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An Analysis of Risk Factors, Timing of Complications and Readmission after Pancreaticoduodenectomy

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Abstract

Objective: Postoperative complications after pancreatico duodenectomy (PD) have been associated with an increased risk of readmission, yet the timing of these complications is unclear.

Methods: The NSQIP database was reviewed to identify patients who underwent PD in 2012. A multivariate analysis assessed postoperative outcomes, timing of complications and impact on readmission.

Results: 3,277 patients underwent PD: 48% experienced a postoperative complication and 16% were readmitted. The readmission rate in those that experienced a postoperative complication was 23%. After a postoperative complication, the readmission rate was 15% for pre-discharge compared with 70% for post-discharge complications (P<*0.05*). Predictors of readmission included: hypertension (RR=1.33, *P<0.05*), re-operation (RR=1.85, *P<0.05*) dependent functional status (RR=2.6, *P<0.05*), duodenal neoplasm (RR=8.81, *P<0.05*), cystic disease (RR=17.07, *P<0.05*) and the occurrence of post-discharge complications (RR=21.59, *P<0.05*). 89% of all complications occurred pre-discharge and 11% occurred post-discharge. Among post-discharge complications, deep space infection was the most common to occur (3.8%) and resulted in a readmission rate of 91%.

Conclusions: Pre-discharge complications were more common but post-discharge complications had a 20-fold increased risk of readmission.

Keywords: Readmission; Pancreaticoduodenectomy; Whipple; NSQIP; Morbidity

Introduction

The first successful pancreaticoduodenectomy (PD) was performed and reported by Whipple, Parsons and Mullins in 1935[1]. The authors reported a case series of three patients who underwent a two stage procedure for the treatment of ampullary carcinoma. A one-stage PD was later reported by Trimble in 1941. During the early stages of this procedure, morbidity and mortality were exceedingly high, up to 50% and 30%, respectively [2-4].

Beginning in the 1970s, peri-operative mortality began to decline [3, 4]. Contemporary reports of peri-operative mortality after PD in high-volume centers are approximately 2% [4-6]. This improvement has resulted from a variety of advancements in surgical technique, critical care, and management of post-operative complications. Although mortality has improved dramatically, morbidity has remained relatively high, at around 40-50% [4, 6, 7].

Because PD continues to be a high-risk procedure, the overall 30-day readmission rate is approximately 15-25%. [6-9]. Readmission rates of up to 38% have been reported during the 90 day peri-operative period [10]. Previous studies have shown an association between post-operative complications and readmission after PD [7, 9]. However, it is currently unclear which complications put patients at highest risk for readmission and how the timing of complications affects this risk.

The objectives of this study were threefold. First, we sought to identify patient characteristics and hospital factors associated with readmission in a large national cohort. Second, we identified patients who experienced a complication after PD to examine how the readmission rate is affected by the occurrence of specific post-operative complications. Third, we characterized complications as occurring before discharge or after discharge to examine the timing of specific complications and to evaluate how the timing of these complications impacts the readmission rate.

Methods

Database: The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database is the first national validated, outcomes-based program designed for the purpose of improving surgical quality of care. In 2012, the ACS NSQIP database collected data from 374 participating sites on more than 300 variables, including preoperative risk factors,

intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting. A trained surgical clinical reviewer is used at participating hospitals to standardize data capture and ensure reliability.

The ACS NSQIP database and the hospitals participating in the ACS NSQIP are the source of the data used herein. They have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors. Approval for the use of patient level data analyzed in this study was obtained from the Institutional Review Board of the University of California Irvine Medical Center and from the ACS NSQIP.

Participant Selection: A retrospective review of the ACS NSQIP Participant User File (PUF) database was performed. Patients who underwent a PD in 2012 were identified using Current Procedural Terminology (CPT) codes: 48150, 48152, 48153, and 48154. The publically available ACS NSQIP PUFs began reporting readmission data in 2011 and capture readmission to any hospital occurring within 30 days of the index procedure. Furthermore, the ACS NSQIP captures both inpatient and outpatient postoperative complications within that same 30 day period. Patients under the age of 18 years (inherent NSQIP exclusion), those with incomplete readmission data, or those that died within 30 days of the operation were excluded from analysis.

