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Learning curve stratified outcomes after robotic pancreatoduodenectomy: International multicenter experience

Leia R. Jones, BSc[a,b,c], Maurice J.W. Zwart, PhD, MD[b,c], Nine de Graaf, MD[a,b,c], Kongyuan Wei, MD[d], Liu Qu, PhD, MD[d], Jin Jiabin, PhD, MD[e], Fu Ningzhen, MD[e], Shin-E Wang, PhD, MD[f], Hongbeom Kim, MD[g], Emanuele F. Kauffmann, PhD, MD[h], Roeland F. de Wilde, PhD, MD[i], I. Quintus Molenaar, PhD, MD[j], Ying Jui Chao, PhD, MD[k], Luca Moraldi, PhD, MD[l], Olivier Saint-Marc, MD[m], Felix Nickel, PhD, MD[n], Cheng-Ming Peng, PhD, MD[o], Chang Moo Kang, PhD, MD[p], Marcel Machado, PhD, MD[q], Misha D.P. Luyer, PhD, MD[r], Daan J. Lips, PhD, MD[s], Bert A. Bonsing, PhD, MD[t], Thilo Hackert, PhD, MD[n], Yan-Shen Shan, PhD, MD[k], Bas Groot Koerkamp, PhD, MD[i], Yi-Ming Shyr, PhD, MD[f], Baiyong Shen, PhD, MD[e], Ugo Boggi, MD[h], Rong Liu, PhD, MD[d], Jin-Young Jang, PhD, MD[g], Marc G. Besselink, PhD, MD[b,c,**], Mohammad Abu Hilal, PhD, MD[a,u,*], for the International Consortium on Minimally Invasive Pancreatic Surgery (I-MIPS)

[a] Department of General Surgery, Istituto Ospedaliero Fondazione Poliambulanza, Brescia, Italy
[b] Department of Surgery, Amsterdam UMC, University of Amsterdam, the Netherlands
[c] Cancer Center Amsterdam, the Netherlands
[d] Department of Surgery, Chinese PLA General Hospital, Beijing, China
[e] Department of Surgery, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, China
[f] Department of Surgery, Taipei Veterans General Hospital, Taiwan
[g] Department of Surgery, Seoul National University College of Medicine, South Korea
[h] Division of General and Transplant Surgery, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy
[i] Department of Surgery, Erasmus MC, Rotterdam, the Netherlands
[j] Department of Surgery, University Medical Center Utrecht, the Netherlands
[k] Department of Surgery, National Cheng Kung University Hospital, Tainan, Taiwan
[l] Department of Surgery, Azienda Ospedaliero Universitaria Careggi, Florence, Italy
[m] Department of Surgery, Center Hospitalier Orleans, France
[n] Department of Surgery, University Hospital of Heidelberg, Germany
[o] Department of Surgery, Chung Shan Medical University Hospital, Taichung, Taiwan
[p] Department of Surgery, Yonsei University Severance Hospital, Sinchon-dong, South Korea
[q] Department of Surgery, Hospital Sírio-Libanês, São Paulo, Brazil
[r] Department of Surgery, Catharina Hospital Eindhoven, the Netherlands
[s] Department of Surgery, Medisch Spectrum Twente, Enschede, the Netherlands
[t] Department of Surgery, Leiden University Medical Center, the Netherlands
[u] Department of Surgery, University Hospital Southampton NHS, United Kingdom

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ABSTRACT

Background: Robotic pancreatoduodenectomy is increasingly being implemented worldwide, with good results reported from individual expert centers. However, it is unclear to what extent outcomes will continue to improve during the learning curve, as large international studies are lacking.

Ugo Boggi, Rong Liu, Jin-Young Jang, Marc G. Besselink, and Mohammad Abu Hilal are senior authors.

* Corresponding authors: Mohammad Abu Hilal, PhD, MD, Department of Surgery, Istituto Ospedaliero Fondazione Poliambulanza, Brescia, Via Leonida Bissolati, 57, Brescia 25124, Italy.

** Marc G. Besselink, PhD, MD, Department of Surgery, Cancer Center Amsterdam, Amsterdam UMC, University of Amsterdam, De Boelelaan 1117 (ZH-7F), Amsterdam 1081 HV, the Netherlands.

E-mail addresses: m.g.besselink@amsterdamUMC.nl (M.G. Besselink), abuhilal9@gmail.com (M. Abu Hilal);

Twitter: @MarcBesselink, @Abuhilal9Abu

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Methods: An international retrospective multicenter case series, including consecutive patients after robotic pancreatoduodenectomy from 18 centers in 8 countries in Europe, Asia, and South America until December 31, 2019, was conducted. A cumulative sum analysis was performed to determine the inflection points for the feasibility (operative time and blood loss) and proficiency (postoperative pancreatic fistula grade B/C and major morbidity) learning curves. Outcomes were compared in 3 groups on the basis of the learning curve inflection points.

