



Expanding the utility of robotics for pancreaticoduodenectomy: a 10-year review and comparison to international benchmarks in pancreatic surgery

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Received: 4 April 2023 / Accepted: 31 August 2023 / Published online: 25 September 2023
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Abstract

Background Robotic pancreaticoduodenectomy (RPD) is an emerging alternative to open pancreaticoduodenectomy (OPD). Although RPD offers various theoretical advantages, it is used in less than 10% of all pancreaticoduodenectomies. The aim of this study was to report our 10-year experience and compare RPD outcomes with international benchmarks for OPD.

Methods A retrospective review of a prospectively maintained institutional database was performed of consecutive patients who underwent RPD between January 2011 and December 2021. Patients were categorized into low-risk and high-risk groups according to the selection criteria set by the benchmark study. Their outcomes were compared to the international benchmark cut off values. Outcomes were then evaluated over time to identify improvements in practice and establish a learning curve.

Results Of 201 RPDs, 36 were low-risk and 165 high-risk patients. Compared to the OPD benchmarks, outcomes of low-risk patients were within the cutoff values. High-risk patients were outside the cutoff for blood transfusions (26% vs. $\leq 23\%$), overall complications (78% vs. $\leq 73\%$), grade I–II complications (68% vs. $\leq 62\%$), and readmissions (22% vs. $\leq 21\%$). Oncologic outcomes for high-risk patients were within benchmark cutoffs. Cases at the end of the learning curve included more pancreatic cancer (42% from 17%) and fewer low-risk patients (10% from 24%) than those at the beginning. After 41 RPD there was a decline in conversion rates and operative time. Between 95 and 143 cases operative time, transfusion rates, and LOS declined significantly. Complications did not differ over time.

Conclusion RPD yields results comparable to the established benchmarks in OPD in both low- and high-risk patients. Along the learning curve, RPD evolved with the inclusion of more high-risk cases while outcomes remained within benchmarks. Addition of a robotic HPB surgery fellowship did not compromise outcomes. These results suggest that RPD may be an option for high-risk patients at specialized centers.

Keywords Robotics · Pancreaticoduodenectomy · Pancreatic surgery · Learning curve · Minimally invasive · Benchmarks

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Pancreaticoduodenectomy (PD) is the necessary treatment for many benign and malignant tumors localized in the head of the pancreas. This remains a challenging operation that is most often performed open, even in tertiary centers. In 2019, Clavien et al. described in an international multi-institutional analysis, the benchmarks for open pancreaticoduodenectomy (OPD) [1]. This was established in order to standardize comparison among centers performing OPD and create a meaningful assessment of the efficacy and safety of the proposed technique. 23 high-volume hepato-pancreato-biliary (HPB) centers were included in the benchmarking study and cutoff values were extrapolated from the 75th percentile of the median data value from each center. In order

to form a more standardized set of values and eliminate confounding from comorbidities, patients included in the study were considered low-risk. Selection criteria for these patients included age over 18 years and OPD for resectable malignant or benign pancreatic disease. Excluded patients were those with prior major abdominal surgery, arterial resection, ASA score ≥ 3 , BMI ≥ 35 , significant cardiac history, Chronic renal failure, COPD, and anticoagulant use. The 20 benchmarks for which to reference as a standard for OPD were operative duration ≤ 7.5 h, blood transfusion rate 23%, hospital stay ≤ 15 days, rates of at least one complication (graded as Clavien–Dindo score) $\leq 73\%$, grade I–II complications $\leq 62\%$, grade \geq III complications $\leq 30\%$, grade IV complications $\leq 5\%$, Comprehensive Complication Index (CCI) ≤ 20.9 , pancreatic fistula rate $\leq 19\%$, grade B fistula $\leq 15\%$, grade C fistula $\leq 5\%$, biochemical leak $\leq 13\%$, severe postoperative bleeding $\leq 7\%$, in-hospital mortality $\leq 1.6\%$, failure-to-rescue rate $\leq 9\%$, readmission rate $\leq 21\%$, R1 resection rate $\leq 39\%$, number of lymph nodes harvested ≥ 16 , and 1 and 3-year disease-free survival of $\geq 53\%$ and 9% , respectively.

As the benefits of minimally invasive surgery have gained popularity over the last few decades, the robotic approach has shown much promise in the HPB sector [2–4]. Robotic pancreaticoduodenectomy (RPD) was introduced over 20 years ago [5]. Described as technically demanding with a substantial learning curve, it is mainly performed at specialized centers [6, 7]. In experienced hands, however, it can result in lower postoperative morbidity and shorter length of stay than open [8, 9]. Patients receiving RPD historically are carefully selected [9]. Indications include benign and resectable malignant pathology of the head of the pancreas and periampullary region [10–12]. Few reports of RPD for advanced resections have been published from large volume centers [13, 14]. There is currently a paucity of data

describing the benefits of RPD in more complex cases and in those with increased perioperative morbidity.

