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Learning curves for robotic pancreatic surgeryfrom distal pancreatectomy to pancreaticoduodenectomy

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Abstract

This study sought to identify the learning curves of console time (CT) for robotic pancreaticoduodenectomy (RPD) and robotic distal pancreatectomy (RDP). Perioperative outcomes were compared between the early group of surgeries performed early in the learning curve and the late group of surgeries performed after the learning curve.

Pancreaticoduodenectomy (PD) is a technically demanding and challenging procedure carrying a high morbidity.

Data for RDP and RPD were prospectively collected for analysis. The learning curve was assessed by cumulative sum (CUSUM). Based on CUSUM analyses, patients were divided into the early group and the late group.

There were 70 RDP and 61 RPD cases. It required 37 cases to overcome the learning curve for RDP and 20 cases for RPD. The median console time was significantly shorter in the late group for both RDP (112 minutes vs 225 minutes, P < .001) and RPD (360 minutes vs 520 minutes, P < .001). Median blood loss was significantly less in the late group for both RDP (30 cc vs 100 cc, P = .003) and RPD (100 cc vs 200 cc, P < .001). No surgical mortality occurred in either group. Clinically relevant pancreatic fistula rate was 22.9% for RDP (32.4% in the early group vs 12.1% in the late group, P = .043), and 11.5% for RPD (0 in early group vs 17.1% in late group, P = .084).

This study demonstrates that the RPD learning curve is 20 cases with prior experience of RDP and confirms the safety and feasibility of both RPD and RDP. Practice and familiarity with the robotic platform are likely to contribute to significant shortening of the learning curve in robotic pancreatic surgery, while knowledge and experience, in addition to practical skills, are also essential to minimize the potential surgical risks of RPD.

Abbreviations: CT = console time, CUSUM = cumulative sum, DEG = delayed gastric emptying, ISGPF = International Study Group for Pancreatic Fistula, PD = pancreaticoduodenectomy, PJ = pancreaticojejunostomy, POPF = postoperative pancreatic fistula, PPH = postpancreatectomy hemorrhage, RDP = robotic distal pancreatectomy, RPD = robotic pancreaticoduodenectomy.

Keywords: distal pancreatectomy, learning curve, pancreaticoduodenectomy, robotic

1. Introduction

Minimally invasive surgery has become a worldwide trend in many surgical fields, including pancreatic surgery.^[1–5] Increasing evidence has demonstrated not only the safety and feasibility of laparoscopic pancreatectomies, but also advantages in terms of postoperative outcome and comparable oncological results.^[6–8] Recently, with the advantageous ergonomics of the da Vinci Robotic Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA), several limitations related to the laparoscopic approach have

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Received: 8 November 2017 / Accepted: 5 October 2018 http://dx.doi.org/10.1097/MD.000000000013000 been overcome. Moreover, given the high-quality three-dimensional and 10 to 15 magnification view, elimination of surgeon's tremor, and articulation of instruments with 540° of motion, robotic approach even allows to facilitate more complex and delicate procedures such as pancreaticoduodenectomy (PD) involving extensive dissection and the restoration of digestive tract continuity for the pancreas, bile duct, and stomach.^[3,6,9]

PD is a technically demanding and challenging procedure carrying a high morbidity. For robotic pancreaticoduodenectomy (RPD), the learning curve would entail the mastery of some facets unique to the use of robotic surgical system, including optimal port placement, good coordination between the console surgeon and bedside assistant, and overcoming the loss of tactile feedback.^[1-3,10-14] Cumulative sum (CUSUM) is a mathematical inspection scheme that was first described by E.S. Page in 1954 as a method to monitor performance in the manufacturing industry, and has since been widely employed in the assessment of new technical skills.^[3,13,15-21] CUSUM method was adopted by the medical profession in the 1970s for the analysis of learning curves in the technical training of a variety of procedures.^[16,22,23] and surgical procedures.^[18,21] Multiple reports on robotic surgery have been published, but only a few reports have evaluated the learning curve for both robotic distal pancreatectomy (RDP)^[17,24] and RPD^[3,13].

