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ORIGINAL ARTICLE

Morbidity and Mortality of Pancreaticoduodenectomy for Benign and Premalignant Pancreatic Neoplasms

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Abstract
Objectives Patients with benign neoplasms of the pancreas are selected for pancreaticoduodenectomy if there is concern for malignant transformation. This study compares outcomes after pancreaticoduodenectomy for patients with premalignant and malignant pancreatic neoplasms.
Study Design This retrospective cohort study included all patients who underwent pancreaticoduodenectomy for histologically confirmed benign/premalignant pancreatic neoplasms and primary pancreatic malignancy reported to National Surgical Quality Improvement Program (NSQIP) from 2005 to 2011. Patient characteristics, intraoperative and postoperative morbidity and mortality were compared.
Results A total of 6085 patients underwent pancreaticoduodenectomy: 744 (12.2 %) for benign/premalignant and 5341 (87.8 %) for malignant pancreatic neoplasms. Patients with benign/premalignant neoplasms were more commonly female, had lower American Society of Anesthesiologists (ASA) class, and were less likely to have major comorbidities (all $p \leq 0.003$). After resection, patients with benign/premalignant neoplasms were more likely to develop organ space infection (13.4 vs. 8.5 %, $p<0.001$) and sepsis (12.2 vs. 9.2 %, $p=0.009$). Cardiovascular, pulmonary, renal, and other organ system complications ($p=0.12$) as well as 30-day mortality (3.0 vs. 2.0 %, $p=0.128$) did not differ.
Conclusions Organ space infection and sepsis are more common after pancreaticoduodenectomy for benign/premalignant neoplasms. Planned improvements in NSQIP data capture should allow for better measurement of this morbidity. A carefully balanced risk and benefit discussion should precede resection in these patients.

Keywords Pancreaticoduodenectomy · Pancreatic neoplasms · IPMN · Pancreatic adenocarcinoma · NSQIP

Introduction

Pancreaticoduodenectomy (PD) is routinely performed for resection of neoplasms of pancreatic head and uncinate process. Current mortality after PD performed at high volume centers is as low as 1–2 % due to improvements in operative technique and perioperative care.[1–5] However, postoperative morbidity remains considerable and ranges from 30 to 60 %. Major complications include pancreatic fistula, delayed gastric emptying, and surgical site infections (SSI).[6–9] Improved postoperative outcomes have arguably extended the indications for PD beyond malignancy to premalignant and benign lesions of the pancreas.

The expanded use of advanced cross-sectional imaging for diagnostics has led to the increased identification of benign

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and premalignant pancreatic neoplasms, particularly pancreatic cysts.[10,11] Current consensus guidelines recommend management strategies including surveillance and resection for specific patients with intraductal papillary mucinous neoplasm (IPMN) and mucinous cystic neoplasm (MCN).[12] Patients with serous cystic neoplasms (SCNs) are generally observed and not resected unless local symptoms or invasion is present. The benefits associated with early resection among patients with potentially premalignant lesions are balanced with potential for morbidity associated with pancreaticoduodenectomy.

Our objective in this study was to define in the contemporary era the morbidity and mortality after PD for patients with benign/premalignant pancreatic neoplasms and compare these with outcomes after PD for primary pancreatic malignancy. Previous studies evaluating outcomes after PD for benign pancreatic disease have been single institution experiences and demonstrated generally favorable outcomes.[10,11,13,14] Objective nationwide comparisons to patients with pancreatic malignancy have not been performed previously. We used the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database to evaluate postoperative morbidity and mortality between patients with benign/premalignant and malignant pancreatic neoplasms.

Methods

NSQIP and Study Population

The current study utilized patient records obtained from the American College of Surgeons National Quality Improvement Program (ACS-NSQIP) public use file (PUF). A brief description of NSQIP methodology is as follows. Within participating centers, preoperative patient characteristics, intraoperative processes of care, and postoperative adverse events within 30 days after the index operation are prospectively collected by trained risk assessment data managers with nursing expertise. Data abstraction occurs consistently with standardized definitions. Within the database, the index operation is defined as the first operation during the hospitalization for patients undergoing multiple operations during their hospital stay. The ACS NSQIP PUF has been designated by the University of Virginia Institutional Review Board for Health Sciences Research as a public data set, as such this study is considered exempt from formal IRB review.

