection (concomitant splenectomy or not), operation time >3 hours, blood loss >250 cc and blood transfusions which did not show any statistically significant differences on analysis (**Table 4**).

Among factors associated with the pancreatic gland, patients in whom the pancreatic duct was not identified had a significantly higher fistula rate occurring in 7 of 12 (58.3%) of these patients compared to 3 of 21 (14.2%) patients with pancreatic duct identified and ligated ( $p=0.024$ ). Pancreatic fistula was commoner in those operated for tumours and trauma compared to those with chronic pancreatitis, in those with

**Table 2 Outcome of distal pancreatectomies**

	Total (n=33)
1. Operative time median (range) mins	230 (180-300)
2. Blood loss median (range) ml	300 (50-500)
3. Hospital stay median (range)	8 (5-10)
4. Complications (n)%	15 (45.5%)
a. Pancreatic fistulas (n)%	10 (30.3%)
b. Pancreatic fistulas (B/C) (n)%	2 (6.1%)
c. Wound infection (n)%	7 (21.2 %)
d. Intraabdominal abscess (n)%	6 (18.2 %)
e. Intraabdominal bleed (n)%	1 (3 %)

**Table 3: Incidence of pancreatic fistula after distal pancreatectomy according to factors reflecting poorer premorbid status**

	<u>Pancreatic fistula</u>						
	Patients (n=33)	No (n=23)	Yes (n=10)	Univariate p value	Multivariate p value	Odd's ratio	95% confidence interval
<u>Age</u>							
• >50	5	1	4 (80%)	0.036	0.148	.106	0.005 -2.218
• <50	28	22	6 (27%)				
<u>Co-morbidities</u>							
• Yes	5	2	3 (60%)	0.298	0.719	1.771	0.079-39.800
• No	28	21	7 (33.3%)				
<u>ASA*</u>							
• >2	6	3	3 (50%)	0.503	0.982	1.035	0.056-19.298
• <2	27	20	7 (26%)				
<u>Hemoglobin</u>							
• <10 gm%	4	1	3 (75%)	0.135	0.165	7.095	0.445-113.105
• >10 gm%	29	22	7 (24.1%)				
<u>Serum creatinine</u>							
• >1.1	6	2	4 (66.7%)	0.099	0.363	3.360	0.247-45.675
• <1.1	27	21	6 (22%)				
<u>Serum albumin</u>							
• <3.5	7	4	3 (42.9%)	0.726	0.295	3.381	0.345-33.123
• > 3.5	26	19	7 (27%)				

\* Pre-operative risk graded according to the American Society of Anesthesiologists (ASA) classification

**Table 4: Incidence of pancreatic fistula after distal pancreatectomy according to factors associated with increased complexity of surgery**

		<u>Pancreatic fistula</u>					
	Patients (n=33)	No (n=23)	Yes (n=10)	Univariate p value	Multivariate p value	Odd's ratio	95% confidence interval
<u>Extent of resection</u>							
• Distal pancreatectomy with splenectomy	21	15	6 (28.6%)	1.00	0.556	1.747	0.273 -11.188
• Distal pancreatectomy spleen preserving	12	8	4 (33.3%)				
<u>Adhesions</u>							
• No	19	10	9 (47.4%)	0.036	0.021	0.053	0.004 -.640
• Yes	14	13	1 (7.1%)				
<u>Operative time</u>							
• <180	13	9	4 (30.8%)	1.00	0.982	1.022	0.159-6.553
• >180	20	14	6 (30%)				
<u>Blood transfusion</u>							
• No	29	20	9 (31%)	1.00	0.574	0.395	0.015-10.086
• Yes	4	3	1 (25%)				
<u>Blood loss</u>							
• >250	14	9	5 (36%)	0.844	0.290	0.335	0.044-2.536
• <250	19	14	5 (26.3%)				

transection at body (larger remnant volume) compared to neck and in those with a soft gland texture but differences were not statistically significant.

Multivariate analysis pertaining to pancreatic fistulae

confirmed pancreatic duct identification with ligation ( $p=0.011$ ) and adhesions ( $p=0.021$ ) as independent risk factors. Age was not found to be statistically significant on multivariate analysis ( $p=0.148$ ) (Table 5).

**Table 5: Incidence of pancreatic fistula after distal pancreatectomy according to factors associated with pancreatic gland**

	Patients (n=33)	Pancreatic fistula		Univariate p p value	Multivariate p value	Odd's ratio	95% confidence interval
		No (n=23)	Yes (n=10)				
<b><u>Indication</u></b>							
• Chronic pancreatitis	13	11	2 (15%)	0.264	0.533	0.333	0.010-10.576
• No pancreatitis	20	12	8 (61%)				
<b><u>Transection site</u></b>							
• Neck	27	19	8 (30%)	1.00	0.618	0.539	0.048-6.090
• Body	6	4	2 (33.3%)				
<b><u>Duct identified</u></b>							
• Yes	21	18	3 (14.3%)	0.024	0.011	12.379	1.775-86.323
• No	12	5	7 (58.3%)				
<b><u>Texture</u></b>							
• Soft	20	12	8 (40%)	0.264	0.533	0.333	0.010-10.576
• Hard	13	11	2 (15.4%)				

## Discussion

Incidence of post-operative PF is highly variable in literature ranging from nil to up to 64% and this has been attributed to the variability of definitions used.<sup>10</sup> The standardization of the definition of a PF by the International Study Group of Pancreatic Fistula (ISGPF) has allowed for better comparisons but has had no impact on incidence with high morbidity and PF rates continuing over time.<sup>11</sup> Many authors have however further refined the ISGPF definition to include only clinically significant fistulas in their studies resulting in only grade B and C PFs being reported.<sup>6,8</sup> This has lead to a more meaningful analysis of risk factors influencing PF. Our series of distal pancreatectomy had a very low clinically significant pancreatic fistula rate of 6.1%.