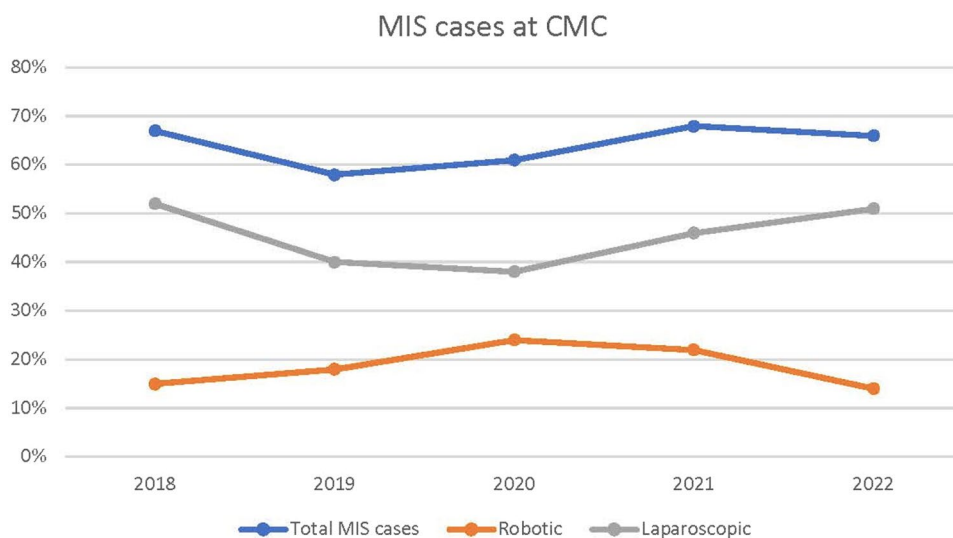
There has been some hesitancy in incorporating RPD in the HPB community for various reasons and OPD remains the standard of care for pancreatic head resections [15, 16]. RPD has the potential to challenge OPD as the gold standard if indications can be expanded to involve complex resections and higher risk patients and the learning curve can be better understood. Currently, there are no benchmarks specifically for RPD. Until now, no comparison of RPD to the open benchmarks has been performed either. In this study we aimed to (1) Report our experience with RPD in low and high-risk patients over the last 10 years, (2) Compare our outcomes with the published international benchmarks for OPD, and (3) Report our institutional learning curve.

Methods

Program background

Atrium Health Carolinas Medical Center (CMC) is a quaternary HPB center in North America where over 1000 HPB cases are performed annually with over 60% being minimally invasive (Fig. 1). We commenced our robotic HPB program in 2006, and since have performed over 1600 robotic HPB cases between two surgeons at our main campus facility alone (two surgeons at a community hospital extension also utilize robotics). RPD from 2011 to 2018 was performed by a single surgeon (JM). Initial indications most commonly included benign disease, ampullary carcinoma and duodenal carcinoma. A second robotic HPB surgeon later joined our faculty in 2018 (DV). Our robotic HPB fellowship was later introduced in 2020. Fellows currently have

Fig. 1 Percentages of MIS HPB cases performed at CMC in the last 5 years



time at the console performing key portions of operations including RPD.

Patient selection

Patients who underwent both standard RPD and pylorus preserving RPD with or without vascular reconstruction were included. Pylorus preserving RPD is the default procedure with standard RPD reserved for cases where a positive margin would occur if the pylorus were preserved. From 2011 to 2016 RPD was offered to patients with benign disease, ampullary carcinoma, distal cholangiocarcinoma, duodenal carcinoma and upfront resectable PDAC of the head and uncinate of the pancreas with or without neoadjuvant chemotherapy. Patients with tumors in the neck of the pancreas with vein involvement were not offered RPD. In the first 2 years, open conversion was planned. After 2016, patients with more advanced PDAC were included as indications for RPD and vein reconstruction was not considered a contraindication. Known preoperative arterial involvement or combined cases with other specialists requiring open surgery were indications to use the open approach. There are no laparoscopic PD performed at CMC. Patients who were deemed unfit for an operation with non-modifiable factors by either cardiac, pulmonary or neurologic means were not offered RPD. Specific comorbidities such as congestive heart failure, advanced COPD, pulmonary hypertension, cirrhosis, ESRD, morbid obesity, previous abdominal surgery or advanced age were not contraindications for RPD and thus did not automatically exclude them from being offered surgery unless specifically instructed by consulting physicians. Severe protein-calorie malnutrition was however a relative contraindication in patients with malignancy.

