

Use of Seamguard to Prevent Pancreatic Leak Following Distal Pancreatectomy

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Objective: To investigate the use of Seamguard, a bio-absorbable staple line–reinforcement product, to prevent pancreatic leak after distal pancreatectomy.

Design, Setting, and Participants: A retrospective study examined 85 consecutive patients undergoing distal pancreatectomy at an academic institution from September 5, 1997, to September 30, 2007.

Main Outcome Measures: Pancreatic fistula and overall mortality and morbidity.

Results: In February 2004, the use of Seamguard in distal pancreas resections was introduced at our institution. Indications for resection included trauma (11 patients), neoplasms (62 patients), and chronic pancreatitis (12 patients). Pancreatic leak was defined as drain output of 25 mL/d or more 7 days postoperatively with a

drain amylase level of 1000 U/L or more. Pancreatic leak occurred in 10 of 38 patients (26%) undergoing conventional resection with suture ligation of the pancreatic duct or nonreinforced stapled resection vs 2 of 47 patients (4%) undergoing staple resection using Seamguard reinforcement. Multivariate analysis showed that use of Seamguard with the stapler independently decreased the risk for pancreatic fistula after distal pancreatectomy (odds ratio, 0.07; 95% confidence interval, 0.01-0.43; $P = .01$).

Conclusions: The use of Seamguard is quickly becoming a common adjunct in distal pancreas resections. Our study shows a lower incidence of pancreatic leak after distal pancreatectomy with the use of this staple line–reinforcing product.

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ALTHOUGH THE MORTALITY from a resection of the distal pancreas remains low (0%-4% range for most published series), the morbidity for this procedure can range from 24% to 56%, depending on the specific complications included.¹⁻⁷ Leakage from the pancreatic remnant remains one of the most commonly encountered problems associated with resection of the distal pancreas and contributes significantly to morbidity from this procedure. Aside from a prolonged hospital stay and the possible need for further procedures to drain or control the leakage, complications may include intra-abdominal abscess, hemorrhage, cystoenteric fistula, and respiratory compromise. As such, there is a great deal of interest in the prevention of this complication.

The roles of multiple patient factors and surgical techniques in the development of a pancreatic leak have been investigated. Novel approaches, including ultrasonic scalpel dissection⁸ and use of a fibrin glue sandwich,⁹ have been described with good

results in small, nonrandomized series. Other studies independently identified body mass index of less than 25 (calculated as weight in kilograms divided by height in meters squared), pancreatic tissue with a fibrotic consistency, and suture ligation of the main pancreatic duct as statistically significant factors in reducing the likelihood of developing a pancreatic leak.^{5,10} The use of fibrin glue or prophylactic octreotide is controversial, and

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studies both support and refute their role in pancreatic resections.^{2,10,11} Concomitant splenectomy and final pathologic characteristics have not been found to influence the rate of pancreatic leak or intra-abdominal complications.^{2,6,12,13} The urgency of surgical treatment has been suggested as a risk factor for leak development; however, 2 series of trauma patients had published leakage rates of 12.5%

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and 14%, which compare favorably to rates after elective procedures.^{6,7,14} A recent review and meta-analysis regarding closure of the pancreatic stump after a distal resection failed to show suture or staple closure to be superior, although there was a trend toward fewer pancreatic leaks in the stapled population.¹⁵ Thus far, the identification of conclusive factors to reduce pancreatic leak after distal pancreatectomy has been elusive.

Seamguard (W. L. Gore & Associates, Flagstaff, Arizona) is a bioabsorbable mesh composed of polyglycolic acid and trimethylene carbonate that is used to reinforce the staple line after resection.¹⁶ It has been used to reduce bleeding at the gastric staple line in bariatric surgery, reduce air leaks in pulmonary resection, and prevent bleeding and staple line disruption in colorectal procedures.¹⁷⁻²⁰ Two small retrospective studies have examined whether Seamguard reduces the risk for pancreatic fistula after a distal pancreatectomy.^{21,22} The purpose of this study was to examine whether this technology could be used to prevent leakage from the pancreatic stump after distal pancreatectomy and to validate these prior studies with a larger cohort of patients.

