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The PD-ROBOSCORE: A difficulty score for robotic pancreatoduodenectomy

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ABSTRACT

Background: Difficulty scoring systems are important for the safe, stepwise implementation of new procedures. We designed a retrospective observational study for building a difficulty score for robotic pancreatoduodenectomy.

Methods: The difficulty score (PD-ROBOSCORE) aims at predicting severe postoperative complications after robotic pancreatoduodenectomy. The PD-ROBOSCORE was developed in a training cohort of 198 robotic pancreatoduodenectomies and was validated in an international multicenter cohort of 686 robotic pancreatoduodenectomies. Finally, all centers tested the model during the early learning curve ($n = 300$). Growing difficulty levels (low, intermediate, high) were defined using cut-off values set at the 33rd and 66th percentile (NCT04662346).

Results: Factors included in the final multivariate model were a body mass index of $\geq$25 kg/m^2 for males and $\geq$30 kg/m^2 for females (odds ratio:2.39; $P < .0001$), borderline resectable tumor (odd ratio:1.98; $P < .0001$), uncinate process tumor (odds ratio:1.69; $P < .0001$), pancreatic duct size <4 mm (odds ratio:1.59; $P < .0001$), American Society of Anesthesiologists class $\geq$3 (odds ratio:1.59; $P < .0001$), and hepatic artery originating from the superior mesenteric artery (odds ratio:1.43; $P < .0001$). In the training cohort, the absolute score value (odds ratio = 1.13; $P = .0089$) and difficulty groups (odds ratio = 2.35; $P = .041$) predicted severe postoperative complications. In the multicenter validation cohort, the absolute score value predicted severe postoperative complications (odds ratio = 1.16, $P < .001$), whereas the difficulty groups did not (odds ratio = 1.94, $P = .082$). In the learning curve cohort, both absolute score value (odds ratio:1.078, $P = .04$) and difficulty groups (odds ratio: 2.25, $P = .017$) predicted severe postoperative

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complications. Across all cohorts, a PD-ROBOSCORE of ≥12.51 doubled the risk of severe postoperative complications. The PD-ROBOSCORE score also predicted operative time, estimated blood loss, and vein resection. The PD-ROBOSCORE predicted postoperative pancreatic fistula, delayed gastric emptying, postpancreatectomy hemorrhage, and postoperative mortality in the learning curve cohort.
Conclusion: The PD-ROBOSCORE predicts severe postoperative complications after robotic pancreatoduodenectomy. The score is readily available via www.pancreascalculator.com

Introduction

Robotic pancreatoduodenectomy (RPD) is gaining momentum.[1] Several pioneer centers have shown that once proficiency is achieved,[2,3] specific outcomes may be superior to open pancreatoduodenectomy (PD).[4–6] Although randomized trials are needed to confirm these results, the growing number of centers willing to start a new program prompts the surgical community to provide a clear pathway for the safe implementation of RPD on a large scale.[7] This undertaking is complicated by the fact that PD is not a uniform procedure due to anatomic variations in liver supply and branching pattern of superior mesenteric vessels,[8] the need to tailor the amount of retroperitoneal dissection based on disease and/or tumor type,[9] variability in digestive reconstruction techniques,[10] and different levels of technical difficulty.[11,12] Minimally invasive PD is associated with additional technical challenges that may sometimes result in major intraoperative adverse events requiring emergency conversion[13] and potentially increasing the risk of death.[14,15]

The experience of the Pittsburgh group[16] and the LAELAPS-3 training program in the Netherlands[17] have shown that structured training programs permit safe implementation of RPD and reduce the learning curve for new adopters. What is currently missing is a reliable difficulty score permitting a safe selection of patients suitable for a robotic approach.[18,19]

The only available difficulty score for RPD was a small, single-center study without external validation.[20] Also, in open PD, there is just 1 difficulty score, developed in 99 procedures without external validation.[12]

We herein provide a new difficulty score for RPD, the PD-ROBOSCORE, developed within the International Consortium on Minimally Invasive Pancreatic Surgery (I-MIPS) (www.i-mips.com).

Methods

This is a retrospective observational cohort study on 1,184 RPDs performed at 9 I-MIPS centers between 2008 and 2020. Data on RPDs were provided by Pisa University Hospital (Pisa, Italy), Catharina Hospital Eindhoven (Eindhoven, The Netherlands), Centre Hospitalier Orleans (Orleans, France), Erasmus MC University Medical Center (Rotterdam, The Netherlands), Medisch Spectrum Twente (Enschede, The Netherlands), National Cheng Kung University Hospital (Tainan, Taiwan), Ruijin Hospital (Shanghai, China), Seoul National University College of Medicine (Seoul, South Korea), and University Hospital of Heidelberg (Heidelberg, Germany). The score was designed based on the Pisa RPD cohort and was validated using an international multicenter cohort. All I-MIPS centers contributed to the learning curve cohort. At each center, data were prospectively entered into an institutional database and were retrieved retrospectively for the purpose of this study.

The study was submitted to the steering committee of I-MIPS by the Pisa group and was cleared on June 2, 2020. The Institutional Review Board of the University of Pisa (CEAVNO—Difficulty Risk Score Robotic PD) provided ethical approval on July 14, 2020, and the study was registered at ClinicalTrials.gov (NCT04662346) on December 10, 2020.