Operative technique

The standardized technique for RPD at CMC has been previously published and remains the approach used today with few changes [17]. Four robotic trocars are placed along the abdomen in a horizontal line. A 15 mm assistant port is placed infraumbilical. The patient is positioned in approximately 10–12 degrees reverse Trendelenburg with the arms out. The surgeon and fellow remain at the console throughout the procedure with a surgical technical assistant at bedside. Arm 1 carries the fenestrated bipolar and the camera is in arm 2. Arm 3 holds the working instruments (scissors, vessel sealer, etc.), and arm 4 uses a grasper mainly as a retracting arm. If deemed necessary, the gallbladder is suspended to the abdominal wall with suture to retract the liver and open the porta-hepatis. Sponges are also used for retraction instead of a separate liver retractor. We perform the resection phase supramesocolic and switch to inframesocolic during transection of the jejunum and dissection of

the ligament of treitz. The duodenum is dissected and transected early followed by the jejunum using a robotic stapler to assist with visualization and streamline exchanges of the stapler by placing robotic arm 3 through the assistant trocar. The remainder of the resection phase is performed with the final step being separation of the bile duct. If a tangential vein resection is anticipated for negative margins, a bulldog clamp is placed on the vein and it is then repaired with suture after the specimen is disconnected. If a segmental vein resection is anticipated, conversion to open is necessary to gain proximal and distal control with minimal portal clamp time. The specimen is not extracted until the end of the case. During reconstruction, the jejunal limb is brought through the transverse mesocolon bare area to the right of the middle colic vessels. The pancreaticojejunostomy (PJ) is fashioned first in two layers with a running posterior layer of barbed suture for a firm pancreas or monofilament suture for a softer pancreas. This is followed by a duct to mucosa layer of interrupted absorbable suture. The anterior layer is sutured similar to the posterior layer. The hepaticojejunostomy (HJ) is typically performed in a single layer with either interrupted suture for a smaller duct or running continuous suture for a larger duct. The duodeno-jejunostomy (DJ) is performed last as an antecolic, retro-omental hand sewn anastomosis with absorbable barbed suture. A drain is placed anterior to the HJ and PJ and a vascularized round ligament flap is harvested and positioned over the GDA stump and behind the PJ. Specimen is extracted from the assistant port site which is extended approximately 3 cm to accommodate.

Study design

We performed a retrospective review of our prospectively maintained institutional database including data for consecutive patients who underwent RPD between January 2011 and December 2021 at CMC. The study was approved by the Institutional Review Board of Atrium Health, Carolinas Medical Center. Patients were placed in either low-risk or high-risk categories determined by the selection criteria outlined in the original international benchmark study for OPD [1]. Outcomes in both groups were then compared to these benchmarks. A post hoc analysis of patients with pancreatic ductal adenocarcinoma (PDAC) was performed to evaluate oncologic outcomes. Patients were then categorized into four chronologic groups. Group 1 ($n = 41$) demonstrated the first 3 years of the initial surgeon's cases or the early learning phase. Group 2 ($n = 54$) represented the second 3 years and the maturation phase. Group 3 ($n = 48$) corresponded with the introduction of a second surgeon and Group 4 ($n = 58$) the introduction of a robotic HPB fellowship. The outcomes of these groups were then compared. Transition points along the learning curve were determined by a combination of

subjective (surgeon confidence level and development of visual haptics) and objective factors (operative time, conversion rate, and a change in clinical outcomes).

The 20 clinically relevant intraoperative and postoperative parameters corresponding to previously published benchmark parameters on OPD were analyzed [1]. Conversion rates were also evaluated as a proposed benchmark for MIS PD. Postoperative complications were graded according to the Clavien–Dindo (CD) classification [18]. Major complications were defined as CD grade III or above. Clinically relevant postoperative pancreatic fistula (CR-POPF) was defined according to the updated international study group on pancreatic fistula classification [19]. The failure-to-rescue rate was calculated according to the international benchmark definition (number of deaths in patients with CD grade \geq II over the total number of patients with CD grade \geq II).

The comprehensive complication Index (CCI), a continuous numeric score ranging from 0 (uneventful course) to 100 points (death), was used to rank the total number of complications by severity for every patient at discharge and 6 months [20]. Patients with pancreatic adenocarcinoma (PDAC) were evaluated for oncologic quality indicators which included R1 resection rates, number of lymph nodes harvested, and disease-free survival (DFS) at 1 and 3 years. Resection margins were considered negative when no tumor was evident within 1 mm (R0) or were otherwise considered microscopically positive (R1) or grossly positive (R2) [21].

Statistical analysis

Data points were described with counts and percentages for categorical variables, and median and interquartile range (IQR) for continuous or ordinal variables. Categorical variables were compared with chi-square or Fisher exact tests when more than 20% of cells had expected frequencies below five. Student's *t* test was used for pairwise comparisons of normally distributed parameters, and the Mann–Whitney *U* test was used for nonparametric data. Wilcoxon two-sample tests or Kruskal Wallis tests were used for continuous or ordinal variables. All analyses were performed in SPSS ver.27 (IBM®, SPSS®, USA) in an intention-to-treat model. Two-tailed *p* values were calculated for all tests, and *p* < 0.05 was the threshold for significance. Data were stored in Research Electronic Database Capture (REDCap), a HIPPA compliant database.