Demographics and outcomes variables: Analyzed variables included: patient demographics (age, sex, race), comorbid conditions (hypertension, dialysis, dyspnea, chronic obstructive pulmonary disease, smoking, diabetes mellitus, congestive heart failure, ascites, steroid use), body mass index (BMI) (derived from height and weight), American Society of Anesthesiologists (ASA) classification, functional status, operative factors (indication, operation time, wound classification, return to the operating room), and hospital factors (length of stay, type of admission, discharge destination).

Post-operative complications and short-term operative outcomes analyzed included: superficial surgical site infection (SSI), deep SSI, organ space SSI, wound disruption, pneumonia, unplanned intubation, on ventilator >48 hours, deep vein thrombosis, pulmonary embolism, acute renal failure, progressive renal insufficiency, urinary tract infection, stroke, cardiac arrest, myocardial infarction, bleeding requiring transfusion, sepsis, and septic shock.

Post-operative complications were then classified as occurring either before or after discharge. Within the ACS NSQIP database, the time (in days) to the onset of a particular complication is tracked. If the time to a complication was less than or equal to the time to discharge, the complication was deemed to have occurred prior to discharge. Patients were classified as those who experienced no complication, those who experienced a complication prior to discharge, and those who experienced a complication after discharge. Readmission rates were then calculated for each group.

Statistical analysis: Statistical analysis was performed with SPSS software, version 22 (IBM Corp, Armonk, NY). All of the factors were analyzed using univariate logistic regression. Forward stepwise multivariable regression models including all of the factors approaching significance ($p<0.1$) on univariate analysis were used to identify factors associated with readmission. The odds ratios generated through regression were adjusted to risk ratios (RR) 95% confidence intervals (CI) given the high frequency of readmissions [11]. Statistical significance was declared if $p<0.05$.

Results

A total of 3,722 patients who underwent a PD in 2012 were identified within the ACS NSQIP database. The overall readmission rate was 16.2% (n=532). Overall, 48% of patients (n=1585) experienced a post-operative complication. The readmission rate among patients who experience a post-operative complication was 23%. The readmission rate among patients who did not experience a post-operative complication was 10%.

Patient demographics, comparing those readmitted to those not readmitted, are shown in table 1.

Table 1: Demographic and Hospital characteristics by readmission status.

Patient Characteristics	Readmitted (n=532)	Not readmitted (n=2745)	Total Cohort (n=3277)	p-value
Age				
Mean, year *	64±12	65±12	65±12	0.04
Median, year	64	66	66	
Female gender	259(48.7%)	1273(46.4%)	1532(46.8%)	0.32
Emergent admission	3(0.6%)	17(0.6%)	20(0.6%)	0.88
Functional Status				
Independent	522(98.1%)	2717(99%)	3239(98%)	0.12
Dependent	10(1.9%)	26(1%)	33(1%)	0.12