This study was to present our experience in robotic pancreatic surgery. CUSUM analysis was conducted to identify the learning curve of the console time for RDP and RPD. Perioperative outcomes were compared between the early group of surgeries

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performed early in the learning curve and the late group of surgeries performed after the learning curve.

2. Patients and methods

Robotic distal pancreatectomy (RDP) was initiated at our institution on September 13, 2011, and the first robotic pancreaticoduodenectomy (RPD) was performed on July 15, 2014. A dedicated team, including SEW and YMS who both had performed more than 500 cases of open PD, was involved in all the robotic cases. The study was approved by our Institutional Review Board (IRB-TPEVGH No.: 2018-05-0093BC). Appropriate written informed consent was obtained from the patients. The da Vinci Si Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) was used for robotic pancreatic surgeries and all of the cases were pure robotic pancreatic surgery, with exclusion of cases needing conversion or hybrid surgery. All perioperative data were prospectively collected, including gender, age, presenting symptoms, laboratory blood data, radiologic imaging, perioperative parameters, surgical outcomes, and pathology. Operative mortality was defined as death within 30 days after operation. Postoperative pancreatic fistula (POPF) was graded according to the International Study Group for Pancreatic Fistula (ISGPF) criteria.^[25] Delayed gastric emptying (DEG)^[26] and postpancreatectomy hemorrhage (PPH)^[27] were identified and classified with standardized criteria defined by an international study group of pancreatic surgery. Postoperative complications were graded according to the Clavien-Dindo classification.[28]

For RDP, 5 ports (4 robotic trocars including a 12-mm camera port and a 12-mm accessory port) were used. A trans-umbilical incision was made for the insertion of a 12-mm camera port, and pneumoperitoneum was established at a pressure of <15 mm Hg. Three 8-mm robotic working ports were placed, with one at the midclavicular line of the left side of the patient's abdomen at the level of umbilicus. The other 2 ports were placed on the right side, with one at the anterior axillary line about 2 cm below the subcostal region and the other at the midclavicular line slightly above the umbilicus level. A 12-mm accessory port was placed in between the camera port and the left side of the robotic working port.

For RPD, 6 ports (4 robotic trocars and 2 accessory ports) were used. A trans-umbilical incision was made for the insertion of a 12-mm accessory port, and pneumoperitoneum was established at a pressure of < 15 mm Hg. A 12-mm camera port was placed. Three 8-mm robotic working ports were placed, including one at the right anterior axillary line about 2 cm below subcostal region, another one at the left midclavicular line slightly above the umbilicus level and the third at the left anterior axillary line about 2 cm below the subcostal region. The 12-mm camera port was set up on the right side about 5 cm from the umbilicus. The other 5mm accessory port was placed on the right midclavicular line slightly below the camera port. The technique of pancreatic reconstruction in RPD was the modified Blumgart pancreaticojejunostomy (PJ), which was similar to that for our open method.^[29]

The learning curve was assessed using the cumulative sum (CUSUM) method similar to that described by Napoli et al.^[3] The CUSUM was obtained by adding up the calculated difference from the overall mean, starting with the first case to the next cumulatively. This method was used for all study cases, taking into account the console time (CT). Patients were chronologically arranged from the earliest to the latest data of surgery. The

CUSUM-CT for the first patient was the difference between the CT for the first patient and the mean CT for all patients. The CUSUM-CT of the second patient was the CUSUM-CT of the previous case added to the difference between the CT of the second patient and the mean CT for all patients. This same method was repeated for each patient except for the last patient, which was calculated as zero. If the CT of a case was more than the mean CT, the addition to the running value of the CUSUM-CT was a positive number (upward slope on the graph), and it was a negative number if the CT of a case was less than the mean CT (downward slope). A linear regression analysis was also performed to fit the CUSUM-CT into a model in order to detect the different phases of learning process. Based on CUSUM analyses, patients were was divided into 2 groups, early group before learning curve and late group after learning curve for both RDP and RPD.