Results: Overall, 2,186 patients after robotic pancreatoduodenectomy were included. The feasibility learning curve was reached after 30–45 robotic pancreatoduodenectomy procedures and the proficiency learning curve after 90 robotic pancreatoduodenectomy procedures. These inflection points created 3 phases, which were associated with major morbidity (24.7%, 23.4%, and 12.3%, $P < .001$) but not 30-day mortality (2.1%, 2.0%, and 1.5%, $P = .670$). Other outcomes mostly continued to improve, including median operative time 432, 390, and 300 minutes ($P < .0001$), conversion 6.0%, 4.7%, and 2.7% ($P = .002$), bile leakage 7.2%, 4.1%, and 2.4% ($P < .001$), postpancreatectomy hemorrhage 6.5%, 6.1%, and 1.8% ($n = 21$) but not R0 resection (pancreatic ductal adenocarcinoma only) 78.5%, 73.9%, and 82.8% ($P = .35$), and 90-day mortality rate 3.1%, 3.5%, and 2.1% ($P = .191$). Centers performing >20 robotic pancreatoduodenectomies annually had lower rates of conversion, reoperation, and shorter median operative time as compared with centers performing 10–20 robotic pancreatoduodenectomies annually.

Conclusion: This international multicenter study demonstrates that most outcomes of robotic pancreatoduodenectomy continued to improve during 3 learning curve phases without a negative effect on 90-day mortality. Randomized studies are needed in high-volume centers that have surpassed the first learning curves, to compare these outcomes with the open approach.

Introduction

In recent years, operative mortality after pancreatoduodenectomy has improved through centralization and specialization,[1,2] but the rates of postoperative morbidity remain high. Minimally invasive pancreatoduodenectomy aims to minimize the impact of surgery. While 4 randomized trials have reported promising yet somewhat conflicting results when comparing laparoscopic pancreatoduodenectomy with open pancreatoduodenectomy,[3–6] no randomized trials are available for robotic pancreatoduodenectomy (RPD).[7] RPD may overcome some of the difficulties encountered during laparoscopic surgery because of the ability of wrist movements, improved 3-dimensional vision, and scaling down of instrument movement.

Several experienced high-volume centers have described good surgical outcomes after RPD.[8–15] Some centers have even reported improved oncologic outcomes and lower risk of postoperative pancreatic fistula after RPD as compared with open pancreatoduodenectomy (OPD).[16,17] A minimum volume of 20 RPDs per year has been recommended by the recent evidence-based Miami guidelines, yet large studies assessing this new volume cut-off are lacking.[18] Outcomes and learning curves of RPD have not been described on an international level, and it is unclear to what extent the outcomes of RPD continue to improve with increasing experience.[8–13,19–23] Furthermore, most studies only report on the feasibility learning curve (based on intraoperative outcomes such as blood loss and operative time), without assessment of proficiency (based on postoperative outcomes such as postoperative pancreatic fistula [POPF] and major morbidity). Proficiency learning curves are arguably the most relevant from a clinical point of view as they provide the optimal outcomes for a procedure.[24]

To address this gap, we performed the first international multicenter study on RPD, with outcomes stratified by different learning phases. In addition, we aimed to provide risk factors for major morbidity, conversion, and postoperative pancreatic fistula and report on the effect of the Miami guidelines RPD volume criteria.

Methods

Patients and design

This international retrospective multicenter study was performed in centers collaborating within the International Consortium on Minimally Invasive Pancreatic Surgery, all of whom have a minimum annual volume of 10 RPD procedures.[18] Data from all consecutive patients after RPD (including conversions) performed from the first procedure until January 1, 2020, were collected from 18 centers in 8 countries, including 10 centers in Europe, 7 centers in Asia, and 1 center in South America. All centers that performed more than 10 procedures annually were contacted for the article. In the United States, we were not able to include centers because of issues with data-sharing agreements. All centers that were included in the article received robotic training and proctoring provided by the robot distributors previously. The International Consortium on Minimally Invasive Pancreatic Surgery is endorsed by the International Hepato-Pancreato-Biliary Association. Ethical approval for this study was waived by the regional Ethics Committee of Amsterdam UMC.

Definitions

Operative time was determined as the time between the first incision and closure of the last incision. Conversion was defined as an urgent or nonurgent switch to laparotomy to complete the procedure, other than specimen extraction.[25,26] Postoperative complications were scored and classified using the Clavien-Dindo classification of surgical complications and was defined as major morbidity with grade 3 or greater.[27] Body mass index (BMI) was calculated as weight in kg/m^2, with patients with a BMI greater than 25 kg/m^2 defined as having obesity. Patients aged older than 75 years were defined as elderly. The definitions of the International Study Group of Pancreatic Surgery and the International Study Group on Liver Surgery were used to score POPF, postpancreatectomy hemorrhage, chyle leakage, and bile leakage.[28–31] Only clinically relevant, grade B/C, complications were included in this study. Resection margins were categorized according to the

Royal College of Pathologists definition and classified into R0 (distance margin to tumor ≥1 mm), R1 (distance margin to tumor <1 mm), and R2 (macroscopically positive margin).[32] Postoperative complications requiring readmission and/or reoperation were recorded up to 90 days.

Data collection

Survey

A survey (Google Survey, Mountain View, CA) was sent to all participants, inquiring about current implementation of robot surgery, annual surgical volumes (both for robot and total volume), and standards of care at the participating institution. This information was used for descriptions of (contra)indications and in the analyses. Survey questions are presented in Supplementary Table S4.

Data collection

Postoperative outcomes of RPD were collected during hospital stay and up to 90 days. Each participating center appointed 1 local study coordinator, who was responsible for all communication with the central study coordinator.