Data were collected and analyzed according to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for observational studies.[21]

Study design

The difficulty score (PD-ROBOSCORE) aims at predicting severe postoperative complications after RPD, defined as grade ≥III according to the Clavien-Dindo classification.[22] The score was constructed based on international experts' opinions, developed and tested in a training cohort, and validated in a collaborative I-MIPS cohort. The first 37 consecutive RPDs performed at each center were excluded from training and validation cohorts to avoid interference from learning curves. The cut-off of 37 procedures was chosen based on 2 recently published systematic reviews.[23,24] Score performance was also tested in the cumulative group of RPDs performed during the learning curve (learning curve cohort).

The senior authors (M.B., M.A.H., U.B.) defined the initial list of factors possibly predicting a difficult RPD. They identified a group of 30 international experts from 12 countries based on surgical experience and contributions to literature in this field (ie, Belgium, China, France, Germany, Ireland, Italy, the Netherlands, Russia, South Korea, Spain, Taiwan, USA) (see list of collaborators). Candidate variables of technical difficulty in RPD were defined based on data from the literature and authors' experience. The final list of 29 predictors was defined and agreed upon according to the feedback received from the expert group before a survey was sent for voting (Microsoft Forms, Microsoft Corporation, Redmond, WA). Scores were assigned based on a 5-point scale (1: low difficulty to 5: high difficulty) (Supplementary Table S1).

Parameters with an average score of ≥3 were used to construct the difficulty score. First, the cumulative burden of risk factors was calculated by summing the individual values identified for each patient in the training cohort. Next, a difficulty score formula was developed and tested in the training cohort. The RPDs were classified into growing levels of difficulty (low, intermediate, high) based on cut-off values at the 33rd and the 66th percentiles. Finally, the difficulty score was validated in the external I-MIPS cohort. Figure 1 presents the flow diagram for the study.

Eligibility criteria

All patients undergoing RPD at recruiting institutions during the study period were enrolled in this study based on an intention-to-treat analysis.

Outcome measures

The incidence of severe postoperative complications was the main outcome measure in this study. Postoperative complications were assessed at 30 days and were defined and graded according to the Clavien-Dindo classification.[22] Pancreas-specific complications (ie, postoperative pancreatic fistula, delayed gastric emptying,

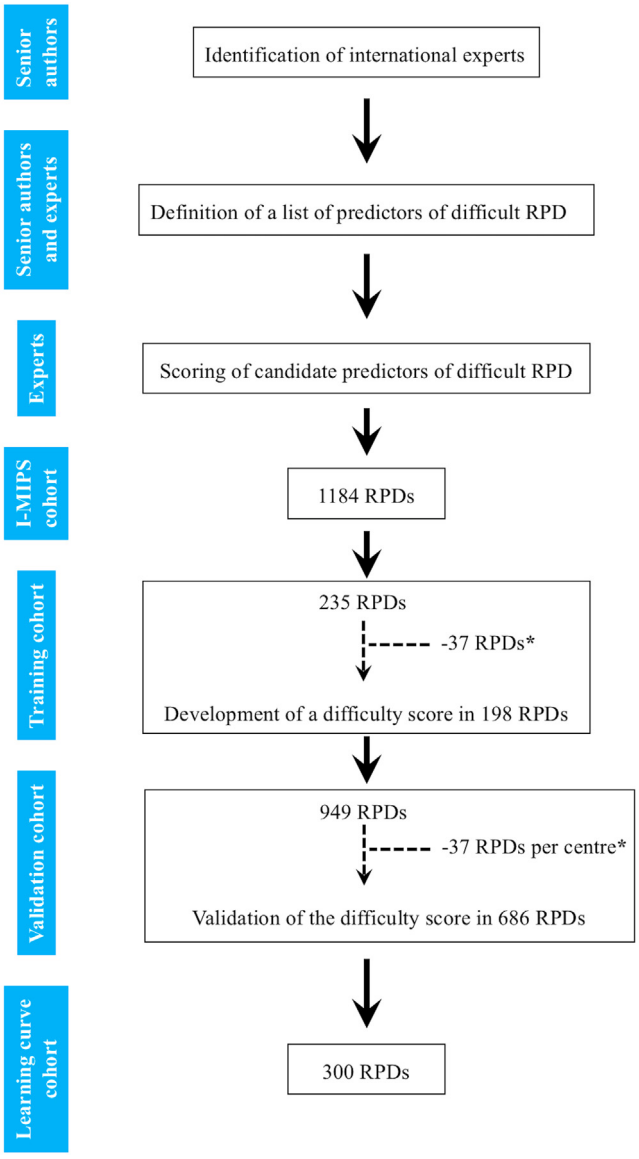

Figure 1. Study flow diagram. *RPD*, robotic pancreatoduodenectomy. *Procedures performed during the learning curve.

postpancreatectomy hemorrhage, chyle leak) were assessed according to the definitions proposed by the international study group of pancreatic surgery.[25–27] Bile leakage was defined and graded according to the international study group of liver surgery.[28,29] Only clinically relevant complications (grade B/C) were included.

Statistical analysis and difficulty score building

The categorical variables are summarized as frequencies, percentages, and rates. Continuous variables are expressed as mean ± SD if normally distributed or as median and IQR if not. Kolmogorov-Smirnov test was used to assess normality distribution.

