Robotic Pancreaticoduodenectomy Is the Future: Here and Now

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BACKGROUND: This study was undertaken to examine our outcomes after robotic pancreaticoduodenectomy and to compare our outcomes with predicted outcomes using the American College of Surgeons (ACS) NSQIP Surgical Risk Calculator and with outcomes reported through ACS NSQIP.

METHODS: We prospectively followed 155 patients undergoing robotic pancreaticoduodenectomy. Outcomes were compared with predicted outcomes calculated using the ACS NSQIP Surgical Risk Calculator and with outcomes documented in ACS NSQIP for pancreaticoduodenectomy from 2012 to 2017. Median data are presented.

RESULTS: Eighty-eight percent of our robotic pancreaticoduodenectomies were performed in 2015 to 2018. Predicted outcomes were like those reported in ACS NSQIP. Actual outcomes were superior to predicted outcomes and outcomes reported in ACS NSQIP for overall complications, serious complications, returned to operating room, surgical site infections, deep vein thrombosis, and length of stay. Seventeen percent had conversions to open operations, generally due to failure to progress or need for major vascular reconstruction; only 3 (3.5%) of the last 80 operations were converted to open. Robotic operations took 423 minutes; estimated blood loss was 200 mL. Biliary fistulas occurred in 5% and pancreatic fistulas occurred in 5%. Six percent of patients died perioperatively; 5 patients died due to cardiac deterioration and 4 (3.1%) patients died after pancreaticoduodenectomy completed robotically.

CONCLUSIONS: Our patients were not a select group, they were like those reported in ACS NSQIP. Their outcomes after robotic pancreaticoduodenectomy were like or better than predicted outcomes or national data. Our mortality was high because of preoperative ill health (eg renal failure) and cardiac risk. Although we believe our results will continue to improve, our current data document the salutary benefits of minimally invasive robotic pancreaticoduodenectomy. (J Am Coll Surg 2019;228:613–626. © 2019 Published by Elsevier Inc. on behalf of the American College of Surgeons.)

Surgeons have always been driven to develop new approaches to improve patient care. Critical care units, total parenteral nutrition, transplantation, and endoscopy represent great examples of the never-ending pursuit of optimal patient care by surgeons. During the past 3 decades, surgeons have vigorously pursued ever-more minimally invasive approaches to operative intervention. Although surgeon application of laparoscopy to many common operations resulted in much-improved patient care, the inherent limitations of laparoscopy hindered its application across a vista of complex operations, such as pancreaticoduodenectomy.

Laparoscopy is primarily limited by the associated skills needed to do complex and fine reconstruction. Although laparoscopy is well suited for suturing during a fundoplication or suturing and stapling during a bowel anastomosis, it and its associated skills are not well suited for fine tasks, such as suturing a 1-mm pancreatic duct anastomosis or a 4-mm

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common hepatic duct anastomosis. Therefore, minimally invasive approaches to pancreaticoduodenectomy languished until a refined robotic platform became widely available. Recently, centers across the US and the Western world have reported their burgeoning experiences with robotic surgery in general, and robotic pancreaticoduodenectomy specifically. High-quality visualization, bimanual instrument use, instantaneous eye-to-instrument coordination, instrument motion damping, instrument wrist articulation, and robotic instrument development have situated the da Vinci robotic platform/computer-aided surgery platform (Intuitive Surgical, Inc) as the widely preferred platform for minimally invasively pancreaticoduodenectomy.

We began to use the robotic platform very slowly beginning around 2013. We began to use it because we thought it would be important for our fellowship and residency training programs. In hindsight, we were not particularly committed to the idea of robotic surgery in the beginning, but as we gained some, albeit limited, early experience, the advantages and salutary benefits of robotic surgery became apparent and encouraged us to push on through an educational process and (occasionally painful) learning curve. By 2015, we were applying robotic surgery to nearly all operations requiring an inordinately complex dissection and/or reconstruction, including most major esophageal, liver, biliary tract, and pancreatic operations. This report is of our experience in developing a program in robotic pancreaticoduodenectomy. Our hypothesis in undertaking this report was that robotic pancreaticoduodenectomy offers a salutary minimally invasive approach with metrics that would encourage additional application.

METHODS

Beginning in 2013, with IRB approval, we began to apply the da Vinci robotic platform to pancreaticoduodenectomy. Our application of the robotic platform was built on a broad experience in hepatopancreaticobiliary surgery. We sought and visited several thought leaders in robotic surgery before undertaking our first robotic pancreaticoduodenectomy. We performed our first robotic pancreaticoduodenectomy within our first 25 robotic operations, most of which had been cholecystectomies.

Our indications and operative goals for robotic pancreaticoduodenectomy did not change from when we applied only an open approach for pancreaticoduodenectomy. Robotic pancreaticoduodenectomy was not attempted in patients with obvious portal vein or superior mesenteric vein invasion or in whom complex arterial (eg a renal artery to proper hepatic artery bypass) or venous reconstruction (eg left renal vein interposition graft) might be necessary. Our operative approach for robotic pancreaticoduodenectomy

