Published in final edited form as:

Ann Surg. 2017 January ; 265(1): 11–16. doi:10.1097/SLA.0000000000001892.

The Cost of Postoperative Pancreatic Fistula vs. the Cost of Pasireotide: Results from a Prospective Randomized Trial

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Abstract

Objective—The objective of this study was to determine the costs of clinically significant postoperative pancreatic fistula (POPF), and to evaluate the cost-effectiveness of routine pasireotide use.

Summary Background Data—We recently completed a prospective randomized trial that demonstrated an 11.7% absolute risk reduction of clinically significant POPF with use of perioperative pasireotide in patients undergoing pancreaticoduodenectomy or distal pancreatectomy (POPF: pasireotide (n=152), 9% vs. placebo (n=148), 21%; p=0.006).

Methods—An institutional modeling system was utilized to obtain total direct cost data from the 300 patients included in the trial. This system identified direct costs of hospitalization, physician fees, laboratory tests, invasive procedures, outpatient encounters, and readmissions. Total direct costs were calculated from the index admission to 90 days after resection. Costs were converted to Medicare dollars.

Results—Clinically significant POPF occurred in 45 of the 300 randomized patients (15%). The mean total cost for all patients was \$23,350 (\$8,017–\$202,494). The mean cost for those who developed clinically significant POPF was \$39,615 (\$13,770–\$202,494) vs. \$20,480 (\$8,017–\$62,941) for those who did not (p=0.001). The mean cost of pasireotide within the treatment group (n=152) was \$3,316 (\$273–\$3,826). The mean cost was lower in the pasireotide (n=152) group than the placebo (n=148) group; however this did not reach statistical significance (pasireotide, \$22,774 vs. placebo, \$23,941: p=0.571).

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[ClinicalTrials.gov](https://clinicaltrials.gov) number, NCT00994110

Conflicts of Interest: For all authors, no conflicts of interest were declared

Conclusions—The development of POPF nearly doubled the total cost of pancreatic resection. In this randomized trial, the routine use of pasireotide significantly reduced the occurrence of POPF without increasing the overall cost of care.

INTRODUCTION

Postoperative pancreatic fistula (POPF) is a major contributor to the significant morbidity and mortality associated with pancreatic resection. Even among high-volume centers, POPF has a reported rate of 10% to 35%^{1–7}. POPF is characterized by the leakage of pancreatic exocrine secretions, which can be inhibited and reduced in vivo by somatostatin, a peptide hormone secreted from pancreatic delta cells. Over the past several decades, a variety of somatostatin analogues have been investigated as prophylactic agents to prevent POPF. The results of these trials however have been mixed, and thus routine somatostatin analogue treatment has not become the standard of care following pancreatic resection^{8–12}.

Pasireotide, the most recently derived somatostatin analogue, has garnered significant interest in the prevention of POPF, as it has shown a broader binding affinity and superior pharmacokinetic profile compared to other somatostatin analogues. Our institution recently published the results of a randomized, double-blind, placebo-controlled trial of perioperative subcutaneous pasireotide in 300 patients who had undergone pancreatic resection¹³. Patients who received pasireotide had a significantly lower incidence of a grade 3 or higher postoperative pancreatic fistula, leak, or abscess compared with those who received placebo. This difference in the occurrence of POPF remained significant in subgroup analysis by type of pancreatic resection, presence or absence of pancreatic duct dilation at the site of transection, and surgical drain placement. In addition, the overall rate of pancreatic complications was lower for patients in the pasireotide study group, and patients who received pasireotide experienced a decreased hospital readmission rate.

The economic ramifications of POPF can be significant^{14–16}. As cost assessments have become an increasingly utilized outcomes measure, it is imperative to evaluate the cost-effectiveness of pasireotide from this recent study. The aim of the current study was to determine the costs of clinically significant POPF, and to evaluate the cost-effectiveness of routine pasireotide use for patients undergoing pancreatic resection.

METHODS

Between November 2009 through June 2013, patients were enrolled in a phase 3, single-center, randomized, double-blind, placebo-controlled trial evaluating the efficacy of pasireotide in reducing the incidence of POPF in pancreatic resections (ClinicalTrials.gov number, NCT00994110). Pancreatoduodenectomy or distal pancreatectomy was performed following standard surgical principles and guidelines, but the particular technique differed according to the patient's needs and the surgeon's preferences¹³. Patients were randomly assigned in a 1:1 ratio to receive 900 mcg of subcutaneous pasireotide or placebo twice a day, beginning preoperatively on the day of surgery and continuing for 7 days postoperatively for a total of 14 doses. Randomization was performed using permuted blocks of random size to stratify group assignments according to type of pancreatic resection and

