

# The learning curve in robotic distal pancreatectomy

Niccolò Napoli<sup>1</sup> · Emanuele F. Kauffmann<sup>1</sup> · Vittorio Grazio Perrone<sup>1</sup> ·  
Mario Miccoli<sup>2</sup> · Stefania Brozzetti<sup>3</sup> · Ugo Boggi<sup>1</sup>

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**Abstract** No data are available on the learning curve in robotic distal pancreatectomy (RADP). The learning curve in RADP was assessed in 55 consecutive patients using the cumulative sum method, based on operative time. Data were extracted from a prospectively maintained database and analyzed retrospectively considering all events occurring within 90 days of surgery. No operation was converted to laparoscopic or open surgery and no patient died. Post-operative complications occurred in 34 patients (61.8 %), being of Clavien–Dindo grade I–II in 32 patients (58.1 %), including pancreatic fistula in 29 patients (52.7 %). No grade C pancreatic fistula occurred. Four patients received blood transfusions (7.2 %), three were readmitted (5.4 %) and one required repeat surgery (1.8 %). Based on the reduction of operative times ( $421.1 \pm 20.5$  vs  $248.9 \pm 9.3$  min;  $p < 0.0001$ ), completion of the learning curve was achieved after ten operations. Operative time of the first 10 operations was associated with a positive slope ( $0.47 + 1.78^*$  case number;  $R^2 0.97$ ;  $p < 0.0001^*$ ), while that of the following 45 procedures showed a negative slope ( $23.52 - 0.39^*$  case number;  $R^2 0.97$ ;  $p < 0.0001^*$ ). After completion of the learning curve, more patients had a

malignant histology (0 vs 35.6 %;  $p = 0.002$ ), accounting for both higher lymph node yields ( $11.1 \pm 12.2$  vs  $20.9 \pm 18.5$ ) ( $p = 0.04$ ) and lower rate of spleen preservation (90 vs 55.6 %) ( $p = 0.04$ ). RADP was safely feasible in selected patients and the learning curve was completed after ten operations. Improvement in clinical outcome was not demonstrated, probably because of the limited occurrence of outcome comparators.

**Keywords** Robot · Da vinci · Distal pancreatectomy · Spleen preserving · Learning curve

## Introduction

The learning curve of an operation refers to the time and the number of operations required to an individual surgeon, a surgical team, or an institution to achieve proficiency when performing the operation [1]. This process is influenced by many factors, including innate abilities [2], more probably corresponds to the achievement of a proficiency zone rather than of a proficiency threshold, and is difficult to define. Further, the completion of the learning curve for a specific operation requires the combination of cognitive knowledge and actual ability to perform surgery consistently well with a good outcome [1].

Minimally invasive distal pancreatectomy (MIDP) is gaining momentum [3]. While no prospective randomized comparison with open surgery is available, the evidence is cumulating that MIDP is associated with improved outcome in properly selected patients [4–6]. Most of currently available information refers to MIDP performed using conventional laparoscopic techniques [3–6]. Despite requiring no digestive or vascular reconstructions, MIDP remains a challenging operation because of the combination of several

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✉ Ugo Boggi  
u.boggi@med.unipi.it  
Niccolò Napoli  
nicco.napo@gmail.com

<sup>1</sup> Division of General and Transplant Surgery, Azienda Ospedaliera Universitaria Pisana, Università di Pisa, Via Paradisa 2, 56124 Pisa, Italy

<sup>2</sup> Biostatistics Unit Research, Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy

<sup>3</sup> Pietro Valdoni Department of Surgery, University of Rome La Sapienza, Rome, Italy

unfavorable factors such as the retroperitoneal location of the pancreas, the close anatomic relationships of the gland with major vasculature, and the threat of inadequate margin clearance in malignant disease. The intrinsic technical limitations of laparoscopy [7], only partially overcome by extensive training, could hence justify the use of the da Vinci surgical system (Intuitive surgical, Sunnyvale, CA, USA) (dVss) in MIDP. The dVss is indeed known to improve surgical dexterity in laparoscopic operations [7]. In MIDP, robotic assistance was associated with reduced rates of conversion to open surgery [8], higher rates of spleen preservation [9], and improved oncologic radicality [8].