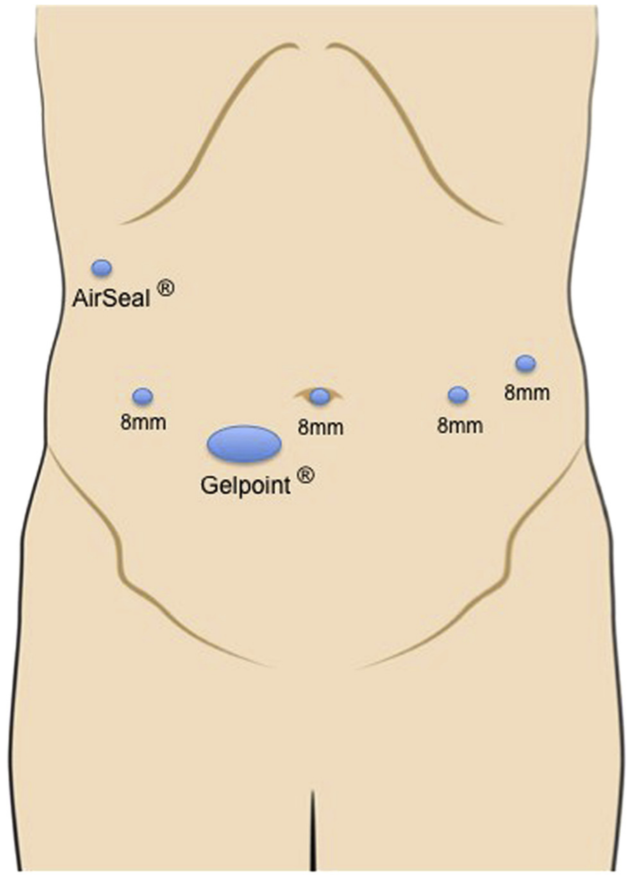

Figure 1. Robotic pancreaticoduodenectomy port site placement.

has been described and has undergone little change since our initial experience.[1] We use 6 ports (Fig. 1). In short, although there are many steps involved in pancreaticoduodenectomy, when we use the robotic platform, we first

Table 1. Serious Complications as Defined by American College of Surgeons NSQIP

Complication
Cardiac arrest/MI
Pneumonia
Progressive renal insufficiency
Acute renal failure
Pulmonary embolism
Deep vein thrombosis
Return to the operating room
Deep incisional surgical site infection
Organ space surgical site infection
Systemic sepsis
Unplanned intubation
Urinary tract infection
Wound disruption

Table 2. Demographic Data and Medical History

Variable	Patient no.						
	1–25	26–50	51–75	76–100	101–125	126–155	Total
Men, n (%)	12 (48)	17 (68)	18 (72)	16 (64)	15 (60)	10 (33)	88 (57)
Age, y, median (mean ± SD)	71 (70 ± 10.3)	70 (70 ± 9.3)	73 (71 ± 10.9)	66 (65 ± 7.9)	62 (63 ± 14.1)	70 (68 ± 0.8)	69 (69 ± 10.8)
BMI, kg/m^2, median (mean ± SD)	28 (27 ± 4.0)	26 (27 ± 4.7)	27 (27 ± 4.6)	26 (26 ± 3.9)	26 (26 ± 4.5)	27 (28 ± 7.2)	27 (27 ± 11.1)
Neoadjuvant therapy, n/N (%)	1/25 (4)	0/25 (0)	1/25 (4)	4/25 (16)	0/25 (0)	0/30 (0)	6/155 (4)
ASA class, median (mean ± SD)	3 (3 ± 0.8)	3 (3 ± 0.6)	3 (3 ± 0.5)	3 (3 ± 0.5)	3 (3 ± 0.5)	3 (3 ± 0.5)	3 (3 ± 0.6)
Earlier abdominal operation, n/N (%)	13/25 (52)	8/25 (32)	16/25 (64)	13/25 (52)	11/25 (44)	17/30 (57)	78/155 (50)

ASA, American Society of Anesthesiologists.

undertake a Kocher maneuver with division of the jejunum with a robotic stapler to the right of the root of the mesentery. Then, we open the gastrohepatic ligament, carry the dissection along the common hepatic artery, and divide the right gastric artery and the gastroduodenal artery to expose the portal vein. The gastrocolic omentum is opened, the right gastroepiploic artery and vein are divided, and the duodenum 3 to 4 cm from the pylorus is divided with a robotic stapler. The superior mesenteric vein is identified along the caudal edge of the pancreas, and the pancreas is divided ventral to the superior mesenteric vein and portal vein. From the division of the jejunum, the jejunal mesentery is divided. The dissection proceeds to the superior mesenteric vein-pancreas interface, ensuring resection of all the uncinate process. The dissection is then continued cephalad and the ventral, lateral, and dorsal aspects of superior mesenteric vein, portal vein, and superior mesenteric artery are skeletonized. The dissection is carried along the proper hepatic artery, the common hepatic duct is transected, the cystic artery is divided, and the gallbladder is freed from the liver. The specimen is placed into an extraction bag and removed.

After specimen extraction via the Applied Gel Port (Applied Medical Resources Corp) (Fig. 1), pneumoperitoneum is re-established, and reconstruction is begun. The hepaticojejunostomy is constructed in 1 layer with running 3-0 V-Loc (Medline Industries, Inc) suture. The pancreaticojejunostomy is a 2-layer anastomosis, with an outer layer of pancreas capsule sewn to the seromuscular layer of the jejunum in a running fashion with 3-0 V-Loc sutures and an inner layer of duct of pancreas sewn to a small hole in the jejunum with interrupted 4-0 V-Loc sutures.

The ligament of Treitz is reconstructed with interrupted 3-0 V-Loc sutures and a duodenojejunostmy is constructed in 1 layer with running 3-0 V-Loc suture. A drain is placed about the biliary and pancreatic anastomosis, the peritoneal cavity is sprayed with dilute bupivacaine, and the incisions are closed with absorbable monofilament sutures and paper strips. Silver impregnated dressings are applied and the operation is complete.