Statistical analyses were carried out using Statistical Product and Service Solutions (SPSS) version 21.0 software (SPSS Inc., IBM, Armonk, NY). All continuous data were presented as median and mean±standard deviation (SD), and frequencies were presented when appropriate for the type of data. Mean values of continuous variables were compared with a 2-tailed Student's *t* test. Nonparametric statistical tests were used if the variables did not follow normal distribution. Categorical variables were presented as numbers and percentages. Categorical variables were compared using Pearson's χ^2 test or Fisher's exact test contingency tables. For all analyses, a *P* value <.05 was considered statistically significant.

3. Results

There were 70 RDP and 61 RPD cases of pure robotic surgery. CUSUM-CT analysis is illustrated in Figure 1A–C for RDP and Figure 2A–C for RPD. Two distinct phases of the learning curve could be identified for both RDP and RPD. It took 37 cases to overcome the learning curve for RDP and 20 cases for RPD. Based on the identification of the learning curve of the CT, an analysis of perioperative outcomes was conducted to compare those in the learning curve cohort (early group) with those in the later procedures after the learning curve (late group). Demographics of patients undergoing RDP and RPD are shown in Table 1, and no significant differences were noted in terms of the demographic data between the early and the late groups for both RDP and RPD.

Table 2 lists the perioperative parameters. The median docking time was significantly shorter in the late group for both RDP (2 minutes vs 5 minutes, P = .008) and RPD (2 minutes vs 3 minutes, P = .004). The median console time was also significantly shorter in the late group for both RDP (112 minutes vs 225 minutes, P < .001) and RPD (360 minutes vs 520 minutes, P < .001). The median blood loss was significantly less in the late group for both RDP (30 cc vs 100 cc, P = .003) and RPD (100 cc vs 200 cc, P < .001).

Surgical outcomes are shown in Table 3. There was no surgical mortality after RDP and RPD in this series, though the surgical morbidity rate was high at 38.6% for RDP (45.9% in the early group vs 30.3% in the late group, P=.059) and 41.0% for RPD (50.0% in the early group vs 36.6% in the late group, P=.708). Clinically relevant pancreatic fistula (CRPF) rate was 22.9% for RDP (32.4% in the early group vs 12.1% in the late group, P=.043) and 11.5% for RPD (0% in the early group vs 17.1% in the late group, P=.084). The rate of significant gastric atonia (grades B and C) was only 3.3% for RPD (5.0% in the early

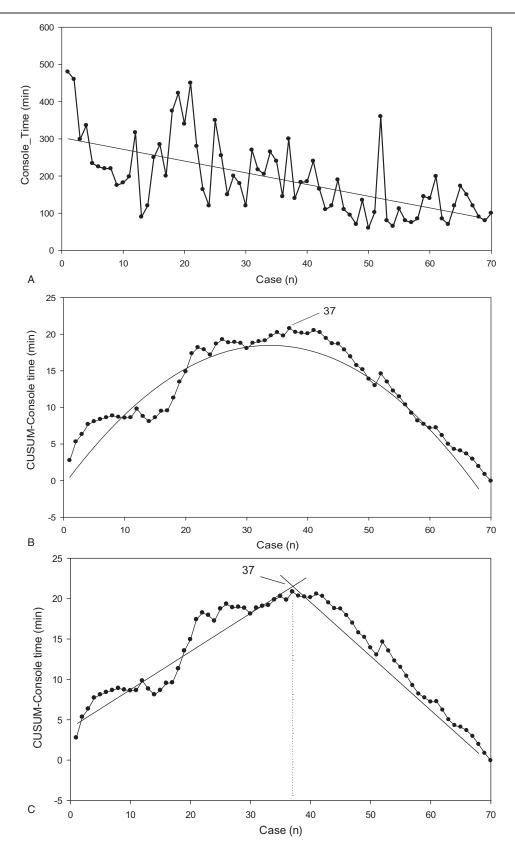


Figure 1. CUSUM analysis for robotic distal pancreatectomy (RDP). (A) Raw console time (CT) plotted for each RDP case arranged in chronological order. (B) Cumulative sum of the console time (CUSUM-CT) plotted against the chronological order of RDP cases modeled as a parabola. (C) Two phases of the learning process in RDP are identified using the CUSUM-CT curve by linear regression analysis. CT =console time, CUSUM = cumulative sum, RDP = robotic distal pancreatectomy.