Race				
White	430(85.1%)	2210(85.9%)	2640(85.8%)	0.64
Black	58(11.5%)	265(10.3%)	323(10.5%)	0.42
Asian or pacific Islander	16(3%)	93(3.4%)	109(3.5%)	0.61
Other	1(0.2%)	4(0.1%)	5(2.2%)	0.82
Comorbidity				
Hypertension*	314(59%)	1493(54.4%)	1807(55.1%)	0.04
Dialysis	0	13(0.5%)	13(0.4%)	0.11
Dyspnea	41(7.7%)	205(7.5%)	246(7.5%)	0.84
COPD	23(4.3%)	128(4.7%)	151(4.6%)	0.73
Smoking	119(22.4%)	564(20.5%)	683(20.8%)	0.34
Diabetes Mellitus	145(27.3%)	676(24.6%)	821(25.1%)	0.2
CHF	1(0.2%)	4(0.1%)	5(0.2%)	0.81
Ascites	2(0.4%)	12(0.4%)	14(0.4%)	0.84
Steroid use	16(3%)	68(2.5%)	84(2.6%)	0.47
Operative Indication				
Adenocarcinoma	274(51.5%)	1511(55%)	1785(54.5%)	0.13
Ampullary Neoplasm*	29(5.5%)	231(8.4%)	260(7.9%)	0.02
Neuroendocrine	1(0.2%)	3(0.1%)	4(0.1%)	0.63
IPMN	8(1.5%)	54(2%)	62(1.9%)	0.47
Biliary Neoplasm*	9(1.7%)	90(3.3%)	99(3%)	0.05
Duodenal Neoplasm	26(4.9%)	102(3.7%)	128(3.9%)	0.2
Benign Pancreas	28(5.3%)	108(3.9%)	136(4.2%)	0.16
Benign Biliary	6(1.1%)	13(0.5%)	19(0.6%)	0.06
Cystic and Pseudocyst	10(1.9%)	54(2%)	64(2%)	0.89
Trauma	0	0	0	
Other	149(28%)	633(23.1%)	782(23.9%)	0.01
ASA				
1	6(1.1%)	17(0.6%)	23(0.7%)	0.2
2	127(23.9%)	681(24.8%)	808(24.7%)	0.62
3	368(69.2%)	1878(68.4%)	2246(68.7%)	0.8
4	31(5.8%)	161(5.9%)	192(5.9%)	0.96
5	0	0	0	
BMI				
Underweight (<18.5)	10(1.9%)	77(2.8%)	87(2.7%)	0.22
Normal (18.5-24.9)	184(34.6%)	991(36.1%)	1175(36%)	0.5
Overweight (25-29.9)	178(33.5%)	935(34.1%)	1113(34%)	0.79
Obese (30-34.9)	96(18.1%)	464(16.9%)	560(17.1%)	0.51
Morbidly Obese (>35)	60(11.3%)	252(9.2%)	312(9.5%)	0.13
Wound classification				
Clean	12(2.3%)	69(2.5%)	81(2.5%)	0.72
Clean/contaminated	457(85.9%)	2304(83.9%)	2761(84.3%)	0.25
Contaminated	50(9.4%)	303(11%)	353(10.8%)	0.26
Dirty/infected	13(2.4%)	69(2.5%)	82(2.5%)	0.92
Hospital Factors				
Operative time, mean	379±140	369±144	370±143	0.11
Return to OR	39(7.3%)	156(5.7%)	195(6%)	0.14
LOS, mean*	11±5	13±12	12±11	<0.01

Discharge Destination				
Skilled Care (not home)	51(9.6%)	265(9.7%)	316(9.6%)	0.94
Unskilled Facility (not home)	0	3(0.1%)	3(0.1%)	0.44
Facility (Home)	2(0.4%)	10(0.4%)	12(0.4%)	0.97
Home*	455(85.5%)	2235(81.4%)	2690(82.1%)	0.03
Separate Acute Care	3(0.6%)	21(0.8%)	24(0.7%)	0.61
Rehab	20(3.8%)	118(4.3%)	138(4.2%)	0.56
Expired	1(0.2%)	84(3.1%)	85(2.6%)	<0.01
Unknown	0	9(0.3%)	9(0.2%)	0.18

* Indicated statistically significant difference between readmitted patients and not readmitted patients

Overall, there was no statistical difference between the two groups with respect to sex, race, comorbid conditions (except hypertension), BMI, ASA classification, functional status, operative time, wound classification, length of stay, and discharge destination. The readmitted group had a slightly lower mean age (64 years vs. 65 years, *p<0.05*), as well as a higher rate of hypertension (59% vs 54%, *p<0.05*), compared to the non-readmitted group. With respect to operative indications, the readmitted group had lower rates of ampullary (5.5% vs 8.4%, *p<0.05*) and biliary (1.7% vs 3.3%, *p<0.05*) neoplasm's, compared to the non-readmitted group.In looking at hospital factors, the readmitted group had, on average, a shorter length of stay (11 days vs. 13 days, *p<0.05*) and a higher rate of discharge to home (85% vs 82%, *p<0.05*) rather than to another living facility.