We herein present one of the largest world experiences with robot-assisted distal pancreatectomy (RADP), with the aim of describing our learning curve. By defining these early outcome metrics, we provide the basic information required for comparative studies on the effectiveness or robotic assistance with respect to either open or laparoscopic surgery. Since completion of the learning curve is required to make meaningful comparison with other surgical techniques possible, we hope that our work may contribute to establish the benchmark for RADP in the view of future comparative studies.

## Methodology

Patients undergoing robot-assisted RADP between April 2008 and September 2014 were considered. All RADPs were performed by a single pancreatic surgeon (UB), who had performed over 700 open or laparoscopic pancreatic resections, before implementing the robotic program.

Data on RADPs were extracted from a prospectively maintained database and analyzed retrospectively. All events occurring within 90 days of surgery were considered. Pancreatic fistula was identified and classified by the International Study Group on Pancreatic Fistula criteria [10]. Post-operative complications were graded according to the Clavien–Dindo classification [11].

## Patient selection

Patients were selected from a large pool of potential candidates at a high volume center performing an average of >100 pancreatic resections per year. Selection criteria evolved over time, based on emerging evidence and increasing personal experience.

Exclusion criteria, valid throughout the study period, were unsuitability for laparoscopy, previous major surgery in upper abdominal quadrants, malignant pancreatic tumors without clear margins at preoperative imaging studies, body mass index  $\geq 35$  kg/m<sup>2</sup>, and lack of timely availability of the dVss.

Initially, pancreatic cancer was considered an absolute contraindication, because of the lack of studies demonstrating appropriateness of robotic-assisted surgery for this tumor type. Based on early encouraging data [12], we became willing to consider also pancreatic cancer, provided that clear surgical margins were demonstrated at preoperative imaging studies.

## Operative technique

Patient position on the operating table and location of patient side cart vary based on tumor location, as shown in Figs. 1 and 2.

Irrespective of spleen preservation, the operation begins with mobilization of the splenic flexure of the colon. The lesser sac is preferentially entered by dividing the reflection of colon and omentum. The peritoneum along the inferior margin of the pancreas is incised and the segment of the pancreas planned for resection is mobilized along the posterior avascular plane. The splenic vein is identified. The neck or body of the pancreas, depending on the level of intended resection, is elevated and two stay sutures of 4/0 polypropylene are placed at the superior and the inferior border of the gland. The pancreas is divided using robotic scissors. The duct is carefully identified, ligated or suture ligated, and the parenchyma is closed in a fish-mouth configuration using interrupted sutures of 4/0 polytetrafluoroethylene.

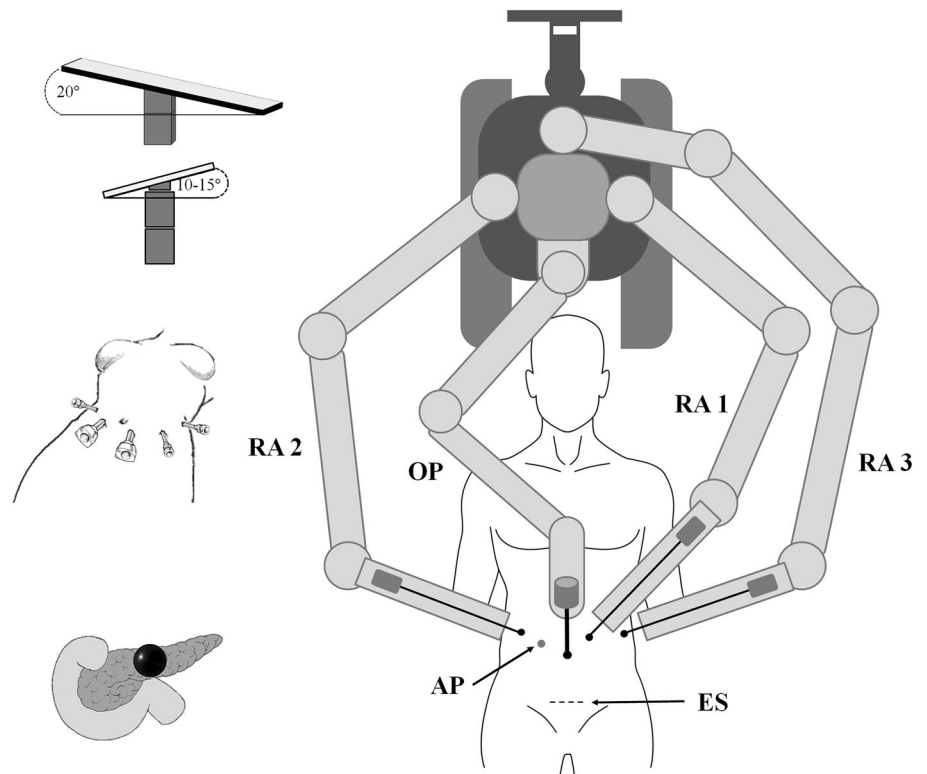
When the spleen has to be removed, the splenic artery is mobilized, doubly ligated, and divided at an early stage. If the splenic vein is thrombosed, and venous effluent is based on collateral circulation, the left gastroepiploic vessels and the short gastric vessels are left intact until the end of the operation. In the other patients, they are immediately divided using a combination of harmonic<sup>®</sup> scalpel and clips. Division of the splenic vein, between ligatures, and mobilization of the spleen complete the operation. The specimen, placed in an endoscopic bag, is retrieved through a transverse suprapubic incision.

