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ORIGINAL ARTICLE

In-hospital Mortality Following Pancreatoduodenectomy: a Comprehensive Analysis

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Abstract

Background While patient- and hospital-level factors affecting outcomes of patients undergoing pancreatoduodenectomy (PD) have been well described separately, the relative impact of these factors on in-hospital mortality has not been comprehensively assessed.

Methods Retrospective review of the National Inpatient Sample database (January 2004–December 2014) was conducted to identify patients undergoing PD. Factors associated with in-hospital mortality after PD were analyzed after adjusting for previously defined patient- and hospital-level risk factors.

Results A total of 9639 patients who underwent a PD at 2325 hospitals were identified. Median patient age was 57 years (IQR 66–73). Overall, mortality following PD was 3.2%. When patient- and hospital-level characteristics were analyzed in the same model, patient-level characteristic associated with increased odds of in-hospital mortality included increasing patient age (OR 1.05, 95% CI 1.03–1.06/per 5 years increase), male sex (OR 1.47, 95% CI 1.16–1.86), the presence of liver disease (OR 3.03, 95% CI 1.99–4.61), chronic kidney disease (OR 1.78, 95% CI 1.18–2.68), and congestive heart failure (OR 2.48, 95% CI 1.65–3.74). The only hospital characteristic associated with odds of mortality following PD included compliance with Leapfrog volume standards (OR 0.70, 95% CI 0.54–0.92).

Conclusion Patient-level factors, such as advanced comorbidities, male sex, and increased age, contributed the most to increased risk of mortality after PD. Hospital volume was the only hospital-level factor contributing to risk of in-hospital mortality following PD.

Keywords Mortality · Pancreas · Pancreatoduodenectomy · Volume

Introduction

Pancreaticoduodenectomy (PD) is the treatment of choice for a variety of malignant and benign tumors of the periampullary region and is the most common surgical procedure performed on the pancreas. PD is considered the most technically complex surgical procedure of the gastrointestinal tract and has historically been associated with a high incidence of postoperative mortality.[1] Consequently, PD has long been a target of quality improvement efforts.[2–7] Over the past three decades, the mortality risk associated with PD has steadily declined, which has been largely attributed to the regionalization of PD at large, high-volume centers.[8, 9] Nevertheless, reported mortality still varies considerably, remaining high among certain groups of patients. For example, Finks et al. reported a mortality of 5.9% following PD, whereas Carroll et al. reported an in-hospital mortality of 8.1% among Medicare patients.[10, 11] In addition, a recent nationwide study from Germany reported a 10.7% in-hospital mortality after PD.[12] In contrast, single-institution reports from high-volume centers of excellence have reported in-hospital mortality as low as 1.7%.[9]

The risk of in-hospital mortality after PD may be related to factors other than simply hospital procedure volume. In fact, observed variations in reported in-hospital mortality following PD suggest that there may be room for improvement in the

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quality of pancreatic surgery even among centralized centers. As such, a better understanding of factors that influence outcomes of patients undergoing PD may help target interventions to improve patient care. While patient- and hospital-level factors affecting outcomes of patients undergoing PD have been well described separately, the relative impact of these factors on in-hospital mortality has not been comprehensively assessed.[4, 13–16] Therefore, the aim of the current study was to quantify patient- and hospital-level factors associated with in-hospital mortality after PD.

Methods

Study Design

Patients undergoing pancreaticoduodenectomy were identified from the Nationwide Inpatient Sample (NIS) between January 2004 and December 2014 using International Classification of Diseases, Ninth Edition codes (proximal pancreatectomy 5251, radical subtotal pancreatectomy 5253, radical pancreatoduodenectomy 527). Hospital-level factors were determined secondarily, meaning that hospitals that performed no PD were not captured. Patients who underwent emergency surgery and individuals with missing data on mortality status, age, sex, hospital bed size, and hospital teaching status were excluded. The Ohio State University institutional review board approved the current study.