A forward stepwise multivariable regression analysis for all of the factors approaching significance ($p < 0.1$) on univariate analysis was performed to identify factors associated with readmission, which is shown in table 2. Having a cystic neoplasm, duodenal neoplasm, or an unspecified tumor type was associated with readmission, with a relative risk of 17 (95%CI 1.06-274.24), 8.8(95%CI 2.03-38.18) and 2.8 (95%CI 1.17-6.83), respectively. Having a dependent functional status as well as having hypertension were associated with readmission, with a relative risk of 2.6 (95%CI 1.04-6.50) and 1.3 95%CI 1.03-1.71), respectively. Return to the operating room was also associated with readmission, with a relative risk of 1.85 (95%CI 1.12-3.05). In contrast, a longer length of stay was associated with decreased rate of readmission, with a relative risk of 0.97 (95%CI 0.95-0.99). This association with length of stay may be due to an inherent bias within the database, which is discussed below.

Table 2: Relative risk of readmission using multivariable analysis for all of the factors approaching significance ($p < 0.1$) on univariate analysis

Patient Characteristics	RR	95% CI	P value
Cystic and Pseudocyst	17.07	1.06-274.24	<0.05
Duodenal Neoplasm	8.81	2.03-38.18	<0.05
Other tumor type	2.83	1.17-6.83	<0.05
Partially or Totally dependent	2.6	1.04-6.50	<0.05
Hypertension	1.33	1.03-1.71	<0.05
Return to operating room	1.85	1.12-3.05	<0.05
Length of stay, mean	0.97	0.95-0.99	<0.05

Overall, 48% of those who underwent a PD (1585 patients) experienced at least one complication during the 30-day peri-operative period. Complications were then classified as occurring before discharge or after discharge. Of all the patients who underwent a PD, 42.8% (n=1403) experienced at least one complication before discharge and 11% (n=361) experienced at least one complication after discharge. Additionally, 4.8% (n=179) experienced a complication before discharge as well as after discharge.

The most common complication was bleeding requiring transfusion, experienced by 26% of patients. All of the bleeding complications occurred before discharge, which is an artifact of the database. Bleeding, requiring blood transfusion is tracked from the time of surgery up to 72 hours post-operatively. The second most common complication was organ space SSI, occurring in 8.3% of patients before discharge and 3.8% of patients after discharge. Organ space SSI was also the most common complication to occur after discharge. Readmission rate associated with each complication, depending on whether the complication occurred before discharge or after discharge were then calculated. Bleeding, which was the most common complication overall, had a readmission rate of 16%. Organ space SSI had a readmission rate of 8.5% when it occurred before discharge and 91.3% when it occurred after discharge. The readmission rates for complications that occurred before discharge ranged from 0-19.4%. The readmission rates for complications that occurred after discharge ranged from 42.1-100% (Table 3).