When the spleen is planned for preservation, the splenic artery and the splenic vein are dissected off the pancreas. Pancreatic veins are either sealed using a combination of energy devices or ligated. Pancreatic arteries are preferentially ligated or suture ligated. The specimen, placed in an endoscopic bag, may be retrieved through either an enlarged port site or a transverse suprapubic incision. Two closed suction drains are left near the pancreatic transection margin.

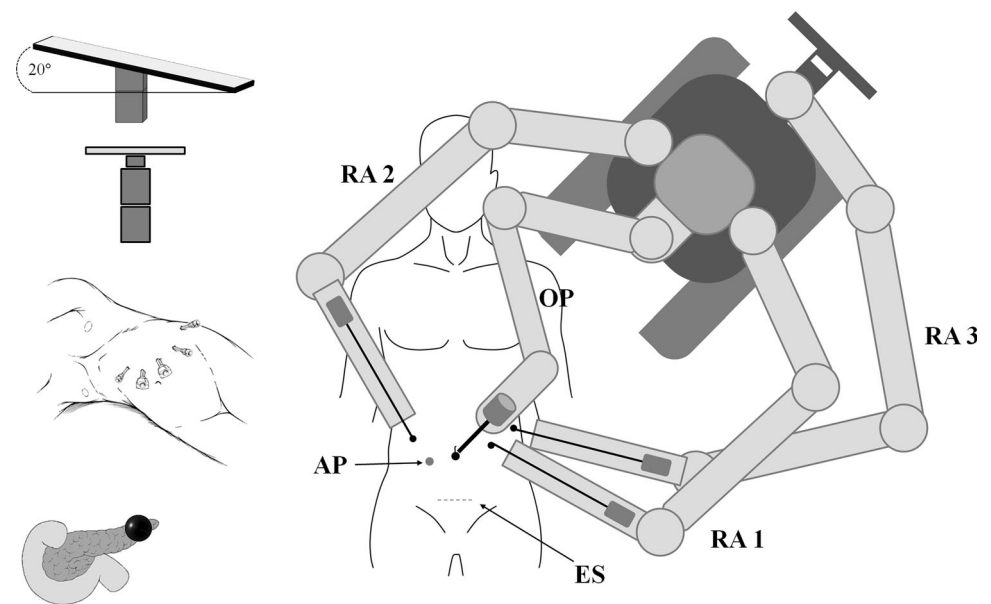
## Assessment of the learning curve

The learning curve of RADP was assessed using the cumulative sum method (CUSUM). The CUSUM was the running total of differences between the individual data points and the mean of all data points. This method was used for each

**Fig. 1** For tumors located in the body of the pancreas, the patient is placed supine and the table is oriented 20° in the reverse Trendelenburg position and tilted to the right side. The patient side cart is docked over the head of the patient with two robotic arms (RA) on the patient's left side. Five ports are used (3, 8 mm; 2, 12 mm). The optic port (OP) is placed in the peri-umbilical area, and the assistant port (AP) is placed in the right para-rectal region. The specimen is extracted through a suprapubic incision (ES), or through an enlarged trocar site depending on whether or not the spleen is also removed



**Fig. 2** For tumors located in the tail of the pancreas, the patient is placed in the right flank position and the table is oriented 20° in the reverse Trendelenburg position. The patient side cart is docked over the left shoulder of the patient with two robotic arms (RA) on the patient's left side. Five ports are used (3, 8 mm; 2, 12 mm). Ports are placed along a smiling line having as a target anatomy the spleen and the pancreatic tail. The specimen is extracted through a suprapubic incision (ES), or through an enlarged trocar site depending on whether or not the spleen is also removed



case, taking into account operative time (OT). Patients were categorized from the earliest to the latest data of surgery. The CUSUM-OT was the difference between the OT for the first patient and the mean OT for all patients. The CUSUM-OT of the second patient was the CUSUM-OT of the previous case added to the difference between the OT of the second patient and the mean OT for all patients. This same method was used for each patient except for the last patient, which was

calculated as zero. A linear regression analysis was also performed to fit the CUSUM-OT into a model to detect the different phases of learning process.