METHODS

DATA COLLECTION

A retrospective review was performed to identify all patients who underwent distal pancreatectomy at our institution from September 5, 1997, to September 30, 2007. We identified 85 consecutive patients, and no patients were excluded from the study. The patient demographics (age and sex), indications for operation (trauma, chronic pancreatitis, and malignant neoplasm), and operative factors (technique for closure for the pancreatic remnant, use of fibrin glue, texture of the pancreatic remnant, use of laparoscopy, concomitant splenectomy, and perioperative octreotide) were collected from the medical records. Treatment with octreotide (100 µg) subcutaneously injected every 8 hours was started postoperatively at the discretion of the surgeon. Prophylactic octreotide use was routine with most surgeons before 2004 and the advent of Seamguard. After 2004, literature did not support conclusively any decreased risk for fistula with somatostatin analogues, and octreotide was used much more sparingly at our institution. The texture of the pancreatic tissue was evaluated based on histopathological analysis. Postoperative mortality and morbidity were evaluated for 30 days after the operation or during the hospital stay, if longer. The postoperative course was evaluated with pancreatic fistula as the main study outcome. This study was approved by the institutional review board.

OPERATIVE TECHNIQUE

Most patients underwent a standard distal pancreatectomy with splenectomy. In selected cases with benign origins, a splenic-preserving distal pancreatectomy was performed. The pancreatic stump was closed with 1 of 3 techniques: stapler alone, ligation of the pancreatic duct, or Seamguard-reinforced staples. The technique for closure of the pancreatic stump and use of fibrin glue at the pancreatic remnant were at the discretion of the surgeon. The placement of a drain at the time of the operation was also at the discretion of the surgeon. The first laparoscopic distal pancreatectomy at our institution was performed in February 2004,²³ and since then, 27 laparoscopic distal pancreas resections have been performed. Seamguard has been

used routinely since its introduction in 2004, unless it was deemed unsafe intraoperatively by the surgeon.

DEFINITION OF PANCREATIC FISTULA

One of the key benefits of Seamguard use is the prevention of pancreatic leak. Because there have been varying definitions of a pancreatic fistula, actual leakage rates can vary widely dependent on the parameters applied. In a recent review of the criteria used to characterize a pancreatic fistula, the leak rates for one group of patients varied from 9.9% to 28.5% based on 4 representative definitions from the literature.²⁴ In this study, drain output in the 10 to 100 mL/d range with amylase-rich fluid after postoperative day 8 gave consistent variables to assess for leakage. More recently, Bassi et al²⁵ standardized the definition as any volume of fluid on or after postoperative day 3 with a drainage amylase level 3 times the serum level. Further grading is based on the clinical severity of the fistula (eg, presence of sepsis, a subsequent operation, mortality, etc). In our review, we used the standardized definition set by this group. Medical records were reviewed to determine the method of resection and outcomes.

STATISTICAL ANALYSIS

SAS statistical software for Windows, version 9.1.3 (SAS Institute Inc, Cary, North Carolina) was used for analysis of the data. The continuous variables were expressed as mean (standard deviation) and analyzed using a 2-sample *t* test. The categorical variables were evaluated with a χ^2 test or Fisher exact test, where appropriate. Logistic regressions were performed for the univariate and multivariate analysis for the variables potentially associated with the main study outcome, pancreatic fistula. The odds of pancreatic leak for categorical predictors and a 95% confidence interval were calculated. The *P* values were 2-sided, and statistical significance was defined as *P* < .05.

RESULTS

PERIOPERATIVE COURSE

From September 5, 1997, to September 30, 2007, 85 consecutive patients (**Table 1**) underwent distal pancreatic resections for indications including trauma (*n* = 11), neoplasms (*n* = 62), and chronic pancreatitis (*n* = 12). No patients were excluded from the analysis. Patients included 44 men and 41 women with a mean (SD) age of 56.7 (20.2) years. Twenty-five patients had a stapled resection alone, 13 had their pancreatic duct suture ligated, and 47 underwent staple resection with Seamguard reinforcement. Concomitant splenectomy was performed in 73 patients (86%). Perioperative deaths included any deaths within 30 days of the distal pancreatic resection. At our institution, the use of Seamguard for distal pancreatic resection was introduced in February 2004. This review includes 47 distal pancreatic resections (27 done laparoscopically) in which Seamguard was applied to the remnant edge of the pancreas.