Difficulty score building started by calculating the average values of the scores received from experts. Factors receiving an average score of ≥3 were used to define a patient-specific cumulative score obtained by summing the single values (hypothetical difficulty score). The correlation between each predictive factor and the hypothetical difficulty score was defined using Spearman's (ρ) rank correlation coefficient. Then, a multivariate linear regression model based on the ordinary least squares method was built using factors with significant Spearman's ρ as dependent variables and the hypothetical difficulty score as the independent variable. Only factors with the highest false discovery rate logworth were included in the final model. Then, we developed a prediction formula using the ß-coefficients of statistically significant factors included in the final model as coefficients of difficulty. The model's multicollinearity was assessed using the correlation matrix and the variance inflation factors. The sensitivity analysis for unobserved confounding was performed using Rpackage *sensemakr* (R Foundation of Statistical Computing, Vienna, Austria). The model's validity was evaluated by checking the normality of residuals, homoscedasticity, and independence assumptions. The minimum sample size ($n = 164$) for developing the model was calculated using Rpackage *pmsampsize* (shrinkage = 0.975; R Foundation for Statistical Computing).

We applied the prediction formula to the training cohort to calculate an actual difficulty score for each patient. Using the 33rd and the 66th percentiles of the distribution of the proposed score as cut-off levels, we divided all patients into 3 groups of difficulty (low, intermediate, high).

The score was tested in the internal cohort and was validated in the external cohort. For the internal validation, we performed a logistic regression between the actual difficulty score (both for numeric value and subdivision in groups) and the development of severe postoperative complications. The Cochran Armitage test for trend was considered appropriate to evaluate the association between difficulty groups and the development of severe postoperative complications. The same methodology was used for external validation and to test the PD-ROBOSCORE in the learning curve cohort.

As the study was designed, we did not address any missing data.

All statistical analyses were done with JMP 15.2.0 (SAS Institute Inc, Cary, NC) and RStudio 2022.07.0 (RStudio Team, Boston, MA).

Results

Baseline characteristics of the training ($n = 198$), validation ($n = 686$), and learning curve ($n = 300$) cohort are reported in Table I. A summary of intraoperative, pathology, and postoperative results is presented in Table II.

Survey

All 30 experts (100%) replied to the survey (Supplementary Figure S1). Six factors received a mean score of ≥4: (1) BMI (body mass index) ≥25 kg/m^2 for males and ≥30 kg/m^2 for females; (2) severe acute pancreatitis (at any time); (3) borderline resectable pancreatic tumor; (4) locally advanced pancreatic tumor; (5) liver cirrhosis and/or severe chronic liver disease; (6) portal hypertension. Fourteen factors had a mean score between 3 and 4: (1) American Society of Anesthesiologists (ASA) class ≥3; (2) chronic pancreatitis; (3) mild acute pancreatitis (<4 weeks before surgery); (4) pancreatic cancer; (5) small main pancreatic duct (<4mm); (6) previous open surgery (upper abdominal quadrants); (7) neoadjuvant chemoradiation therapy; (8) tumor size of ≥5 cm; (9) tumor in the neck of the pancreas; (10) tumor in the uncinate process of the pancreas; (11) common or right hepatic artery originating from the superior mesenteric artery; (12) denial of blood transfusions; (13) recurrent cholangitis; (14) median arcuate ligament syndrome.

Prediction formula.

The median value of the hypothetical difficulty score in the training cohort was 6.8 (3.7–10.2). The factors with a significant

Table I
Baseline characteristics of training, validation, and learning curve cohorts

	Training cohort ($N = 198$)	Validation cohort ($N = 686$)	Learning curve cohort ($N = 300$)
Age, y, median (IQR)	65 (56–73)	62 (55–69)	63 (55–71)
BMI, kg/m^2, median (IQR)	24.2 (21.9–26.6)	23.245 (21.508–25.220)	24.3 (21.9–27.2)
Females, *n* (%)	113 (57.1%)	359 (52.3%)	136 (45.0%)
Males with BMI ≥25 kg/m^2	40 (47.1%)	85 (26.0%)	78 (47.6%)
Females with BMI ≥30 kg/m^2	12 (10.6%)	10 (2.8%)	15 (11.0%)
Any comorbidity and medical history, *n* (%)	123 (62.1%)	408 (59.5)	189 (63.0%)
Diabetes	36 (18.2%)	132 (19.2)	56 (18.7%)
Heart disease	20 (10.1%)	53 (7.7%)	31 (10.3%)
Pulmonary disease	10 (5.1%)	34 (5.0%)	33 (11.0%)
Oncologic disease <5 y prior RPD	16 (8.1%)	93 (13.6%)	
Neurologic disease	9 (4.5%)	17 (2.5%)	17 (5.7%)
ASA physical status, *n* (%)			
I	13 (6.6%)	194 (28.3%)	55 (18.3%)
II	70 (35.3%)	426 (62.1%)	163 (54.3%)
III	108 (54.5%)	65 (9.5%)	79 (26.3%)
IV	7 (3.5%)	1 (0.1%)	3 (1.0%)
Previous open abdominal surgery, *n* (%)	44 (22.2%)	51 (7.4%)	46 (15.3%)
Previous laparoscopic abdominal surgery, *n* (%)	56 (28.3%)	63 (9.2%)	42 (14.0%)
Neoadjuvant chemo(radio)therapy, *n* (%)	3 (1.5%)	17 (2.5%)	8 (2.7%)

ASA, American Society of Anesthesiologists; *BMI,* body mass index; *RPD,* robotic pancreatoduodenectomy.