Results

Patient characteristics

1447 robotic HPB cases were performed between 2011 and 2021. Of 418 robotic pancreatic resections (including

pancreaticoduodenectomy, distal pancreatectomy, central pancreatectomy, total pancreatectomy and pancreatic enucleations) 215 RPD were performed. 14 patients were lost to follow up leading to 201 RPDs included in the study (Fig. 2). Median age was 65 (56–70.5) years, half of the patients were male (49.2%) and the median body mass index was 25.9 (22.4–29.3). The most common indication for RPD was malignancy (67.2% *n* = 135), with PDAC accounting for almost half of these patients (*n* = 66) (Fig. 3). Other indications were chronic pancreatitis (10.4%), neuroendocrine tumors (9.5%) and cystic neoplasms (9.5%). Table 1 summarizes the patient demographics in both low and high-risk groups.

Comparison of low- and high-risk patients

A total of 36 low-risk and 165 high-risk patients were compared. Patients in the high-risk group had higher ASA scores, were older, and more frequently diagnosed with adenocarcinoma (71.5% vs 47.2%, *p* = 0.005) and PDAC (36.4% vs 16.7%, *p* = 0.022). Patients with PDAC more often received neoadjuvant chemotherapy in the high-risk group compared to low-risk patients (*p* = 0.04) (Table 1).

Overall outcomes between low-risk and high-risk patients did not differ significantly (Table 2). There was a trend towards higher conversion rates (23% vs 11%), CR-POPF (12.1% vs 8.3%), major complications (32.1% vs 27.8%) and minor complications (41.8% vs 36.1%) in high-risk patients, however, none of these were significant. Furthermore, median CCI at 6 months was the same at 20.9. The 1-year DFS for patients in both groups with PDAC was 66.7%.

Comparison with international benchmarks for OPD

Table 2 summarizes outcomes as they compare to the benchmark cutoff values. The low-risk group outcomes were within the cutoff values of the published benchmark with the exception of readmissions (25% vs cutoff of \leq 21%). CR-POPF rate for this group was 8.1%. Both major and minor complication rates were far fewer than the benchmarks and length of stay was 7 days compared to the benchmark cutoff of \leq 15 days. High-risk outcomes exceeded benchmark values in categories of blood transfusions (26.1% vs \leq 23%), readmissions (22% vs \leq 21%), and major complications (32.1% vs 30%). However, CCI at 6 months (20.9 vs \leq 20.9), CR-POPF (12.1% vs \leq 19%), severe postoperative bleeding (3% vs \leq 7%), failure-to-rescue rates (1.9% vs \leq 9%), and in hospital mortality (1.2% vs \leq 1.6%) were within benchmarks.

Oncologic outcomes for patients with pancreatic cancer

Most patients with PDAC (*n* = 66), had T2 (51.5%) or T3 (43.9%) disease and 75.8% of patients received neoadjuvant