Patient Selection and Case Definitions

A retrospective review of the prospectively maintained NSQI P PUF for 2005 to 2011 was performed for all adult (age ≥18 years) patients who underwent pancreaticoduodenectomy as their index operation. Patients who underwent pancreaticoduodenectomy with distal gastrectomy current procedural terminology ((CPT) 48150) or pylorus-sparing pancreaticoduodenectomy (CPT 48153) were included. Patients were stratified by benign and malignant pancreatic neoplasm codes using the International Statistical Classification of Diseases, Ninth revision (ICD-9) diagnosis codes. Benign/premalignant pancreatic neoplasms were defined using the following: benign neoplasm of pancreas, except islets of Langerhans (211.6), and neoplasm of unspecified nature of digestive system (239.0). Malignant pancreatic neoplasms were identified using ICD-9 code 157 including the following: malignant neoplasm of head of pancreas (157.0), malignant neoplasm of body of pancreas (157.1), malignant neoplasm of pancreatic duct (157.3), malignant neoplasm of other specified sites of pancreas (157.8), malignant neoplasm of pancreas, part unspecified (157.9).

Variable Definitions, Preoperative Characteristics, and Outcomes

All analyzed variables reflect standardized NSQIP definitions.[15] Preoperative risk factors and comorbidities reported to NSQIP included in this study were age, sex, American Society of Anesthesiologists (ASA) class, diabetes, weight loss, current smoker/drinker (ETOH), chronic obstructive pulmonary disease (COPD), preoperative dyspnea, congestive heart failure (CHF), myocardial infarction, previous percutaneous coronary intervention (PCI), bleeding disorder, preoperative transfusion, preoperative albumin, preoperative chemotherapy, and preoperative sepsis. Length of operative duration and postoperative length of hospital stay were recorded.

Reported medical and surgical complications/outcomes included the following: unplanned intubation, acute renal failure, stroke, myocardial infarction (MI), deep venous thrombosis (DVT)/thrombophlebitis, sepsis, superficial incisional surgical site infection (SSSI), deep incisional surgical site infection (DSSI), organ/space surgical site infection (OSSI), pulmonary embolism (PE), urinary tract infection (UTI), bleeding/transfusions, re-operation, and 30-day or in-hospital mortality. Composite surgical site infections (SSIs) include patients with SSSI, DSSI, and/or OSSI.

Statistical Analysis

All statistical analyses performed in this study were designed to test the null hypothesis that preoperative characteristics and comorbidities and postoperative medical and surgical complications/outcomes are not significantly different depending on indication for pancreaticoduodenectomy. Categorical data are presented as within-group percentages and were compared using either chi-squared or Fisher's exact tests where appropriate. Continuous data are represented as median

(interquartile range). Data management and statistical analyses were performed using Predictive Analytics SoftWare (PASW) statistics software, version 19.0.0 (IBM Corporation, Somers, NY).

Results

Patient Demographics and Preoperative Comorbidities

There were 6085 pancreaticoduodenectomies performed during the study period: 5341 (87.8 %) for pancreatic malignancy and 744 (12.2 %) for benign/premalignant neoplasms. Malignant cohort by ICD-9 code includes the following: 157.0=3665 (69 %) patients, 157.1=65 (1 %) patients, 157.3=234 (4 %) patients, 157.8=353 (7 %) patients, and 157.9=1024 (19 %) patients; benign/premalignant cohort by ICD-9 code includes the following: 211.6=570 (77 %) patients and 239.0=174 (23 %) patients. The preoperative characteristics and comorbidities of these two groups are summarized in Table 1. Patients with premalignant and benign pancreatic neoplasms were younger (median [interquartile range (IQR)]: 62 [54–72] vs. 66 [58–74]years, $p<0.001$) and more commonly female (54.6 vs. 48.3 %, $p=0.003$). Patients without malignancy were also healthier and had fewer associated comorbidities including lower ASA class and lower proportion of preoperative diabetes mellitus, weight loss, transfusion requirements, chemotherapy use, and sepsis (all $p\leq0.035$). Preoperative albumin was significantly higher in patients without malignancy ($p<0.001$). Operative duration was longer in patients with benign and premalignant pancreatic neoplasms (median [IQR]: 369 [296–458] vs. 349 [274–405]min, $p<0.001$). Postoperative length of hospital stay was also longer in patients with benign and premalignant neoplasms (median [IQR]: 10 [7–15] vs. 9 [7–14]days, $p=0.015$).

Perioperative Complications

Pancreaticoduodenectomy for benign and premalignant pancreatic neoplasms was associated with a different