Clinical outcomes

Collected baseline characteristics included sex, age, BMI, comorbidity, medical history, and American Society of Anesthesiologists physical status (ASA score). The primary endpoints of this study were operative time, blood loss, major morbidity, and postoperative pancreatic fistula. Intraoperative variables included portomesenteric venous involvement and conversion. Postoperative outcomes included length of hospital stay (day of surgery to discharge), bile leakage, postpancreatectomy hemorrhage, chyle leakage, readmission, reoperation, 30-day or in-hospital, and 90-day mortality. Furthermore, tumor size, rate of R0/1 resections, number of malignant lymph nodes, and total number of retrieved nodes were collected.

Learning phase groups

Outcomes were presented in learning phase groups based on learning curve inflection points identified with cumulative sum (CUSUM) analysis within this cohort. After this CUSUM analysis, the phases were divided as consecutive RPD procedures: 1–29, 30–89, and 90+.

Statistical analyses

Data were analyzed using IBM SPSS Statistics for Mac, version 28.0 (IBM Corp, Armonk, NY) or R's programming environment (version 1.4.1106; R Foundation for Statistical Computing, Vienna, Austria). Student *t*, Mann-Whitney *U*, χ^2, or Fisher exact tests were used as suitable. Categorical data were presented as proportions, and continuous data were presented as either mean and standard deviation or median and interquartile range (IQR) as applicable. Alpha was set at a *P* value <.05, and all analyses were 2-sided. Missing data were resolved by multiple imputation wherever appropriate. Regression analyses were performed using univariate and multivariate regression analyses for dichotomous variables.

Learning curve CUSUM analysis

Risk-adjusted (RA) CUSUM analyses assessed the feasibility learning curves for operative time and blood loss and the proficiency learning curve for major morbidity and POPF. All consecutive procedures from the 18 centers were included in the CUSUM analyses, corrected for annual volume and total volume, and using regression analysis.

For risk-adjusting, a regression analysis was performed and significant variables were included in the final model to adjust for pre-existing risk factors and therefore limit the influence of case selection on the analysis of the learning curve. First, a univariate analysis was performed, and significant variables ($P < .1$) were included in a multivariate analysis. Variables that remained significant in the multivariate analysis (on the basis of a 2-sided $P < .05$) were included in the risk-adjusted CUSUM analysis. The RA-CUSUM analysis could include all procedures since all consecutive procedures starting from the first procedure were collected and the CUSUM analyses were corrected for center total experience and annual volume. For binary outcomes (major morbidity and POPF), a logistic regression model was fitted. For continuous data (operative time and blood loss), a linear regression model was fitted and these variables were standardized. The differences between the observed minus the expected outcome values were cumulated. The case-consecutively ranked cumulated differences were plotted on the y-axis, and the consecutive cases were plotted on the x-axis, ranked from the first-to last consecutive case per center.

These RA-CUSUM graphs were used to identify inflection points corresponding to a representable overall learning curve. When interpreting the CUSUM graph, "slope" is the informative part, wherein an uphill slope indicates an outcome above average and a downhill slope indicates an outcome below average. Vertical lines located in the turning point (defined as inflection point) of the curvature indicate the point at which a center transitions from one phase to another and overcomes the specific learning curve. However, the effect of centers on the learning curve was only up to their total number of inclusions. Thus, at case number 50, the total learning curve was affected by centers that included >50 procedures only, and, at case number 100, the total learning curve was affected by centers that included >99 procedures only, etc.

The identified inflection points for the feasibility and proficiency learning curves were used as cut-off points for defining learning phases to compare operative outcomes. These 2 inflection points created 3 groups.

Regression analysis

Preoperative risk factors were determined for conversion, postoperative pancreatic fistula, and major morbidity. Univariate and multivariate regression analyses were performed to identify significant risk factors.

Results

Center and patient characteristics

Overall, 2,186 patients after RPD were included, including 608 patients from Europe, 1,548 patients from Asia, and 30 patients from South America. The total center RPD volume ranged from 15 to 197 for European centers and from 28 to 481 for non-European centers. The Miami guidelines volume advice per center of at least 20 RPD procedures annually was met by 12 of 18 (67%) centers. The remaining 6 centers all performed at least 10 RPD procedures per year. The median age was 63 years [IQR 55–71], and median BMI was 23.7 [IQR 21.6–25.8]. Most patients had ASA score 2 ($n = 1,260$, 57.6%). Patient baseline characteristics are presented in Table I and stratified on the basis of learning phases in Supplementary Table S2. The total number of procedures included per center is presented in Supplementary Table S3. For each center, 1 dedicated HPB team, specialized in RPD procedures, is responsible for all consecutive procedures per center. These teams consisted of

Table I
Patient baseline characteristics

Characteristics	$n = 2,186$
Age, yr, median [IQR]	63 [55.0–71.0]
Age $\geq$75 yr, n (%)	305 (14.0)
BMI kg/m^2, median [IQR]	23.7 [21.6–25.8]
BMI $\geq$25 kg/m^2, *n* (%)	731 (33.4)
Female, *n* (%)	1,074 (49.1)
Any comorbidity, *n* (%)	1,065 (48.7)
Cardiovascular disease	440 (20.1)
Pulmonary disease	118 (5.4)
Diabetes	416 (19.0)
Malignant comorbidity	181 (8.3)
Neurologic disease	77 (3.5)
ASA physical status, *n* (%)	
1	482 (22)
2	1,260 (57.6)
3	409 (18.7)
4	15 (0.7)
Previous open abdominal surgery, *n* (%)	227 (10.4)
Previous laparoscopic abdominal surgery, *n* (%)	179 (8.2)
Neoadjuvant chemo(radio)therapy, *n* (%)	37 (1.7)

ASA, American Society of Anesthesiologists; *BMI*, body mass index; *IQR*, interquartile range.

