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Routine Drainage of the Operative Bed Following Elective Distal Pancreatectomy Does Not Reduce the Occurrence of Complications

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Abstract

Background—Routine drainage of the operative bed following elective pancreatectomy remains controversial. Data specific to distal pancreatectomy (DP) have not been examined in a multi-institutional collaborative.

Methods—Data from the American College of Surgeons-National Surgical Quality Improvement Program Pancreatectomy Demonstration Project were utilized. The impact of drain placement on development of pancreatectomy-related and overall morbidity were analyzed. Propensity scores for drain placement were calculated, and nearest neighbor matching was used to create a matched cohort. Groups were compared using bivariate and logistic regression analyses.

Results—Over 14 months, 761 patients undergoing DP were accrued; 606 were drained. Propensity score matching was possible in 116 patients. Drain and no drain groups were not different with respect to multiple preoperative and operative variables. All pancreatic fistulas ($p<0.01$) and overall morbidity ($p<0.05$) were more common in patients who received a drain. The placement of a drain did not reduce the incidence of clinically relevant pancreatic fistula nor the need for postoperative procedures.

Conclusions—Placement of drains following elective distal pancreatectomy was associated with a higher overall morbidity and pancreatic fistulas. Drains did not reduce intra-abdominal septic

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ACS NSQIP Disclaimer:

The American College of Surgeons-National Surgical Quality Improvement Program and the hospitals participating in the ACS-NSQIP are the source of that data used herein; they have not verified and are not responsible for the statistical validity of that data or the conclusions derived by the authors.

morbidity, clinically relevant pancreatic fistulas nor the need for postoperative therapeutic intervention.

Keywords

drain; fistula; outcome; pancreas; surgery

INTRODUCTION

Drain placement in the surgical bed at the time of elective pancreatectomy remains a commonly utilized but controversial practice. In theory, drains allow for controlled evacuation of pancreatic secretions if a leak occurs thereby reducing potential complications such as bleeding, pseudocyst and/or abscess formation. These complications often mandate therapeutic intervention including the potential need for reoperation and may lead to an increase in procedure related mortality. Moreover, drains might allow for the early recognition of a pancreatic fistula or of postoperative bleeding. Drains, however, are not innocuous and have been associated with septic morbidity from retrograde infection as well as erosion into peri-pancreatic vessels and regional hollow viscera.^{1–5} In addition, closed suction drainage could promote a pancreatic fistula.^{3,5–6} Drain failure may occur due to isolation from the pancreas by surrounding tissues. Finally, if suspicious fluid collections do arise postoperatively, image guided percutaneous drainage has improved greatly and is typically readily available.

Prior studies examining drain utilization following elective pancreatectomy have most often suggested no benefit to their placement.^{2,57–14} However, a recent multicenter randomized controlled study found that the frequency and severity of complications were increased if drains were eliminated following pancreaticoduodenectomy.¹⁵ In addition, analyses specific to those undergoing distal pancreatectomy have been sparse.^{5,10,11} To address these issues, we used a propensity score matched cohort from the American College of Surgeons–National Surgical Quality Improvement Program (ACS-NSQIP) Pancreatectomy Demonstration Project multi-institutional database to assess the association between intraoperative drain placement and postoperative complications following elective distal pancreatectomy. We hypothesized that the use of drains would mitigate the development of intra-abdominal morbidity and the need for therapeutic intervention postoperatively.