Patient- and Hospital-Level Variables for Analysis

Basic demographic information, including age, sex, race/ethnicity, comorbid conditions, severity of illness, patient risk of mortality, benign/malignant diagnosis, was collected for all patients. For each patient, hospital-level factors were collected and included hospital bed size, hospital teaching status, and pancreatectomy volume. Hospital bed size was defined as small, medium, or large as a categorical variable, based on the institution's number of acute care beds, geographical location, and teaching status, as described by the Agency for Healthcare Research and Quality.[17] Hospital teaching status was defined as a binary variable (teaching vs. nonteaching) based on data reported by the American Hospital Association Annual Survey of Hospitals.[17] Hospitals meeting Leapfrog criteria for pancreatic resection were defined as those performing at least 20 elective pancreatic resections per year, according to the published Leapfrog Group minimum volume standards.[18]

Statistical Analysis

Descriptive statistics were presented as median and interquartile range (IQR) and frequency (relative frequency [%]) for continuous and categorical variables, respectively. Bivariate analyses to detect associations between in-hospital mortality and demographic and comorbid conditions were conducted using the Mann-Whitney *U* test and chi-square test. Where appropriate, Fisher's exact test was used instead. To identify patient- and hospital-level characteristics independently associated with in-hospital mortality, logistic regression was utilized. All statistical analyses were performed using SAS v9.4. Statistical significance was assessed at $\alpha = 0.05$.

Results

Patient and Hospital Characteristics

A total of 9639 patients who underwent PD at 2325 hospitals were included in the study. Median patient age was 57 years (IQR 66–73). Overall, the incidence of mortality following PD was 3.2% ($n = 310$). Perhaps not surprisingly, patients who experienced in-hospital mortality were more likely to have severe loss of function ($n = 256$, 82.6% vs. $n = 1230$, 13.2%) and an extreme likelihood of dying ($n = 249$, 80.3% vs. $n = 742$, 8%) compared with patients who did not experience in-hospital mortality (all $p < 0.001$). In addition, patients who died during the index hospitalization were more likely to be male ($n = 192$, 61.9% vs. $n = 4822$, 51.7%), to have chronic obstructive pulmonary disease (COPD, $n = 55$, 17.7% vs. $n = 1253$, 13.4%), liver disease ($n = 27$, 8.7% vs. $n = 333$, 3.6%), chronic kidney disease (CKD, $n = 30$, 9.7% vs. $n = 334$, 3.6%), peripheral vascular disease ($n = 29$, 9.4% vs. $n = 356$, 3.8%), and congestive heart failure (CHF, $n = 31$, 10% vs. $n = 264$, 2.8%) compared with patients who were discharged alive (all $p < 0.001$). Interestingly, there was no difference in the proportion of benign ($n = 13$, 4.2% vs. $n = 579$, 6.2%) and malignant ($n = 297$, 95.8% vs. $n = 8750$, 93.8%) diagnoses, as well as in the proportion of MIS ($n = 22$, 7.1% vs. $n = 716$, 7.7%) versus open surgery ($n = 288$, 92.9% vs. $n = 8613$, 92.3%) among patients who experienced in-hospital mortality versus patients who were discharged alive following a PD (all $p > 0.05$). Moreover, patients who died were more likely to be insured by Medicare ($n = 214$, 69% vs. $n = 4750$, 50.9%) and less likely to have private insurance (21.6%, $n = 67$ vs. 41%, $n = 3823$) ($p < 0.001$) (Table 1).