Patient inclusion criteria

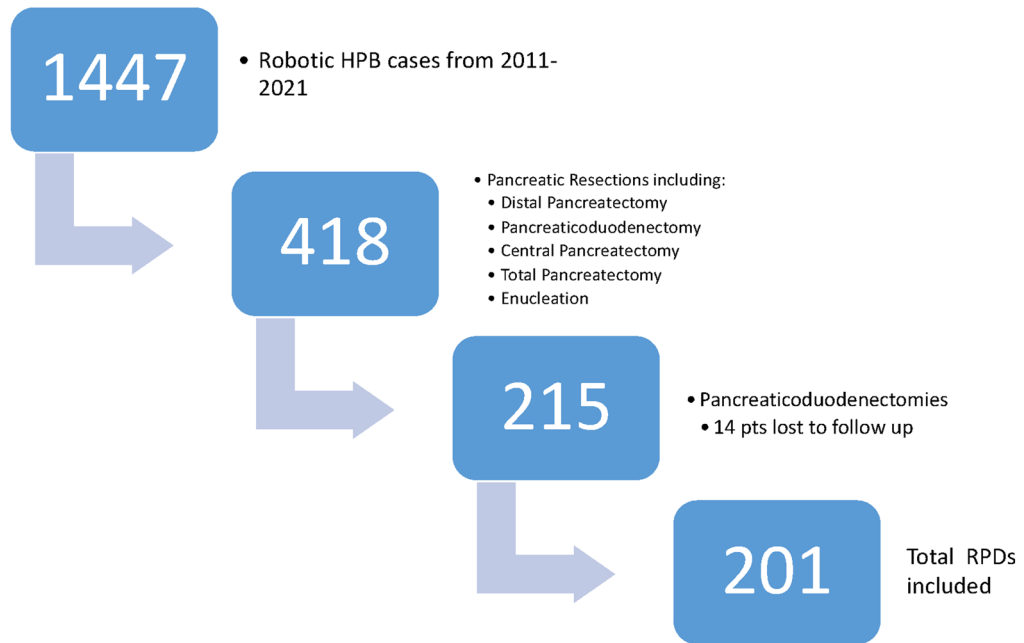
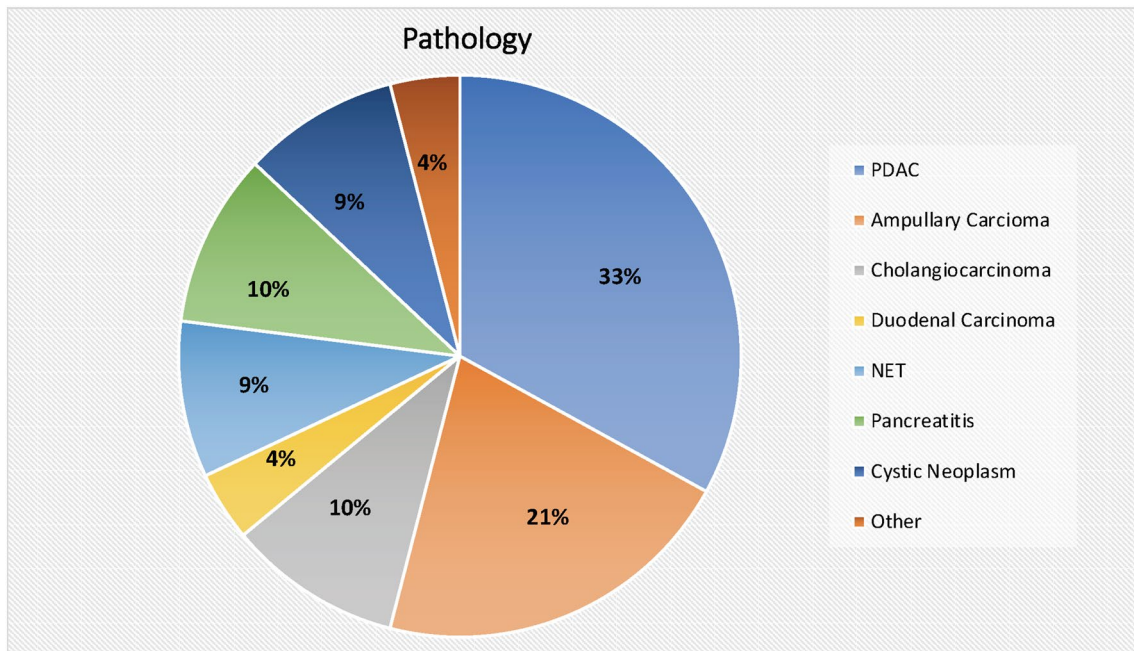


Fig. 2 Breakdown of patients retrospectively selected for the study analysis



Abbreviations: PDAC= Pancreatic ductal adenocarcinoma, NET= Neuroendocrine tumors

Fig. 3 Pathologic evaluation of all 201 RPDs

Table 1 Patient demographics in low-risk and high-risk groups from a total of 201 cases of robotic pancreaticoduodenectomy

Patient demographic	Low-risk (<i>n</i> =36)	High-risk (<i>n</i> =165)	<i>p</i> value
Age, years ^a	54 (43–65)	67 (60–71)	<0.001
Male sex	15 (41.7)	85 (51.5)	0.28
BMI, kg/m ^{2a}	25.8 (22.0–28.9)	26.2 (22.6–29.4)	0.43
ASA status			<0.0001
II	36 (100)	2 (1.2)	
III	0	150 (90.9)	
IV	0	13 (7.9)	
Pathology			
Adenocarcinoma	17 (47.2)	118 (71.5)	0.005
PDAC	6 (16.7)	60 (36.4)	0.022
Ampullary	6 (16.7)	36 (21.8)	
Duodenal	1 (2.8)	6 (3.6)	
Cholangiocarcinoma	4 (11.0)	16 (9.6)	
NET	5 (13.9)	14 (8.5)	
Chronic pancreatitis	6 (16.7)	15 (9.1)	
Cystic neoplasm	6 (16.7)	13 (7.9)	
Other	2 (5.6)	5 (3.0)	
Neoadjuvant chemotherapy in patients with PDAC	2 (33.3)	34 (56.7)	0.04
Staging in PDAC			
T stage			0.33
TX ^b	1 (16.7)	1 (1.7)	
T1	0 (0)	1 (1.7)	
T2	2 (33.3)	32 (53.3)	
T3	3 (50.0)	25 (41.7)	
T4	0 (0)	1 (1.7)	
N stage			0.53
N0	2 (33.3)	15 (25.0)	
N1	4 (66.7)	30 (50.0)	
N2	0 (0)	15 (25.0)	

BMI body mass index, NET Neuroendocrine tumor, PDAC Pancreatic ductal adenocarcinoma

^aData are given as *n* (%) and median (IQR)