**Statistical analysis**

Based on CUSUM analyses, the population was divided into two groups (Group A and Group B). Intra- and post-

operative results were compared between the groups using  $\chi^2$  and Fisher's exact test. Data differences between groups were considered statistically significant at the level of  $p < 0.05$  [13].

All statistical analyses were performed using SAS JMP 9.0.1 (SAS Institute Inc., SAS Campus Drive, Cary, NC 27513, USA) for Mac.

## Results

During the study period, 81 patients underwent RADP. Twenty-six patients (32.0 %) requiring associated surgical procedures were excluded (adrenalectomy,  $n = 3$ ; subtotal parathyroidectomy,  $n = 2$ ; incisional hernia repair,  $n = 1$ ; removal of ovarian cysts,  $n = 2$ ; cholecystectomy,  $n = 8$ ; en-bloc resection of celiac trunk,  $n = 1$ ; reconstruction of the splenic vein,  $n = 1$ ; colonic resection,  $n = 1$ ; liver metastasectomy,  $n = 1$ ; removal of abdominal mass,  $n = 1$ ; uterine myomectomy,  $n = 1$ ), making a total of 55 patients available to assess the learning curve (Tables 1, 2). Main intra- and post-operative outcome data are summarized in Table 3.

A graph of raw operative times plotted in each of the patients arranged in chronological order is shown in Fig. 3. The CUMSUM-OT learning curve was modeled as a second-order polynomial fit (parabola). The equation of the CUMSUM-OT curve was equal to  $27.47 - 0.47 * \text{case number} - 0.014 * (\text{case number} - 28)^2 + 0.00061 * (\text{case number} - 28)^3$  with an  $R^2$  value of 0.88 and a  $p < 0.0001^*$  (analysis of variance).

From the fitted model line plot of the CUSUM-OT, two phases of the learning process were identified. The first

**Table 1** Baseline characteristics of patients undergoing RADP

	Frequency or mean	Percentage or SD
Sex (F–M)	37–18	67.2–32.8 %
Mean age	56.6	13.2
Mean BMI (kg/m <sup>2</sup> )	25.3	4.9
COPD	5	9 %
Diabetes	9	16.4 %
Heart disease	1	1.8 %
ASA physical status classification		
I	9	16.4 %
II	30	54.5 %
III	15	27.3 %
IV	1	1.8 %
V	0	–
Previous abdominal surgery	28	50.9 %

COPD chronic obstructive pulmonary disease, ASA American Society of Anesthesiology

**Table 2** Tumor types

	Frequency	Percentage
Neuroendocrine tumor	13	23.6
Serous cystadenoma	11	20.0
Mucinous cystadenoma	9	16.5
Intraductal papillary mucinous neoplasm	7	12.7
Malignant intraductal papillary mucinous neoplasm	6	10.9
Ductal adenocarcinoma	4	7.3
Neuroendocrine carcinoma	1	1.8
Adenosquamous carcinoma	1	1.8
Mucinous cystadenocarcinoma	1	1.8
Intrapancreatic accessory spleen	1	1.8
Inflammatory tumor	1	1.8