When hospital characteristics were analyzed, patients who died during the index hospitalization were less likely to have undergone PD at teaching hospitals ($n = 236$, 76.1% vs. $n = 8088$, 86.7%) ($p < 0.001$). In addition, in-hospital mortality was more likely among patients who had surgery at small and medium bed size hospitals (small $n = 8$, 2.6% vs. alive $n = 133$, 1.4%; medium $n = 66$, 21.3% vs. alive $n = 1108$, 11.9%) compared with large bed size hospitals ($n = 236$, 76.1% vs. alive $n = 8088$, 86.7%) ($p < 0.001$). Moreover, patients who experienced in-hospital mortality were more likely

Table 1 Patient- and hospital-level characteristics

Variable	Total*n* = 9639	Alive at discharge*n* = 9329	In-hospital mortality*n* = 310 (3.2%)	*p* value
Age (median, IQR)	57 (66–73)	66 (57–73)	71 (64–77)	< 0.001
Gender				
Male	5014 (52%)	4822 (51.7%)	192 (61.9%)	< 0.001
Female	4625 (48%)	4507 (48.3%)	118 (38.1%)	
Severity of illness				< 0.001
Minor loss of function	87 (0.9%)	87 (0.9%)	0 (0%)	
Moderate loss of function	1068 (11.1%)	1067 (11.4%)	1 (0.3%)	
Major loss of function	6998 (72.6%)	6945 (74.4%)	53 (17.1%)	
Severe loss of function	1486 (15.4%)	1230 (13.2%)	256 (82.6%)	
Patient risk of mortality				< 0.001
Minor likelihood of dying	3123 (32.4%)	3116 (33.4%)	7 (2.3%)	
Moderate likelihood of dying	3519 (36.5%)	3504 (37.6%)	15 (4.8%)	
Major likelihood of dying	2006 (20.8%)	1967 (21.1%)	39 (12.6%)	
Extreme likelihood of dying	991 (10.3%)	742 (8%)	249 (80.3%)	
Race				0.94
White	7475 (77.5%)	7237 (77.6%)	238 (76.8%)	
Black	834 (8.7%)	806 (8.6%)	28 (9%)	
Other	1330 (13.8%)	1286 (13.8%)	44 (14.2%)	
Teaching status				
Rural	141 (1.5%)	133 (1.4%)	8 (2.6%)	< 0.001
Urban nonteaching	1174 (12.2%)	1108 (11.9%)	66 (21.3%)	
Urban teaching	8324 (86.4%)	8088 (86.7%)	236 (76.1%)	
Comorbidities				
Diabetes	348 (3.6%)	337 (3.6%)	11 (3.5%)	0.95
Alcohol abuse	291 (3%)	280 (3%)	11 (3.5%)	0.58
COPD	1308 (13.6%)	1253 (13.4%)	55 (17.7%)	0.029
Liver disease	360 (3.7%)	333 (3.6%)	27 (8.7%)	< 0.001
Obesity	901 (9.3%)	869 (9.3%)	32 (10.3%)	0.55
Chronic renal failure	364 (3.8%)	334 (3.6%)	30 (9.7%)	< 0.001
Peripheral vascular disease	385 (4%)	356 (3.8%)	29 (9.4%)	< 0.001
CHF	295 (3.1%)	264 (2.8%)	31 (10%)	< 0.001
Hypertension	5257 (54.5%)	5095 (54.6%)	162 (52.3%)	0.41
Hospital bed size				< 0.001
Small	141 (1.5%)	133 (1.4%)	8 (2.6%)	
Medium	1174 (12.2%)	1108 (11.9%)	66 (21.3%)	
Large	8324 (86.4%)	8088 (86.7%)	236 (76.1%)	
Insurance status				< 0.001
Medicare	4964 (51.5%)	4750 (50.9%)	214 (69%)	
Medicaid	522 (5.4%)	503 (5.4%)	19 (6.1%)	
Private insurance	3890 (40.4%)	3823 (41%)	67 (21.6%)	
Self-pay	263 (2.7%)	253 (2.7%)	10 (3.2%)	
Surgical approach				0.71
Open	8901 (92.3%)	8613 (92.3%)	288 (92.9%)	
MIS	738 (7.7%)	716 (7.7%)	22 (7.1%)	
Disease type				0.15
Malignant	9047 (93.9%)	8750 (93.8%)	297 (95.8%)	
Benign	592 (6.1%)	579 (6.2%)	13 (4.2%)	
Leapfrog compliant				< 0.001
Yes	3739 (38.8%)	3652 (39.2%)	87 (28.1%)	