presence or absence of pancreatic duct dilation. All members of the clinical team were unaware of the group assignments. Details of the patients' presenting characteristics, the intraoperative and perioperative period, and the 90-day postoperative follow-up period was prospectively collected. The primary endpoint of this trial was the development of a grade 3 or higher pancreatic fistula, leak, or abscess at 60 days postoperatively, as defined by the Memorial Sloan-Kettering Cancer Center (MSKCC) Surgical Secondary Events System¹³. Secondary endpoints included the overall rate of all pancreatic complications and the rate of grade B or grade C pancreatic fistula as defined by the International Study Group on Pancreatic Fistula (ISGPF)¹⁷.

Institutional accounting data were used to estimate total medical direct costs for the 300 patients enrolled in this trial. Total direct costs were estimated from the date of the index admission for surgery through 90 days postoperatively. All direct costs were inflation adjusted to 2013 US dollars using the Consumer Price Index-All Items. Institution-specific costs were converted to 2013 Medicare reimbursement levels using an approach similar to the method Medicare uses to determine reimbursement levels for hospital care¹⁸. This method has been used previously to normalize hospital-specific cost estimates¹⁹. Costs were adjusted to Medicare dollars by calculating the proportion of all costs that would be reimbursed by Medicare using diagnosis-related group (DRG) level reimbursements for inpatient admissions and Healthcare Common Procedure Coding System (HCPCS) code for outpatient visits. Costs of each unit of service were then multiplied by the relevant proportion (one for the initial inpatient admission, one for all outpatient visits, and one for readmissions) to estimate the amount of total costs that would be reimbursed by Medicare. This resulting amount was treated as the direct cost of services in Medicare dollars. For example, a hospital-specific outpatient visit that cost \$100 would be reported as \$50 if the proportion of all outpatient costs (for all patients) to HCPCS reimbursement levels (for all patients) was estimated at 50%.

The cost of pasireotide was based on Medicare reimbursement for the 900 mcg dosing formulation using a reimbursement level of 95% of the average wholesale price (AWP) in 2013 (\$287.68 per 900 mcg)²⁰. Therefore, the estimated cost of one dose of pasireotide in 2013 Medicare dollars was \$273.30. The total cost of the study drug was calculated based on the number of doses each patient received. This amount was added to the total direct cost for each patient.

Data analysis was performed using IBM SPSS version 22 and Microsoft Excel 2007. Two-sample t-test was used to evaluate for difference in means between comparison groups. A *p*-value <.05 was considered significant.

RESULTS

300 patients were included for analysis. 152 patients were randomized to receive pasireotide and 148 patients to receive placebo. In the pasireotide group, 111 patients underwent pancreaticoduodenectomy and 41 patients underwent distal pancreatectomy. The median length of stay (LOS) for the index admission was 7 days (range 4–27 days) for patients who underwent pancreaticoduodenectomy and 5 days (range 4–9 days) for those who underwent

distal pancreatectomy. In the placebo group, 109 patients underwent pancreaticoduodenectomy with median LOS of 7 days (range 4–72 days), and 39 underwent distal pancreatectomy with median LOS of 7 days (range 4–13 days). Patient characteristics, operative details, and postoperative outcomes are presented in Table 1.

The primary endpoint was met in 45 patients (15.0%). In the pasireotide group, 14 of 152 patients (9.2%) met the primary endpoint, and 31 of 148 patients (20.9%) in the placebo group met the primary endpoint ($p = .006$). The absolute risk reduction with pasireotide administration was 11.7%, with the number needed to treat in order to prevent one event being 8. A significant risk reduction was also seen during subgroup analysis by type of resection (pancreaticoduodenectomy or distal pancreatectomy), presence or absence of duct dilation, and surgical drain placement. Grade B and C fistula rates as defined by the ISGPF were also recorded and occurred in 37 patients (12.3%). In the pasireotide group, 12 patients (7.9%) developed a grade B POPF, and none developed a grade C POPF. In the placebo group, 20 patients (13.5%) developed a grade B POPF and 5 (3.4%) developed a grade C POPF ($p = .02$ between pasireotide and placebo group). Overall, 54 patients (18.0%) developed any grade of pancreatic complication, with 17 patients (11.2%) from the pasireotide group and 37 patients (25.0%) from the placebo group ($p = .002$) experiencing these events. Readmission occurred in 29 of 45 patients (64%) with clinically significant POPF and 40 of 255 (16%) patients without clinically significant POPF ($p < .001$). The readmission rate was also higher in the placebo group (43/148, 29%) than the pasireotide group (26/152, 17%) ($p = .02$).

