Journal Pre-proof

Impact of Surgical Approach According to PD-ROBOSCORE in Pancreaticoduodenectomy: a Single-center External Validation and Comparative Study

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Study Design and Sample

2020-2025:

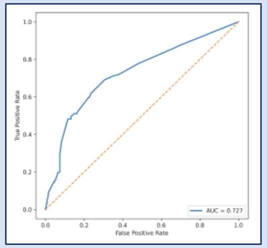
381 Pancreaticoduodenectomies (PDs)

279 Open PDs

102 Robotic PDs

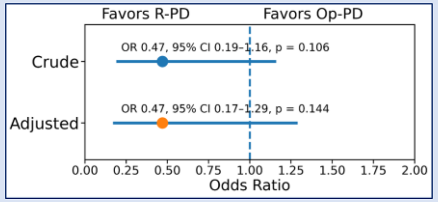
1. Discriminative ability of **PD-ROBOSCORE** in predicting **major complications**
2. **Impact** of surgical approach in high-difficulty procedures (**PD-ROBOSCORE ≥9**).
3. To **determine** whether **PD-ROBOSCORE** provides **incremental predictive value beyond baseline patient-related risk factors**.

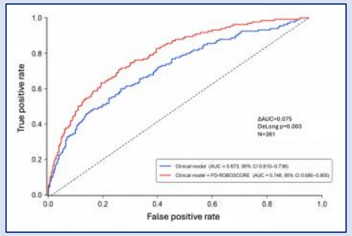
Major Result 1



ROC analysis demonstrated good **discrimination of the PD-ROBOSCORE** in predicting major postoperative complications (**AUC of 0.72**) independently of the surgical approach

No significant differences in major postoperative complications between robotic and open PDs in either crude or adjusted analyses in high-difficulty procedures





When added to a baseline model **PD-ROBOSCORE** demonstrated an **incremental prognostic value beyond patient-related factors**

Conclusions

PD-ROBOSCORE is significantly associated with major postoperative morbidity, and demonstrates good discriminative performance after PD.

The score appears to quantify procedural complexity independently of surgical approach

PD-ROBOSCORE provides incremental predictive value beyond baseline clinical variables

Clinical Implications

1. Anticipation of clinical complexity (tailoring operative strategy)
2. Allows fairer comparison of outcomes between centers and techniques
3. Useful during implementation of robotic surgery programs

SURGERY

Giuseppe Quero, Matteo Aulicino, Claudio Fiorillo et al.

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Abstract

Background

Pancreaticoduodenectomy (PD) remains a technically demanding procedure associated with substantial postoperative morbidity. The PD-ROBOSCORE was developed to quantify procedural difficulty using preoperative variables, but external validation and its clinical relevance across different surgical approaches remain limited. This study aimed to validate PD-ROBOSCORE and assess its prognostic performance in predicting major postoperative complications.

Methods

We conducted a retrospective single-center study including consecutive patients undergoing open or robotic PD between 2020 and 2025. PD-ROBOSCORE was calculated using the original weighted formula and analyzed as a continuous variable, by quartiles, and using the predefined high-difficulty threshold(≥9). The primary endpoint was major postoperative complications (Clavien–Dindo ≥3). Associations were evaluated using logistic regression. Discrimination was assessed using receiver operating characteristic(ROC) analysis. Incremental predictive value was examined by comparing a baseline clinical model with and without PD-ROBOSCORE.

Results

A total of 381 patients were included;36.5% developed major complications. Higher PD-ROBOSCORE values were independently associated with increased odds of major morbidity(OR 1.12, 95% CI 1.01–1.15; $p = 0.02$), with a significant trend across quartiles($p=0.011$). The score demonstrated good discrimination(AUC 0.727), with similar performance in open and robotic PD($p=0.91$). Among high-difficulty cases(n=98), no statistically significant difference in major postoperative complications was observed between robotic and open PD. Addition of PD-ROBOSCORE improved predictive accuracy compared with the clinical model alone(AUC 0.748 vs 0.673; $p=0.003$).

Conclusions

PD-ROBOSCORE is an effective predictor of major postoperative morbidity after PD and provides incremental prognostic value beyond patient-related factors. It may support preoperative risk stratification and surgical decision-making, particularly in technically complex cases.