Table II
Intraoperative, pathology, and postoperative outcomes in training, validation, and learning curve cohorts

	Training cohort (N = 198)	Validation cohort ($N = 686$)	Learning curve cohort ($N = 300$)
Intraoperative data			
Type of procedure			
Pylorus preserving PD, n (%)	175 (88.4%)	194 (28.3%)	125 (41.7%)
Pylorus resecting PD, n (%)	10 (5.1%)	62 (9.0%)	51 (17.0%)
Classic Whipple, n (%)	13 (6.6%)	430 (62.7%)	124 (41.3%)
Operative time, min., median (IQR)	505 (450–565)	303.5 (265–360)	420 (360–504)
Estimated blood loss, ml, median (IQR)	863.2 (510.7–1315)	200 (100–400)	250 (100–600)
Portomesenteric venous resection, n (%)	27 (13.6%)	63 (9.2%)	32 (10.7%)
Conversion, n (%)	4 (2.0%)	18 (2.6%)	11 (3.7%)
Tumor/disease			
Pancreatic ductal adenocarcinoma, n (%)	114 (57.6%)	291 (42.4%)	127 (42.3%)
Intraductal papillary mucinous neoplasm, n (%)	17 (8.6%)	112 (16.3%)	43 (14.3%)
Distal common bile duct cancer, n (%)	11 (5.6%)	7 (1.0%)	11 (3.7%)
Ampullary carcinoma, n (%)	13 (6.6%)	83 (12.1%)	30 (10.0%)
Neuroendocrine neoplasm, n (%)	18 (9.1%)	55 (8.0%)	26 (8.7%)
Chronic pancreatitis, n (%)	0 (0%)	20 (2.9%)	11 (3.7%)
Other tumor types/disease	25 (12.6%)	27 (3.9%)	25 (8.3%)
Additional pathology data			
Tumor size, mm, median (IQR)	27 (20–35)	15 (3–25)	20 (12–30)
Lymph node harvest, PDAC*, median, (IQR)	38.5 (30–49)	10 (6–16)	13 (7–21)
Involved nodes PDAC*, median, (IQR)	2 (0–5)	0 (0–1)	0 (0–2)
R0 resection in PDAC*, n (%)	60 (52.6%)	259 (89.0%)	88 (69.3%)
Postoperative results			
Length of hospital stay, d, median (IQR)	17 (12–26)	15 (10–22)	14 (10–23)
Readmission within 30 d, n (%)	18 (9.1%)	20 (2.9%)	42 (14.0%)
Clavien-Dindo complication > 2, n (%)	48 (24.2%)	100 (14.6%)	73 (24.3%)
Clinically relevant POPF, n (%)	36 (18.2%)	88 (12.8%)	51 (17.0%)
Grade B	27 (13.6%)	80 (11.7%)	44 (14.7%)
Grade C	9 (4.5%)	8 (1.2%)	7 (2.3%)
DGE (Grade B/C), n (%)	66 (33.3%)	17 (2.5%)	55 (18.3%)
PPH (Grade B/C), n (%)	31 (15.7%)	10 (1.5%)	23 (7.7%)
Chyle leak (Grade B/C), n (%)	2 (1.0%)	2 (0.3%)	7 (2.3%)
Bile leak (Grade B/C), n (%)	4 (2.0%)	6 (0.9%)	17 (5.7%)
Reoperation, n (%)	20 (10.1%)	21 (3.1%)	28 (9.3%)
In-hospital mortality or 30-day mortality, n (%)	9 (4.5%)	6 (0.9%)	8 (2.7%)

DGE, delayed gastric emptying; *PD,* pancreatoduodenectomy; *PDAC,* pancreatic ductal adenocarcinoma; *POPF,* postoperative pancreatic fistula; *PPH*, post-pancreatectomy hemorrhage.

Spearman's ρ were: (1) high BMI (odds ratio [OR]:0.47, $P < .0001$); (2) ASA class ≥3 (OR:0.31, $P < .0001$); (3) chronic pancreatitis (OR:0.14, $P = .043$); (4) mild acute pancreatitis (OR:0.23, $P = .0001$); (5) severe acute pancreatitis (OR:0.28, $P < .0001$); (6) small main pancreatic duct (OR:0.20, $P = .004$); (7) borderline resectable pancreatic tumor (OR:0.34, $P < .0001$); (8) tumor size ≥5 cm (OR:0.22, $P = .002$); (9) tumor in the uncinate process of the pancreas (OR:0.27, $P = .0001$); (10) common or right hepatic artery originating from the superior mesenteric artery (OR:0.26, $P = .0003$); (11) liver cirrhosis and/or severe chronic liver disease (OR:0.22, $P = .002$), (12) portal hypertension (OR:0.15, $P = .032$); (13) previous open surgery (upper abdominal quadrants) (OR:0.18, $P = .010$); and (14) recurrent

	Yes	No
High Body Mass Index	+ 2.3933047235	- 2.393304724
ASA ≥3	+ 1.5938845396	- 1.59388454
Uncinate process tumor	+ 1.6900660558	- 1.690066056
Hepatic artery from SMA	+ 1.4312802108	- 1.431280211
Duct size < 4 mm	+ 1.5898228944	- 1.589822894
Borderline resectable tumor	+ 1.9795579382	- 1.979557938

\+ 12.319933924 =

Risk score

Figure 2. Prediction formula. *ASA*, American Society of Anesthesiologists; *SMA*, superior mesenteric artery.