METHODS

Pancreatectomy Demonstration Project (PDP)

ACS-NSQIP is a standardized multicenter national database which prospectively collects multiple demographic, laboratory and comorbidity variables to provide risk-adjusted rates of overall postoperative morbidity and mortality.^{16–19} The ACS-NSQIP Pancreatectomy Demonstration Project was piloted from November 2011 through December 2012 to evaluate the feasibility of prospective collection of variables relevant to the short term outcomes following pancreatectomy.²⁰ The ACS-NSQIP Pancreatectomy Demonstration Project was queried to identify patients having elective distal pancreatectomy. This database was derived from 43 volunteer institutions in the United States participating in the ACS-

NSQIP Procedure Targeted pancreatectomy module (see Acknowledgements). In addition to the standard variables from the ACS-NSQIP database, the pancreatectomy-specific variables collected in this demonstration project are listed in Table 1. Pancreatic duct size and remnant consistency were determined by the operating surgeon. In cases of stapled transection, and when the surgeon did not provide information, duct size was estimated by the Surgical Clinical Reviewers from preoperative imaging and/or endoscopic pancreatography. Duct size options included < 3mm, 3–6 mm and >6 mm. Gland texture options included soft, intermediate and hard. Variables not captured in this database include method of remnant closure and type of drain utilized.

Propensity Score Analysis

A propensity score for the placement of a drain at the time of pancreatic resection was generated using the following variables: age, gender, race, body mass index (BMI), preoperative albumin, pancreatic texture and duct size, the presence of concurrent organ or vascular resection, and the final pathology. Patients who received peritoneal drainage at the time of resection and those who did not were then matched based on propensity scores using nearest neighbor matching. Once the propensity-matched cohort was derived, groups were compared relative to the utilization of neoadjuvant therapy as well as intraoperative variables including operative approach, operative time and transfusions. Neoadjuvant therapy included those receiving chemotherapy or radiation therapy individually or in combination.

Outcomes

Outcomes that were assessed included 30-day overall morbidity, serious morbidity, which included deep incisional and/or organ space surgical site infection (SSI), wound disruption, cerebral vascular accident or stroke, myocardial infarction, cardiac arrest requiring cardiopulmonary resuscitation, pulmonary embolism, and ventilator dependence longer than 48 hours, acute renal failure, bleeding complications and sepsis or septic shock. Specific to distal pancreatectomy, outcomes included overall and clinically relevant pancreatic fistula, deep incisional and organ space SSI, the need for postoperative therapeutic percutaneous drainage and/or reoperation. Clinically relevant pancreatic fistulas were defined as those requiring percutaneous drainage, reoperation and/or death. Thus, most Grade B and all Grade C pancreatic fistulas as defined by the International Study Group for Pancreatic Fistulas (ISGPF) were captured. In addition, overall pancreatic fistulas also captured Grade A fistulas which required more than seven days of drains. However, Grade A fistulas with prolonged drainage were not captured if drain amylase was not measured. Median length of stay also was determined.

Statistical Analysis

Unadjusted analyses were performed to compare characteristics between the two propensity-score matched groups using t-tests for continuous variables and chi-square tests for categorical variables. Multivariate logistic regression analysis was used to determine the independent association between drain use and clinically relevant pancreatic fistula, organ space and deep incisional SSI, the need for percutaneous drainage and/or reoperation and a composite outcome combining organ space and deep incisional SSI, postoperative percutaneous drainage, and reoperation. Comparisons between groups were analyzed using

bivariate and logistic regression analyses. Statistical significance was assessed at the 95th percentile.

RESULTS

Patient Demographics

Data were accumulated on 761 patients undergoing elective distal pancreatectomy during the study period. Six hundred and six (80%) underwent prophylactic drainage of the operative bed whereas 155 (20%) had no drain. Using predetermined variables specific to pancreatic resection, propensity score matching was possible in 116 patients. Thirty-nine patients not having drainage could not be matched due to incomplete data or lack of an adequate peer who received a drain. Overall mortality in the 761 DP patients occurred in eight patients (1.1%). Within the group of patients excluded from the propensity matched cohort were all eight deaths – three in those who received a drain, and five among those with no drain.

Specific to our propensity-matched cohort, no difference was observed between those who did have prophylactic drainage (n=116) and those who did not (n=116) with respect to age, gender, race, BMI, neoadjuvant therapy, American Society of Anesthesia (ASA) class or, preoperative albumin. In addition, the drain and no drain patients did not differ with respect to operative duration, minimally invasive surgery, gland texture, duct size, intraoperative transfusions, concurrent organ or vascular resection or pathology (Table 2). While a higher percentage of patients had a soft pancreatic remnant in the no drain group (65 vs. 58%), this difference did not reach statistical significance.