^bOne patient from each group had complete pathologic response after neoadjuvant chemotherapy

systemic therapy. Two patients, one from each group, had a complete pathologic response after neoadjuvant therapy. R0 resection was achieved in 48 patients (72.7%). Median lymph node harvest was above the benchmark cutoff of ≥ 16 in both groups (low-risk = 24 nodes, high-risk = 22 nodes). There were higher rates of R1 resection in the low-risk group (50% vs 20%). Only the high-risk group met the benchmark parameter of $\leq 39\%$. Median overall survival was 33.7 ± 8.7 months (95% CI 16.5–50.9 months). The overall 1-year disease-free survival in patients with PDAC was 69.6% which was greater than the benchmark cutoff of $\geq 53\%$.

Assessment of the institutional learning curve

Group 1 (the initial learning phase) had the highest number of low-risk cases (24% vs 22%, 17%, 10%, $p=0.04$), the

lowest number of PDAC patients (17% vs 22%, 48%, 42%; $p=0.03$), and the longest operative time (7.3 h vs 6.5 h, 5.9 h, 7.1 h; $p<0.001$) compared to groups 2, 3, and 4, respectively. Blood transfusions were also more frequent in this group (46% vs 28%, 21%, and 12%; $p=0.001$). During transition from group 1 to group 2 there was a drop in conversion rates (13% vs 32%) which was significant ($p=0.026$), and CR-POPF (5.6% vs 9.7%) which was not ($p=0.437$). CCI was similar throughout the study period and was within the benchmark cutoff at 6 months. Group 4 did not have statistically significant differences in complications despite having a higher number of high-risk patients and integrating fellows' participation in cases. Outcomes throughout the learning curve are compared in Table 3.

Table 2 Comparison of postoperative outcomes after RPD for low-risk and high-risk groups and the international benchmark cutoff values for open PD

	Low-risk (<i>n</i> = 36)	High-risk (<i>n</i> = 165)	<i>p</i> value	Benchmark cut off
Operation duration, h ^a	6.7 (5.8–8.1)	6.7 (5.8–7.7)	0.9	≤ 7.5 h
Blood transfusion	8 (22.2)	43 (26.1)	0.63	≤ 23%
Conversion rate ^b	4 (11.1)	38 (23.0)	0.11	
Length of stay, days ^a	7 (5.5–8)	7 (6–12)	0.04	≤ 15d
Postoperative 6 months morbidity				
At least 1 complication	23 (63.9)	122 (73.9)	0.22	≤ 73%
Grade I–II	13 (36.1)	69 (41.8)		≤ 62%
Grade ≥ III	10 (27.8)	53 (32.1)	0.62	≤ 30%
Grade IV	1 (2.8)	9 (5.5)		≤ 5%
CCI	20.9 (0–33.6)	20.9 (0–34.6)	0.26	≤ 20.9
CR-POPF	3 (8.3)	20 (12.1)	0.51	≤ 19%
Grade B	1 (2.9)	13 (7.9)		≤ 15%
Grade C	2 (5.6)	7 (4.3)		≤ 5%
Biochemical leak	2 (5.6)	12 (7.3)	0.48	≤ 13%
Severe postoperative bleeding (> III)	1 (2.8)	5 (3.0)	1	≤ 7%
In hospital mortality	0 (0)	2 (1.2)	1	≤ 1.6%
Failure-to-rescue rate	0 (0)	2 (1.9)	1	≤ 9%
Readmission rate	9 (25)	36 (22)	0.68	≤ 21%
Oncological outcomes in patients with PDAC	<i>n</i> = 6	<i>n</i> = 60		
R1 rate	3 (50.0)	12 (20.0)	0.09	≤ 39%
# of lymph nodes harvested	24 (16–30)	22 (17–25)	0.78	≥ 16
1-year DFS	4 (66.7)	40 (66.7)	1	≥ 53%
3-year DFS ^c	0	5 (8.3)		≥ 9%

CCI Comprehensive complication index, DFS Disease-free survival, PDAC Pancreatic ductal adenocarcinoma

^aValues are listed as median (IQR)

^bNot a benchmark parameter in the original OPD study. However, this was included as a suggested parameter for minimally invasive PD

^cActuarial 3-year DFS

Discussion

Robotic pancreaticoduodenectomy is slowly evolving as an accepted treatment for many patients with disease of the head of the pancreas and current literature describes its utility for low-risk patients [22, 23]. Very few centers are performing RPD for more complex diseases such as borderline resectable and locally advanced pancreatic head and uncinate cancers [24, 25]. PD is quite complex and carries high risk for complications. Minimally invasive techniques have been described to improve on some of these complications and provide shorter length of hospital stay [26, 27]. We have found that the robot is extremely useful for complex dissections of the hepatic hilum and major abdominal vasculature as well as fashioning delicate anastomoses with precision. Thus, in 2011 our center began performing RPD as a minimally invasive option for an otherwise complex open surgery. As with many other centers, RPD was initially offered to patients with less complex disease (ie: ampullary carcinoma, distal cholangiocarcinoma, IPMN of the

head and uncinate, and small resectable pancreas cancers). Very few patients had received neoadjuvant chemotherapy upfront which can create a desmoplastic reaction making dissection difficult. With increasing confidence and associated development of visual haptics, the indications for RPD were expanded to include complex pancreas cancer cases and patients at higher risk for complications. Despite this, we found that pancreas specific complications remained low, operative time continued to decline and LOS became shorter over time. More importantly, oncologic outcomes were superior to open in some respects [28].