2 surgeons per center in 13 centers and 3–4 surgeons in 5 centers. The operating room team in each center is additionally trained to support robotic procedures and handle all robotic materials.

Survey

The number of surgeons performing RPD procedures per center ranged from 1 to 4, meaning 1 team is responsible for the learning curve per center. Most centers (13/18, 72%) performed RPD procedures with 2 surgeons (a "console surgeon" and a "tableside surgeon"). We would like to emphasize that 1 team per center has performed all procedures included in this study, and the number of surgeons per team per center ranged from 2 surgeons in 13 centers and 3–4 surgeons for 5 centers. Indications for RPD were largely similar as for OPD, with the exception of vascular invasion in the beginning of the learning curve.

Relative contraindications for RPD included previous abdominal surgery that prohibits minimal invasive surgery and for some centers an inappropriate general condition that hinders an extended period of pneumoperitoneum. Chronic pancreatitis, central obesity, and BMI greater than 35 kg/m^2 were considered as a relative contraindication, although centers report that such patients could be considered eligible with increasing experience.

Learning curve based on CUSUM analyses

Missing data

For the risk-adjusted CUSUM analyses, we imputed missing data for BMI (1.1%, $n = 25$) and ASA score (0.9%, $n = 20$).

Feasibility learning curve

The RA-CUSUM analysis of operative time revealed a decrease of the operative time after 30 RPD procedures (Figure 1). This was confirmed when comparing the learning phases, showing a significant decrease in operative time ($P < .001$).

A reduction of intraoperative blood loss was identified after 45 RPD procedures (Figure 1). This was confirmed when comparing the learning phases, showing a significant decrease in blood loss ($P < .001$).

We then used these cutoffs to determine the effect of the first inflection point (30 RPD procedures) of the feasibility learning curve on the rate of POPF (16.2% before vs 13.8% after 30 procedures, $P = .188$) and for major morbidity (24.8% before vs 15.7% after 30 procedures, $P < .001$). The 30-day or in-hospital mortality rate (2.0% before vs 1.6% after 30 procedures, $P = .541$) did not significantly differ before and after the feasibility inflection point.

Proficiency learning curve

The RA-CUSUM analysis of major morbidity showed an improvement after 93 RPD procedures (Figure 2). This was confirmed when comparing the rate of major morbidity before and after this inflection point (24.2 vs 12.2%, $P < .001$).

The learning curve of POPF showed a decreasing trend after 90 procedures (Figure 2). The improvement was confirmed when comparing the rate of POPF before and after this inflection point (17.7 vs 11.4%, $P < .001$).

The 30-day or in-hospital mortality rate (2.0% before vs 1.5% after 90 procedures, $P = .393$) and the 90-day mortality rate (3.3 vs 2.1%, $P = .085$) did not significantly differ on the basis of the proficiency inflection point.

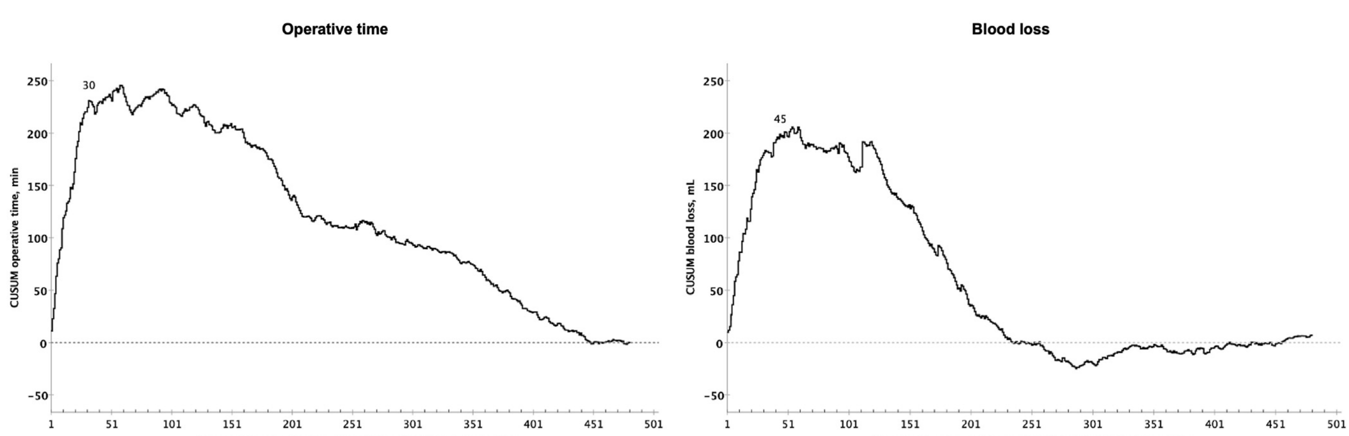

Figure 1. Feasibility learning curve for robotic pancreatoduodenectomy. The x-axis indicates consecutive cases of all centers. The y-axis indicates the CUSUM analysis for operative time and blood loss. The first label ($n = 30$ for operative time and $n = 45$ for blood loss) indicates the highest inflection point of the learning curve, whereafter, a gradual downward slope and stabilization of the learning curve occurs. Number of centers contributing to the learning curve: 1–29 procedures, $n = 18$; 30–89 procedures, $n = 13$; and 90+ procedures, $n = 5$. *CUSUM*, cumulative sum.