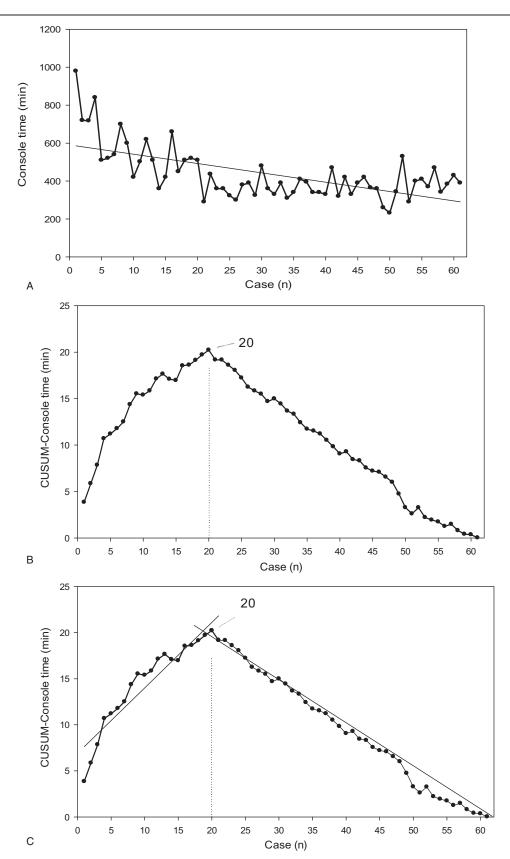


Figure 2. CUSUM analysis for robotic pancreaticoduodenectomy (RPD). (A) Raw console time (CT) plotted for each RPD case arranged in chronological order. (B) Cumulative sum of the console time (CUSUM-CT) plotted against the chronological order of RPD cases modeled as a parabola. (C) Two phases of the learning process in RPD are identified using the CUSUM-CT curve by linear regression analysis. CT = console time, CUSUM = cumulative sum, RDP = robotic distal pancreatectomy.

Table 1

Demographics of patients undergoing robotic pancreaticoduodenectomy and distal pancreatectomy.

	Robotic pancreaticoduodenectomy					Robotic distal pancreatectomy		
	Total	Early group	Late group	P value	Total	Early group	Late group	P value
Case number	61	20	41		70	37	33	
Gender, n (%)				.415				.789
Female	29 (47.5%)	11 (55.0%)	18 (43.9%)		37 (52.9%)	19 (51.4%)	18 (54.5%)	
Age, y/o				.927				.236
Median	66	65	66		55	52	59	
Range	29-88	40-88	29-86		25-80	28-79	25-80	
Mean \pm SD	65±13	65 ± 13	65±13		55 ± 15	53 <u>+</u> 14	57±16	
Preoperative BMI, kg/m ²				.619				.259
Median	23.6	23.5	23.6		22.8	22.9	22.6	
Range	17.0-34.5	17.0-27.6	17.5–34.5		15.9–31.1	15.9-31.1	18.3-29.0	
Mean \pm SD	24.0±3.7	23.6 ± 2.9	24.1 ± 4.0		23.6±3.2	24.0+3,3	23.2+30	
Primary tumor origin				.196				.178
Pancreatic head adenocarcinoma	13 (21.3%)	8 (40.0%)	5 (12.2%)		9 (12.9%)	2 (5.4%)	7 (21.2%)	
Ampullary adenocarcinoma	27 (44.3%)	9 (45.0%)	18 (43.9%)		0	0	0	
Distal CBD adenocarcinoma	4 (6.6%)	0	4 (9.8%)		0	0	0	
Duodenal adenocarcinoma	2 (3.3%)	0	2 (4.9%)		0	0	0	
NET	0	0	0		13 (18.6%)	5 (13.5%)	8 (24.2%)	
Serous cystadenoma	0	0	0		18 (25.7%)	10 (27.0%)	8 (24.2%)	
Mucinous cystadenoma	0	0	0		7 (10.0%)	4 (10.8%)	3 (9.1%)	
Mucinous cystadenocarcinoma	0	0	0		1 (1.4%)	0	1 (3.0%)	
IPMN	7 (11.5%)	1 (5.0%)	6 (14.6%)		5 (7.1%)	3 (8.1%)	2 (6.1%)	
Solid and pseudopapillary tumor	1 (1.6%)	0	1 (2.4%)		5 (7.1%)	5 (13.5%)	0	
Other benign	6 (9.8%)	12 (10.0%)	4 (9.8%)		2 (2.9%)	1 (2.7%)	1 (3.0%)	
Other malignancy	1 (1.6%)	0	1 (2.4%)		10 (14.3%)	7 (18.9%)	3 (9.1%)	