Table 1 Patient demographics and preoperative comorbidities

	Benign/premalignant ($n=744$)	Malignant ($n=5341$)	p value
Age (years)	62 (54–72)	66 (58–74)	<0.001
Sex			0.003
Male	336 (45.2)	2757 (51.6)	
Female	406 (54.6)	2578 (48.3)	
ASA class			<0.001
1	14 (1.9)	48 (0.9)	
2	257 (34.5)	1450 (27.2)	
3	448 (60.2)	3526 (66.0)	
4	24 (3.2)	311 (5.8)	
Diabetes mellitus	144 (19.3)	1406 (26.3)	<0.001
Weight loss	62 (8.3)	1167 (21.8)	0.001
Current smoker	152 (20.4)	1100 (20.6)	0.92
ETOH	24 (3.7)	123 (2.7)	0.15
COPD	41 (5.5)	244 (4.6)	0.25
Dyspnea	70 (9.4)	444 (8.3)	0.58
CHF	1 (0.1)	17 (0.3)	0.39
MI	1 (0.1)	15 (0.3)	0.45
Previous PCI	48 (7.4)	312 (6.8)	0.58
Bleeding disorder	17 (2.3)	135 (2.5)	0.69
Preoperative transfusion	0 (0)	33 (0.6)	0.032
Preoperative albumin (g/dL)	4.1 (3.8–4.4)	3.7 (3.3–4.1)	<0.001
Chemotherapy	5 (0.8)	186 (4.0)	<0.001
Preoperative sepsis	1 (0.1)	30 (0.5)	0.035
Operative duration (minutes)	369 (296-458)	349 (274-405)	<0.001
Length of stay hospital stay (days)	10 (7-15)	9 (7-14)	0.015

Data reported as *n (%)* except for age, preoperative albumin, operative duration, and length of hospital stay which are reported as median (interquartile range)

ASA American Society of Anesthesiology, *ETOH* alcohol, *COPD* chronic obstructive pulmonary disease, *CHF* congestive heart failure, *MI* myocardial infarction, *PCI* percutaneous coronary intervention

complication profile compared to patients undergoing pancreaticoduodenectomy for pancreatic malignancy. Proportions of overall complications did not differ between the benign/premalignant diagnoses and patients with malignancy (37.0 vs. 40.4 %, $p=0.079$, respectively). Postoperative complications are summarized in Table 2 (complications related to surgical infection) and Table 3 (complications not related to surgical infection). Patients undergoing pancreaticoduodenectomy for benign/premalignant neoplasms were more likely to develop postoperative urinary tract infection (6.5 vs. 4.6 %, $p=0.02$), organ space infection (13.4 vs. 8.5 %, $p<0.001$), and sepsis (12.2 vs. 9.2 %, $p<0.01$). Diagnosis of pancreatic malignancy, however, was associated with higher proportion of superficial infection (9.6 vs. 5.5 %, p, 0.001), venous thromboembolism (2.2 vs. 1.2 %, $p=0.02$), and perioperative transfusions (14 vs. 7.4 %, all $p<0.001$).

Medical complications, such as unplanned intubation, renal failure, stroke, and myocardial infarction, were the same in patients with malignant and benign/premalignant diagnoses (all $p\geq0.12$). The proportion of patients requiring re-operation (6.3 vs. 6.5 %, $p=0.85$) and 30-day mortality (2 vs. 3 %, $p=0.13$) did not differ between the two groups.

Discussion

At present, benign and premalignant pancreatic neoplasms are identified with increasing frequency due to the expanded use of cross-sectional imaging.[11·13] Predominant justification for pancreaticoduodenectomy in these patients is concern for malignancy or potential for malignant transformation. We aimed to define the nationwide morbidity and mortality after pancreaticoduodenectomy for patients with benign/premalignant pancreatic neoplasms in the contemporary era and compare these with outcomes after PD for primary pancreatic malignancy. Analysis of the large, standardized NSQIP database demonstrates significant differences in postoperative patient-specific complications.

Table 2 Complications related to surgical infection

	Benign/premalignant ($n=744$)	Malignant ($n=5341$)	p value
SSSI	41 (5.5)	513 (9.6)	<0.001
DSSI	10 (1.3)	126 (2.4)	0.08
OSSI	100 (13.4)	453 (8.5)	<0.001
Composite SSI	142 (19.1)	1020 (19.1)	>0.99
UTI	48 (6.5)	244 (4.6)	0.02
Sepsis	91 (12.2)	493 (9.2)	0.01

Data reported as *n (%)*

SSSI superficial incisional surgical site infection, *DSSI* deep incisional surgical site infection, *OSSI* organ/space surgical site infection, *SSI* surgical site infection, *UTI* urinary tract infection

Table 3 Postoperative complications not related to surgical infection

	Benign/premalignant ($n=744$)	Malignant ($n=5341$)	p value
Unplanned intubation	34 (4.6)	257 (4.8)	0.77
Acute renal failure	7 (0.9)	63 (1.2)	0.57
Stroke	3 (0.4)	21 (0.4)	0.97
MI	2 (0.3)	42 (0.8)	0.12
DVT/thrombophlebitis	9 (1.2)	117 (2.2)	0.02
Pulmonary embolism	5 (0.7)	46 (0.9)	0.60
Bleeding/transfusions	55 (7.4)	752 (14)	<0.001
Re-operation	47 (6.3)	347 (6.5)	0.85
Overall complications	275 (37.0)	2157 (40.4)	0.079
Mortality	15 (2)	161 (3)	0.13