The mean total direct cost for all 300 patients from the index admission to 90 days postoperatively was \$23,350 (range \$8,017–\$202,494). The mean total direct cost in the pasireotide group was \$22,774 (range \$10,419–\$80,304). The placebo group experienced a higher mean total direct cost of \$23,941 (range \$8,017–\$202,494); however this did not reach statistical significance ($p = .571$) (Table 2). The mean cost of pasireotide treatment was \$3,316 (range \$273 – \$3,826), and 76% of patients in the pasireotide group (115/152) received the complete 14-dose treatment regimen (Table 3). In the pasireotide group, 26 of the 37 patients were withdrawn from the study prior to completion of the 14-dose regimen due to nausea or vomiting that was temporally related to drug administration.

The mean total direct cost was two times higher in the 45 patients who developed a grade 3 or higher pancreatic complication (mean \$39,615, range \$13,770–\$202,494) compared with the 255 patients who did not (mean \$20,480, range \$8,017–\$62,941) ($p = .001$). In the group of 45 patients who developed POPF, the 14 patients who received pasireotide also had a lower mean total cost compared with the remaining 31 patients who received placebo (\$32,079 vs \$43,018, $p = .224$).

DISCUSSION

Pancreatic resection continues to be a procedure that has significant morbidity and measurable mortality^{6, 21, 22}. Pancreatic fistula, leak, and abscess (referred to in this study as pancreatic leak), are a group of complications related to the anastomosis (pancreaticoduodenectomy) or closure (distal pancreatectomy) of the pancreatic remnant.

Pancreatic complications are presumed secondary to the leakage of pancreatic exocrine secretions and/or enteric contents, and are the most common major complication following pancreatectomy; they have been reported in 10% to 35% of patients who undergo resection^{1–7}. We previously reported on the significance of this group of complications in a retrospective series of 908 patients who underwent pancreaticoduodenectomy or distal pancreatectomy at our institution over a five-year time period (2000–2005)¹⁶. Pancreatic leaks requiring prolonged use of surgical drains or additional interventions occurred in 158 of the 908 resected patients (17%) and re-operation was required in 26 patients (5%). The mortality rate of the 158 patients within this retrospective series who experienced leak was 5% (compared with a mortality rate of 2% in patients without pancreatic complications).

Numerous alterations in operative technique and management strategies have been trialed to reduce the prevalence of POPF with limited success and difficulties in reproducibility^{23–28}. The results from trials of other somatostatin analogs have been conflicting, and many surgeons have been hesitant to incorporate the routine use of somatostatin analogs into their practice^{2, 9, 12, 29, 30}. Our recently published randomized clinical trial evaluated a new somatostatin analogue pasireotide, which has a much longer half-life than octreotide and a higher binding affinity for a wider range of somatostatin receptors³¹. This favorable pharmacokinetic profile may provide the rationale for the demonstrated benefit we found with pasireotide in reducing the occurrence of POPF.

Postoperative pancreatic fistulas also represent a significant economic burden. Gani et al reported on the total hospital costs of 971 patients who underwent pancreatic resection at a high-volume academic center¹⁴. The median total costs nearly doubled in those who developed a postoperative complication following pancreatic resection compared with those who did not. Enestvedt et al reported similar results in a review of 144 patients undergoing pancreaticoduodenectomy in a network of community-based hospitals composed of both low- and high-volume centers¹⁵. The median cost was also nearly doubled for those with major complications, from \$29,038 to \$56,224. The development of pancreatic fistula was an independent predictor of increased total cost, and fistula alone accounted for a 1.3 times increase in the total cost, similar to the doubling in cost we report in our study in patients with POPF. Enestvedt also found that postoperative complications tended to occur in clusters, and pancreatic fistula was generally associated with at least four other complications, further contributing to the accumulation of incurred costs. Complications after pancreatic resection represent an important area for quality improvement in order to maximize the value of care. An intervention, such as pasireotide which can dramatically reduce POPF rates, must be considered in order to improve the efficiency of resource use within our healthcare system. The primary goal is not only to reduce health care costs, but to improve the value of care.

In this study, we found the routine use of pasireotide did not increase overall costs in pancreatic resection. The total direct costs in patients who received pasireotide was actually lower than patients who received placebo (\$22,774 vs \$23,941); however, this was not statistically significant ($p=.571$). This demonstrates that the use of pasireotide is a cost-effective measure which can improve patient outcomes by reducing the incidence of POPF and the associated subsequent complications without increasing overall costs. The lack of a

statistically significant cost difference between the pasireotide and placebo group is potentially a reflection of one of our study limitations in which the cost data during the 90 day postoperative follow-up period only included costs incurred at our institution. We were not able to obtain cost data if a patient had chosen to seek care at an outside institution during this 90 day period. This is particularly applicable for patients who developed postoperative complications and had cause to seek additional, non-routine postoperative care, and require. Using our institutional cost data, the pasireotide group had a lower, although not statistically significant, mean total cost than the placebo group. Potentially, if outside institutional cost data were incorporated, a statistically significant cost difference may emerge due to differences in the cost of postoperative care, as the placebo group did have significantly more occurrences of POPF as well as a higher percentage of readmission at our institution alone.