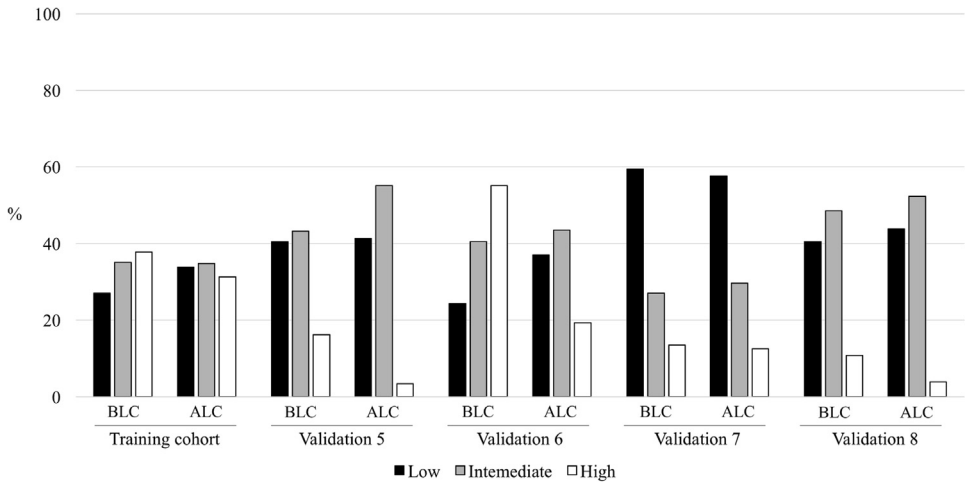

Figure 3. The proportion of low (black bars), intermediate (gray bars), and high (white bars) difficulty groups before and after completion of the learning curve in the training cohort and in 4 centers from the validation cohort that completed the learning curve. *BLC*, before completion of the learning curve; *ALC*, after completion of the learning curve.

cholangitis (OR:0.28, $P < .0001$). The factors included in the final multivariate model were: (1) high BMI (OR:2.39, $P < .0001$); (2) small central pancreatic duct (OR:1.59, $P < .0001$); (3) borderline resectable pancreatic tumor (OR:1.98, $P < .0001$); (4) ASA class ≥3 (OR:1.59, $P < .0001$); (5) tumor in the uncinate process of the pancreas (OR:1.69, $P < .0001$); and (6) common or right hepatic artery originating from the superior mesenteric artery (OR:1.43; $P < .0001$). The prediction formula is shown in Figure 2 and can be used online at www.pancreascalculator.com.

Additional considerations on training, validation, and learning curve cohorts

The RPD programs at the 9 participating I-MIPS centers started between 2008 and 2019. Consequently, individual center contributions varied from 20 to 450 procedures. Two centers had not surpassed the learning curve, whereas 2 centers had just crossed the line by 1 and 6 cases, respectively.

Levels of difficulty were evenly distributed in the training cohort. At the 4 centers contributing to the validation cohort, the proportion of patients with a high difficulty score was 3.4%, 19.3%, 12.5%, and 3.8%, respectively. Interestingly, the center providing 413 RPDs to the validation cohort had a low proportion of patients with a high difficulty score (3.8%). The low proportion of high-risk patients may be one of the reasons for the very low mortality rate (4/686;0.6%) at 30 days in the validation cohort. Patient distribution according to difficulty levels remained quite stable before and after the completion of the learning curve at each participating center (Figure 3).

Difficulty score in the training cohort

Applying the prediction formula to the training cohort, the median value of the difficulty score was 8.01 (4.83–9.61). The low difficulty group (n = 67,33.8%) had a median score of 4.82 (1.64–4.83), the intermediate difficulty group (n = 69,34.8%) had a median score of 8.01 (7.69–8.20), and the high difficulty group (n = 62,31.4%) had a median score of 11.06 (9.62–12.80). Both absolute score values (OR:1.13, $P = .0089$) and difficulty groups (high vs low risk - OR:2.35, $P = .041$) predicted the development of severe postoperative complications.

The PD-ROBOSCORE score also predicted operative time, estimated blood loss, administration of blood transfusions, vein resection, 30-day readmission, grade B/C postpancreatectomy hemorrhage, and postoperative mortality (Table III).

External validation of the difficulty score

Applying the prediction formula to the validation cohort (686 RPD from 4 centers), the median value of the difficulty score was 5.02 (1.64–6.43). The low difficulty group (n = 322,46.9%) had a median score of 1.64 (1.64–4.82), the intermediate difficulty group (n = 313,45.6%) had a median score of 5.02 (5.02–8.01), and the high difficulty group (n = 51,7.4%) had a median score of 11.40 (9.81–13.0).

The absolute score value (OR:1.16, $P < .001$) predicted the development of severe postoperative complications, whereas difficulty groups (high- vs low-risk - OR:1.94, $P = .082$) showed a trend toward statistical significance.