POSTOPERATIVE COURSE

The overall postoperative mortality was 4% (3 patients). All 3 patients were trauma patients with multiple injuries. Two patients died of multiorgan system fail-

Table 1. Descriptive Variables Associated With Pancreatic Leak^a

Variable	Pancreatic Leak (n=12)	No Pancreatic Leak (n=73)	P Value
Age, mean (SD), y	54.6 (18.4)	57.0 (20.5)	.70
Sex			.62
Female	5 (42)	36 (49)	
Male	7 (58)	37 (51)	
Diagnosis			.43
Cancer	7 (58)	55 (75)	
Chronic pancreatitis	2 (17)	10 (14)	
Trauma	3 (25)	8 (11)	
Consistency of pancreatic remnant			.76
Fibrotic	6 (50)	33 (45)	
Normal	6 (50)	40 (55)	
Fibrin glue used			.76
No	5 (42)	27 (37)	
Yes	7 (58)	46 (63)	
Octreotide used			.03
No	6 (50)	59 (81)	
Yes	6 (50)	14 (19)	
Concomitant splenectomy			.68
No	2 (17)	10 (14)	
Yes	10 (83)	63 (86)	
Surgical method			.09
Open	11 (92)	47 (64)	
Laparoscopic	1 (8)	26 (36)	
Closure of pancreatic remnant			.007
Ligation of duct	5 (42)	8 (11)	
Stapler alone	5 (42)	20 (27)	
Seamguard ^b with stapler	2 (17)	45 (61)	

^aData are given as the number (percentage) of patients unless otherwise indicated.

^bSeamguard is a bioabsorbable mesh made of polyglycolic acid and trimethylene carbonate (W. L. Gore & Associates, Flagstaff, Arizona).

ure, whereas 1 patient died of a severe intracranial hemorrhage. The overall morbidity was 31% (26 patients). Morbidity and mortality were evaluated based on the urgency of the operation. Eleven patients underwent an emergency distal pancreatectomy after sustaining blunt or penetrating trauma. Perioperative death and multiorgan system failure were the only 2 outcomes that were statistically associated with the urgency of the operation. Pancreatic fistula was noted in 12 patients, whereas 10 patients developed an abscess. Conservative treatment with octreotide, total parenteral nutrition, and computed tomography-guided drainage was successful in 10 patients (83%) who developed a pancreatic fistula. Two patients required reoperation for their leaks.

RISK FACTORS FOR PANCREATIC LEAK

Pancreatic leak occurred in 10 of 38 patients (26%) undergoing conventional resection with suture ligation of the pancreatic duct or nonreinforced stapled resection vs 2 of 47 patients (4%) undergoing stapled resection with Seamguard reinforcement. Univariate analysis of variables potentially associated with pancreatic leak is detailed in Table 1. No statistically significant association was noted with age, sex, indication for procedure, consistency of the pancreatic remnant, use of fibrin glue, con-

comitant splenectomy, or use of laparoscopy. Despite not reaching statistical significance, 1 patient in the laparoscopic group (4%) developed a fistula and 11 patients developed a leak after an open procedure (19%). The method of closure of the pancreatic stump ($P = .007$) and octreotide use ($P = .03$) were the only factors shown to affect pancreatic leak rates. Multivariate analysis also showed a significance in the same 2 variables that were shown in the univariate analysis, octreotide use ($P = .048$) and the method of closure of the pancreatic stump ($P = .02$). The odds of pancreatic fistula for patients who received octreotide injections after the procedure were 4.2 times higher than for those who did not, after adjusting for the method of closure of the pancreatic stump (95% confidence interval, 1.01-17.59; $P = .048$). Therefore, the odds of pancreatic leak for the group of patients whose pancreatic remnant was closed with Seamguard-reinforced staplers was 7% of that for the group of patients who did not receive Seamguard, adjusting for octreotide usage (95% confidence interval, 0.01-0.43; $P = .01$). Alternatively, the odds of pancreatic leak for the group that did not receive Seamguard-reinforced staples was 14.3 times higher than the group with Seamguard, after adjusting for octreotide usage.

Two patients developed a leak with use of Seamguard after distal pancreatectomies. The first patient's course was complicated by infection at the pancreatic bed, which was controlled by percutaneous drains. After conservative management failed to treat the leak, he returned to the operating room 6 months later, where the pancreatic stump was re-resected and oversewn. The second patient had undergone a standard open distal pancreatectomy with splenectomy and subsequently developed a pancreatic fistula and abscess. The abscess and fistula were treated conservatively with computed tomography-guided drainage, intravenous antibiotics, and octreotide.

COMMENT

This study was designed to evaluate the performance of Seamguard, a bioabsorbable mesh composed of polyglycolic acid and trimethylene carbonate, that is used to reinforce the staple line in distal pancreatic resections.¹⁶ This product has become a useful adjunct to thoracic, bariatric, and colorectal surgical procedures.¹⁷⁻²⁰ Since its introduction for use during distal pancreatic resections at our institution in February 2004, observed leak rates have decreased compared with the more traditional methods of pancreatic stump closure. The overall mortality in this series was 4%, and all 3 of those who died were trauma patients with multiple other intra-abdominal and thoracic injuries or severe intracranial hemorrhage. The univariate and multivariate analysis showed that use of Seamguard-reinforced staples decreased the risk for developing pancreatic fistulas.