The risk factors for pancreatic fistulas have been widely studied but still remain poorly characterized. We systematically classified the patient and surgical risk factors into those reflecting a poorer pre-morbid status, those associated with increased complexity of surgery and those related to the pancreas. Perhaps a more complete classification would also take into account factors influencing pancreatic secretions at the sealed transected surface post-operatively including the use of somatostatin analogues and pancreatic stenting to divert the secretions.<sup>12,13</sup> Among pre-operative factors literature has shown that the ASA score, decreased albumin levels, and increased body weight are significantly associated with a PF, including clinically relevant fistulae.<sup>8,9</sup> Rest of the pre-operative risk factors for a PF analysed in our study including lower haemoglobin, higher serum creatinine, age and presence of co-morbidities have been analysed in few previous studies, but have not been found to be significantly associated with

pancreatic fistulae.<sup>1-9</sup> In this context, the value of pre-operative risk stratification using complex scores like the Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM) has been found useful for risk assessment for pancreatic resection and other surgical entities.<sup>14,15</sup> But because of difficulty in applying these complex score in clinical practice, they are not widely used. We included a simple analysis of factors reflecting a patient's poor pre-morbid status and found an increased incidence of pancreatic fistulae statistically significant only for age >50 years on univariate analysis, however this was not found to be an independent predictor on multivariate analysis. A scientific explanation easy to understand would be that these poorer pre-morbid risk factors may be associated with poorer healing and hence increased incidence of pancreatic fistulae.

Our study identified pancreas related factors to be also associated with a higher incidence of pancreatic fistulae. Sutured closure without ligation of the main pancreatic duct was a significant risk factor and an independent predictor on multivariate analysis. Many studies have identified no specific ligation of the main pancreatic duct as an independent risk factor for pancreatic fistula and demonstrated that identification and ligation of the pancreatic duct as an important factor in reducing the incidence of PF.<sup>7,16</sup> Sandwich fibrin glue, prolamine and ultrasonic dissection have also been shown to reduce pancreatic stump leak and these studies indirectly support mechanical occlusion of ducts especially the main pancreatic duct to reduce overall leakage and manifestation as a PF.<sup>17-19</sup> A recent meta-analysis comparing stapled and hand-sutured closure failed to draw firm conclusions on the optimal method for stump closure and did not reveal significant difference between stapled and hand-sutured closure; although there was



a trend favouring stapled closure.<sup>20</sup> All studies in favour of sutured closure of the pancreatic remnant indirectly support the practice of main duct ligation, since all patients who underwent sutured closure had ligation of the main duct, whereas stapled closure did not.

Manual assessment of gland texture has been used since earlier times to differentiate a firm fibrotic gland from a soft fatty non-fibrotic parenchyma. The texture of the pancreatic parenchyma is one of the risk factors for pancreatic fistula and patients with soft pancreatic tissue had higher incidence of pancreatic leakage compared with the presence of firm tissue,<sup>21,22</sup> implying fibrotic pancreas is less likely to pancreatic leakage. Analysis of pathology revealed that chronic pancreatitis is associated with lower PF rate secondary to textural alterations and a congestion of pancreatic duct allowing easy identification and ligation of the main pancreatic duct.<sup>23,24</sup>

Studies have identified the site of transection at the body in comparison to the pancreatic neck as an independent risk factor for pancreatic fistula.<sup>7</sup> Recent studies have included volumetry on imaging to show larger size of the remaining gland as a risk factor for pancreatic fistula.<sup>25</sup> The latter leads to a logical observation that larger the volume of the remaining gland, the greater the quantity of actively secreting parenchyma with its effects on the sealed transection area; providing at the same time scientific explanation for previously observed correlation with transection sites.

Among factors increasing operative complexity we have identified extensive peri-pancreatic adhesions as a significant factor for reducing risk of pancreatic fistulae on univariate analysis and an independent predictor on multivariate analysis representing a strange observation with no studies in the literature studying this as a risk factor. Though we have studied this factor, the severity of adhesions is difficult to characterize and very subjective and difficult to compare and will need studies to further confirm its role. Possibly peri-pancreatic adhesions represent repeated attacks of inflammation of the gland associated with increased degree of fibrosis not necessarily reflected as textural alterations. Other factors increasing complexity of surgery reported to increase fistula rates<sup>8</sup> were not found significant in our study. We found that increasing complexity was described more in context of multivisceral resections in these studies but our study did not include multivisceral resections and was focussed on increased complexity with the newly adopted method of spleen preserving distal pancreatectomy. The role of splenic preservation after DP remains debatable. Studies subclassifying fistulae into

clinically significant fistulae demonstrate that splenectomy is not associated with an increased risk of developing a PF as was found in our series also but is associated with an increased risk of a clinically significant grade B/C PFs suggesting that splenic preservation does not decrease the occurrence of PF but may protect against its progression to infectious complications.<sup>8</sup>

In conclusion, it is important to identify specific risk factors in patients which predispose them to development of pancreatic fistulae. Identification and ligation of the main pancreatic duct can help reduce the incidence of pancreatic fistulae and was the most important predisposing factor that we identified in our study.

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