Surgery ■■ (2017) ■■–■■

Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/ymsy

Minimally invasive pancreatoduodenectomy: is the incidence of clinically relevant postoperative pancreatic fistula comparable to that after open pancreatoduodenectomy?

Olga Kantor [a], Henry A. Pitt [b], Mark S. Talamonti [c,d], Kevin K. Roggin [a], David J. Bentrem [e], Richard A. Prinz [c,d], and Marshall S. Baker [c,d,*]

[a] *Department of Surgery, University of Chicago, Chicago, IL*
[b] *Department of Surgery, Temple University, Philadelphia, PA*
[c] *Department of Surgery, NorthShore University HealthSystem, Evanston, IL*
[d] *Pritzker School of Medicine, University of Chicago, Chicago, IL*
[e] *Department of Surgery, Northwestern Medicine, Chicago, IL*

ARTICLE INFO

Article history:
Accepted 1 December 2017

ABSTRACT

Background. Studies evaluating the efficacy of minimally invasive approaches to pancreatoduodenectomy (MIS-PD) compared to open pancreatioduodenectomy (OPD) have been limited by selection bias and mixed outcomes.

Methods. ACS-NSQIP 2014–2015 pancreas procedure-targeted data were used to identify patients undergoing PD. Intention-to-treat analysis was performed.

Results. Of 7907 PD patients, 1277 (16%) underwent MIS-PD: 776 (61%) robotic or laparoscopic PD, 304 (24%) hybrid, and 197 (15%) unplanned conversions. There were no differences in demographics or comorbidities. Patients undergoing MIS-PD were less likely to have pancreatic ductal adenocarcinoma (30.9% vs 53.9%, $P < 0.01$) and less likely to have a dilated pancreatic duct (21.8% vs 46.7%, $P < 0.01$). 30-day morbidity was less for MIS-PD (63.6% vs 76.9%, $P < 0.01$), due to decreased delayed gastric emptying DGE) in the MIS-PD group (8.6% vs 15.5%, $P < 0.01$). 30-day mortality, length-of-stay, and readmissions were not significantly different. Patients undergoing MIS-PD had greater rates of CR-POPF (15.3% vs 13.0%, $P = 0.03$). On adjusted multivariable analysis, MIS-PD was not associated with CR-POPF (OR 1.05, 95% CI 0.87–1.26) but was associated with decreased DGE (OR 0.57, 95% CI 0.46–0.71).

Conclusion. MIS-PD has comparable short-term outcomes to open PD. While CR-POPF rates are greater for MIS-PD, this increased risk appears related to case-selection bias and not inherent to the MIS-approach. (Surgery 2017;160:XXX-XXX.)

Recent prospective and retrospective studies have demonstrated that minimally invasive approaches to pancreatoduodenectomy (MIS-PD) are safe and provide short-term oncologic outcomes comparable to the gold standard of open pancreatoduodenectomy (OPD). These studies have included several large multicenter retrospective comparisons of MIS-PD to OPD and several meta-analyses, which have demonstrated similar rates of perioperative morbidity and mortality for MIS-PD compared to OPD,[1-3] similar short-term oncologic outcomes (rates of margin-negative resection and lymph node yields) in malignant periampullary tumors when comparing MIS-PD to OPD,[4-6] and similar long-term overall survival rates for pancreatic adenocarcinoma (PDAC).[7,8]

While these results have been taken as promising and have driven a measurable increase in the utilization of MIS-PD for pathology in the pancreatic head,[9] they continue to be viewed with some skepticism. There are currently no randomized trials comparing these 2 operative approaches. No studies demonstrate any substantive benefit to the MIS approaches and are none are able to completely adjust for selection biases that result in patients with technically challenging pathologies being managed primarily by OPD. In many of these studies, MIS-PD broadly encompasses robotic, laparoscopic, hybrid (robotic assisted laparoscopic), and robotic or laparoscopic procedures with open assistance. This makes performing intent to treat analyses impossible. Several of the studies also identify a steep and potentially costly (although surmountable) learning curve.[6,10,11] Few studies include grading of pancreas-specific outcomes. Specifically, very few studies rightly evaluate the impact

Presented as an oral presentation at the 2017 Central Surgical Association Annual Meeting on August 1, 2017 in Chicago, IL.

* Corresponding author. Department of Surgery, NorthShore University HealthSystem, 2650 Ridge Avenue, Evanston, IL 60201.
E-mail address: mba475@gmail.com (M.S. Baker).

https://doi.org/10.1016/j.surg.2017.12.001
0039-6060/

on clinically relevant postoperative pancreatic fistula (CR-POPF) and delayed gastric emptying (DGE).

Given these gaps in evidence evaluating the efficacy of minimally invasive approaches to pancreatoduodenectomy and the technical sophistication of and expense associated with learning these approaches, there continues to be general hesitancy to apply these approaches clinically. The vast majority of pancreatic head resections continue to be done by open approaches. In an effort to better understand the impact of MIS-PD on pancreatic fistula and other outcome measures, we use high quality, nationally accruing multi-institutional data from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) to compare pancreas-specific outcomes of MIS-PD and OPD, with a focus on CR-POPF. This dataset includes appropriate classification of unplanned conversions from MIS to open approaches and allows for intention to treat analysis. We hypothesized that pancreatic-specific outcomes would be similar between MIS and OPD groups.

