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ORIGINAL ARTICLE

Pancreatic fistula risk for pancreatoduodenectomy: an international survey of surgeon perception

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Abstract

Introduction: Clinically relevant postoperative pancreatic fistula (CR-POPF) is a morbid complication following pancreatoduodenectomy (PD). It is unclear how pancreatic surgeons perceive risk for this complication, and the implications thereof.

Methods: A web-based survey was distributed to members of 22 international GI surgical societies. CR-POPF risk factors were categorized as follows: (i) patient factors, (ii) pancreatic gland characteristics, (iii) intraoperative variables, (iv) perioperative mitigation techniques, or (v) institutional features.

Results: Surveys were completed by 897 surgeons worldwide. The most commonly cited contributors to CR-POPF risk were gland characteristics (90.7%), while patient and intraoperative factors were selected 71.2 and 69.3% of the time, respectively. Conversely, institutional features (31.7%) and perioperative mitigation techniques (21.3%) were rarely recognized. Eighty percent of surgeons use drain amylase concentration to guide drain removal decision-making; however, only 45.2% of surgeon remove drains early based upon drain amylase values. When evaluating clinical scenarios, surgeons were able to identify both negligible and high risk scenarios but struggled to differentiate between low and moderate CR-POPF risk.

Conclusion: This international study analyzed how surgeons discern CR-POPF risk for PD. There was considerable variability in surgeons' perceptions of risk, which may have an adverse effect on the clinical use of risk adjustment measures.

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Introduction

Clinically relevant postoperative pancreatic fistula (CR-POPF) is a common and morbid complication following pancreatoduodenectomy (PD).[1] Although perioperative mortality rates have decreased markedly with advances in surgical technique and postoperative care, the rate of CR-POPF has persisted at approximately 15%.[2,3] Early definitions of CR-POPF in the surgical literature varied substantially;[4] however, the 2005 International Study Group of Pancreatic Fistula (ISGPF) established a standardized definition for pancreatic fistula based upon the concept of clinical severity.

Although the ISGPF was a breakthrough for defining CR-POPF, the standards used to stratify CR-POPF risk still vary greatly. These often include one or more of the following: patient factors (e.g., patient acuity), gland characteristics (e.g., gland texture), intraoperative factors (e.g., blood loss, anastomotic technique), institutional features (e.g., volume), and perioperative mitigation techniques (e.g., transanastomotic stents or prophylactic somatostatin analogues). Some of these factors – particularly the mitigation techniques – have been tested in randomized controlled trials (RCT), but inconsistent approaches to risk stratification have often contributed to inconclusive or

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even contradictory findings. For instance, the use of externalized stents may have selective benefit in cases of increased anastomotic risk, although definitions of "risky" cases have varied across trials.[5,6]

To address the absence of standardization in CR-POPF risk assessment, the Fistula Risk Score (FRS) was introduced in 2013.[1,7] This externally validated tool incorporates both endogenous (i.e., gland texture, duct diameter, and disease pathology) and operative (i.e., blood loss) variables to predict patients' risk for CR-POPF formation at the point of anastomotic construction.[3,8] The FRS has subsequently been utilized in risk-stratified comparisons of fistula mitigation strategies (e.g., intraoperative drains,[9–11] somatostatin analogues,[12] and stents,[13]) as well as assessments of surgeon and institutional performance.[3] Moreover, the use of the FRS as a supplement to conventional American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) variables has been shown to significantly improve the prediction of major morbidity, mortality, and reoperation following PD – underscoring the importance of considering procedure-specific (i.e., CR-POPF) risk when studying outcomes following PD.[14]

Since accurate measurement of CR-POPF risk is imperative for impartial comparisons of operative and management strategies, as well as surgeon and institutional performance, this study queried how pancreas surgeons perceive CR-POPF risk for PD. The primary objectives of this study were two-fold. The first sought to establish surgeons' perceptions of purported CR-POPF risk factors and determine whether various perspectives correlated with particular surgeon characteristics. Collective responses were compared to highest-level evidence to assess the validity of the reported opinions. The second objective was to evaluate how surgeons measure aggregate CR-POPF risk; surgeons graded a series of clinical vignettes and these results were compared with CR-POPF risk estimates using the FRS, as well as actual CR-POPF outcomes derived from a multi-national, multi-institutional database of over 5000 PDs.

Methods

This study was approved by the institutional review board at the University of Pennsylvania. A structured, web-based survey was designed and administered to surgeons who perform pancreatic surgery through 22 international gastrointestinal surgical societies. Support was first engendered from several of the larger international societies: the International Hepato-Pancreato-Biliary Association (IHPBA), Society for Surgery of the Alimentary Tract (SSAT), and Pancreas Club. These organizations distributed the survey to their extensive global memberships. Next, major IHPBA regional associations – Americas (AHPBA), Asian/Pacific (A-PHPBA), European/African/Middle Eastern (E-AHPBA) – were targeted, as well as many of the corresponding national chapters under their purview. To facilitate global catchment, the e-surveys were made available in eight different native languages: English, Chinese (i.e., Mandarin), French, German, Italian, Japanese, Portuguese, and Spanish. Although the precise number of surgeons offered the survey was not evident – due to overlapping memberships between the various participating organizations – it is estimated that this totaled between 1500–2000 surgeons globally. One component of this survey was previously used to demonstrate global variation in the practice of PD.[15]

Surgeons initially indicated their region of practice. Geographical boundaries were established *a priori* as follows: North America, South/Middle America, Asia/Australia, and Europe/Africa/Middle East. Next, respondents were asked to report any relevant fellowship training, as well as other experience-related parameters – age, annual- and career-volume, and years of experience as an attending/staff surgeon. The scope of their current clinical practice was also characterized.

Surgeons' understanding of CR-POPF risk was investigated based on their region of practice, fellowship training, clinical practice, years of experience as an attending ($\leq$10, 11–20, or >20), annual PD volume (high-volume: upper quartile, $\geq$25 PDs/year), and surpassing the PD learning curve ($\geq$50 PDs during career[16]). CR-POPF risk factors were broadly categorized as follows: (i) patient factors – patient acuity, nutrition, medications; (ii) pancreatic gland characteristics – texture, duct size; (iii) intraoperative variables – anastomotic technique, blood loss, fluid management; (iv) perioperative mitigation techniques – stents, somatostatin analogues, drain management; (v) institutional features – volume, multi-disciplinary support. Management decisions included factors that influence their decision to remove or keep drains and whether the surgeons practice early drain removal (postoperative day [POD] $\leq$ 3) based upon drain amylase values.

Surgeons were also presented with two hypothetical clinical scenarios and asked to select the one with the highest risk for CR-POPF development. These scenarios included information regarding pancreatic parenchyma (i.e., soft vs. firm texture), pancreatic duct diameter, disease pathology, and intraoperative blood loss. Surgeons were presented with four additional scenarios and asked to rank the relative risk (i.e., no risk, low risk, moderate risk, or high risk) for the development of a CR-POPF. Actual CR-POPF outcomes associated with each scenario were derived from a multi-national, multi-institutional (N = 17) database of 5323 patients who underwent PD.

Statistical analysis

Descriptive statistics are presented as frequencies for categorical variables, and mean ± standard deviation (SD) and median (Interquartile range [IQR]) for continuous variables. Pearson's χ^2 or Fisher's exact test and Independent Student's *t*-tests or ANOVA testing were used to analyze categorical and continuous variables, respectively. Non-parametric comparisons of continuous variables were assessed by the Wilcoxon rank sum test or Kruskal–Wallis one-way analysis of variance. P-values $\leq$0.05

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