The PD-ROBOSCORE score also predicted operative time, estimated blood loss, vein resection, length of hospital stay, and grade ≥III postoperative complications. The PD-ROBOSCORE did not predict grade B/C chyle leak ($P = .0844$), readmission ($P = .0988$), or need for reoperation (P = .1204) with statistical significance (Table III).

Difficulty score in the learning curve cohort

Applying the prediction formula to the learning curve cohort (n = 300, 9 centers), the median value of the difficulty score was 6.41 (4.82–9.61). The low difficulty group (n = 118,39.3%) had a median score of 4.82 (1.64–4.82), the intermediate difficulty group (n = 111,37.0%) had a median score of 8.0 (6.43–8.78), and the high difficulty group (n = 71,23.7%) had a median score of 12.48 (10.39–12.80). Both absolute score values (OR:1.078, $P = .04$) and difficulty groups (high risk vs low risk - OR:2.25; $P = .017$) predicted the development of severe postoperative complications.

The PD-ROBOSCORE score also predicted operative time, estimated blood loss, vein resection, length of hospital stay, clinically relevant postoperative pancreatic fistula, grade B/C delayed gastric emptying, grade B/C postpancreatectomy hemorrhage, and postoperative mortality. The PD-ROBOSCORE did not predict readmission (P = .079), need for reoperation (P = .0517), or grade C postoperative pancreatic fistula (P = .064) with statistical significance (Table III).

PD-ROBOSCORE above the 90th percentile

A posthoc analysis showed that a PD-ROBOSCORE above the 90th percentile, corresponding to a score of ≥12.51, doubled the incidence of severe postoperative complications in all study groups (training cohort: 21.7% vs. 47.3%; $P = .02$) (validation cohort: 16.5% versus 33.3%; $P = .02$) (learning curve cohort: 22.2% versus 40.0%; $P = .03$).

The PD-ROBOSCORE is readily available via www.pancreascalculator.com

Discussion

In 1,184 RPD, the PD-ROBOSCORE predicted the risk of severe postoperative complications, longer operative time, higher blood loss, and vein resection. In the learning curve cohort, it also predicted the length of hospital stay and onset of postoperative pancreatic fistula, delayed gastric emptying, postpancreatectomy hemorrhage, and postoperative mortality.

Only 1 previous score is available for the RPD. This score was set in 72 interventions performed by 3 surgeons over 6 years and included patients operated on during the learning curve. There was no external validation. The main bias in this study is that the score was built from RPD results rather than preoperative information.[20] Moreover, the results are likely to be biased by a learning curve effect, given the low annual volume (12 RPD) and limited experience of individual surgeons (24 RPD).

The term "difficult" does not have a common definition in surgery.[30] It could be a procedure associated with technical complexity or a high complication rate.[31] On a technical level, all PD are complex procedures. Given that patient outcomes are most important in surgery, we assumed that a difficult operation is a procedure associated with an increased incidence of severe complications.[30] As highlighted in the Miami guidelines, patient comorbidity is a major factor in postoperative complications and an important parameter in selecting patients for minimally invasive pancreatic surgery.[32] In PD, severe postoperative complications prolong the length of hospital stay,[33] increase costs,[33] results in higher rates of postoperative mortality,[34] reduce the probability of receiving adjuvant chemotherapy and delay delivery of oncologic treatments,[35] and decrease overall and disease-free survival in patients with pancreatic ductal adenocarcinoma.[36] From that perspective, a difficult RPD is a procedure with an increased likelihood of adverse outcomes.

The incidence and severity of postoperative complications after PD are certainly multifactorial, but the quality of surgery remains essential to achieve good outcomes.[37,38] Ideally, surgeons performing PDs should have received formal training, and their performance should have been tested before starting or continuing clinical practice.[39] In open PD, Tseng et al showed that 60 procedures are required to decrease estimated blood loss, operative time, and length of hospital stay and increase the margin negative resection rate. Further improvements were reported after 120 PDs, despite increased complexity, and the authors concluded that "improvement in measured outcomes continues throughout the operative career."[40] Unfortunately, PD is a highly complex procedure often performed at relatively low volumes.[41] Volume and/or outcome interactions have been better documented for institutions than for individual surgeons, but also surgeon volume appears to be associated with outcomes, even though more experienced surgeons often operate on more complex cases.[42] According to the Miami guidelines, annual individual surgeon's volume (grade 2C) and center volume (grade 1B) affect outcomes, with recommended annual volumes of 10 and 20 minimally invasive PD to reduce mortality and morbidity, respectively.[32]

The PD-ROBOSCORE predicted severe postoperative complications across the 3 RPD cohorts. The 3 difficulty groups predicted severe postoperative complications in the training and the learning curve cohorts but not in the multicenter validation cohort. The low rate of severe postoperative complications in the latter group (14.6%), possibly reflecting the low prevalence of patients with ASA class 3 or higher (9.6%) and high difficulty procedures (7.4%), can explain why statistical significance was not reached. However, in the validation cohort, the proportion of patients with severe postoperative complications progressively increased according to difficulty groups (12.4%, 15.7%, 21.6%). Across all cohorts, a PD-ROBOSCORE of ≥12.51 doubled the risk of severe postoperative complications raising concerns about the indication of RPD. We suggest that patients with this high score be carefully considered for RPD, and only after achieving the proficiency level.[2–6]