Our analysis is one of the largest single-center studies with 201 cases of RPD over a 10-year period performed by only two surgeons. To our knowledge it is the first report of a comparison to international benchmark standards. We divided our patients into low-risk and high-risk groups because the benchmark parameters were framed around patients who were considered “low-risk” in the original study [1]. Patients outside these criteria were considered high-risk. Centers that had a higher proportion of low-risk

Table 3 Outcomes throughout the learning curve

	Group 1 (n = 41)	Group 2 (n = 54)	Group 3 (n = 48)	Group 4 (n = 58)	p value
Low risk case	10 (24.4)	12 (22.2)	8 (16.7)	6 (10.3)	0.24
Pancreatic cancer case	7 (17.1)	12 (22.2)	23 (47.9)	24 (41.4)	0.003
Operation duration, h	7.3 (6.2–7.9)	6.5 (5.8–7.5)	5.9 (5.3–7.1)	7.1(6.4–8.8)	0.0002
Blood transfusion	19 (46.3)	15 (27.8)	10 (20.8)	7 (12.1)	0.001
Conversion rate	13 (31.7)	7 (13.0)	10 (20.8)	12 (20.7)	0.18
Length of stay, days	8 (6–11)	7 (6–14)	6.5 (6–9)	7 (5–12)	0.02
Postoperative 6-months morbidity					
At least 1 complication	32 (78.1)	38 (70.4)	35 (72.9)	40 (69)	0.78
Grade I–II	21 (51.2)	14 (25.9)	24 (50)	23 (39.7)	
Grade ≥ III	11 (26.8)	24 (44.4)	11 (22.9)	17 (29.3)	0.09
Grade IV	2 (4.9)	2 (3.7)	1 (2.1)	5 (8.6)	
CCI at discharge	8.7 (0–20.9)	4.3 (0–29.6)	8.7 (0–20.9)	8.7(0–30.8)	0.75
CCI 6 months	20.9 (8.7–29.6)	26.2 (0–42.6)	20.9 (0–29.6)	20.9 (0–34.6)	0.41
CR-POPF	4 (9.7)	3(5.6)	6 (12.5)	10 (17.2)	0.42
Grade B	3 (7.3)	1 (1.9)	4 (8.3)	6 (10.3)	
Grade C	1 (2.4)	2 (3.9)	2 (4.2)	4 (6.9)	
Biochemical Leak	0	7 (12.7)	4 (8.3)	3 (5.2%)	0.08
Severe postoperative bleeding (> III)	1 (2.4)	0 (0)	2 (4.2)	3 (5.2)	0.4
In-hospital mortality	0 (0)	1 (1.9)	1 (2)	0 (0)	0.71
Failure-to-rescue rate	0 (0)	1 (6.7)	1 (20)	0 (0)	0.11
Readmission rate	13 (31.7)	14 (25.9)	8 (16.7)	10 (17.2)	0.25

Comparison among initial phase of learning (Group1), maturation phase (Group 2), addition of a second surgeon (Group 3), and initiation of a Robotic HPB Fellowship (Group 4)

Data are presented as n (%) or median (IQR)

CCI Comprehensive Comorbidity Index, CR-POPF clinically relevant postoperative pancreatic fistula

cases had higher rates of CR-POPF, postoperative morbidity and mortality than centers that performed more high-risk cases. Within a center, those with a higher ASA score had increased morbidity and mortality rates outside the benchmark cutoff. In our study over 80% of patients were considered high-risk according to these criteria. The most common reason for high-risk qualification was ASA score ≥ 3 . The high-risk patients at our center also more commonly had PDAC. Similarly, we saw a slightly higher increased morbidity compared to the benchmarks reflected in Clavien-Dindo grade $\geq III$ complications. Pancreas specific complications however, (CR-POPF and post-pancreatectomy hemorrhage) were much lower than the benchmark. By the same respect, failure-to-rescue and therefore mortality rates were also lower. CCI for this cohort at 6 months was within the benchmark cutoff in both low and high-risk groups. Our study did not exclude patients with borderline resectable pancreatic cancer as a criteria for RPD. Of the patients who were converted to open, 17% were planned conversions (the first seven cases), 14% converted for difficulty with dissection or failure to progress most commonly from inflammation and desmoplastic reaction, 9% converted due to bleeding,

and 54% converted because of vascular involvement. Despite this, four patients in the high-risk group had a vein reconstruction performed robotically. There were no deaths in these four patients and the highest Clavien-Dindo score was II. These findings suggest that RPD may be an option for high-risk patients in selected cases performed by those who have gone through their learning curve for RPD.