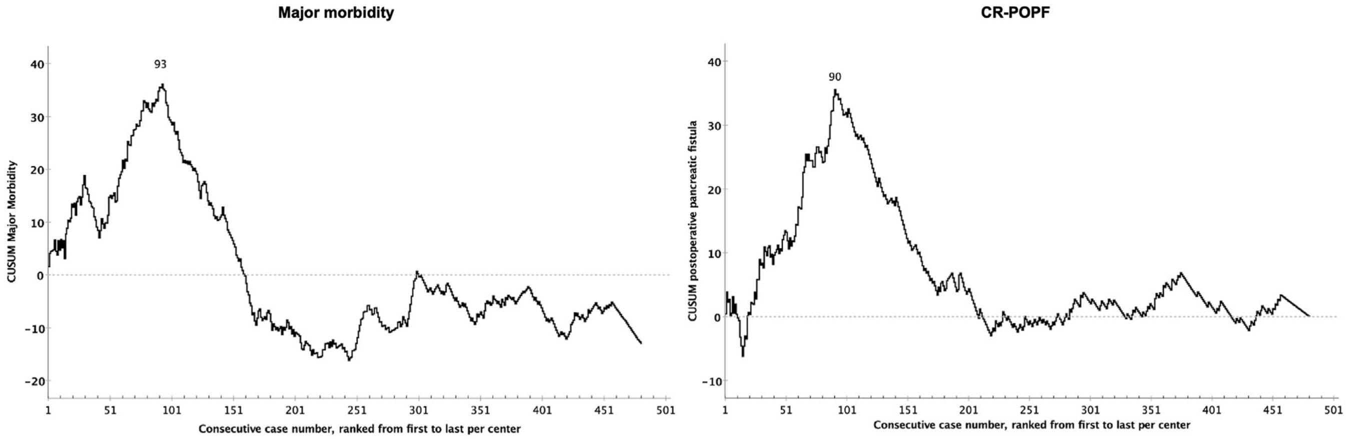

Figure 2. Proficiency learning curve for robotic pancreatoduodenectomy. The x-axis indicates consecutive cases of all centers. The y-axis indicates the CUSUM analysis for major morbidity and CR-POPF. The first label (n = 93 for major morbidity and n = 90 for CR-POPF) indicates the highest inflection point of the learning curve, whereafter, a steep downward slope and stabilization of the learning curve occurs. Number of centers contributing to the learning curve: 1–29 procedures, n = 18; 30–89 procedures, n = 13; and 90+ procedures, n = 5. *CR-POPF*, clinically relevant-POPF; *CUSUM*, cumulative sum.

Intraoperative outcome

Table II provides an overview of clinical outcomes in the 3 learning phases. The median operative time continued to improve during the 3 phases, 432 minutes [IQR 360–515], 390 minutes [IQR 320–468], and 300 minutes [IQR 245–410] (P < .001), as did median blood loss with 215 mL [IQR 109–477], 200 mL [IQR 100–400], and 200 mL [IQR 100–300] (P < .001) and the conversion rate with 6.0% (n = 29), 4.7% (n = 24), and 2.7% (n = 32) (P = .002). The R0-resection rate in patients with pancreatic ductal adenocarcinoma (PDAC) was 78.5% (n = 179), 73.9% (n = 130), and 82.8% (n = 391) (P = .035), respectively.

Postoperative outcome

Postoperative outcomes are presented in Table II. The rates of postoperative pancreatic fistula were 16.0% (n = 78), 18.9% (n = 96), and 11.6% (n = 138) (P < .001); bile leakage, 7.2% (n = 35), 4.1% (n = 21), and 2.4% (n = 28) (P < .001); chyle leakage, 1.4% (n = 7), 2.4% (n = 12), and 4.2% (n = 50) (P = .007); postpancreatectomy hemorrhage, 6.5% (n = 32), 6.1% (n = 31), and 1.8% (n = 21) (P < .001); and reoperation, 7.6% (n = 37), 5.7% (n = 29), and 2.1% (n = 25) (P < .001). The reduction in 30-day/in-hospital mortality was not statistically significant, with 2.1% (n = 10), 2.0% (n = 10), and 1.5% (P = .67), as was the 90-day mortality rate with 3.1% (n = 15), 3.5% (n = 18), and 2.1% (n = 25) (P = .191).

Risk factors for complications

Conversion

Logistic regression analysis revealed the following risk factors for conversion: increasing tumor size, portomesenteric venous involvement, and PDAC/pancreatitis as histopathologic diagnosis (Table III).