BMI=body mass index; CBD=common bile duct; NET=neuroendocrine tumor; IPMN=intraductal papillary mucinous neoplasm.

group vs 2.4% in the late group, P = .685), with no occurrence of gastric atonia for RDP. The chyle leakage rate was 8.6% for RDP (10.8% in the early group vs 6.1% in the late group, P = .479) and 8.2% for RPD (0% in the early group vs 12.2% in the late group, P = .162).

4. Discussion

PD is considered a challenging surgical procedure that involves complex surgical anatomy and extensive dissection and requires meticulous and tedious technique to restore digestive continuity. Moreover, it carries a high rate of potential postoperative morbidity such as pancreatic fistula, intraabdominal bleeding, sepsis, and delayed gastric emptying, which can contribute to a prolonged hospital stays.^[6,30,31] Despite its complexity, use of robotic approach for pancreatic resections has been increasing in some centers, ^[1,5,6,10] Perhaps the most appreciated aspect of the robotic approach is the shorter learning curve. The 7 degrees of freedom, 3-dimensional view, ergonomics, and tremor filtration are possible reasons for this reduced learning curve, as compared with the laparoscopic approach.^[32] Robotic approach in pancreatic surgery may be superior to the traditional open approach in terms of intraoperative blood loss, wound pain, and length of hospital stay.

In traditional open surgery, surgeons stand beside the patient, are fully embedded in the operative environment, and have the opportunity to use the full range of their surgeons' senses, including tactile feedback. In laparoscopic surgery, surgeons are still close to the patient and embedded in the operative environment, but many of the technical advantages of open surgery are not available, such as direct tactile feedback. In the robotic surgery, surgeons operate on patients in a virtual reality system without directly contacting the patients, with a total lack of tactile feedback and without direct perception of the position of the surgical instruments outside the endoscopic vision. In light of the complete absence of haptic feedback and lack of direct visual control of the instrument position in robotic surgery, various adaptations and the establishment of a new model of team cooperation have become necessary.^[3] Therefore, a learning curve would exist for any surgeon embarking on performing robotic surgery irrespective of the surgeon's extent of prior experience in traditional open or laparoscopic surgery.

It has been demonstrated that surgeons with higher volumes have better outcomes, which suggests the presence of a learning curve for PD.^[33] In fact, the learning curve for open PD corresponds to 50 to 60 operations.^[33–35] In laparoscopic PD, Speicher et al^[36] reported that 50 cases of team-based laparoscopic PD were required for the learning curve to achieve in reducing operation time and blood loss as compared with the open approach. The reported learning curve for RPD is variable. Zureikat et al^[10] suggested that the learning curve resulting in comparable outcomes to the open approach in terms of surgical risks and oncological results could be overcome after 80 RPD procedures. Chen et al^[37] reported that comparable results could be achieved by RPD when treating pancreatic diseases after a learning curve of 40 cases. While the Pittsburgh group analyzed 200 consecutive RPD cases and showed that operation time dropped after 80 procedures,^[13] the Shanghai group analyzed 60 RPD cases in the context of a prospective comparison with 120 open PD cases and showed reduction in operation time, blood loss, and incidence of complications after 40 procedures.^[38-40]

CUSUM, a cumulative summation technique, has been effectively used to assess the learning curve of a novel surgical procedure because it can display the variance from the mean on a

Table 2

Perioperative parameters for robotic pancreaticoduodenectomy and distal pancreatectomy.