Data about patient demographics, robotic operations, and patient recovery are collected concurrently. Data from the American College of Surgeons (ACS) NSQIP, collected by the ACS from 2012 to 2017, were used to compare our outcomes with a national benchmark. Our patients' projected outcomes were determined using the ACS NSQIP Surgical Risk Calculator (riskcalculator.facs.org/RiskCalculator/); their projected outcomes were compared with patient outcomes in the ACS NSQIP database to ascertain whether our patients were like those cataloged in the ACS NSQIP database. Lastly, our patients' actual outcomes

Table 3. Operative Data

Variable	Patient no.						
	1–25	26–50	51–75	76–100	101–125	126–155	Total
Operative duration, min, median (mean ± SD)	420 (425 ± 95.4)	411 (411 ± 149.3)	362 (362 ± 63.0)	512 (512 ± 127.2)	429 (434 ± 109.7)	404 (396 ± 61.5)	418 (425 ± 102.1)
Conversion to open, n/N (%)	40 (10/25)	16 (4/25)	40 (10/25)	4 (1/25)	4 (1/25)	7 (1/30)	17 (27/155)
Estimated blood loss, mL, median (mean ± SD)	325 (449 ± 375.0)	250 (287 ± 180.4)	200 (462 ± 531.9)	150 (174 ± 127.3)	200 (243 ± 232.7)	123 (229 ± 438.7)	200 (307 ± 360.8)
Tumor size, cm, median (mean ± SD)	3 (3 ± 1.1)	3 (3 ± 1.6)	3 (3 ± 1.0)	3 (3 ± 1.7)	3 (3 ± 1.2)	3 (3 ± 1.2)	3 (3 ± 1.3)

were compared with those in the ACS NSQIP database and those predicted by the ACS NSQIP Surgical Risk Calculator. Nominal data were analyzed using contingency testing and ratio scales data were analyzed using nonparametric testing of mean data or through regression analysis for trends. Significance was accepted with 95% probability.

At times, purely for illustrative purposes, our patients are presented in 6 groups separated in chronological order; the first 5 groups are of 25 patients each and the last (ie most recent) group of patients included are in a group of 30 patients to accommodate all 155 of our patients.

Our initial operations (1 to 25) were performed using the Si model of the Intuitive Surgical, Inc robotic platform. All subsequent operations were undertaken using the Xi model.

The durations of the operations and their components (in minutes) performed were recorded and defined as follows: patient preparation time: patient entrance into the operating room to time of incision; skin incision time: time from first incision to surgeon sitting at the console; extraction time: time from sitting at the console to specimen being out; reconstruction time: from specimen being out to surgeon leaving console; closure time: time from leaving the console to dressings on the incisions; console time: time that surgeon(s) sat at the console; operative duration: time from first incision to the dressings being on; time under anesthesia: duration of anesthesia care; operating room time: time from patient entering the operating room ("wheels down") to "wheels up" as patient leaves the operating room.

Complications, *serious complications* (Table 1), and other terms associated with ACS NSQIP are used as defined by ACS NSQIP. Pancreatic fistula was defined using the recommendations of the International Study Group on Pancreatic Fistulas. Per their recommendations, a postoperative pancreatic fistula was considered a failure of healing/sealing of a pancreatic-enteric anastomosis or a parenchymal leak not directly related to an anastomosis. An all-inclusive definition is a drain output of any measurable volume of fluid on or after postoperative day 3 with an amylase content more than 3 times the serum amylase level. Three different grades of postoperative pancreatic fistula (grades A, B, C) were used according to the clinical impact on the patient's hospital course. Grade A fistulas caused no change in patients' clinical management. Grade B fistulas required active therapeutic intervention (ie drainage by interventional radiology) but were manageable without reoperation. Grade C fistulas required reoperation.

A biliary fistula was defined as drain output with a bilirubin concentration of at least 3 times the serum bilirubin concentration on or after postoperative day 3, or as the

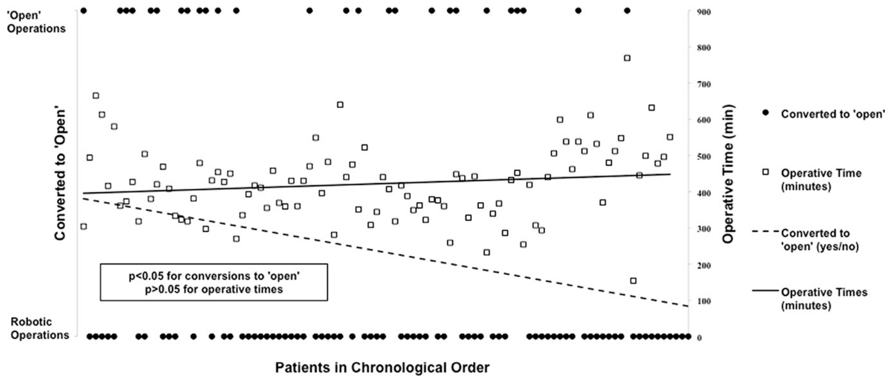

Figure 2. Conversion of robotic pancreaticoduodenectomy operations to open operations and operative duration.

need for radiologic or operative intervention resulting from biliary collections or bile peritonitis. Using this criterion, severity of bile leakage was classified according to its impact on patients' clinical progress. Grade A biliary fistulas caused no change in patients' clinical management. Grade B biliary fistulas required active therapeutic intervention, but were manageable without reoperation. Grade C biliary fistulas required reoperation.

Everyone for whom a robotic pancreaticoduodenectomy was attempted through December 2017 are included in this report.