Table 1 (continued)

Variable	Total$n = 9639$	Alive at discharge$n = 9329$	In-hospital mortality$n = 310$ (3.2%)	*p* value
No	5900 (60.2%)	5677 (60.1%)	223 (71.2%)	
Year of surgery				0.016
2004	250 (2.6%)	241 (2.6%)	9 (2.9%)	
2005	258 (2.7%)	242 (2.6%)	16 (5.2%)	
2006	291 (3%)	276 (3%)	15 (4.8%)	
2007	292 (3%)	278 (3%)	14 (4.5%)	
2008	703 (7.3%)	676 (7.2%)	27 (8.7%)	
2009	603 (6.3%)	578 (6.2%)	25 (8.1%)	
2010	1145 (11.9%)	1116 (12%)	29 (9.4%)	
2011	1790 (18.6%)	1736 (18.6%)	54 (17.4%)	
2012	1194 (12.4%)	1155 (12.4%)	39 (12.6%)	
2013	1499 (15.6%)	1456 (15.6%)	43 (13.9%)	
2014	1614 (16.7%)	1575 (16.9%)	39 (12.6%)	

Table 2 Multivariable analysis of patient- and hospital-level factors affecting in-hospital mortality following pancreatoduodenectomy

Characteristic	OR (95% CI)	*p* value
Patient Characteristics		
Gender		
Male	1.45 (1.14–1.83)	*0.005*
Female	Ref	
Age		*< .0001*
<65 years	Ref	
>65 years	2.19 (1.70–2.81)	
Comorbidities		
Chronic obstructive pulmonary disease	1.21 (0.89–1.64)	0.726
Liver disease	3.00 (1.97–4.56)	*0.002*
Renal Failure	1.91 (1.26–2.88)	*< 0.001*
CHF	2.64 (1.75–3.99)	*< 0.001*
Surgical Approach		
Open	Ref	
MIS	0.99 (0.63–1.54)	0.532
Malignancy		
Yes	1.54 (0.87–2.72)	0.958
No	Ref	
Hospital-level characteristics		
Bed Size		
Large	Ref	
Medium	1.26 (0.93–1.71)	0.133
Small	1.46 (0.97–2.20)	0.072
Teaching Status		
Urban nonteaching	0.83 (0.39–1.78)	0.629
Urban teaching	0.47 (0.22–0.98)	*0.044*
Rural	Ref	
Leapfrog criteria (≥ 20)	0.72 (0.55–0.94)	*0.006*

The *p*-values in italics denote statistical significance

to have undergone surgery at hospitals that did not meet Leapfrog volume criteria ($n = 223$, 71.2% vs. $n = 87$, 28.1%) compared with patients who underwent surgery at Leapfrog compliant hospitals ($p < 0.001$) (Table 1).

Of note, while rates of in-hospital mortality varied across the study period, overall, the incidence of patients experiencing mortality during the index hospitalization decreased from 2004 to 2014 (Fig. 1).

Multivariable Analysis of Factors Associated with In-hospital Mortality after PD

When patient- and hospital-level characteristics were analyzed together in the same model, patient-level characteristics associated with increased odds of in-hospital mortality included age (> 65 years OR 2.19, 95% CI 1.70–2.81), male gender (OR 1.45, 95% CI 1.14–1.83), the presence of liver disease (OR 3.00, 95% CI 1.97–4.56), CKD (OR 1.91, 95% CI 1.26–2.88), and CHF (OR 2.64, 95% CI 1.75–3.99). Of note, a malignant diagnosis (OR 1.54, 95% CI 0.87–2.72) and open surgical approach (MIS vs. open OR 0.99, 95% CI 0.63–1.54) were not associated with increased odds of in-hospital mortality following PD. In the multivariable logistic regression model, hospital characteristics associated with mortality following PD included hospital teaching status (urban teaching hospital OR 0.47, 95% CI 0.22–0.98) and non-compliance with Leapfrog volume standards (compliant vs. non-compliant OR 0.71, 95% CI 0.54–0.93) (Table 2).