Table 3: Readmission rates for complications occurring before or after discharge

	Overall Complication Rate N (%)	Pre-discharge complication rate	Post-discharge complication rate	Readmission rate when occurring before discharge	Readmission rate when occurring after discharge
Superficial SSI	335 (10.2%)	228 (6.9%)	107 (3.3%)	14.5%	42.1%
Deep SSI	98 (3%)	59 (1.8%)	39 (1.2%)	18.6%	79.5%
Organ/Space SSI	398 (12.1%)	272 (8.3%)	39 (1.2%)	8.5%	91.3%
Wound disruption	59 (1.8%)	40 (1.2%)	19 (0.6%)	17.5%	84.2%
Urinary Tract Infection	160 (4.9%)	136 (4.15%)	24 (0.7%)	14.7%	62.5%
DVT requiring treatment	91 (2.8%)	67 (2%)	24 (0.7%)	14.9%	66.7%
Pulmonary embolus	34 (1%)	25 (0.7%)	9 (0.3%)	20.0%	77.8%
Pneumonia	137 (4.2%)	120 (3.6%)	17 (0.5%)	10.0%	100%
Bleeding requiring transfusion	854 (26%)	854 (26%)	0	16.0%	N/A
Unplanned intubation	153 (4.7%)	135 (4.1%)	18 (0.5%)	7.4%	100%
Ventilator >48hour	133 (4%)	124 (3.7%)	9 (0.3%)	5.6%	100%
Progressive renal insufficiency	34 (1%)	29 (0.8%)	5 (0.2%)	13.8%	100%
Acute renal failure	42 (1.3%)	38 (1.1%)	4 (0.1%)	0%	75%
Cerebrovascular accident	15 (0.5%)	10 (0.3%)	5 (0.2%)	10%	80%
Cardiac Arrest requiring CPR	38 (1.2%)	35 (1%)	3 (0.1%)	0%	100%
MI	39 (1.2%)	31 (0.9%)	8 (0.2%)	19.4%	75%
Sepsis	295 (9%)	221 (6.7%)	74 (2.3%)	11.8%	95.5%
Septic Shock	137 (4.2%)	122 (3.7%)	15 (0.5%)	2.5%	100%

Complication rate percentages calculated based on total cohort of n=3,277

Overall, if a patient experienced any complication before discharge, the readmission rate was 15%. If a patient experienced any complication after discharge, the readmission rate was 70%. This difference was statistically significant ($p < 0.05$). On multivariate analysis, a complication after discharge had a relative risk of readmission of 21.59 (95%CI 16.48-28.28) (Table 4).

Table 4: Relative risk of readmission based on the timing of the complication using a multivariable analysis

Patient Characteristics	RR	95% CI	P value
Pre-discharge Occurrence of Complications	1.1	0.86-1.41	0.42
Post-discharge Occurrence of Complications	21.59	16.48-28.28	<0.05

Discussion

PD is a complex operation with a high inherent risk for complication and readmission, but studies examining the reasons for readmission after PD are sparse and most are based on single institution data [7, 8, 10, 12-15]. None of these studies have examined how the timing of complications might impact readmission rates. The present study highlights a few important points. First, at a national level with contemporary data, PD remains a high-morbidity procedure, with a substantial readmission rate: up to 23% in patients who developed a post-operative complication compared to 10% in those who did not. Complications that occur after discharge are associated with a significantly higher readmission rate compared to complications that occur prior to discharge. Furthermore, we found that the most frequent complications after PD were bleeding before discharge and infectious complications after discharge.

In our results, there did not appear to be clinically relevant demographic differences between patients who were readmitted and those who were not readmitted to provide an explanation for the need for readmission. Although we found a statistical difference in age and the rate of hypertension, these differences are likely trivial and not clinically significant. In contrast, tumor characteristics were associated with readmission. Patients who underwent PD for cystic or pseudo-cystic lesions as well as for malignant tumors in the duodenum had significantly higher rates of readmission. It is possible that this is a function of the consistency of the pancreas and the size of the pancreatic duct which are both risk factors for pancreatic fistula. This information is not available in the 2012 NSQIP database but will now be available with the specific pancreatic data parameters which were incorporated in 2015.

We found an overall complication rate of 48%, which is consistent with previous single institution studies reporting rates of 30-58% [4, 8, 9, 16]. Although post-operative complications have previously been associated with readmission [7-9, 14], our results show that only complications that occur after discharge are associated with readmission. We found no statistically significant difference in the risk of readmission between those who experienced a complication before discharge and those that did not experience any complication. In contrast, patients who experienced a complication after discharge had a significantly increased risk of readmission compared to those that did not experience a complication. While it may seem intuitive that having a complication after discharge puts patients at higher risk for readmission, it is interesting that having a complication before discharge does not appear to increase the readmission risk. These data suggest that even though we might expect patients who experience a complication before discharge to be more debilitated or sick, addressing a complication during the index hospitalization seems to return patients to their "baseline" state of health as if they had experienced no complication. Similarly, when complications occur after discharge, patients are not likely to be in a position to have that particular complication identified and treated immediately, as might occur if they were still in an acute care setting. Therefore, when the complication is recognized, it may be at a more advanced stage requiring more intensive management and possibly readmission.