	Robotic pancreaticoduodenectomy					Robotic distal pancreatectomy		
	Total	Early group	Late group	P value	Total	Early group	Late group	P value
Case number	61	20	41		70	37	33	
Predocking time, minutes				.285				<.001
Median	20	20	20		21	25	18	
Range	10-40	10-40	13-30		10-44	10-44	10–35	
Mean + SD	21+5	22+8	21+4		22+8	26+8	18+6	
Docking time, minutes				.004				.008
Median	2	3	2		3	5	2	
Range	5–15	5–15	0.5–5		5-48	1-48	0.5–15	
Mean + SD	2±3	4 ± 4	2±1		5±7	7±8	3±3	
Console time, minutes				< .001				<.001
Median	395	520	360		178	225	112	
Range	232-980	360-980	232-530		60-450	90-450	60-360	
Mean \pm SD	438 ± 141	581 ± 152	369 ± 60		188 ± 93	240 ± 86	1332 ± 64	
Blood loss, ml				< .001				.003
Median	100	200	100		50	100	30	
Range	20-650	45-650	1-300		2 -120	2-1200	2-520	
Mean \pm SD	161 ± 135	232 ± 167	111±82		183 ± 263	271 ± 320	85 ± 122	
Hospital stay, day	_	_	_	.430	_	_	_	.040
Median	24	24	23		7	6	8	
Range	10-77	10-53	10-77		4–56	4-39	4-56	
Mean \pm SD	26 ± 15	24 ± 11	28 ± 17		11 ± 9	8±6	13 ± 12	
Lymph node count harvested,				.230				N/A
Median	13	15	13					
Range	4 - 43	4-43	3–32					
Mean \pm SD	16 ± 8	17 ± 10	15 ± 7					
Cost, USD								
Total cost for hospitalization				.956				.535
Median	21.242	22,086	20,538		11.675	11,681	11,433	
Range	13,485–50,195	14,965 - 32,706	13,485–50,195	<.001	9340-23,230	9658-22,254	9340-23,230	.316
Mean \pm SD	$22,730 \pm 6876$	$22,798 \pm 4846$	$22,691 \pm 7871$		$12,357 \pm 2510$	$12,175 \pm 2274$	$12,563 \pm 2777$	
Instrument cost for robotic surgery	22,100 <u>-</u> 0010	22,100 1 1010	22,001 - 1011		12,001 - 2010		12,000 2 2111	
Median	7,939	9,773	7395		6,988	6987	6,989	
Range	3940–15,906	5422-15,906	3940-12,263		642–9475	5462-8540	642–9475	
Mean \pm SD	8503 ± 1869	$10,030 \pm 1937$	7631 ± 1137		6805 ± 1174	6942 ± 798	$6,50 \pm 1488$	

case-by-case basis.^[17] In the present study, 2 distinct phases of the learning curve were identified for both RDP and RPD by CUSUM-CT analyses. It took 37 cases to complete the learning curve of RDP in the context of no prior experience in robotic surgery. Nevertheless, only 20 cases were needed for us to overcome the learning curve for RPD, which was initiated with earlier experience of performing RDP. Both the learning curves of RPD and RDP were shorter than those previously reported in the literature. With no experience in robotic surgery, but with a high volume of open PD surgeries, our team approached the integration of the robotic surgery with RDP first, and the RPD program was not initiated until nearly 3 years later. Actually, we did not have selection bias irrespective of BMI and pathological diagnosis, except significant vascular involvement by cancer. This study clearly revealed that our prior experience in RDP played a significant role in the development of skill in RPD. Practice and familiarity with the robotic platform are likely to contribute to a significantly reduced learning curve for a complex and risky procedure such as RPD