Table II
Outcomes of RPD in 3 learning curve phases

Intra- and postoperative outcomes	1–29 RPD procedures (n = 486)	30–89 RPD procedures (n = 509)	90+ RPD procedures (max. 450) (n = 1191)	P value
Operative time, min, median [IQR]	432 [360–515]	390 [320–468]	300 [245–410]	<.001
Blood loss, mL, median [IQR]	215 [109–477]	200 [100–400]	200 [100–300]	<.001
Conversion, n (%)	29 (6.0)	24 (4.7)	32 (2.7)	.002
Reason bleeding	7 (1.4)	2 (0.4)	7 (0.6)	.219
Reason vascular involvement	9 (1.9)	8 (1.6)	14 (1.2)	.868
Reason adhesions	2 (0.4)	3 (0.6)	8 (0.7)	.624
Reason tumor advancement	2 (0.4)	4 (0.8)	2 (0.2)	.209
Reason insufficient overview	3 (0.6)	1 (0.2)	3 (0.3)	.565
Reason technical reason	3 (0.6)	1 (0.2)	1 (0.1)	.204
Reason other	2 (0.4)	0 (0.0)	2 (0.2)	.394
Postoperative pancreatic fistula (grade B/C), n (%)	78 (16.0)	96 (18.9)	138 (11.6)	<.001
Bile leakage (grade B/C), n (%)	35 (7.2)	21 (4.1)	28 (2.4)	<.001
Postpancreatectomy hemorrhage (grade B/C), n (%)	32 (6.5)	31 (6.1)	21 (1.8)	<.001
Chyle leakage (grade B/C), n (%)	7 (1.4)	12 (2.4)	50 (4.2)	.007
Clavien-Dindo complication grade ≥3, n (%)	120 (24.7)	119 (23.4)	147 (12.3)	<.001
Length of hospital stay, d, median [IQR]	16 [10–24]	16 [10–24]	17 [13–24]	.002
Readmission within 30 d, n (%)	52 (10.7)	38 (7.5)	28 (2.4)	<.001
Reoperation, n (%)	37 (7.6)	29 (5.7)	25 (2.1)	<.001
30-d or in-hospital mortality, n (%)	10 (2.1)	10 (2.0)	18 (1.5)	.670
90-d mortality, n (%)	15 (3.1)	18 (3.5)	25 (2.1)	.191
Oncologic outcomes for PDAC (n = 876)				
Lymph node harvest, median [IQR]	15 [10–21]	14 [8–19]	16 [10–22]	.028
Involved nodes, median [IQR]	1 [0–4]	2 [0–5]	0 [0–2]	<.001
R0 resection, n (%)	179 (78.5)	130 (73.9)	391 (82.8)	.035

IQR, interquartile range; *PDAC*, pancreatic ductal adenocarcinoma; *RPD*, robotic pancreatoduodenectomy.

Table III
Risk factors for conversion, POPF B/C, and major morbidity

Variable	Conversion, *n* (%)	Odds ratio (95% CI)	*P* value
Tumor size, cm			
<2	13 (1.8%)	1 [Reference]	
2–4	42 (4.5%)	1.97 [1.03–3.77]	.040
>4	18 (5.8%)	3.09 [1.45–6.60]	.003
Portomesenteric venous involvement			
No	61 (3.1%)	1 [Reference]	
Yes	22 (13.3%)	4.48 [2.47–8.12]	<.001
BMI >25 kg/m^2			
No	48 (3.3%)	1 [Reference]	
Yes	37 (5.1%)	1.48 [0.91–2.43]	.120
PDAC/pancreatitis			
Other histologic diagnoses	25 (2.0%)	1 [Reference]	
PDAC/pancreatitis	60 (6.4%)	2.643 [1.53–4.56]	<.001
Age >75 yr			
No	66 (3.5%)	1 [Reference]	
Yes	19 (6.2%)	1.77 [0.99–3.18]	.056
Variable	**POPF B/C, *n* (%)**	**Odds Ratio (95% CI)**	***P* value**
Pancreatic duct diameter			
>5 mm	27 (6.0%)	1 [Reference]	
<5 mm	174 (16.7%)	12.13 [1.62–91.03]	.015
PDAC/pancreatitis			
PDAC/pancreatitis	118 (12.6%)	1 [Reference]	
Other histologic diagnoses	193 (15.4%)	1.43 [1.02–2.0]	.039
Age >75 yr			
No	256 (13.6%)	1 [Reference]	
Yes	55 (18.0%)	1.6 [1.07–2.4]	.022
Sex			
Female	118 (11.0%)	1 [Reference]	
Male	189 (17.1%)	1.99 [1.43–2.77]	<.001
BMI >25 kg/m^2			
No	162 (11.1%)	1 [Reference]	
Yes	149 (20.4%)	1.84 [1.35–2.52]	<.001
Variable	**Major morbidity, *n* (%)**	**Odds Ratio (95% CI)**	***P* value**
Pancreatic duct diameter, mm			
>5	59 (13.0%)	1 [Reference]	
<5	211 (20.3%)	1.69 [1.23–2.33]	.001
Age >75 yr			
No	311 (16.5%)	1 [Reference]	
Yes	75 (24.6%)	1.54 [1.09–2.17]	.013
Sex			
Female	157 (14.6%)	1 [Reference]	
Male	221 (20.0%)	1.62 [1.22–2.14]	<.001
BMI >25 kg/m^2			
No	231 (15.9%)	1 [Reference]	
Yes	155 (21.2%)	1.28 [0.97–1.69]	.081
Previous abdominal surgery			
No	265 (16.2%)	1 [Reference]	
Yes	75 (19.6%)	1.25 [0.91–1.73]	.175

BMI, body mass index; *CI*, confidence interval; *IQR*, interquartile range; *PDAC*, pancreatic ductal adenocarcinoma; *POPF B/C*, postoperative pancreatic fistula grade B/C.