RESULTS

As of December 2017, we attempted 155 robotic pancreaticoduodenectomies; 88% were performed since January 2015. Of the 155 patients, 57% were men, their mean age was 69 years, their mean BMI was 27 kg/m^2, and 50% had undergone previous abdominal operations (Table 2). Neoadjuvant therapy had been given to 4%. Mean American Society of Anesthesiologists class was 3 (Table 2).

Twenty-seven (17%) patients had conversions to open operations (Table 3). The major reasons for conversion were failure to progress due to adhesions and/or obesity (18 [12%] patients), encountering an unexpectedly large tumor with major vascular invasion (7 [5% patients]), or hemorrhage, real or potential (2 [1%] patients); 2 (3.6%) of the last 55 patients and 3 (3.7%) of the last 80 patients had conversions to open operations. The rate of conversion to open operations decreased with experience (Fig. 2; $p < 0.01$). The average robotic pancreaticoduodenectomy took (ie operative duration) 418 minutes; operative duration did not decrease with experience (Tables 3 and 4, and Fig. 2). Excluding robotic pancreaticoduodenectomies converted to 'open' operations did not meaningfully change operative duration(Table 5). Mean estimated blood loss was 200 mL (Table 3) and mean tumor size was 3 cm in broadest diameter, without change during our experience (Table 3). Estimated blood loss decreased during our experience ($p < 0.01$; Table 3, Fig. 3).

Postoperative complications were experienced by 26% of the 155 patients (Table 6). The complications experienced were varied, with 22 patients having complications specific to pancreaticoduodenectomy (with redundancy involving deep organ space infection and pancreatic/biliary fistula) (Tables 7 and 8). Biliary stenosis occurred early postoperatively in 1 patient with a bile duct diameter <4 mm at the time of reconstruction. He had a percutaneous transhepatic cholangiography placed early postoperatively and the anastomosis was dilated progressively, and the catheter was removed at 3 months after his robotic pancreaticoduodenectomy. Eight patients experienced superficial and organ space surgical site infections, of which none were serious. Serious complications were experienced by 13% (Table 9). Additionally, 5% (8 patients) experienced biliary fistulas and 5% (8 patients) experienced pancreatic fistulas; of these, 3 patients experienced both. Of pancreatic

Table 4. Robotic Pancreaticoduodenectomy and Operative Duration, and the Components of Operative Duration

Variable	Data, median (mean ± SD) (n = 155)
Patient preparation time, min	52 (54 ± 18.3)
Skin incision time, min	30 (36 ± 19.9)
Extraction time, min	196 (218 ± 109.9)
Reconstruction time, min	187 (193 ± 64.3)
Closure time, min	47 (111 ± 106.2)
Console time, min	274 (253 ± 132.5)
Operative duration, min	418 (42 ± 102.1)
Time under anesthesia, min	495 (508 ± 108.9)
Operating room time, min	486 (492 ± 108.7)

Table 5. Operative Data of Operations Completed Robotically

Variable	Data, median (mean ± SD) (n = 128)
Patient preparation time, min	52 (54 ± 15.7)
Skin incision time, min	28 (34 ± 18.4)
Extraction time, min	190 (213 ± 114.8)
Reconstruction time, min	195 (201 ± 64.3)
Closure time, min	33 (49 ± 45.8)
Console time, min	310 (329 ± 77.7)
Operative duration, min	423 (432 ± 99.9)
Time under anesthesia, min	501 (513 ± 108.2)
Operating room time, min	488 (500 ± 108.1)

fistulas, 6 were grade A and 2 were grade B. Of biliary fistulas, 5 were grade A and 3 were grade B.

Median length of ICU days was 0 days (Table 6). In our early experience, hospital policy mandated ICU admission overnight after pancreaticoduodenectomy (and other complex operations), but this policy was discontinued with a commensurate decrease in ICU admissions. Median length of stay was 5 days but trending shorter (Table 6). In-hospital mortality was 6% (10 patients) with 2 (2.5%) of the last 80 patients dying. From patient 48 through patient 74, we had 8 (31%) deaths (Tables 6 and 10). The 30-day readmission rate was 14% and was quite constant over time (Table 6).

The cause of death for the 10 patients is listed in Table 10. Notably, 60% of the patients who died had conversions to open operations. The timing and cause of the postoperative deaths are listed in Table 10.

Of the pancreaticoduodenectomies performed, 81% were for adenocarcinoma (Table 11); an additional 17% were for nonmalignant neoplastic disease and 1% were for chronic pancreatitis (Table 11). One patient with a complex preoperative evaluation ultimately was found to have B-cell lymphoma with a pseudocyst.

The outcomes for the patients undergoing pancreaticoduodenectomy during 2012 to 2017 listed in the ACS NSQIP database are displayed in the Table 12. Predicted outcomes for our patients using the ACS NSQIP Surgical Risk Calculator are also shown in Table 12. With 1 exception, the outcomes for patients in the ACS NSQIP database and the predicted outcomes for our patients were very similar (Table 12); our patients were more likely to be discharged to an intermediate care facility than the patients cataloged in ACS NSQIP ($p < 0.05$).

When the actual outcomes of our patients are compared with those predicted for our patients using the Surgical Risk Calculator or the patients in the ACS NSQIP database, many differences are noted (Table 12). Our patients fared significantly better in the frequency of complications (49% of predicted), serious complications (46% of predicted), surgical site infections (28% of predicted), venous thromboembolism (100% less than predicted), return to the operating room (13% of predicted), median length of stay (50% less than predicted), and discharge to rehabilitation facility or intermediate care facility (81% of predicted) (Table 12). Our in-hospital mortality rate, as mentioned previously, was higher than expected, as was our incidence of renal failure (Table 12).