Figure 2 describes the relative impact of each factor on inpatient mortality ordered sequentially from greatest to least. Among all factors, patient-related factors such as the presence of advanced comorbidities, for example, liver disease, CKD, and CHF, had the strongest impact in the odds of experiencing in-hospital mortality after PD. Following patient-related factors, hospital volume and teaching status also influenced the

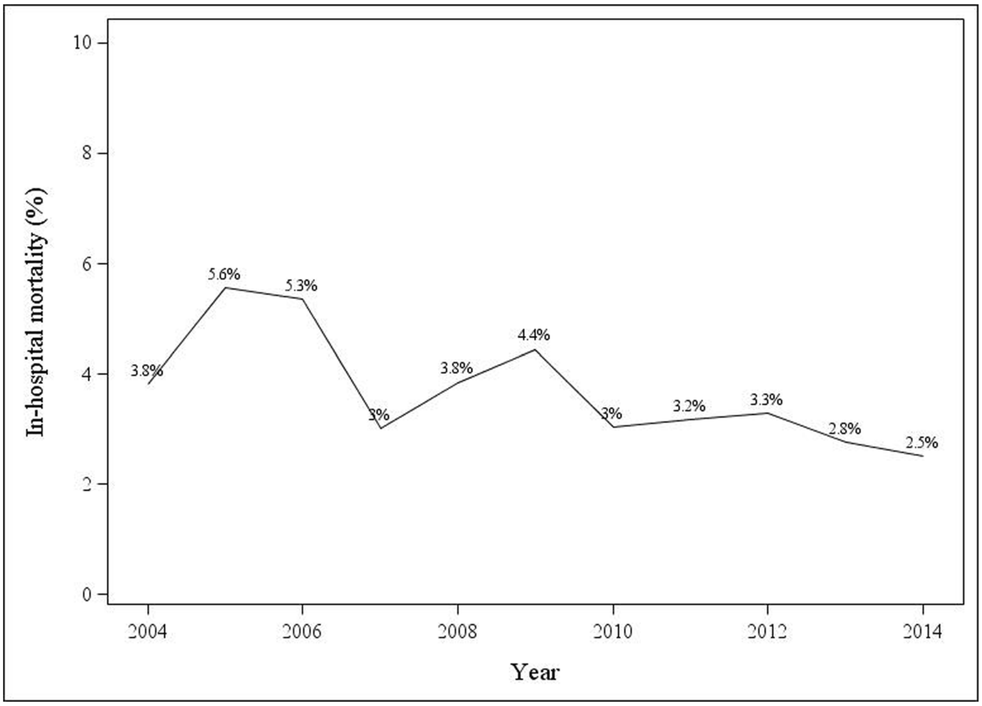

Fig. 1 Trends in in-hospital mortality after PD across the study period

odds of mortality, however to less extent than patient-related factors. Other hospital-related factors such as small hospital bed size and nonteaching status did not impact the odds of on in-hospital mortality after PD.

Discussion

PD is the most common surgical procedure performed on the pancreas and is considered a complex, high-risk, procedure even in the hands of experienced surgeons.[1] As such, a better understanding of factors associated with in-hospital mortality after a PD is of clinical relevance to patients, surgeons, and policymakers. Previous studies have largely focused on analyzing either patient- or hospital-level factors associated with mortality after PD with an emphasis on the effect of procedure volume on outcomes.[4, 13–16] In contrast, the current study performed a more comprehensive assessment of the factors influencing patient risk of experiencing mortality during the index hospitalization following a PD. The current study was important because it quantified the relative impact of various patient- and hospital-level factors on in-hospital mortality.