Multiple studies have evaluated the patient and procedure characteristics that predispose patients to developing a leak after pancreatic resection. Thus far, few risk factors have been irrefutably associated with the development of a pancreatic leak. In previous studies, age, sex,

Table 2. Leakage Rates for Distal Pancreatic Resections

Source	Institution/Country of Study	No. of Patients (No. of Leaks)			Total No. of Leaks (Leakage Rate, %)
		Stapled	Sutured	Both/Anastomosis	
Lillemoe et al, ³ 1999	The Johns Hopkins Medical Institutions	11 ^a	204 ^a	20 ^a	12 (5)
Benoist et al, ⁴ 1999	France	23 ^a	17 ^a	0	9 (23)
Sugo et al, ⁹ 2001	Japan	0	31 (6)	0	6 (19)
Fahy et al, ⁶ 2002	University of California–Davis	23 (3)	28 (10)	0	13 (26)
Bilimoria et al, ² 2003	University of Texas MDACC	20 (4)	91 (18)	15 (2)	25 (20)
Fernández-Cruz et al, ²⁹ 2004	Spain	19 (3)	0	0	3 (16)
Lebedyev et al, ³⁰ 2004	Israel	0	0	12 (2)	2 (17)
Sledzianowski et al, ⁵ 2005	France	32 (2)	26 (4)	3 (0)	6 (10)
Thaker et al, ²¹ 2007	Washington University	35 (3)	5 (2)	0	5 (13)
Jimenez et al, ²² 2007	University of Connecticut	31 (7)	0	0	7 (23)

Abbreviation: MDACC, M. D. Anderson Cancer Center.

^aStudy did not categorize the leakage rate by method of closure.

diabetes mellitus present before the operation, malignant neoplasm, simultaneous splenectomy, size of the pancreatic duct, and consistency of the pancreas have not been found to affect leak rates with statistical significance.^{5,6} Also, Bilimoria et al² found no relationship between pancreatic leak and contiguous organ resection, estimated blood loss of 920 mL, blood transfusion of 2 units of packed red blood cells, 7 hours of operating time, or 100 µg twice a day to 300 µg three times a day of octreotide. The benefit of fibrin glue remains disputed.^{2,10,11} However, a body mass index of more than 25 has been observed to significantly increase the number of intra-abdominal complications after distal pancreatectomy.⁵ Two other areas of focus are the urgency of the operation and the method of stump closure.

The use of octreotide in our study was associated with an increased risk for subsequent development of pancreatic fistula after distal pancreatectomy. Before 2004, octreotide was used in most cases for its potential theoretical advantage in reducing pancreatic leaks. However, because recent literature did not support its role in decreasing fistula rates,^{26,27} our institution has used it more sparingly and usually only in situations of established pancreatic leak. Therefore, from this retrospective study, it is unclear whether this increased risk shown from the multivariate analysis is the cause or the effect of a pancreatic fistula.

Owing to the low incidence of traumatic pancreatic injuries, less data are available on pancreatic resections in trauma patients. Trauma patients in our series had a higher morbidity and the only mortalities. Because of its anatomical location and the mechanisms required to injure the pancreas, multiple organs are usually involved in the inciting traumatic event. Furthermore, severely injured trauma patients frequently have some magnitude of hypothermia, acidosis, and coagulopathy at initial presentation to complicate their treatment. Cogbill et al⁷ and Fitzgibbons et al¹⁴ published leakage rates of 12.5% and 14%, respectively, in their reports specific to trauma patients. Comparatively, Fahy et al⁶ reported 9 leaks in 15 traumatic resections, yielding a rate of 60%, which was

a statistically significant risk factor for development of a fistula. Our series also noted a higher rate of pancreatic leak after trauma, 3 of 11 patients (27%), compared with elective procedures, although this difference did not reach statistical significance. The large series by Cogbill et al⁷ consisting of 74 patients with pancreatic injuries, published in 1991, noted that only 46% were caused by blunt injury. In contrast, 8 patients (73%) had traumatic injuries caused by blunt trauma in our study, one of whom arrived in traumatic full arrest. The difference in the observed leak rates could be attributable to the variable definition of pancreatic leakage, an increase in the number and severity of blunt injuries, or a result of advancements in prehospital treatment and efficient transport of severely injured patients to trauma facilities. Because Seamguard was only used in 3 trauma patients, its benefit in this high-risk group is less clear, although none of these patients had a complication related to the pancreatic remnant.

