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Developing and validating a center-specific preoperative prediction calculator for risk of pancreaticoduodenectomy

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Results detailed in this manuscript were presented in part at the April 2016 meeting of the International Hepato-Pancreato-Biliary Association (IHPBA) in São Paulo, Brazil.

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ABSTRACT

Background: The American College of Surgeons (ACS) Surgical Risk Calculator predicts postoperative risk based on preoperative variables. The ACS model was compared to an institution-specific risk calculator for pancreaticoduodenectomy (PD).

Methods: Observed outcomes were compared with those predicted by the ACS and institutional models. Receiver operating characteristic (ROC) analysis evaluated the models' predictive ability. Institutional models were evaluated with retrospective and prospective internal validation.

Results: Brier scores indicate equivalent aggregate predictive ability. ROC values for the institutional model (ROC: 0.675-0.881, P < 0.01) indicate superior individual event occurrence prediction (ACS ROC: 0.404-0.749, P < 0.01-0.860). Institutional models' accuracy was upheld in retrospective (ROC: 0.765-0.912) and prospective (ROC: 0.882-0.974) internal validation.

Conclusions: Identifying higher-risk patients allows for individualized care. While ACS and institutional models accurately predict average complication occurrence, the institutional models are superior at predicting individualized outcomes. Predictive metrics specific to PD center volume may more accurately predict outcomes.

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1. Introduction

The American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP®) database was used to generate the ACS NSQIP Surgical Risk Calculator,¹ which aims to illustrate perioperative risk based on patient variables and to facilitate preoperative patient-surgeon discussions. With regionalization of complex procedures such as pancreaticoduodenectomy (PD) to high-volume specialty centers,²,³ the ACS models currently do not account for surgeon or center volume with a specific procedure, surgeons' specialty training, and institution-specific practices such as Enhanced Recovery After Surgery® (ERAS®) protocols. Surgeon training and center volume in complex procedures such as PD influence outcomes including mortality.³-5 The independent predictive influence of both hospital and surgeon volume on outcomes following pancreatectomy has been demonstrated by

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previous risk calculators generated with national surgical outcomes data for patients undergoing pancreatectomy.^{4–7} Center- and surgeon-specific factors may differentiate individual centers' results from aggregate-based predictions and should be considered to avoid homogenization of predicted outcomes.⁸

Several studies have sought to better quantify and predict the risk of morbidity and mortality in patients undergoing treatment for pancreatic cancer.^{2,4,9}—12 Despite reductions in morbidity and postoperative mortality associated with performance of PD at high-volume centers, a morbidity rate of up to 40% following PD² requires the appropriate selection of surgical candidates according to patient and disease characteristics and quantified perioperative risks

Prior to adopting the ACS Risk Calculator into preoperative patient discussions at our center, we retrospectively evaluated the ACS Risk Calculator's predictions in a population of patients who underwent PD at our institution. Given the importance of centerand surgeon-specific metrics in performing PD,^{3–7} we hypothesized that predictions derived from an aggregate-based risk calculator for PD may be inaccurate in an individual high-volume PD center. After evaluating the predictive capability of the ACS

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Risk Calculator, clinical outcomes data for PD at our center were used to construct institution-specific predictive algorithms to more precisely predict individual patient outcome risks for PD.

2. Materials and methods

Following Institutional Review Board approval, clinical data were obtained from 400 patients undergoing PD within the Division of HPB Surgery at Carolinas Medical Center (CMC) between January 1, 2008, and December 31, 2014. Pre- and post-surgical clinical outcomes data were collected by trained reviewers from electronic medical records (EMRs) and entered into a Research Electronic Data Capture (REDCap) database.¹³ The same patient data were then entered into the ACS Risk Calculator, and generated event risk probabilities were recorded for each patient. All statistical analyses were performed using STATA statistical software, v.13 (Statacorp, College Station, TX, USA).¹⁴ Records were evaluated by a surgeon (RK) for the presence and severity of postoperative pancreatic fistula (POPF) and delayed gastric emptying (DGE) based on international definitions.^{15,16} Postoperative complications were

stratified according to the Clavien-Dindo classification system with complications >IIIa characterized as *serious* complications.¹⁷

2.1. Comparison of the ACS model versus CMC model

Individual logistic models were created to assess the predictive capacity of the ACS models, defining outcomes as previously described by NSQIP.^{2,18} When calculating probability of outcomes using the ACS model, 21 patient comorbidity covariates were entered into the ACS Risk Calculator; the surgeon adjustment of risk function was not applied retrospectively.

The CMC models were generated with the 21 variables used in the ACS Risk Calculator; an additional 23 laboratory, demographic, and comorbidity variables collected in the institutional database were analyzed for inclusion in the CMC models (Table 1). The observed outcome variables were coded as binary, and 44 independent explanatory variables were coded as continuous, categorical, or binary (Table 1). Variables considered clinically relevant to an outcome were included in the model regardless of significance value. Bivariate analyses were performed to test all

Table 1Variables used to generate the ACS and CMC predictive outputs.

ACS inputs $(n = 21)$	CMC inputs (n = 44)
Age group	Age group
Sex	Sex
Functional status	Functional status
Emergency case	Emergency case
ASA class	ASA class
Wound class	Wound class
Steroid use for chronic condition	Steroid use for chronic condition
Ascites within 30 days prior to surgery	Ascites within 30 days prior to surgery
Systemic sepsis within 48 h prior to surgery	Systemic sepsis within 48 h prior to surgery
Ventilator-dependent	Ventilator-dependent
Disseminated cancer	Disseminated cancer
Diabetes medication (oral or insulin)	Diabetes medication (oral or insulin)
Hypertension requiring medication	Hypertension requiring medication
Previous cardiac event	Previous cardiac event
Congestive heart failure prior to surgery	Congestive heart failure prior to surgery
Dyspnea	Dyspnea
Current smoker within 1 year	Current smoker
History of severe COPD	History of severe COPD
Dialysis	Dialysis
Acute renal failure	Acute renal failure
BMI	BMI
	Race
	-American Indian
	-Asian
	-African American or Black
	-White
	Current alcohol use within 1 month
	Family history of HPB disease
	Family history of cancer
	Family history of stroke
	Family history of MI
	Family history of HPB malignancy
	Family history of diabetes
	Current medication — Angiotensin receptor blocker
	Current medication — Calcium channel blocker
	Current medication — ACE inhibitors
	Current medication — Loop diuretics
	Current medication — Beta blockers
	Albumin level (g/dL)
	Hemoglobin (g/dL)
	Potassium (mmol/L)
	Creatinine (mg/dL)
	Alkaline phosphatase (IU/L)
	AST (IU/L)
	ERCP with biliary stent prior to surgery
Abbreviations: ACS, American College of Surgeons; CMC, Carol	inas Medical Center; COPD, chronic obstructive pulmonary disease;

Abbreviations: ACS, American College of Surgeons; CMC, Carolinas Medical Center; COPD, chronic obstructive pulmonary disease; BMI, body-mass index; HPB, hepatopancreatobiliary; MI, myocardial infarction; ACE, angiotensin converting enzyme; AST, aspartate aminotransferase; ERCP, endoscopic retrograde cholangiopancreatography.

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