We also believe that RPD has an oncologic benefit compared to OPD. Previously, our center has published outcomes from a propensity-matched analysis of RPD vs OPD in patients with pancreatic cancer [28]. We found that in the RPD group the lymph node harvest was significantly higher than in the OPD group. This was also demonstrated in the current study. Median lymph node yield was 24 for low-risk and 22 for the high-risk groups. The median number of lymph nodes from the benchmark study was 19 ranging across 23 different centers, establishing a cutoff value of 16 nodes. Similarly, we saw a higher 1-year DFS of 66.9% compared to the benchmark 53%.

The learning curve has been described as a cause for hesitancy with incorporating robotics into routine HPB practice [29]. However, literature published in other aspects of

robotic HPB surgery has suggested the learning curve may be significantly quicker than laparoscopy [30]. A generally accepted definition of the learning curve is missing in pancreatic surgery and several procedure specific outcomes have been measured to evaluate the learning process. Different groups have suggested inflexion points of RPD at 10–100 cases [22, 31]. Mastery of a procedure may be reflected by a temporal improvement of outcomes at different stages. In an initial phase of competency, improvement can be measured by intraoperative outcomes (ie: operative time and blood loss). A subsequent phase of mastery may show progress in postoperative outcomes [5]. At our center the senior surgeon, JM, initiated the robotic HPB program in 2006. After 5 years and mastery of lower complexity cases (robotic cholecystectomy, biliary bypass, pancreatic necrosectomy and cyst-gastrostomy, minor liver resections, etc.) robotic pancreas resections including RPD were introduced. As previously described, indications for RPD were initially narrower and included cases that anticipated an easier dissection and reconstruction phases such as ampullary cancers and distal cholangiocarcinoma. Overtime, the indications expanded to include more complex resections and those with higher risk factors for morbidity. Prior to the addition of a second robotic HPB surgeon, our study uniquely shows the learning curve of a single surgeon transitioning into the competency phase of learning around 40 cases. This was evidenced by a decline in operative time and conversion rates. Interestingly, after a second surgeon joined the practice, operative times continued to decline peaking at 5.9 h indicating that the original surgeon may have transitioned into mastery phase between 100 and 140 cases. In 2020, our center began a unique fellowship program for robotic HPB surgery. One fellow per year was enrolled after completion of a prior HPB surgery fellowship. Fellows are active participants in all robotic HPB cases including RPD. There was an increase in operative time from group 3 to group 4 which was likely a result of this incorporation. Despite these changes in the HPB practice, morbidity and mortality rates did not significantly differ over the 10-year period.

This study has several limitations. First, this was a single high-volume institutional study including two HPB surgeons with previous robotic experience. We believe the learning curve to be a unique experience dependent on prior robotic training, hospital financial capabilities, and skill of the robotic staff. Therefore, our results may not be directly applicable to other smaller centers. Second, the original benchmark cutoffs were assessed from patients with low risk for morbidity. The majority of our study patients were high-risk, specifically with higher ASA scores. Therefore, overall complications would be expectedly be higher. This was not believed to be the consequence of utilizing a robotic approach but likely confounded by co-morbidities as was similarly seen in the original benchmark analysis for OPD.

We attempted to overcome this by evaluating patients in low-risk and high-risk groups separately. Finally, our inclusion criteria for this study were solely based on patients who had RPD performed in the first 10 years of our program. There were 14 patients that were lost to follow up and outcomes were not able to be calculated in these cases and thus they were excluded. Despite this, the retrospective nature of the study cannot be ignored allowing for selection bias.

In conclusion, we demonstrated that RPD can produce results comparable to the established benchmarks in OPD. Incorporating high-risk patients and complex cases did not increase morbidity and mortality remained < 1% overall. The learning curve may be delineated by transition to proficiency after 40 cases and mastery after 100, although this should be individualized. RPD in the hands of experienced surgeons may be an option for complex disease and high-risk patients. Mastery of the learning curve for robotics should be achieved prior to implementing RPD into practice. Multi-institutional analyses from highly specialized centers worldwide are needed to help develop new benchmarks for RPD.

Declarations

Disclosures John Martinie is a consultant with Intuitive Surgical as a course director, proctor for robotic surgery, case observation host and speaker. Dionisios Vrochides is a consultant for Intuitive Surgical. Frances McCarron's fellowship stipend is supported by Intuitive Surgical. Yoshino, Mueller, Ricker, Wang, Driedger, Beckman, Vrochides, Clavien, Wang and Mantha have no conflicts of interest or financial ties to disclose.

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