All patients in the drain and no drain propensity score matched groups survived surgery. Overall morbidity was higher in the drained patients (43 vs 30%, $p < 0.05$) (Figure 1, Table 3). While no single individual complication was different between groups, the aggregate of all complications combined was significantly higher in those who received a drain. Serious morbidity did not differ between the two groups (31 vs 23%, $p = 0.17$) (Figure 1, Table 3).

A statistically significant higher incidence of all pancreatic fistulas as defined in the PDP was observed in those who received a drain (21.7 vs. 7.0%, $p < 0.01$) (Figure 2). However, when analyzed specific to clinically relevant pancreatic fistulas, this difference was not statistically significant (10.3 vs 4.3%, $p = 0.41$) (Figure 2, Table 4). No difference with respect to organ space or deep incisional SSI, the need for postoperative percutaneous drainage or the need for reoperation was observed between those who did and did not have a drain placed following pancreatectomy. Combining deep incisional and organ space infection along with postoperative percutaneous drainage and reoperation as a composite outcome did not demonstrate a difference between those with and without a drain. Median length of hospital stay did not differ between the two groups (6 days each).

DISCUSSION

Results of this propensity score matched cohort derived from the ACS-NSQIP Pancreatectomy Demonstration Project suggest that prophylactic drainage of the surgical bed following distal pancreatectomy is associated with increased overall morbidity and

pancreatic fistulas. However, the incidence of serious morbidity, clinically relevant pancreatic fistulas and the need for postoperative therapeutic intervention was not reduced in patients who received a prophylactic drain. This analysis suggests that drains may be avoided selectively in low-risk patients undergoing distal pancreatectomy.

The impact of drain placement as a means to reduce postoperative intra-abdominal morbidity following pancreatic resection has been analyzed in several studies of varied design – most often involving pancreaticoduodenectomy (PD). In 1992, Jeekel reported 22 consecutive patients having Whipple procedures without drainage.⁷ Major intra-abdominal morbidity was limited to three patients with an intra-abdominal abscess (IAA) – all treated by non-operative means suggesting the elimination of drainage did not lead to adverse outcomes.⁷ Several retrospective case cohort studies have supported this conclusion. In a study by Heslin et al, 38 of 89 well matched patients did not have prophylactic drainage following PD.⁸ Groups did not differ with respect to the incidence of IAA, pancreatic and/or biliary fistulae, or the need for postoperative therapeutic intervention. Hospital length of stay was equivalent. Over a 5-year time period, Fisher and colleagues compared 47 consecutive patients (17 undergoing DP) without peritoneal drainage to a cohort of 179 patients (56 DP) having pancreatic resection immediately preceding the withdrawal of routine drainage.⁹ Two-thirds of the patients in this study had a Whipple procedure. Those without peritoneal drainage experienced less overall complications, and the median complication grade was reduced. However, hospital readmission and the need for postoperative abdominal percutaneous drainage were higher in those without drainage. A subset analysis relative to distal pancreatectomy was not performed.

Mehta et al reported 709 patients who had a Whipple procedure over a 7-year period.¹⁴ Patients who received a drain and those who did not were well matched with respect to preoperative demographics though the quality of the pancreatic remnant was not reported. However, patients who received a drain were more likely to have had a longer operative time, portal vein resection, higher intraoperative blood loss and to receive intraoperative blood transfusions. In a multivariable analysis these variables did not significantly increase the incidence of clinically relevant pancreatic fistula or the need for postoperative therapeutic intervention. The need for postoperative percutaneous drainage, reoperation, readmission and 30 day mortality also were not different between groups. Adham and colleagues noted similar findings in 242 patients one-half of whom had a pancreaticoduodenectomy.¹¹ Demographics were not different between those with a drain and those without; however, right and left pancreatectomy were not analyzed separately. Of those having a Whipple procedure, groups were not different with respect to the need for postoperative percutaneous drainage or reoperation.