The method of closure of the pancreatic stump and its relationship to the development of pancreatic fistula have undergone numerous investigations. Multiple large series have found no difference between sutured or stapled closure and leak rate.^{2,12-14} Lillemoe et al³ demonstrated an impressive 5% overall leakage rate in 235 patients treated at The Johns Hopkins Hospital, of whom 87% underwent sutured closure of the pancreatic stump. Similarly, Bilimoria et al² found that control of the pancreatic duct by suture ligation resulted in a leakage rate of 10% (7 of 73 patients) vs 34% (18 of 53 patients) without ligation of the duct ($P = .001$). Other studies demonstrated leakage rates of 22% to 36% for sutured closures of the stump.^{2,6,28} This variation in results is most likely reflective of the experience with sutured closures at these high-volume institutions.

In contrast, recently published leakage rates for stapled distal pancreatic resections range from 13% to 20% (**Table 2**). A recent meta-analysis of sutured vs stapled closures confirmed a trend toward fewer leaks with stapled resections, although no statistically significant result was observed.¹⁵ The popularity of stapling devices contin-

ues to increase secondary to its efficiency and consistency with less operator dependent variability when compared with sutured closure of the pancreatic stump. When incorporated in the pancreatic parenchyma, the splenic vessels can also be taken comfortably with the same reinforced stapler firing. In our results, we found that mesh-reinforced stapled closure had a leak rate of 4%, which was significantly less than the 20% rate for stapled closure alone. When compared with the leak rates of stapled resections in other series previously mentioned, the Seamguard group had one-third to one-fifth the leakage rate observed at these other institutions as well. In our 2 leaks with use of Seamguard, 1 patient eventually required another operation to close an unresolved leak, and over-sewing of the stump remnant was used. The other patient was treated nonoperatively without incident.

There are 2 recently published small series that examine the utility of Seamguard in decreasing pancreatic fistulas after a distal pancreatectomy. Thaker et al²¹ performed 29 distal pancreatectomies using the absorbable mesh and had a leak rate of 3.5%. Comparatively, Jimenez et al²² operated on fewer patients (n=13) but demonstrated no pancreatic leaks. Both smaller studies concurred with our results that use of Seamguard decreased pancreatic fistula rates during transection of the pancreatic stump.

CONCLUSIONS

Because the technology is still relatively new, it will take time to build the experience necessary to adequately evaluate the performance of this new staple line reinforcement agent during pancreatic resections. Although there is absolutely no substitute for experience, the stapler and Seamguard offer more efficient and consistent results that are superior to sutured closure of the pancreatic stump. A large multi-institutional study would likely best define the true effect of Seamguard in reducing pancreatic leak rates after distal pancreatic resection.

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INVITED CRITIQUE

To Mesh or Not to Mesh, That Is the Question

Yamamoto and colleagues are to be congratulated on the third and, thus far, the largest single-institution series examining the addition of a buttress to reinforce a stapled distal pancreatic transection. I, along with my colleagues, have also presented a case series on this subject,¹ and, like my own, the article by Yamamoto et al has a number of significant shortcomings that prevent a definitive conclusion regarding the effectiveness of buttressing.

In this series, the authors interpret their data to suggest that the use of Seamguard to reinforce a stapler likely reduces the incidence of pancreatic occlusion failure. The major weakness of their conclusion stems from the fact that this is a retrospective review of nonstandardized techniques used at the surgeon's discretion. The possibility that these results represent nothing more than accidental selection of a favorable patient group should be strongly considered. An example of how surgeon bias can unwittingly return a statistically significant result in a retrospective review is present in this same article. The authors demonstrate that use of octreotide causes a significant increase in the rate of pancreas occlusion failure (odds ratio, 4.2). As the authors hint at in the "Comment" section, it is more likely that surgeons used octreotide if they believed the risk for leakage was elevated. The authors rightfully conclude that a multi-

institutional study would likely best define the true effect of buttressing a staple line. In our experience, not all pancreases can be stapled, including, for example, the very thick pancreas, the fibrotic pancreas, and the pancreas with a triangular shape. We believe nothing short of a randomized, controlled trial will adequately address the significant potential for selection bias. To avoid bias, surgeons could determine the randomization schema after they decide that a pancreas is suitable for stapling. To measure the effect of the buttressing material, a uniform stapler and stapler size should be predetermined. The appropriate comparison group would not be all other closure types but a naked staple line vs a buttressed staple line.

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