The rate of severe postoperative complications in all RPD cohorts (24.2%, 14.6%, 24.3%) was below the threshold for open PD in benchmark patients (ie, ≤28%). This is a remarkable achievement, as benchmarking excludes ASA class ≥3 patients,[43] who were

Table III
Outcomes in training, validation, and learning curve cohorts based on difficulty groups

	Training cohort			*P* value	Validation cohort			*P* value	Learning curve cohort			*P* value
	Low (*N* = 67)	Intermediate (*N* = 69)	High (*N* = 62)		Low (*N* = 322)	Intermediate (*N* = 313)	High (*N* = 51)		Low (*N* = 118)	Intermediate (*N* = 111)	High (*N* = 71)	
Severe postoperative complications, n (%)	12 (17.9%)	15 (21.7%)	21 (33.9%)	.018*	40 (12.4%)	49 (15.7%)	11 (21.6%)	.0340*	23 (19.5%)	25 (22.5%)	25 (35.2%)	.0101*
Operative time, min., median (IQR)	485 (440–540)	500 (460–552.5)	540 (470–600)	.009	300 (248.75–360)	305 (270–360)	370 (310–458)	< .001	408.5 (359.5–480)	420 (353.5–498)	450 (389.25–551.25)	.004
Estimated blood loss, ml, median (IQR)	785 (387.3–1078)	828 (399.5–1161.4)	1057.4 (694.2–1656.9)	.005	200 (100–400)	200 (100–400)	320 (200–600)	< .001	250 (100–571.15)	250 (100–500)	450 (150–800)	.015
Vein resection, n, (%)	0 (0%)	10 (14.5%)	17 (27.4%)	< .0001*	0 (0%)	41 (13.1%)	22 (43.1%)	< .0001*	0 (0%)	17 (15.3%)	15 (21.1%)	< .0001*
Conversion, n, (%)	1 (1.5%)	1 (1.5%)	2 (3.2%)	.245*	9 (2.8%)	6 (1.9%)	3 (5.9%)	.3350*	5 (4.2%)	3 (2.7%)	3 (4.2%)	.4565*
Length of hospital stay, d, median (IQR)	15 (11–26)	19 (14.5–24)	19.5 (13.5–25.5)	.323	14 (10–20)	16 (12–24)	13 (8–18)	< .001	12 (9–18.5)	16 (10–23)	19 (11–28.25)	.002
Readmission within 30 d, n (%)	4 (6%)	5 (7.3%)	9 (14.5%)	.047*	11 (3.4%)	7 (2.2%)	2 (3.9%)	.0998*	11 (9.3%)	17 (15.3%)	14 (19.7%)	.079*
Grade of postoperative complications												
Grade III, n (%)	11 (16.4%)	10 (14.5%)	13 (21%)	.252*	35 (10.9%)	45 (14.4%)	10 (19.6%)	.0276*	16 (13.6%)	22 (19.8%)	16 (22.5%)	.0511*
Grade IV, n (%)	1 (1.5%)	2 (2.9%)	2 (3.2%)	.264*	4 (1.2%)	1 (.3%)	1 (2.0%)	.3392*	6 (5.1%)	3 (2.7%)	3 (4.2%)	.3358*
Grade V, n (%)	0 (0%)	3 (4.4%)	6 (9.7%)	.004*	1 (0.3%)	3 (1.0%)	0 (0%)	.3202*	1 (0.8%)	1 (0.9%)	6 (8.5%)	.0014*
Clinically relevant POPF, n (%)	10 (14.9%)	15 (21.7%)	11 (17.7%)	.331*	43 (13.4%)	36 (11.5%)	9 (17.6%)	.4443*	14 (11.9%)	15 (13.5%)	22 (31.0%)	.0009*
Grade B	8 (11.9%)	12 (17.4%)	7 (11.3%)	.468*	40 (12.4%)	31 (9.9%)	9 (17.6%)	.4541*	12 (10.2%)	14 (12.6%)	18 (25.4%)	.0034*
Grade C	2 (3%)	3 (4.4%)	4 (6.5%)	.173*	3 (0.9%)	5 (1.6%)	0 (0%)	.4635*	2 (1.7%)	1 (0.9%)	4 (5.6%)	.064*
DGE (Grade B/C), n (%)	15 (22.4%)	30 (43.5%)	21 (33.9%)	.076*	7 (2.2%)	7 (2.2%)	3 (5.9%)	.1420*	19 (16.1%)	17 (15.3%)	19 (26.8%)	.0492*
PPH (Grade B/C), n (%)	7 (10.5%)	9 (13%)	15 (24.2%)	.017*	3 (.9%)	6 (1.9%)	1 (2.0%)	.1592*	2 (1.7%)	6 (5.4%)	15 (21.1%)	< .0001*
Chyle leak (Grade B/C), n (%)	1 (1.5%)	1 (1.5%)	0 (0%)	.202*	2 (.6%)	0 (0%)	0 (0%)	.0844*	2 (1.7%)	3 (2.7%)	2 (2.8%)	.2949*
Bile leak (Grade B/C), n (%)	2 (3%)	0 (0%)	2 (3.2%)	.475*	3 (.9%)	3 (1.0%)	0 (0%)	.3392*	5 (4.2%)	8 (7.2%)	4 (5.6%)	.2967*
Reoperation, n (%)	7 (10.5%)	6 (8.7%)	7 (11.3%)	.441*	7 (2.2%)	12 (3.8%)	2 (3.9%)	.1204*	7 (5.9%)	12 (10.8%)	9 (12.7%)	.0517*
PDAC cases	*N*= 35	*N* = 40	*N* = 39		*N* = 145	*N* = 130	*N* = 16		*N* = 50	*N* = 40	*N* = 36	
R0 resection in PDAC, n (%)	18 (51.4%)	23 (57.5%)	19 (48.7%)	0.398*	132 (91.0%)	114 (87.7%)	13 (81.3%)	.0946*	36 (72%)	31 (75.6%)	21 (58.3%)	.108*