DISCUSSION

There are other reports of burgeoning experiences with robotic pancreaticoduodenectomy, but ours is one of the largest. Unlike other reports, this is a report of "all comers" undergoing attempted pancreaticoduodenectomy and covers our very early experience with robotic

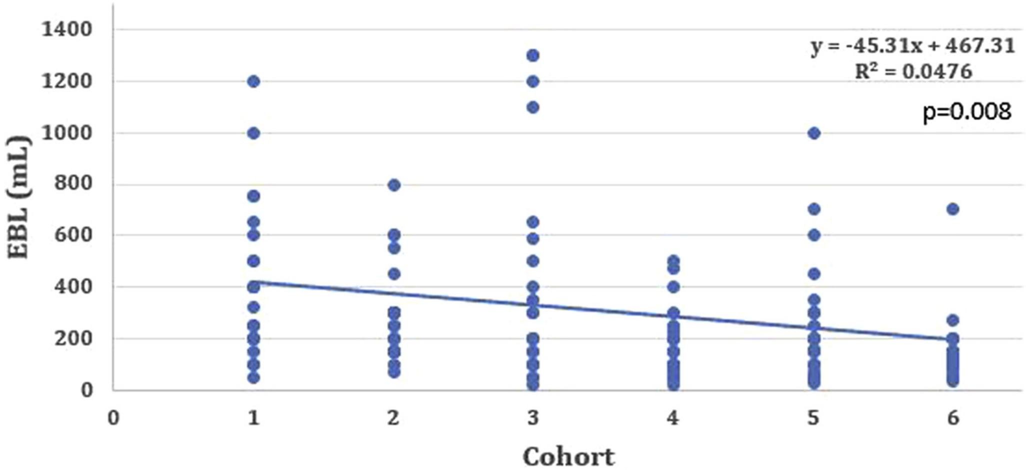

Figure 3. Estimated blood loss (EBL) by cohort. Each cohort is in chronological order of 25 patients, except cohort 6, which has 30 patients.

Table 6. Details Specific for the Postoperative Period Denoting Hospital Course

Variable	Patient no.						
	1–25	26–50	51–75	76–100	101–125	126–155	Total
Postoperative complication, n/N (%)	5/25 (20)	6/25 (24)	10/25 (40)	6/25 (24)	7/25 (28)	7/30 (23)	41/155 (26)
ICU, d, median (mean ± SD)	1 (1 ± 0.6)	0 (0 ± 0.7)	0 (3 ± 6.3)	0 (0 ± 1.5)	0 (0 ± 0.0)	0 (0 ± 0.3)	0 (1 ± 3.1)
Length of stay, d, median (mean ± SD)	6 (9 ± 7.6)	6 (11 ± 13.9)	6 (9 ± 6.5)	5 (10 ± 13.2)	5 (6 ± 3.4)	5 (7 ± 4.5)	5 (9 ± 9.8)
In-hospital mortality, n/N (%)	0/25 (0)	1/25 (4)	7/25 (28)	0/25 (0)	1/25 (4)	1/30 (3)	10/155 (6)
30-day readmission, n/N (%)	5/25 (20)	3/25 (12)	1/25 (4)	5/25 (20)	4/25 (16)	4/30 (13)	22/155 (14)

surgery. A learning curve is apparent with our experience, and progress continues with accumulating experience, although the acquisition of proficiency at a level we seek will only be apparent with more experience and, then, with another review of our patients' outcomes. Nonetheless, there is much to be learned from this report of our acquisition of experience with robotic pancreaticoduodenectomy after many years of experience with pancreatic procedures.

Our patients undergoing attempted robotic pancreaticoduodenectomy are not unique; they are like patients undergoing pancreaticoduodenectomy across the US as presented in the ACS NSQIP database and as documented by comparing our patients' predicted outcomes with those in the ACS NSQIP database. Our patients were more likely to be discharged to a nursing facility (long-term acute care facility) or rehabilitation facility, reflecting their general ill health and deconditioned state.

Our patients were generally late-middle age to elderly. They were generally deconditioned with significant comorbidities, including obesity, diabetes, hypertension, and vascular/coronary artery disease, like the usual and customary patients undergoing pancreaticoduodenectomy in the US. Most had neoplastic and malignant disease, most commonly ductal adenocarcinoma of the pancreas.

Relatively few patients had conversions to open pancreaticoduodenectomy. Fewer than 1 in 5 had conversions to open operations, and most conversions occurred early in our experience, with fewer than 1 in 25 patients undergoing conversions to open pancreaticoduodenectomy in our last 80 patients. Conversions were generally due to a lack of progress for more than 15 minutes (most commonly); unanticipated need for major vascular reconstruction; poor exposure; or bleeding, real or potential. With experience we had fewer occurrences of a lack of progress for more than 15 minutes and we were more adept at preventing bleeding or controlling and correcting it. Early on, we particularly were "working without a net," as we were uncertain about our robotic skills. Our conversion rate fell quickly and after our 25th patient, progress was clear, though mortality was a vexing problem until our 75th patient. Generally, those patients undergoing conversion to an open pancreaticoduodenectomy had poor outcomes, generally for the same reasons they were poor candidates for robotic pancreaticoduodenectomy, including obesity, previous intra-abdominal operations (often with mesh), advanced cancers, and/or generally poor health. Operative mortality with operations completed robotically was fewer than 1 in 30. Mortality with operations completed open was much higher (nearly 1 in 4) for the reasons mentioned; there is always a reason why a robotic operation is converted to open and that