Two randomized controlled studies on the role of peritoneal drainage following pancreatic resection have yielded opposite results. Conlon et al randomized 179 patients 75% of whom had a Whipple resection.² Groups were well matched with respect to age, comorbidities, operative time, blood loss and pathology. Those who received a drain had a statistically higher incidence of pancreatic fistula and intra-abdominal abscess (IAA). Further, four patients in this group developed an enterocutaneous fistula. No difference between groups was observed with respect to the need for postoperative therapeutic intervention

(percutaneous drainage and/or re-operation), hospital readmission or procedure related mortality. In the only randomized study to date demonstrating deleterious outcomes if drains are not utilized, Fisher and colleagues analyzed 137 patients undergoing a Whipple procedure in a multi-institutional study.¹⁵ The groups did not differ with respect to demographics, comorbidities, pancreatic texture and anastomotic technique, vascular resection, the need for blood transfusion, readmission or reoperation. However, those who did not receive a drain had a statistically significant higher incidence of delayed gastric emptying, IAA, the need for postoperative percutaneous drainage and a prolonged length of stay (LOS). This study, however, was terminated early by the Data Safety Monitoring Board due to a significant increase in mortality from 3% to 12% in those that did not receive a drain.

Finally, two recent meta-analyses have assessed the utility of peritoneal drainage as a means to reduce complications following pancreatectomy.^{12,13} Both, however, were performed prior to Fisher's randomized trial. van der Wilt et al found that the proportion of patients with major complications was lower in those who did not have drains placed though this difference did not reach statistical significance.¹² Predefined inclusion criteria limited this meta-analysis to only three studies.^{2,8,9} Kaminsky and Mezhir noted that drains had no impact on reducing pancreatic fistula, total complication, LOS or hospital readmission.¹³ However, patients at high risk for a PF such as those with a soft remnant or excessive blood loss were more likely to have had prophylactic drainage. The authors concluded that the data support a selective approach toward drainage. This meta-analysis was hindered by the absence of any predefined criteria regarding inclusion or exclusion of studies. In addition, neither meta-analysis assessed distal pancreatectomy specifically.

In contradistinction to pancreaticoduodenectomy, the role of prophylactic peritoneal drainage following distal pancreatectomy has received much less attention. Studies that have included distal pancreatectomy along with pancreaticoduodenectomy have, in many instances, also failed to perform distinct subset analyses relative to this former group of patients.^{2,9,11} Adham et al identified no difference in the need for postoperative therapeutic intervention or reoperation with or without placement of a drain amongst 66 patients undergoing distal pancreatectomy though data on this cohort were limited.¹¹ A retrospective analysis by Paulus et al examined 69 patients, including 30 without drainage, having open distal pancreatectomy over a 14 year time period.¹⁰ Groups were well matched with respect to age, pathology, remnant consistency, the absence of main duct ligation, blood loss greater than 500cc and concurrent extrapancreatic organ removal. No difference was observed between patients with a drain and those without with regard to PF, IAA or postoperative pseudocyst formation. Similar to findings of the current study, the need for postoperative percutaneous drainage of the operative bed and the need for reoperation were not different regardless of the presence or absence of a drain.

Correa-Gallego and colleagues reviewed 350 patients undergoing distal pancreatectomy over a recent 5 year time period – 196 of whom did not have peritoneal drainage.⁵ In common with the results reported herein, no difference was found between groups with respect to serious complications, the need for percutaneous drainage, reoperation or hospital readmission. However, blood loss and operative time were significantly higher in those who

received a drain suggesting that there may have been surgeon bias toward draining more high risk patients.