Minimization of blood loss has been one of the benefits provided by the robotic approach, which was reported to range from 100 to 634 mL for RPD.^[6,13] In this study, we also showed that the medians of blood loss were significantly less in the late groups compared to the early group (100 mL vs 200 mL for RPD and 100 mL vs 30 mL for RDP, respectively), which could be a reflection of improved tissue dissection using the robotic approach after the learning curve. However, other major surgical parameters including harvested lymph node count, surgical morbidity, and pancreatic leakage were not significantly different before and after the learning curve for RPD. In this study, we had no surgical mortality after robotic pancreatic surgeries. Our results suggest that surgical outcomes may not differ when the robotic approach is used for PD by high-volume surgeons who possess sound expertise in open PD. In other words, surgical knowledge and experience, in addition to practical skills, are also essential to minimize surgical risks in attempting robotic pancreatic surgery.

In conclusion, this study has identified a RPD learning curve of 20 cases in the context of prior experience of RDP, and has confirmed the safety and feasibility of both RPD and RDP. Practice and familiarity with the robotic platform are likely to contribute to the significant shortening of the learning curve in robotic pancreatic surgery. A shorter learning curve for RPD can be predicted based on robust prior experience in open and robotic surgery. Therefore, surgical knowledge and experience, in addition to practical skills, are essential to minimize the potential surgical risks of robotic pancreatic surgery.

Table 3

Surgical risks after robotic pancreaticoduodenectomy and distal pancreatectomy.

	Robotic pancreaticoduodenectomy					Robotic distal pancreatectomy		
	Total	Early group	Late group	P value	Total	Early group	Late group	P value
Case number	61	20	41		70	37	33	
Surgical mortality	0	0	0	1.000	0	0	0	1.000
Surgical morbidity	25 (41.0%)	10 (50.0%)	26 (36.6%)	.408	27 (38.6%)	17 (45.9%)	10 (30.3%)	.059
Postoperative complications				.403				.301
Clavien–Dindo 0	36 (59.0%)	10 (50.0%)	26 (63.4%)		43 (61.4%)	20 (54.1%)	23 (69.7%)	
Clavien–Dindo I	18 (29.5%)	6 (30.0%)	12 (29.3%)		24 (34.3%)	16 (43.2%)	8 (24.2%)	
Clavien–Dindo II	1 (1.6%)	1 (5.0%)	0		2 (2.9%)	1 (2.7%)	1 (3.0%)	
Clavien–Dindo III	3 (4.9%)	1 (5.0%)	2 (4.9%)		0	0	0	
Clavien–Dindo IV	3 (4.9%)	2 (10.0%)	1 (2.4%)		1 (1.4%)	0	1 (3.0%)	
Pancreatic leakage				.702				.011
Grade A	7 (11.5%)	4 (20%)	3 (7.3%)		12 (17.1%)	8 (21.6%)	4 (12.1%)	
Grade B	6 (9.8%)	0	6 (14.6%)		16 (22.9%)	12 (32.4%)	4 (12.1%)	
Grade C	1 (1.6%)	0	1 (2.4%)		0	0	0	
Overall	14 (23.0%)	4 (20%)	10 (24.4%)		28 (40.0%)	20 (54.1%)	8 (24.2%)	
POPF (grade B and C)	7 (11.5%)	0	7 (17.1%)	.084	16 (22.9%)	12 (32.4%)	45 (12.1%)	.043
Gastric atonia, grade B and C	2 (3.3%)	1 (5.0%)	1 (2.4%)	.685	0	0	0	1.000
Postpancreatectomy hemorrhage	3 (4.9%)	0	3 (7.3%)	.544	1 (1.4%)	0	1 (3.0%)	.286
Intraabdominal abscess	2 (3.3%)	1 (5.0%)	1 (2.4%)	1.000	5 (7.1%)	5 (13.5%)	0)	.028
Wound infection	1 (1.6%)	1 (5.0%)	0	.328	0	0	0	1.000
Chyle leakage	5 (8.2%)	0	5 (12.2%)	.162	6 (8.6%)	4 (10.8%)	2 (6.1%)	.479
Bile leakage	2 (3.3%)	1 (5.0%)	1 (2.4%)	1.000				N/A

POPF = postoperative pancreatic fistula.

Author contributions

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