DGE, delayed gastric emptying; *PDAC*, pancreatic ductal adenocarcinoma; *POPF*, postoperative pancreatic fistula; *PPH*, postpancreatectomy hemorrhage.
**P*: Cochrane-Armitage test for trend

instead included in all RPD cohorts in this study (58.0%, 9.6%, 27.3%). The rate of conversion to open surgery was also remarkably low (33/1184 RPD; 2.7%). Robotic assistance is known to have a low risk of conversion to open surgery,[13] ranging from 1.1% to 5.1%.[44] In a multicenter study, RPD was associated with a 5-fold reduction in conversion compared with laparoscopic PD.[13] Conversion, particularly if caused by bleeding, is expected to aggravate surgical outcomes. Experimental evidence shows that robotic assistance reduces task errors at all levels of experience,[45] eliminates the operative handedness observed in conventional laparoscopy,[46] and enhances ergonomics.[47] When all these factors are taken together, it seems perfectly logical that robotic assistance entails low conversion rates in a complex procedure such as PD.

In addition, the PD-ROBOSCORE predicted operative time, estimated blood loss, and vein resection in all 3 cohorts. In the learning curve cohort, it also predicted the length of hospital stay, postoperative pancreatic fistula, delayed gastric emptying, postpancreatectomy hemorrhage, and postoperative mortality. Postoperative mortality was also predicted in the training cohort but not in the validation cohort. Again, the small number of deaths in this group (4/686; 0.6%) may explain why a relationship could not be established.

We have not defined the number of RPDs that could permit progression from one group of difficulty to the next because the study was not designed to provide this information. This number could be affected by several surgeon-specific characteristics such as overall level of surgical experience, pre-emptive practice with laparoscopic pancreatoduodenectomy, innate aptitude for robotic surgery, and formal training in RPD. In our opinion, progression should be permitted once proficiency is gained. In addition, stratification of RPD based on complexity will allow a more objective assessment of the center's and surgeon's performance.

In the training cohort, the proportion of difficult RPD did not increase after the completion of the learning curve. In the validation cohort, the proportion of difficult RPD decreased after the learning curve was completed, showing the high predictive value of the PD-ROBOSCORE. Indeed, as underscored by the Miami guidelines, careful patient selection is a key component to achieve good results in minimally invasive pancreatic procedures.[32] Results in the validation cohort were remarkably good, showing the importance of an ideal patient selection.

Five of the 6 factors contributing to PD-ROBOSCORE are known risk factors for increased difficulty in RPD. Indeed, high BMI,[48] high ASA class,[49] small pancreatic duct,[48,49] borderline resectability,[49,50] and tumor location in the uncinate process[51] have all been associated with increased difficulty in RPD. Results of RPD in the presence of hepatic arteries originating from the superior mesenteric group were reported in detail by 2 groups. The Pittsburgh group showed that variations in arterial liver supply were not associated with worse outcomes in a group of 30 patients.[52] The Chicago group reported similar results in 15 RPD.[53] Altogether, these data show that variations in arterial liver supply permit safe RPD in the hands of experienced surgeons. However, the fact that 2 pioneer groups decided to publish their relatively small series on this issue shows the practical importance of replaced or accessory hepatic arteries from the superior mesenteric artery in RPD.

Study Limitations

The results of this study should be interpreted considering some limitations. First, the retrospective design may have introduced selection and reporting bias. Therefore, our results should be validated in a prospective study. In particular, among the parameters included in the final PD-ROBOSCORE, the retrospective study design could influence the definition of a borderline resectable tumor. A uniform definition of a borderline resectable pancreatic tumor should be adopted in a prospective study, and the local tumor stage should be externally validated. Second, only a small proportion of patients received preoperative oncologic treatments. Neoadjuvant chemotherapy and chemoradiotherapy are increasingly used in patients with pancreatic cancer but can potentially increase the difficulty of RPD because of the induction of peripancreatic fibrosis. Third, the score was constructed based on factors identified by expert surgeons. The average surgeon, and even more a trainee, might have identified additional difficulty factors. Fourth, individual surgeon and center performance are important determinants of successful surgery. A major strength of this study is the large multicenter design allowing for the development of a robust model within and beyond the learning curve phase.

In conclusion, the PD-ROBOSCORE can be used by surgeons for risk stratification when considering patients for RPD. The score could also permit stepwise implementation of RPD, starting with low-risk patients. Future studies should determine the added value of such an approach on patient outcomes and safety.

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Supplementary materials

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