Postoperative pancreatic fistula

Logistic regression analysis revealed the following risk factors for postoperative pancreatic fistula: pancreatic duct <5 mm, other histologic diagnosis than PDAC/pancreatitis, age older than 75 years, male sex, and BMI greater than 25 kg/m^2 (Table III).

Major morbidity

Logistic regression analysis revealed the following risk factors for major morbidity: main pancreatic duct size below 5 mm, age older than 75 years, and male sex (Table III).

Miami guidelines volume advice

Outcomes were compared for centers on the basis of the Miami guidelines annual volume advice of at least 20 RPD procedures per center,[18] high-volume centers compared with centers with an annual volume of 10–19 procedures (medium-volume). The rates of conversion (3.3% vs 8.9%, $P < .001$), reoperation (3.6% vs 8.5%, $P < .001$), and median operative time (354.5 minutes [IQR 280–450] vs 415 minutes [IQR 302–525], $P < .001$) were lower in the high-volume centers. Other outcomes including major morbidity, postoperative pancreatic fistula, bile leakage, readmission, 30-day/in-hospital mortality, and 90-day mortality did not significantly differ between these groups (Supplementary Table S1).

Discussion

This first international multicenter study on experience stratified outcomes of RPD showed good clinical outcomes, which continued to improve in the 3 learning phases (cutoffs at 30 and 90 consecutive procedures based on the inflection points). The improvements included major morbidity, operative time, blood loss, conversion, readmission, and reoperation rate without significant differences in mortality. Centers meeting the Miami guidelines annual volume criteria had lower rates of conversion and reoperation and a shorter operative time, without affecting mortality, as compared with centers with an annual volume of 10–19 RPD procedures.

Outcomes of laparoscopic pancreatoduodenectomy were good in 3 randomized trials, all performing in experienced centers from India, Spain, and China.[3,4,6] However, 1 Dutch multicenter trial performed early in the learning curve was terminated because of safety concerns.[5] RPD is a relatively new technique[33] and both patients, surgeons, and centers that want to engage with this approach deserve reliable data, especially from a safety perspective. Since the robotic approach is now getting momentum and many centers have an experience beyond 100 procedures, it is important to show how and to what point outcomes will improve with growing experience compared with the early experience. This also allows us to determine the effect of a training program, skills development, acquired experience, and possible modification of techniques and postoperative management on surgical outcomes over time. This study collected all consecutive procedures starting from the first one, so the outcomes could be analyzed and set out in the learning phases over time.

From a United States perspective, hospital stay was relatively long in this series and did not improve over the phases of experience (16, 16, and 17 days). In the Pittsburgh series, median hospital stay was 8 days.[34] However, this hospital stay does not differ that much from the hospital stay reported by the GAPASURG consortium, wherein the hospital stay in European audits ranged from 11 to 16 days.[35] The final answer on the effect of RPD on hospital stay and other outcomes will have to come from randomized trials in centers that have surpassed all learning curves. Herein, to objectify the length of stay for international centers with different discharge protocols, "time to functional recovery" can be used as an endpoint, as was done in previous randomized trials.[36–38] Randomized trials on RPD have not yet been published, although recently the EUROPA trial was completed in Heidelberg and the international DIPLOMA-2 trial of the E-MIPS consortium and the PORTAL trial in China are ongoing.[39–42]

It is unclear how the rates of postoperative pancreatic fistula compare after RPD and OPD. In all 4 randomized trials comparing laparoscopic to open pancreatoduodenectomy, the rate of postoperative pancreatic fistula was not greater after the laparoscopic approach.[3,4,6,40] Notably, a single-center propensity-matched analysis from the highly experienced Pittsburgh group even reported a lower rate of postoperative pancreatic fistula after RPD as compared with OPD.[16] In their largest single-center Western series of 500 RPD procedures, the rate of postoperative pancreatic fistula was 7.8%, major morbidity 24.8%, conversion 5.2%, and 30-day mortality 1.4%.[8] These results are largely comparable with those reported in the current study, especially when looking at the last learning phase group (11.6%, 12.3%, 2.7%, and 1.5%, respectively).

A safe introduction of RPD is obviously essential.[43] Several studies from the Pittsburgh group have confirmed that surgical training in RPD is feasible and associated with good outcomes.[22,44–46] On the basis of this experience, the multicenter Dutch LAELAPS-3 training program was designed and reported good outcomes with an improvement of operative time after 22 RPD procedures. Moreover, no negative effect of the learning curve was noted, highlighting the merits of such an approach.[23]

Determining outcomes stratified by learning phases can help centers identify phases where extra caution is required and when selection criteria (eg, vascular involvement and BMI >35 kg/m^2) may be extended and new surgeons can be trained. Previous single-center studies and 1 systematic review found 3 learning curve cutoff points at 25, 100, and 240 procedures.[13,34,47] These were similar to the learning curve cutoff points based on this first international series; here, respectively, at 30 and 90 procedures. The survey performed in the present study confirms well-known (relative) contraindications for RPD, namely, previous extensive abdominal surgery, history of chronic pancreatitis, central obesity, and vascular resections in the beginning of the learning curve.[48,49] Two studies have suggested that robotic vascular resections are safe when performed in highly experienced centers by surgeons who have surpassed the RPD proficiency/mastery learning curve.[49,50]