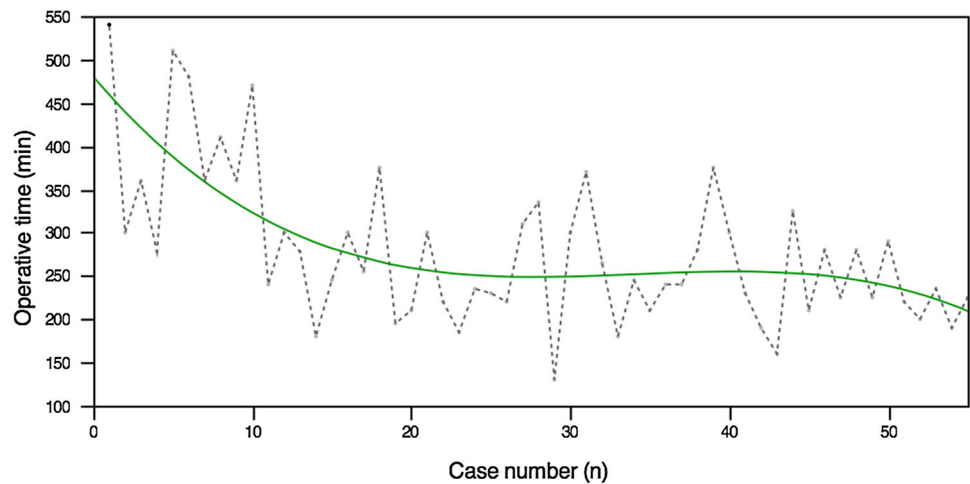
**Table 3** Main intra- and post-operative outcome measures

	Frequency or mean	Percentage or SD
Operative time (min)	278.2	89.3
Conversion to open	0	0 %
Spleen preserving (Yes–No)	34–21	61.9–38.1
Blood transfusions (Units)	4	8.3 %
Post-operative complications	34	61.8 %
Clavien–Dindo I	2	3.6 %
Clavien–Dindo II	30	54.5 %
Clavien–Dindo III	2	3.6 %
Clavien–Dindo IV	0	0 %
Clavien–Dindo V	0	0 %
Pancreatic fistula	29	52.7 %
Grade A	4	7.2 %
Grade B	25	45.4 %
Grade C	0	0 %
Reoperation	1	1.8 %
Length of hospital stay (days)	12.6	6.4
Readmission (90-day)	3	5.4 %

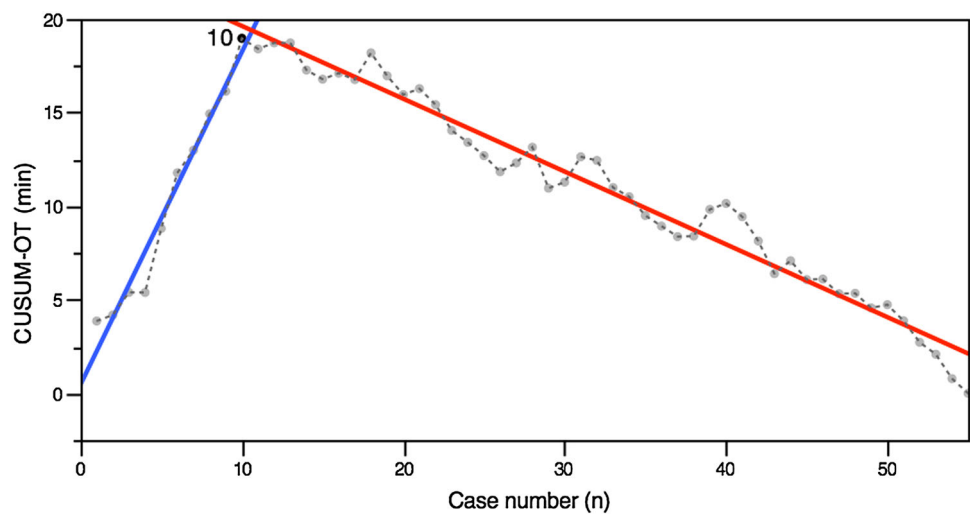
phase included the first 10 procedures (Group A) and the second phase following the remaining 45 operations (Group B).

In Fig. 4, the best fit model line of each phase was obtained using a regression analysis between CUSUM-OT and chronological case number. The positive slope ( $0.47 + 1.78 * \text{case number}$ ;  $R^2 0.97$ ;  $p < 0.0001^*$ ) during the first phase indicates longer operative time while the negative slope ( $23.52 - 0.39 * \text{case number}$ ;  $R^2 0.97$ ;  $p < 0.0001^*$ ) during the second phase underscored the relevance of learning process in reducing operative time.

**Fig. 3** Graph of raw operative times plotted for each of the 55 consecutive patients



**Fig. 4** Two phases of the learning process are identified using CUSUM-OT curve. The first phase presents a positive slope, while the second phase a negative slope



As shown in Table 4, group A (before completion of the learning curve) and group B (after completion of the learning curve) were comparable for all baseline characteristics.