Table 7. Postoperative Complications as Defined by American College of Surgeons NSQIP

Complication	Patient no.						Total
	1–25	26–50	51–75	76–100	101–125	126–155	
Superficial incisional SSI	0	0	2	1	0	0	3
Deep incisional SSI	0	0	0	0	0	0	0
Organ space SSI*	1	1	0	1	0	2	5
Wound disruption	0	0	0	0	0	0	0
Pneumonia	0	0	1	0	0	0	1
Unplanned intubation	0	0	0	0	0	0	0
Pulmonary embolism	0	0	0	0	0	0	0
Deep vein thrombosis	0	0	0	0	0	0	0
Ventilator >48 h	0	0	0	0	0	0	0
Progressive renal insufficiency	0	0	0	0	0	0	0
Acute renal failure	1	0	1	0	0	0	2
Urinary tract infection	0	1	0	0	0	0	1
Stroke	0	0	0	0	0	0	0
Cardiac arrest	0	0	2	1	0	0	3
MI	0	0	0	0	0	1	1
Return to the operating room*	0	0	0	0	1	0	1
Systemic sepsis	0	1	3	0	1	0	5
Total	2	3	9	3	2	3	22

*Complications directly related to pancreaticoduodenectomy.
SSI, surgical site infection.

reason can impact outcomes after conversion to open. But conversion to an open operation is not failure, but good judgment; if conversions to open operations are considered failure, then attempts at attaining robotic proficiency will be viewed punitively.

Operative duration did not decrease during our experience, though it did for others.[2] We cannot explain this. And our operations seemed to take too long. Maybe we delegate too much for making the incisions, robot docking, and wound closures. We will focus on this.

Comparing the outcomes of our patients with the outcomes in ACS NSQIP or those predicted by the ACS NSQIP Surgical Risk Calculator reflects well on our body of work. Because the clear majority of the patients in the ACS NSQIP database underwent open pancreaticoduodenectomies, allowing for an "apples to oranges" comparison, the salutary benefit of the robotic approach in this report is apparent. It can be argued that the superiority of the robotic approach in this report is because of us, as surgeons, rather than the robotic approach, but we do not think so. Although we are as egocentric as any surgeon, maybe more so, we believe that the robotic approach yields faster recoveries, less pain, less tumult, and a shorter time delay to receive adjunctive therapy, though the conventional belief is that robotic pancreaticoduodenectomy takes longer than open pancreaticoduodenectomy. We believe that the duration of robotic pancreaticoduodenectomy will be shorter going forward, with our goal now to routinely take fewer than 4 hours of console time when completing

Table 8. Postoperative Complications Not Defined by American College of Surgeons NSQIP

Complication	Patient no.						Total
	1–25	26–50	51–75	76–100	101–125	126–155	
Pancreatic/biliary fistula*	3†	1	0	3	4	5†	13‡
Blood loss requiring transfusion*	0	1	1	0	0	1	3
Ileus	1	1	0	0	1	0	3
Biliary stenosis*	0	0	0	1	0	0	1
Total	3†	3	1	4	5	4†	20

*Complications directly related to pancreaticoduodenectomy.
†Patient with both a pancreatic and biliary fistula.
‡Three patients had both a pancreatic and a biliary fistula.

Table 9. Postoperative Serious Complications as Defined by American College of Surgeons NSQIP

ACS NSQIP serious complication category	Actual data n	%
Cardiac arrest/MI	4	3
Pneumonia	1	1
Progressive renal insufficiency/acute renal failure	2	1
Pulmonary embolism	0	0
Deep vein thrombosis	0	0
Return to the operating room	1	1
Deep incisional SSI	0	0
Organ space SSI	5	3
Systemic sepsis	5	3
Unplanned intubation	0	0
Urinary tract infection	1	1
Wound disruption	0	0
Total	20	13

ACS, American College of Surgeons; SSI, surgical site infection.

pancreaticoduodenectomy. It is apparent from our data that we also need to focus on the "edges" of our operating room times; they seem excessive, particularly preparation time and closure time. Shorter time of confinement, reductions in complications relative to national norms (ie ACS NSQIP), and relatively fewer pancreatic and biliary fistulas support robotic application. Nonetheless, although the robot platform aids surgeons and the application of their skills, the platform does not make surgeons superfluous and the platform will not transform "bad" surgeons into "mavens of surgery."

There is a plethora of reasons for surgeons not to seek to apply the robotic platform to pancreaticoduodenectomy or any other complex intra-abdominal operation (Table 13). Among the weightiest reasons is a sense of loss of control for the surgeons. For example, during an open operation, bleeding can be controlled easily with finger pressure and vessel repair, but the robot has no fingers. It takes experience and competency with the robot and experience doing pancreatic operations to stay out of trouble and salvage the situation if trouble strikes.