This study has several limitations. Like any retrospective cohort comparing treatment interventions, a potential exists for selection bias. Patients who did not receive drains may have had favorable characteristics identified by surgeons intraoperatively that led to avoidance of drain placement. We attempted to mitigate this bias by performing a propensity score matched analysis. The participating institutions of the Pancreatectomy Demonstration Project are more commonly high-volume institutions than might be encountered in general practice; and thus, our study findings may be limited to these centers with specialized expertise in performing pancreatic surgery. The wide confidence intervals in our regression modeling suggest that our study may be underpowered to detect significant differences amongst drain use. We were only able to analyze 116 of the 155 potentially evaluable patients without a drain which also could lead to a sampling bias. Furthermore, while eight patients died in this database no deaths were captured in our propensity-matched cohort. Five deaths occurred in those not receiving a drain, but no matched peer was possible within the large pool that received a drain. This fact could represent a sampling bias but could also suggest that these deaths were due to factors outside those assessed in this study.

The definition of clinically relevant pancreatic fistula captured by the Pancreatectomy Demonstration Project differs from the ISGPF classification but is perhaps more strict in terms of clinical relevance. All Grade C pancreatic fistulas as defined by ISGPF either require therapeutic intervention or lead to death. Grade B (ISGPF) fistulas managed solely by antibiotics and/or octreotide are unusual. Thus, while the PDP definition of a clinically relevant pancreatic fistula might not capture some Grade B fistulas, as defined by the ISGPF, no Grade A fistulas are included. Finally, the Pancreatectomy Demonstration Project only accrued 30-day data from the time of surgery. Some complications following distal pancreatectomy, such as a pancreatic pseudocyst, may be recognized weeks or even months following the index procedure. Thus, this study may not have captured all procedure-related morbidity because outcomes in ACS-NSQIP are assessed at 30 days after surgery. Furthermore, the issue of early versus late drain removal was not addressed in this study but will be in a separate analysis.

CONCLUSION

The advantage of the ACS-NSQIP Pancreatectomy Demonstration Project is that it allows multi-institutional capture of data points critical to comparing outcomes following pancreatectomy such as BMI, remnant consistency and concurrent organ and vascular resection – variables not uniformly recorded in multi-institution analyses which enhance validity when compared to single institution case series. Doing so allowed the development of a well-matched propensity scoring cohort for comparison of drain utilization following distal pancreatectomy. With these advantages and limitations in mind our data do suggest that serious morbidity and the need for therapeutic intervention postoperatively following elective distal pancreatectomy is equivalent whether or not drains are utilized. This analysis did not address the issues of early versus late drain removal, which is the subject of a separate analysis. Prior studies have suggested that early drain removal (post-operative day

three or sooner) in patients with low drain fluid amylase, reduces complications including pancreatic fistula and intra-abdominal abscess.^{3,4} Thus, a randomized trial specific to distal pancreatectomy comparing drains versus no drains inclusive of data with respect to drain removal is necessary.

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- IU University
- IU Methodist
- Johns Hopkins
- Kaiser Permanente SF
- Kaiser Walnut
- Leigh Valley
- Massachusetts General
- Mayo- Methodist
- Mayo-St Mary's
- Northwestern University
- Ohio State University
- Oregon Health Sciences Center
- Penn State University
- Providence Portland
- Sacred Heart
- Stanford University
- Tampa General
- Thomas Jefferson University
- University Alabama
- UC Irvine

- UC San Diego
- University Iowa
- University Kentucky
- University Minnesota
- University Texas Medical Branch
- University Virginia
- University Wisconsin
- Vanderbilt University
- Wake Forest University
- Wash University St. Louis
- Winthrop University

IU = Indiana University, SF=San Francisco, UC= University of California

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Figure 1.
Overall and Serious Morbidity in Drain and No Drain Patients

Figure 2.
Pancreatic Fistulas in Drain and No Drain Patients

Table 1

Variables Unique to ACS-NSQIP Pancreatectomy Demonstration Project

PREOPERATIVE

Preoperative jaundice

Biliary stent placement

Neoadjuvant chemotherapy/radiation (in 90 days before operation)