A comparison between the two groups, regarding the main intra- and post-operative parameters, is provided in Table 5. The two groups, as expected, had different operative times ( $421.1 \pm 20.5$  vs  $248.9 \pm 9.3$  min;  $p = 0.0001$ ) but similar clinical outcomes. Completion of the learning curve was associated with more frequent malignant histology (0 vs 35.6 %;  $p = 0.002$ ), higher lymph node yields ( $11.1 \pm 12.1$  vs  $20.9 \pm 18.5$ ;  $p = 0.04$ ), but lower rates of spleen preservation (90 vs 55.6 %;  $p = 0.04$ ).

### Discussion

Despite lack of prospective randomized comparison, evidence is cumulating that MIDP, when compared to open surgery, is associated with reduced morbidity [4, 5], lower

blood loss [4–6], reduced need for blood transfusions [4, 5], reduced incidence of surgical site infection [4, 5], shorter length of hospital stay [4–6], and shorter time to first flatus and oral intake [4–6]. Further, in appropriately selected patients, MIDP does not appear to compromise oncologic radicality [4, 5, 8] and facilitates spleen preservation [5, 9].

The first dVss was installed at our hospital in the year 2000, to be used in heart surgery. At that time, the dVss was believed to be especially useful to permit minimally invasive heart surgery, such as mitral valve repair of coronary artery by-pass [14]. For several years, we were not interested in exploring the potential of the dVss in pancreatic operations, because of the lack of encouraging data from the literature and concerns on additional costs. We were already practicing minimally invasive surgery, including advanced laparoscopic procedures [15, 16], and we were already offering MIDP to selected patients [17]. Managing a high volume center for pancreatic surgery makes it important to master all surgical techniques, to

**Table 4** RADP: baseline characteristics in group A and group B

	Group A ( <i>n</i> = 10)		Group B ( <i>n</i> = 45)		<i>p</i>
	Frequency or mean	Percentage or SD	Frequency or mean	Percentage or SD	
Age	59.2	15.8	58.4	12.8	0.89
BMI (kg/m <sup>2</sup> )	25.2	3.8	25.2	5.2	0.59
Sex					
Male	3	30 %	15	33.3 %	1.00
Female	7	70 %	30	66.7 %	1.00
Heart disease	0	–	1	2.2 %	1.00
COPD	1	10 %	4	8.9 %	1.00
Hypertension	7	70 %	20	44.4 %	0.17
Diabetes	0	–	9	20 %	0.18
Previous abdominal surgery	4	40 %	24	53.3 %	0.5
Symptoms	4	40 %	17	41.5 %	1.00

offer each patient the best treatment option. Subsequently, based on emerging evidence [18, 19] and having verified the tremendous improvement in dexterity offered by the dVss, we became willing to explore the potential of robotic assistance in minimally invasive surgery of the pancreas. It is clear that the ideal bench work for this type of evaluation is pancreaticoduodenectomy [20], but we believe that the enhanced surgical dexterity offered by robotic assistance may provide an opportunity for improvement also in distal pancreatectomy. Robotic assistance, in particular, could facilitate preservation of the spleen and the splenic vessels, could facilitate wider adoption of laparoscopy for pancreatic cancer, and could improve reproducibility of the operation.

Quite surprisingly completion of the learning curve in open distal pancreatectomy has not received the same attention of other pancreatic operations, such as pancreaticoduodenectomy [21]. When laparoscopic distal pancreatectomy was implemented at a high volume center, reduction in operative time and conversion rate was achieved after the first ten operations, but blood loss, post-operative morbidity and length of hospital stay were not reduced, even after additional experience in ten further patients [22].

Interesting operative time in our experience also improved after ten patients, confirming that a new procedure, defined according to the last SAGES guidelines [23], can be learned quickly by an experienced team. Even more importantly, our results show that RADP can be safely implemented under appropriate cognitive and operative conditions. Actually, our results were so favorable that most of conventional outcome measures employed to define the benefits of the completion of the learning curve (e.g., conversion rate, blood transfusions, etc.) could not be compared between before and after completion of the

learning curve. We were only able to show a clear reduction in operative time after the first ten operations, despite significantly more patients had a malignant histology, which probably explains the higher lymph node yields and the lower rate of spleen preservation. It is also worth noting that we have not recorded any unusual or new complication related to the use of the dVss.

Regarding tumor types, we would like to underscore that the high percentage of patients with benign cystic tumors reported in this series should be read in the light of our entire contemporary experience, which includes several additional hundreds of patients operated using an open approach or simply followed up. The criteria used to devise pancreatic resection should not be extended because of the availability of minimally invasive techniques.