Methods

Data source

ACS-NSQIP is a quality improvement database that collects preoperative and postoperative data through 30-days after a variety of surgical procedures.[12] NSQIP has several procedure-targeted databases, including a pancreas-procedure targeted dataset that became publically available starting in 2014.[13] The NSQIP pancreas data set includes 5,184 cases from 106 contributing NSQIP sites in 2014 and 6,032 cases from 120 sites in 2015.[14] The procedure targeted dataset for pancreas captures presence of preoperative jaundice or biliary stent, intraoperative documentation on pancreatic ductal diameter, pancreatic gland texture, vascular reconstruction, type of pancreatic reconstruction, use of closed suction drains, and measurement of postoperative drain amylase levels, day of drain removal, presence of pancreatic fistula or delayed gastric emptying, the use of percutaneous drainage, and pathology results. All data collected are compliant with the privacy requirements of the Health Insurance Portability and Accountability Act. Institutional review board approval was not required for this study as the available data were deidentified, no protected health information was reviewed, and analysis was retrospective.

Study population and variables examined

The NSQIP pancreas specific data from 2014–2015 was used for analysis. Patients undergoing pancreatoduodenectomy were identified using primary Current Procedure Terminology codes 48150, 47152, 48153, or 48154. All patients who underwent pancreatoduodenectomy for any indication were included in the study population. The primary endpoint was CR-POPF. The secondary endpoints included DGE, duration of stay, 30-day morbidity, and 30-day mortality rates. In the study, 30-day morbidity rates were defined as ≥1 complications in any of the NSQIP complication variables (wound infection, dehiscence, pneumonia, reintubation, respiratory failure, vent support >48 hours, urinary tract infection, renal failure, cardiac arrest, stroke, myocardial infarction, thromboembolic event, sepsis, septic shock, delayed gastric emptying, pancreatic fistula, postoperative transfusion, reoperation) or pancreas-specific variables (POPF, DGE) within 30 days. MIS-PD were identified by the variable "pan approach" and included any laparoscopic, robotic, and hybrid PD. MIS cases converted to open were clearly identified in the NSQIP dataset and also were included in the MIS-PD group in effort to perform an intention to treat analysis. Body mass index (BMI), American Society of Anesthesiologists class, pancreatic duct diameter, pancreatic gland texture, and pathology were reported in the database and analyzed as categorical variables. Age was analyzed as a continuous variable and other variables were analyzed as binary indicator variables.

Definition of CR POPF and DGE

The NSQIP does not specifically identify or code a pancreatic fistula as clinically relevant. CR-POPF was assigned using the International Study Group on Pancreatic Fistula definition as a guide to the extent possible given the constraints of the data available.[15,16] Patients having had the designation of having a "pancreatic fistula" or those with a drain amylase >300 U/dL on postoperative day ≥3 within the NSQIP dataset were graded as having a CR-POPF if they also had at least one of the following: drain in place for >14 days in context of a prolonged hospital stay >21 days, organ space surgical infection, postoperative percutaneous drain placement, reoperation, sepsis, shock, or multisystem organ failure (respiratory or renal failure). This definition was also used in our previous work in identifying a risk score model for CR-POPF using NSQIP.[17] DGE was defined in NSQIP as no oral intake by postoperative day 14 or gastric/nasogastric tube to drainage or reinserted on postoperative day 14.[14]

Statistics

All statistical analyses were performed using SPSS statistical software version 19.0 (SPSS Corp., Armonk, NY). χ^2 and *t* tests were used to analyze unadjusted data between categories of MIS-PD and OPD. Variables significant on univariate analysis were then incorporated into multivariable regressions to identify predictors associated with CR-POPF and DGE. Missing data were analyzed as a separate category of "unknown" for each variable so that all patients could be included for analysis in the multivariable models. An odds ratio (OR) > 1 indicates increased odds of CR-POPF or DGE. Confidence intervals (CIs) are reported to a 95% level of significance. All reported *P* values are 2-sided.

Results

Cohort characteristics

In the study, 7,907 patients underwent PD: 1,277 (16%) as MIS-PD and 6,630 (84%) as OPD. Of all MIS-PD, 197 (15%) underwent unplanned conversion to open. The breakdown of laparoscopic, robotic, and hybrid cases are further delineated in Fig.

Baseline demographics and comorbidities were similar between patients undergoing MIS-PD and OPD (Table 1). Patients undergoing MIS-PD were less likely to have jaundice (14.6% vs 40.1%, $P < .01$) or biliary stenting (16.1% vs 42.6%, $P < .01$) preoperatively. Additionally, patients undergoing MIS-PD had lesser rates of preoperative chemotherapy (7.8% vs 14.8%, $P < .01$) and radiation (3.4% vs 7.1%, $P < .01$) within 90 days of operation.

Univariable comparisons of intraoperative characteristics and postoperative outcomes

On univariable comparison, patients undergoing MIS-PD were less likely to have pancreatic adenocarcinoma (PDAC, 30.9% vs 53.9%, $P < .01$) and more likely to have benign pathology (28.7% vs 15.1%, $P < .01$) than those undergoing OPD. There were observed differences in other captured intraoperative characteristics including pancreatic duct size, gland texture, and need vascular resection, likely reflecting the differences in pathology with patients undergoing MIS-PD being statistically more likely to have small pancreatic ducts, softer gland texture, and less likely to require a major vascular resection during the PD (Table 2). Operative time was noted to be similar for MIS-PD (mean of 376 ± 140 vs 368 ± 128 min, $P = .05$) than

Please cite this article in press as: Olga Kantor, Henry A. Pitt, Mark S. Talamonti, Kevin K. Roggin, David J. Bentrem, Richard A. Prinz, and Marshall S. Baker, Minimally invasive pancreatoduodenectomy: is the incidence of clinically relevant postoperative pancreatic fistula comparable to that after open pancreatoduodenectomy?, Surgery (2017), doi: 10.1016/j.surg.2017.12.001