The strength of this study results from the fact that these data were derived from a randomized controlled trial, mitigating the effects of any potential bias, and ensuring the close monitoring and follow-up of all patients. While this was a single-institution randomized control trial, we hope the dramatic reduction in POPF we demonstrated with pasireotide use will encourage other institutions to participate in a larger, multi-institutional study for further validation. As with any single institution trial, our results are potentially affected by certain institutional practices, such as our use of surgical drains. Surgical drains are selectively place at our institution based on the surgeon's perception of a high-risk gland, and any association between drain placement and POPF development is most likely a reflection of this high-risk nature, and not causative. In subgroup analysis of patients who had surgical drain placement, the rate of clinically significant POPF was significantly lower in the pasireotide group than the placebo group. As surgical drain placement remains routine in many institutions, this suggests that our results can be applied to a breadth of different surgical practices.

Another strength of our study is the utilization of the true costs, and not patient charges or hospital reimbursements, as our outcomes metric. As the study patients were all treated at our institution, we were able to obtain the actual costs for each patient, without the utilization of any cost estimation models. In order to demonstrate the broader applicability of our results beyond our specific institution, we converted all hospital costs to Medicare adjusted dollars. Grenda et al reviewed Medicare claims data for inpatient hospitals across the United States, and demonstrated this cost metric to be a highly reliable measure of outcomes, allowing for comparison across varying hospital systems³². Our study was not limited to Medicare patients so Medicare adjusted dollars was used in place of Medicare claims data; however, the use of this standardized cost platform allows for greater generalizability of the cost-effectiveness of pasireotide in preventing POPF in a wide range of hospital settings.

CONCLUSION

Pasireotide administration during pancreatic resection significantly reduces the incidence of clinically significant postoperative pancreatic complications without increasing the overall

cost of care. Pasireotide is a cost-effective intervention and should be strongly considered to be incorporated into the standard of care for pancreatic resections.

Acknowledgments

none

Source of Funding: Funded by Novartis Pharmaceuticals.

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Table 1

Patient characteristics, operative details, and postoperative course.

	Pasireotide group N = 152	Placebo group N = 148	All N = 300
Gender			
Male	82 (54%)	83 (56%)	165 (55%)
Age in years, median (range)	64 (37–86)	65 (30–89)	65 (30–89)
Dilated duct	63 (41%)	73 (49%)	136 (45%)
Duct size mm, median (range)	3 (1–15)	4 (1–16)	3 (1–16)
Procedure			
Pancreaticoduodenectomy	111 (73%)	109 (74%)	220 (73%)
Distal pancreatectomy	41 (27%)	39 (26%)	80 (27%)
Soft pancreatic gland	81 (53%)	77 (52%)	158 (53%)
Surgical drain placement	43 (28%)	36 (24%)	79 (26%)
Index admission LOS, median (range)			
Pancreaticoduodenectomy	7 (4–27)	7 (4–72)	7 (4–72)
Distal pancreatectomy	5 (4–9)	7 (4–13)	6 (4–13)
Pancreatic complication grade 3	14 (9%)	31 (21%)	45 (15%)
ISGPF Grade			
B	12 (8%)	20 (14%)	32 (11%)
C	0	5 (3%)	5 (2%)
Any pancreatic complication	17 (11%)	37 (25%)	54 (18%)
Patients who received all 14 doses of pasireotide or placebo	115 (76%)	128 (86%)	243 (81%)
Postoperative readmission	26 (17%)	43 (29%)	69 (23%)

LOS indicates length of stay; ISGPF, International Study Group of Pancreatic Fistula.

Table 2

Comparison of total costs in the pasireotide and placebo group.

	Total costs of pasireotide group	Total costs of placebo group	p-value
Mean	\$22,774±\$9,488	\$23,941±\$23,223	.571
Minimum	\$10,419	\$8,017	
Maximum	\$80,304	\$202,494	

Table 3

Pasireotide dosages and costs.

	Number of pasireotide doses	Pasireotide costs
Mean	12±4	\$3,316±\$1,082
Minimum	1	\$273
Maximum	14	\$3,826