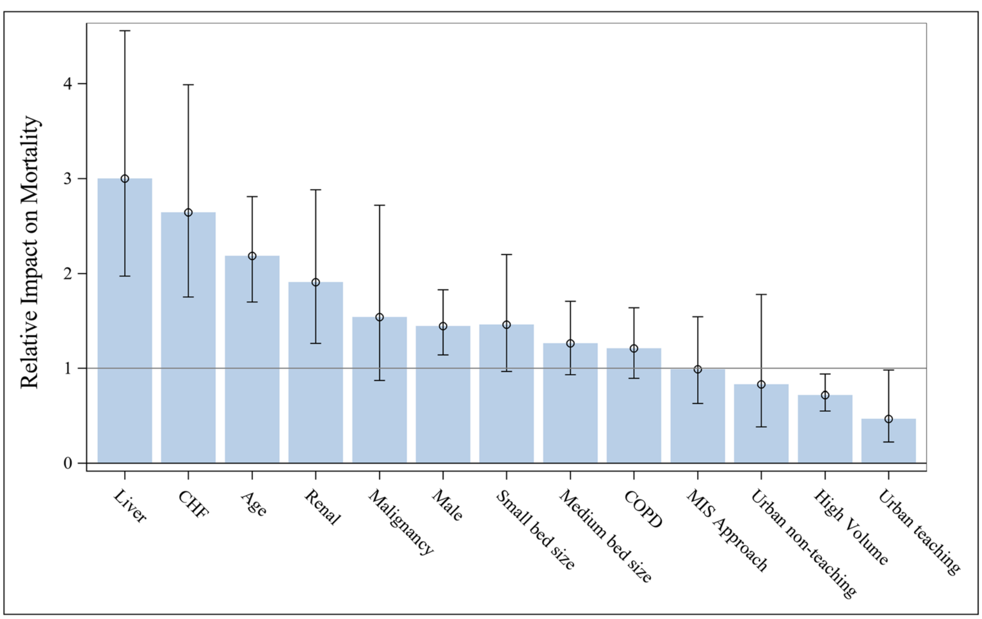

Fig. 2 Relative impact of several patient- and hospital-level factors on mortality following PD

Specifically, the presence of advanced comorbidities and male gender had the highest impact on in-hospital mortality after PD, while other patient-level factors such as age had a lower effect. In addition, patient factors such as surgical approach and malignant diagnosis did not impact the risk of mortality among patients undergoing PD. In contrast, the only hospital-related factor that had a substantial impact on the odds of mortality after PD was hospital volume. Collectively, the findings provide insight that might be used to support and guide continued quality improvement efforts for patients undergoing PD.

Data from the current study demonstrated that the most important factor associated with mortality risk among patients undergoing PD occurred at the patient level. Perhaps not surprisingly, among all factors analyzed, the presence of advanced comorbidities had the highest relative impact on the odds of in-hospital mortality following PD. Specifically, the presence of chronic liver disease and CHF resulted in 3- and 2.64-fold higher odds of postoperative death, respectively. In addition to the presence of these advanced comorbidities, male sex was associated with 45% increased odds of mortality, while patient age > 65 years had over 2-fold higher odds of mortality versus younger patients. Indeed, the association between male sex and older age with increased mortality risk following PD has been consistently reported in the literature.[15, 19–22] Interestingly, in the current study, the use of open or MIS surgical approach was not associated with risk of in-hospital mortality among patients undergoing PD. Another important finding was that a benign diagnosis incurred a similar mortality risk as a malignant diagnosis. These findings are relevant not only to guide appropriate patient selection but also to inform shared decision-making.[23] With an increasing number of elder patients undergoing PD, and an increasing number of patients being diagnosed with benign pancreatic head tumors that might have a surgical indication, it is important to consider that a patient with a benign diagnosis undergoing a PD will have a similar, nontrivial, risk of experiencing postoperative mortality as patients with a malignant disease.[24] In the presence of multiple patient-related factors associated with in-hospital mortality after PD, decision-making should be tailored accordingly.