INTRAOPERATIVE

Type of operation

Operative approach

Pylorus-preservation

Pancreatic duct size

Pancreatic gland texture

Vascular resection

Method of pancreatic reconstruction

Ante vs. retrocolic enteric reconstruction

Intraoperative drain placement (PJ/HJ, both)

POSTOPERATIVE

POD #1 Highest drain amylase

POD #2–30 Highest drain amylase

Date drain removal

Pancreatic fistula

Percutaneous drainage

Delayed gastric emptying

Pathology

Malignant

Type

T-stage

N-stage

M-stage

Benign

Type

Tumor size

PJ= pancreaticojejunostomy

HJ = hepaticojejunostomy

Table 2

Demographics and Intraoperative Variables in Drain and No Drain Groups

	Drain (n=116)	No Drain (n=116)	P-Value
Demographic			
Age (years)	57	59	0.41
Gender-Male %	42.4	47.4	1.00
Minority	17.2	15.5	0.72
BMI (%)			0.60
Underweight	2	1	
Normal	31	34	
Overweight	36	34	
Obese	31	31	
Neoadjuvant therapy (%)	8	2	0.15
ASA Class (%)			0.26
I	2	0	
II	33	29	
III	63	68	
IV	2	3	
Albumin (g/dl)	3.9	3.9	0.86
Intraoperative Variables			
Operative Duration (hrs)	3.7	3.8	0.99
Minimally Invasive Surgery (%)	28	28	0.85
Texture (%)			0.61
Hard	31	22	
Intermediate	11	13	
Soft	58	65	
Duct Size (%)			0.81
>6mm	13	12	
3–6mm	19	24	
<3mm	68	64	
Intraoperative Transfusion (%)	3	0	0.24
Concurrent Organ Resection (%)	4	4	0.99
Concurrent Vascular Resection (%)	11.4	7.9	0.36
Pathology (%)			0.23
malignant	70	62	
benign	30	38	

Table 3

Overall and Serious Morbidity

	Drain (n=116) (n)	No Drain (n=116) (n)	p-Value
Perioperative transfusions * (%)	19	12	0.203
Superficial surgical site infection (%)	11	4	0.067
Organ space surgical site infection * (%)	11	4	0.083
Post-op sepsis * (%)	10	8	0.816
Deep venous thrombosis (%)	8	4	0.253
Urinary tract infection (%)	6	5	1.000
Post-op pneumonia (%)	4	4	1.000
Ventilator for > 48 hours * (%)	3	1	0.622
Pulmonary embolism * (%)	2	6	0.171
Deep incisional infection (%)	2	3	1.000
Wound dehiscence * (%)	2	1	0.377
Post-op cardiopulmonary resuscitation * (%)	1	0	1.000
Acute renal failure * (%)	1	0	1.000
Post-op myocardial infarction * (%)	0	2	0.498
Progressive renal insufficiency * (%)	0	1	1.000
Unplanned intubation * (%)	0	0	n/a
Stroke * (%)	0	0	n/a

* Serious morbidity, **post-op=postoperative**

Table 4

Multivariate Logistic Regression of Postoperative Complications: Drain versus No Drain Groups

	Drain (n=116)(%)	No Drain (n=116) (%)	OR (C.I.)	P-Value
Pancreatic Fistula				
All	21.7	7.0	3.58 (1.47, 8.73)	0.004
Clinically Relevant	10.3	4.3	2.58 (0.87, 7.52)	0.412
Organ Space SSI	9.5	4.3	2.33 (0.78, 6.92)	0.120
Deep Incisional SSI	0.9	2.6	0.33 (0.03, 3.20)	0.310
Percutaneous Drainage	14.0	9.2	1.61 (0.67, 3.87)	0.290
Reoperation	0.9	2.7	0.34 (0.03, 3.29)	0.620
Composite Outcome *	17.2	14.6	1.21 (0.60, 2.46)	0.590

SSI = surgical site infection; OR = odds ratio; C.I. = confidence interval

* Organ space SSI, deep incisional SSI, percutaneous drainage or reoperation