We do not believe that a randomized controlled trial will ever be done to compare the salutary benefits of the robotic approach with those of the open or laparoscopic approach. This study does denote significant reductions in several metrics pejoratively defining pancreaticoduodenectomy (eg complications). Although it is conventionally believed that about 50% to 60% of patients undergoing pancreaticoduodenectomy will experience some morbidity (eg surgical site infection, delayed gastric emptying, and pancreatic fistula), we did not see that. Across the board, our outcomes were equivalent to or superior to those predicted by ACS NSQIP Surgical Risk Calculator and those seen in the ACS NSQIP database. Why? No answer is readily at hand. Improved visualization? High-dexterity bimanual instrument application? Optimal exposure? The robot platform has many advantages and the answer is probably multifactorial. Surgeon skill in using the robot plays a part, certainly. A well-

Table 10. Causes of Perioperative Death

Patient no.	Age, y/sex	BMI, kg/m^2	Comorbidity	Cause of death	Postoperative day of death
48	72/F	32	Diabetes, duodenal perforation	Duodenojejunostomy leak	34
52*	48/M	31	Diabetes	MI	14
55	78/M	21	Hyperlipidemia, hypertension, cardiac stents	MI	14
61*	70/M	33	Coronary artery disease, hyperlipidemia, diabetes, hypertension, abdominal aortic aneurysm	MI	9
62*	82/M	28	Hypertension, diabetes, duodenal perforation	Acute renal failure	14
68*	61/F	26	None	Acute respiratory distress syndrome/sepsis	79
73*	73/M	30	Hypertension, lung carcinoma	Respiratory failure	22
74*	83M	28	Atrial fibrillation, cholangitis, prostate carcinoma	Sepsis	22
118	68/F	117	Neurofibromatosis, COPD	MI	5
146	68/M	29	Pacemaker, coronary artery disease, hypertension, diabetes	MI	3

F, female; M, male.

Table 11. Tumor Pathology

Pathology	Patients, n
Adenocarcinoma	125
Intraductal papillary mucinous neoplasm	18
Neuroendocrine tumor	6
Villous duodenal adenoma	3
B-cell lymphoma/pseudocyst	1
Chronic pancreatitis	2
Total	155

planned, well-conducted operation for a patient properly selected and prepared is a necessity.

We had more patients die than would be expected. The causes of death were varied but, in general, were cardiac in nature. For example, 1 patient had a major MI as we closed his upper abdominal transverse incision after converting because of a lack of progress, in part a consequence of obesity, a tumor larger than expected, and adhesions from a previous open colectomy.

Open operations have generally been well tolerated for decades, so why did these conversions do so poorly? They were a select group of patients that failed a robotic approach; they were generally obese, had larger tumors with unexpected vascular ingrowth to major vessels, had notable intraperitoneal adhesions, had aberrant vascular anatomy, and/or other reasons that could be associated with untoward outcomes with an open operation. Nonetheless, death was due most often to MI, despite thorough preoperative cardiac clearance. Most of our deaths occurred during a bad stretch of operations numbered from 48 to 74. Bad news seems to come in bunches. In this stretch of 26 patients we had deaths in nearly 1 in 3 patients.

There is a small but growing number of clinical series of robotic pancreaticoduodenectomy. There are many systematic reviews relative to the number of large clinical experiences of robotic pancreaticoduodenectomy; it seems more surgeons write about robotic pancreaticoduodenectomy than do it.

The penetration of the robotic platform into pancreatic surgery is low; in 2014 to 2015, it was believed to be about 3%.[3] Even if it had doubled by the end of 2018, it is still low.

The learning curve for robotic pancreaticoduodenectomy has been studied. Different metrics (eg complications vs operative duration) have different learning curves.[4] A report of outcomes from multiple centers in the US denotes a short learning curve for anastomotic complications, but they reported a 10% reoperation rate.[5] After 80 robotic pancreaticoduodenectomies, there might be a notable decrease in operative duration and serious complications.[2,6] With experience with robotic distal pancreaticoduodenectomy and/or pancreaticobiliary surgery in general, the learning curve for robotic pancreaticoduodenectomy is believed by some to be in the range of 15 to 40 operations.[4,7,8] These authors have reported more limited experiences than we have, and we

Table 12. Comparisons among American College of Surgeons NSQIP Database, American College of Surgeons NSQIP-Predicted Outcomes, and Actual Outcomes

Variable	ACS NSQIP outcome	ACS NSQIP-predicted outcome	Actual outcome
Patients, n	—	155	155
Serious complication, %	26	26	12*,‡
Any complication, %	30	31	14*,‡
Pneumonia, %	3	4	1
Cardiac complication, %	2	3	3
Surgical site infection, %	18	19	5*,‡
Urinary tract infection, %	3	3	1
Deep vein thrombosis, %	2	3	0*,‡
Renal failure, %	1	2	5§
Readmission, %	16	16	14
Return to operating room, %	5	5	1*,‡
Length of stay, d, median (mean ± SD)	NA	10 (10 ± 2)	5 (8 ± 8)*
Death, %	2	2	6†,§
Discharge to nursing or rehabilitation, %	10	16§	13

*<predicted, $p < 0.05$.
†≥predicted, $p < 0.05$.
‡≤ACS NSQIP, $p < 0.05$.
§≥ACS NSQIP, $p < 0.05$.
ACS, American College of Surgeons; NA, not available.

Table 13. Reasons Why Surgeons Might Not Want to Engage the Robotic Platform in Their Practice

Reason
Change is painful
Fear of complications and the consequences
Fear of failure, eg conversions to open operations
Fear of peer disapproval and censure
Lack of forces pushing adoption
Increased duration of operations and time in the operating room
Need for a capable assistant or "wingman"
Robot availability
A requirement for new skills
An unfamiliar toolbox
Time away from practice to train and acquire robotic skills
Perceptions of cost and economic impact
Lack of institutional conviction (eg risk management, operating room staff training)
Lack of mentor, educator, teacher, support
Unfamiliar technology

disagree. We believe competency is not so easily attained and that our learning curve is not yet flat at now more than 200 robotic pancreaticoduodenectomies.