Importantly, in the current study, hospital-level factors had the lowest relative impact on in-hospital mortality compared with patient-level factors (Fig. 2). Nevertheless, noncompliance with Leapfrog volume standards and hospital teaching status were hospital-level factors predictive of mortality. Similar to our findings, Varley et al. reported that hospital teaching status was protective with respect to failure-to-rescue following PD.[13] While it has been suggested that superior outcomes of surgical patients at teaching hospitals may be attributed to higher procedure volume,[25] Hyder et al. mitigated the effect of volume as a confounder at teaching hospitals by analyzing outcomes of patients undergoing hepatopancreatobiliary surgery only at high-volume hospitals. The authors noted that receipt of surgery at a nonteaching, high volume hospital was independently associated with 32% increased odds of death during the hospital stay.[15] While the protective effect of teaching hospitals on mortality risk after PD is undoubtedly multifactorial, it might be explained, in part, by heightened surveillance provided by resident participation in the postoperative care of patients, which may provide early recognition of clinical derangements and prompt response to adverse events. In turn, more efficient and timely management of complications may lead to increased rates of rescue of patients at these institutions.[26] In addition, teaching hospitals are more likely to implement standardized care pathways, which are also associated with improved outcomes following PD.[27]

The inverse relationship between hospital surgical volume and mortality for high-risk surgical procedures has been demonstrated in several studies over the past two decades.[2, 7, 8, 28–33] Despite the increasing body of evidence in the literature supporting the volume-outcomes relationship among patients undergoing PD, no consensus regarding the optimal cut-off for hospital volume has been achieved to date. In the absence of an established definition, previous studies have defined high- versus low-volume hospitals based on volume strata determined according to the authors' discretion or by means of adopting empirical cut-offs, leading to heterogeneous definitions of procedure volume.[15, 21, 28, 34, 35] In the current study, we elected to utilize the volume standard proposed by the Leapfrog group.[36] Leapfrog is a large coalition of healthcare purchasers focused on promoting patient safety strategies and healthcare quality improvement. For pancreatic resections, Leapfrog targets a minimum of 10 resections per year at the surgeon level and 20 resections per year at the hospital level.[36, 37] In the current study, patients who underwent PD at hospitals meeting the Leapfrog volume standards had 30% lower odds of experiencing in-hospital mortality. Indeed, roughly 70% of the patients who died during the index hospitalization underwent PD at hospitals noncompliant with Leapfrog volume standards. Collectively, the data strongly indicate that increased hospital PD volume was associated with decreased risk of in-hospital mortality. Additionally, the current study supports the adoption of the Leapfrog group minimum volume standard for benchmarking hospitals performing PD. The minimum volume standard proposed by the Leapfrog group can be useful not only to guide referral practices for PD, but also to standardize the definition of PD volume for research purposes.

The results of the current study should be interpreted in light of several limitations, with most being inherent to the use of claims and registry data.[38] For example, errors in procedural codes cannot be completely ruled out. In addition, important patient-level characteristics, such as tumor stage and receipt of neoadjuvant therapy, were not available in the NIS database. In addition, the NIS does not provide data on surgeon volume; therefore, the effect of surgeon volume on in-hospital mortality after PD could not be accounted for in the current study. Similarly, data on nurse-to-patient ratio, which may be an important hospital factor, was also not available in the NIS. Finally, NIS did not provide information regarding processes of care that differ between hospitals, which might also have played an important role in in-hospital mortality.

In conclusion, patient-level factors, such as advanced comorbidities, male sex, and increased age, had the greatest contribution to increased risk of mortality during the index hospitalization after PD. While hospital size was not associated with mortality, hospital-level factors such as teaching status and Leapfrog hospital volume standards had a high relative contribution to increased risk of in-hospital mortality following PD. Because certain patient-level factors are non-modifiable, adequate patient selection is essential when planning the optimal management of patients with periampullary lesions requiring a PD. Moving forward, future research should focus on understanding the processes of care that are associated with improved mortality after PD at the hospital level.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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