Despite our favorable initial experience with RADP, the challenges of robotic-assisted surgery should not be underestimated. The dVss represent a unique surgical interface requiring individual and team familiarity. Ideally, the robotic team should include a pancreatic surgeon at the console, an experienced laparoscopic surgeon at the table, and a scrub nurse who has completed a period of training on robotic surgery. Trainees are expected to be part of the robotic team but should be gradually introduced to the new technology. The surgeon at the console will experience fantastic improvement of his/her laparoscopic dexterity, but will also face new operative hurdles. Indeed, unlike in open or laparoscopic operations, he or she will not be in direct visual and physical contact with the other members of the surgical team, potentially resulting in communication problems, will not have haptic feedback, and will not have any perception of the position of the robotic instruments outside the field of view. Further, the ergonomics of the surgeon at the table may be troublesome because of the

**Table 5** RADP: group A vs group B

	Group A ( <i>n</i> = 10)		Group B ( <i>n</i> = 45)		<i>p</i>
	Frequency or mean	Percentage or SD	Frequency or mean	Percentage or SD	
Operative time (min)	421.1	20.5	248.9	9.3	<0.0001*
Conversion to open	0	–	0	–	–
Spleen preserving (Yes–No)	9	90 %	25	55.6 %	0.04**
Blood transfusions	1	10 %	3	7.9 %	1.00
Post-operative complications	6	60 %	28	62.2 %	0.89
Clavien–Dindo I + II	6	100 %	26	92.9 %	1.00
Clavien–Dindo III + IV	0	–	2	6.9 %	1.00
Pancreatic fistula	6	60 %	23	51.1 %	0.73
Grade A	0	0 %	4	8.8 %	–
Grade B	6	60 %	19	42.2 %	1.00
Grade C	0	–	0	–	–
Reoperation	0	–	1	6.7 %	2.2
Length of hospital stay (days)	12.7	7.2	12.6	6.3	0.59
Post-operative mortality	0	–	0	–	–
Malignant histology	–	–	16	35.6 %	0.002***
Margin negative resection	–	–	16	100 %	–
Examined lymph nodes	11.1	12.2	20.9	18.5	0.04*
Readmission (90 days)	0	–	3	6.7 %	1.00

\* Mann-Whitney test

\*\* Chi-squared test

\*\*\* Fischer's exact test

confined space between robotic arms and the need to simultaneously manage some of the traditional laparoscopic tasks (e.g., suction/irrigation, insertion/withdrawal of needles, etc.) and change the robotic instruments, some of which require connection to energy sources. Getting through all these constraints requires that the action of the surgeon at the console and the surgeon at the table become coordinated. While the surgeon sitting at the console is still identified as the main surgeon, robotic surgery actually requires the simultaneous, independent, but coordinated action of two surgeons. Robotic assistance clearly reduces man power in favor of team power. In general, we discourage the implementation of RADP in centers not dedicated to pancreatic surgery and not having a sound background in advanced laparoscopic surgery. No technology, including the dVss, can replace the individual surgical ability and medical knowledge.

An additional issue, strictly related to the learning curve, is how to safely introduce trainees to RADP. Admittedly, we have no clear answer to this question and we are not aware of any systematic analysis on this topic. The value of the second console, permitting an experienced surgeon to mentor a trainee while both are sitting at their respective console, is a new and interesting concept that has not been unambiguously validated yet [24]. In robot-assisted pancreaticoduodenectomy, the group from the Duke

University suggested to divide the operation into several steps and introduce trainees to each of them in a progressive stepwise fashion [25]. After becoming proficient with a step, the trainee should be allowed to advance to the next stage. There is no evidence that this approach is fruitful, but it appears logical and basically reproduces the standard way of teaching surgery in most of the other operations.

In conclusion, RADP is feasible in the hands of dedicated pancreatic surgeons already proficient with advanced laparoscopy. The reliability of the dVss is demonstrated by the lack of conversion to open surgery, in a relatively large number of consecutive operations, and by the good clinical results. We wish to underscore the importance of patient selection and the fact that no modern technology, including the dVss, can replace surgical capability and competence.

**Conflict of interest** None.

**Ethical Standard** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Research involving human participants or animals** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed consent** Patients were extensively counseled about their disease, the operation that was planned, and the use of robotic assistance. All patients signed an informed consent.

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