Hospital volume thresholds for minimally invasive pancreaticoduodenectomy were studied in 2016.[9] Mean hospital volume in this report was 6 minimally invasive pancreaticoduodenectomies per hospital per year. Most patients (83%) were cared for in low-volume hospitals, defined as those undertaking 22 or fewer minimally invasive pancreaticoduodenectomies per year. Increasing hospital volume was associated with reduced complications[9]; high-volume hospitals were associated with fewer perioperative complications.[9]

Much has been written comparing robotic with open pancreaticoduodenectomy. It is generally believed that robotic pancreaticoduodenectomy takes more time than open pancreaticoduodenectomy and incurs greater cost.[10-15] Not all series report longer operative duration.[16] Conversely, most reports also denote that robotic pancreaticoduodenectomy results in less blood loss, shorter length of confinement, less delayed gastric emptying, superior lymph node harvest, reduced wound infection rate, higher R0 resection rate, and shorter time to receive adjuvant therapy.[3,10-12,14,15] Rates of complications and biliary/pancreatic fistulas seem equal generally, although they sometimes seem high.[11-13,15,16] Using the National Cancer Database, short-term oncologic outcomes after minimally invasive pancreaticoduodenectomy were studied.[17] Such reports show much of what has been mentioned, but also show equivalency in margins attained, lymph node harvests, and receipt of adjuvant therapy.[17] Little to nothing is known about long-term outcomes after robotic pancreaticoduodenectomy relative to open pancreaticoduodenectomy.

CONCLUSIONS

Patient safety, operative efficacy, and issues with widespread adoption remain in the spotlight as Surgery grapples with the dissemination of robotic surgery across all corners of the world. Going forward, our goals will be to minimize morbidity and mortality, understand and minimize cost, reduce time to adjuvant therapy, and minimize return to full functional activities. We also seek to understand the long-term outcomes after robotic pancreaticoduodenectomy. Although pancreatic cancer remains a formidable foe, hope abounds.[18]

Author Contributions

Study conception and design: Rosemurgy, Ross, Sucandy
Acquisition of data: Bourdeau, Spence, Alvior, Craigg
Analysis and interpretation of data: Rosemurgy, Bourdeau
Drafting of manuscript: Rosemurgy, Bourdeau,
Critical revision: Rosemurgy

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Discussion

DR STEVEN J HUGHES (Gainesville, FL): The study design is, in essence, a case series exploring an early experience in adopting robotic pancreatoduodenectomy (PD). The authors reported 155 consecutive cases; 17% required conversion, but this rate dramatically declined in the second half of the experience. The length of stay was an impressive 5 days, and the report of a 14% readmission rate and an overall complication rate of 28% is equally impressive, but enthusiasm must be tempered by the 6% operative mortality rate that the authors honestly report.

This is not a good study design to demonstrate superiority or even equivalence of robotic PD to open approaches. In fact, there are now 3 randomized controlled trials regarding minimally invasive PD that are conflicting in their conclusions, but they support the minimally invasive PD, with or without the robot. This offers a small but iterative benefit to patients, but is not proven to be transformative to the field.

Nonetheless, there are some important details here that warrant our attention. This really represents an old dog going out and finding his own new trick and is strong evidence in support of Dr John Cameron's comments this past September at the International Hepato-Pancreato-Biliary Association in Geneva, Switzerland. In essence, he said if you want to be in this business 10 years from now, you need to start doing minimally invasive and robotic PD.

I think the opportunity here for our members and guests comes from a better understanding of the 6% mortality rate and particularly in the timing of the series where it was observed. From afar, this appears to represent a second learning curve when the group began to expand the inclusion criteria and/or take on greater technical challenges that they encountered during the operation in hopes of completing the procedure robotically.

In the manuscript, it is more specific and describes that between cases 48 and 74, you lost 8 patients, for a mortality rate of 31% during that period; 60% of those deaths were in the setting of conversion to an open procedure. How many of these conversions were emergent? More specifically, how many of these patients went into shock during conversion or before conversion?

Was there a change in your exclusion criteria during this period? Was there a change in personnel, including scrub technicians or other people who may be assisting in the operating room, like advanced practice practitioners, etc, or did you begin to provide access to the learners during this time? I am inviting you to offer us what you learned during this particular period of your experience, and what you can share with us today.

The second concept I would like you to expand upon is a potential benefit of minimally invasive PD that is less well characterized. These are not important questions that can be well compared with your NSQIP data or its predictions. You report an impressive infection rate of 5%. What I want to know is, did these infections affect the receipt of adjuvant therapy in eligible patients? What was the percentage of patients for whom adjuvant therapy was indicated who received that therapy? How quickly were they able to begin that therapy? I think this is a very important concept, and perhaps one of the nice surrogate indicators of the adequacy of the operation should be what percent of patients go on to receive adjuvant therapy and at what time.

DR NIPUN B MERCHANT (Miami, FL): This study adds to the increasing literature of minimally invasive PD, particularly focusing on the robotic platform. The literature on this topic highlights the heterogeneity of the surgeon experience, as well as the center experience, a hybrid of minimally invasive approaches and data from centers working through their procedural learning curves.

These are the limitations that must be addressed before an accurate comparison of open vs robotic PD outcomes can be formulated. A clear correlative relationship between PD volume and outcomes is well established, both for the open approach and the robotic approach, generally around 40 to 50 cases for the open approach and reported up to 80 cases for a robotic approach.

Two recent National Cancer Database assessments of open and minimally invasive PD reported an increased 30-day mortality associated with the minimally invasive approach over the open approach and did not demonstrate any difference in those patients who received adjuvant therapy or time to initiation of adjuvant chemotherapy for the cohort of patients with pancreatic cancer.

In addition, to overcoming the limitations of assessing outcomes during the learning curve phase, another multicenter study compared perioperative outcomes in more than 1,000 patients, including more