Data reported as *n (%)*

MI myocardial infarction, *DVT* deep venous thrombosis

Advances in operative technique, perioperative management, and centralization of care have reduced the mortality after pancreaticoduodenectomy to 1–2 % at high volume centers.[1–5] However, procedure-specific complications, such as pancreatic fistula and/or delayed gastric emptying and infectious complications, after this operation remain high.[1·3·16·17] Previous studies evaluating postoperative complications after pancreaticoduodenectomy either focus on single institution experience or patients with chronic pancreatitis.[10·18·19]

Patients with diagnosis of chronic pancreatitis were specifically excluded from this study. Both pancreatic gland texture and pancreatic duct size typically differ between patients with chronic pancreatitis and non-malignant pancreatic neoplasms. While patients with chronic pancreatitis have a firm pancreas and often an enlarged pancreatic duct, patients with benign or premalignant pancreatic neoplasms frequently have a soft pancreas and normal, non-dilated, pancreatic duct. Both pancreatic gland texture and duct size have been implicated as risk factors for postoperative pancreatic fistula and resultant intraabdominal infection.[20·21]

In general, surgical site infection (including pancreatic fistula) is the most considerable cause of morbidity, hospital readmission, and mortality after pancreaticoduodenectomy.[6–9·22] While proportion of overall composite SSI between the two cohorts did not differ, resection for pancreatic malignancy was associated with higher proportions of postoperative superficial SSI. Preoperative biliary obstruction and biliary instrumentation could contribute to higher proportion of wound infections in this population.[23] In contrast, patients who underwent

pancreaticoduodenectomy for benign and/or premalignant neoplasms had significantly higher proportion of postoperative organ space surgical site infection. Pancreaticojejunostomy leak and pancreatic fistula are associated with pancreatic texture and duct diameter. Studies evaluating patient characteristics and the development of pancreatic fistula following pancreaticoduodenectomy have demonstrated associations between benign and premalignant pancreatic cystic neoplasms and postoperative pancreatic fistula.[21,24,25] In addition, postoperative pancreatic fistula has been identified as an independent predictor of postoperative intraabdominal abscess and other infectious complications.[26–28] Presumably, the majority of patients with OSSI in our study had either grade B or grade C pancreatic fistula; however, other causes of OSSI could include bile leak, gastrointestinal leaks, or other causes of peritonitis. In general, OSSI metric underestimates the true incidence of pancreatic fistula in NSQIP.[29]

Present NSQIP data collection does not include pancreas-specific parameters, such as pancreatic gland texture and duct size. In addition, the specific diagnoses (i.e., pancreatic adenocarcinoma, neuroendocrine carcinoma, IPMN) are not recorded by NSQIP. Instead, diagnoses are categorized using the non-specific ICD-9 classification. Improvements in NSQIP data collection have been recently introduced to permit better measurement of postpancreatectomy operative characteristics and outcomes. The recently implemented ACS-NSQIP Pancreatectomy Demonstration Project and the updated ACS NSQIP procedure-targeted variables and definitions include 16 pancreas-specific variables in addition to standard NSQIP variables collected prospectively from 33 participating institutions.[30] While collection of pancreas-specific parameters will improve measurement of postpancreatectomy outcomes, documentation of pancreas-specific diagnoses (pancreatic adenocarcinoma, neuroendocrine carcinoma, side-branch IPMN, main duct IPMN, etc.) and other non-ICD-based diagnosis fields would be required to truly evaluate outcomes after pancreatic surgery on a national scale.

A limitation of our data is lack of information detailing the type, size, or location of either malignant diagnosis (i.e., adenocarcinoma vs. neuroendocrine carcinoma) or benign/premalignant diagnosis (SCN, MCN, or IPMN). However, NSQIP data collection uses ICD-9 coding based on pathologic diagnosis after resection ensuring that patients are categorized based on the presence or absence of malignancy. As such, our analysis allows for a meaningful comparison of outcomes after pancreaticoduodenectomy for relatively homogeneous cohorts of patients with benign or premalignant disease or primary pancreatic malignancy. Further survival analysis or evaluation of long-term patient outcomes are beyond the scope of NSQIP data.

Conclusion

In conclusion, patients who undergo pancreaticoduodenectomy are at risk for similar major morbidity, regardless of diagnosis. However, patients with benign and/or premalignant pancreatic neoplasms have considerably higher rates of OSSI after pancreaticoduodenectomy as compared to patients with primary pancreatic malignancy. Although this is likely due to technical characteristics of postpancreaticoduodenectomy reconstruction, planned improvements in NSQIP data capture should lead to better measurement of postpancreatectomy morbidity. Lastly, preoperative informed discussion of the risks of pancreaticoduodenectomy and the increased risk of major infectious complications, such as OSSI and sepsis, is imperative for patients with benign or premalignant pancreatic neoplasms considering resection.

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