Although our data show that patients who experience a complication after discharge have a significantly higher rate of readmission, it is difficult to delineate the specific reasons for readmission. For some complications that occur after discharge, such as septic shock or unplanned intubation, a readmission is understandable and expected. However, for other complications that occur after discharge, such as a superficial SSI or UTI, one might expect that these could be treated on an outpatient basis without the need for a readmission. Yet there were substantial rates of readmission associated with superficial SSI and UTI that occurred after discharge, 42% and 62%, respectively. As with all statistical analyses, these associations do not imply causation, and reasons for readmission are not well captured in NSQIP. Moreover, PD-specific complications, such as delayed gastric emptying and pancreatic leak are also not captured within NSQIP. Also, dependent functional status was associated with readmission. Therefore, other factors that could not be examined in this study may have contributed to the readmissions, and these seemingly benign complications may simply be a marker of overall illness rather than the impetus for readmission. In other words, these complications may have been discovered incidentally upon readmission for another reason. These findings help explain why, despite a significant research effort into this area, prediction of readmissions after surgery has proved to be so challenging. The clinical reality is that the reasons for most readmissions after surgery are complex and nuanced, and probably influenced by many poorly captured socioeconomic factors.

In our study, a shorter post-operative hospital stay was associated with readmission. This finding is in contrast to multiple previous studies, which have demonstrated that longer hospital stay is associated with both early and late readmission after PD [7-9, 13, 15]. Within NSQIP, readmission is tracked up to 30 days from the day of the principle operation rather than from the day of discharge. Consequently, patients who have a longer hospital stay have fewer days for which readmission will be recorded. Therefore, we believe this study's result could be an artifact of the NSQIP database. Nevertheless, our result highlights a struggle for many surgeons: decreasing hospital length of stay while simultaneously minimizing readmissions. The Centers for Medicare & Medicaid Services (CMS) introduced the Prospective Payment System (PPS) in 1983, which provides a fixed reimbursement for a particular admission and diagnosis-related group (DRG). After the implementation of PPS, there was a dramatic decrease in average length of stay [17], with a concomitant increase in the rate of readmission [18]. To incentivize a reduction in readmission, CMS recently introduced the Hospital Readmissions Reduction Program (HRRP) as well as the Bundled Payments for Care Improvement (BPCI). The full effects of these programs are yet to be seen. Nevertheless, because of the high morbidity of PD, surgeons likely will continue to struggle with finding an appropriate balance between length of stay and readmission. Based on our results, we believe that initiatives directed at lowering rates of post-discharge complications may also help reduce readmissions.

There are a few limitations to this study. The ACS NSQIP database is limited to 30-day postoperative morbidity and mortality; therefore, any complications or readmissions occurring after this time period are not captured. Also, the post-operative complications tracked are generic and not PD-specific, such as delayed gastric emptying, pancreatic leak, or marginal ulceration. Readmission is defined as within 30 days from surgical procedure, not from hospital discharge. Therefore, patients who have a longer length of stay have fewer days in which a readmission will be captured, leading to bias in the analysis. Finally, although ACS-NSQIP extensively tracks patient comorbidities and many potential postoperative complications, it lacks many social and economic factors (insurance status, income, education, etc.) that may affect the risk or readmission. Despite these limitations, this study provides an overview of the types of complications that occur after PD and how those complications influence readmission.

Conclusions

Pancreaticoduodenectomy continues to be a high-risk procedure with high rates of post-operative complications and readmission. The occurrence of a complication before discharge is not associated with an increased rate of readmission. While numerous factors were found to influence the risk of readmission in our study, the single most influential factor was the occurrence of a complication after discharge (readmission rate of 70% and a relative risk of readmission of 21). Initiatives directed at lowering rates of post-discharge complications and identifying high risk patients that may benefit from closer postoperative surveillance may help reduce the rate of readmissions after PD.

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