The present study further validates the recommendation of the Miami guidelines to perform at least 20 RPDs per year (12/18 centers) for conversion and reoperation rates although no difference in 30-day or in-hospital mortality and other outcomes was seen versus centers with an annual volume of 10–19 procedures (6/18 centers) (Supplementary Table S1). Since none of the participating centers performed fewer than 10 RPD procedures, no conclusion can be drawn for this subgroup, and this may also explain the absence of an effect on morbidity and mortality. The importance of centralization and annual volume was also confirmed by a multicenter study from the United States, in which the authors found a lower mortality after RPD in academic centers (overall annual RPD volume above 20) as compared with nonacademic centers (volume overall lower than 5) (1.8% vs 6.7%, $P = .013$).[51] Future studies should elaborate on postoperative management of patients since this strongly influences morbidity and mortality.[52]

Study limitations

The results of this study should be interpreted in light of some limitations. First, the retrospective nature of this study provides inherent limitations such as selection bias. Yet, selection for RPD is actually highly recommended in clinical practice, for which the survey objectified the selection criteria used for RPD. Second, data were collected using standardized databases based on a registry database per center and consequently limited details were available. It would be interesting to assess the effect of differences in surgical techniques (eg, anastomotic technique) and drain and fistula management strategies compared with outcomes. However, these data were not available. Data on pancreatic texture and exact pancreatic duct size were also not available. These outcomes are used to predict postoperative pancreatic fistula, and the International Study Group of Pancreatic Surgery recommends to report this for better comparability of results.[53] Third, data on previous experience in laparoscopic and robotic surgeries were not obtained. Since previous experience may influence the learning curve of a surgeon, future studies should aim to take these data into account.

The main strength of this study is that it reports on a large dataset from 18 centers in 8 countries from 3 continents. Exchanging knowledge and collaboration is key, and the use of online lectures and videos as well as on-site training programs can speed up the learning phases.[47]

In conclusion, this first multicenter international study on RPD reported good outcomes in high-volume centers, identifying a feasibility inflection point at 30–45 procedures and a proficiency inflection point at 90 procedures. This study provides the reference points for international outcomes and the feasibility and proficiency learning curves, which could be used as minimum requirements for centers to participate in future randomized trials. Future studies should focus on the implementation and impact of high-quality training programs to shorten the learning curve (such as is being done in the European LEARNBOT training program for RPD), for which this study can function as a baseline. Hereafter, randomized trials should compare outcomes of RPD and OPD in centers who have surpassed the learning curves (such as is being done in the PORTAL and DIPLOMA-2 trials). Lastly, centers should aim to use the outcomes in the study as a reference for their learning phases.

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Conflict of Interest/Disclosure

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CRediT authorship contribution statement

Leia R. Jones: Conceptualization, Data curation, Formal analysis, Writing – original draft, Writing – review & editing. **Maurice J.W. Zwart:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Formal analysis. **Nine de Graaf:** Conceptualization, Writing – original draft, Writing – review & editing. **Kongyuan Wei:** Writing – review & editing, Data curation, Project administration. **Liu Qu:** Data curation, Project administration, Writing – review & editing. **Jin Jiabin:** Data curation, Project administration, Writing – review & editing. **Fu Ningzhen:** Data curation, Project administration, Writing – review & editing. **Shin-E Wang:** Data curation, Project administration, Writing – review & editing. **Hongbeom Kim:** Data curation, Project administration, Writing – review & editing. **Emanuele F. Kauffmann:** Data curation, Project administration, Writing – review & editing. **Roeland F. de Wilde:** Data curation, Project administration, Writing – review & editing. **I. Quintus Molenaar:** Data curation, Project administration, Writing – review & editing. **Ying Jui Chao:** Data curation, Project administration, Writing – review & editing. **Luca Moraldi:** Data curation, Project administration, Writing – review & editing. **Olivier Saint-Marc:** Data curation, Project administration, Writing – review & editing. **Felix Nickel:** Data curation, Project administration, Writing – review & editing. **Cheng-Ming Peng:** Data curation, Project administration, Writing – review & editing. **Chang Moo Kang:** Data curation, Project administration, Writing – review & editing. **Marcel Machado:** Data curation, Project administration, Writing – review & editing. **Misha D.P. Luyer:** Data curation, Project administration, Writing – review & editing. **Daan J. Lips:** Data curation, Project administration, Writing – review & editing. **Bert A. Bonsing:** Data curation, Project administration, Writing – review & editing. **Thilo Hackert:** Data curation, Project administration, Writing – review & editing. **Yan-Shen Shan:** Data curation, Project administration, Writing – review & editing. **Bas Groot Koerkamp:** Data curation, Project administration, Writing – review & editing. **Yi-Ming Shyr:** Data curation, Project administration, Writing – review & editing. **Baiyong Shen:** Data curation, Project administration, Writing – review & editing. **Ugo Boggi:** Data curation, Project administration, Writing – review & editing, Conceptualization. **Rong Liu:** Data curation, Project administration, Writing – review & editing, Conceptualization. **Jin-Young Jang:** Data curation, Project administration, Writing – review & editing, Conceptualization. **Marc G. Besselink:** Data curation, Project administration, Writing – review & editing, Conceptualization, Methodology. **Mohammad Abu Hilal:** Conceptualization, Data curation, Project administration, Writing – review & editing.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [https://doi.org/10.1016/j.surg.2024.05.044].

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