Key words: pancreaticoduodenectomy, robotic pancreatic surgery, post-operative outcomes

Introduction

Pancreaticoduodenectomy (PD) remains one of the most technically demanding procedures in abdominal surgery and continues to be associated with substantial postoperative morbidity despite improvements in perioperative management and centralization of pancreatic care. Even in high-volume centers, major complications occur in approximately 30–40% of patients, reflecting the intrinsic complexity of the operation rather than solely patient-related risk factors [1,2]. Accurate preoperative risk stratification has therefore become a central objective in modern pancreatic surgery, with implications for patient counseling, operative planning, and outcome benchmarking.

Traditional predictive models in pancreatic surgery have primarily focused on patient characteristics such as age, comorbidity burden, and physiological status [3–6]. Although these factors contribute to perioperative risk, they do not fully account for the technical challenges inherent to PD. Operative complexity is strongly influenced by anatomical and disease-related variables, including tumor location, vascular variants, pancreatic duct diameter, gland texture, and the presence of borderline resectable disease. Increasing evidence suggests that surgical outcomes are determined by the interaction between patient frailty and procedure-specific technical difficulty, supporting the concept that operative complexity represents an independent dimension of surgical risk [5,7,8].

The progressive adoption of minimally invasive PD has further highlighted the need for objective tools capable of quantifying technical difficulty before surgery. Robotic platforms have been increasingly implemented to facilitate complex dissection and reconstruction through enhanced visualization and instrument articulation, potentially expanding the indications for minimally invasive approaches [9,10]. However, safe implementation of robotic PD relies heavily on appropriate case selection, particularly during early institutional experience [11–13]. In this context, standardized preoperative metrics able to predict operative complexity may play a crucial role in guiding surgical strategy and optimizing outcomes.

Recently, Napoli et al. developed the PD-ROBOSCORE, a preoperative model designed to estimate technical difficulty in robotic PD using readily available clinical and anatomical variables [14]. The score incorporates factors such as borderline resectable disease, arterial anatomical variants, uncinate process involvement, pancreatic duct size, and patient-related characteristics, providing a quantitative assessment of expected procedural complexity. Although originally conceived within the robotic setting to assist in case selection and anticipate intraoperative challenges, the variables included in the PD-ROBOSCORE primarily reflect intrinsic anatomical features of the operation rather than elements specific to a particular surgical approach.

It remains unclear whether PD-ROBOSCORE represents a measure of general procedural complexity applicable to both robotic and open PD. In particular, its performance in open PD has not been adequately explored, despite the fact that the anatomical determinants of operative difficulty are largely shared between open and robotic surgery. Demonstrating comparable predictive performance across approaches would suggest that the score measures fundamental aspects of surgical complexity rather than technology-dependent factors. Moreover, while the score was originally developed to predict operative difficulty, its relationship with clinically meaningful postoperative outcomes and its incremental prognostic value beyond established patient-related risk factors remain insufficiently investigated.

The present study was therefore designed to perform a single-center external validation of PD-ROBOSCORE in a contemporary cohort of patients undergoing PD, including both open and robotic procedures. Specifically, we aimed to assess the association between PD-ROBOSCORE and major postoperative morbidity, evaluate its discriminative performance, explore the impact of surgical approach in high-difficulty cases, and determine whether PD-ROBOSCORE provides incremental predictive value beyond baseline clinical variables.

Materials and Methods

Study design and population

A retrospective single-center observational study was conducted including all consecutive patients who underwent PD at the Pancreatic Surgery Unit of the Fondazione Policlinico "Agostino Gemelli" IRCCS of Rome between January 2020 and December 2025. Both robotic and open procedures were included and analyzed according to an intention-to-treat principle. Selection of surgical approach was based on institutional multidisciplinary evaluation and surgeon judgment, taking into account tumor characteristics, anatomical complexity, patient-related factors, and robotic platform availability. Robotic PD was progressively implemented during the study period within a dedicated high-volume pancreatic surgery program. All procedures were performed by the same experienced pancreatic surgery team. Patients undergoing procedures other than PD were excluded.

Clinical, perioperative, and postoperative data were extracted from a prospectively maintained institutional database. Post-operative complications were classified according to the Clavien-Dindo classification [15]. Post-operative pancreatic fistula (POPF), delayed gastric emptying (DGE) and post-pancreatectomy hemorrhage (PPH) were defined and graded according to the International Study Group of Pancreatic Surgery (ISGPS) criteria [16–18]. Post-operative mortality was defined as any death occurring within 30 days from surgery. Ninety-day mortality was additionally evaluated. Histopathological variables collected included tumor diameter, number of harvested lymph nodes, number of positive lymph nodes, and resection margin status (R status). R1 resection was defined according to the Royal College of Pathologists criteria as the presence of tumor cells within 1 mm of the resection margin.

The study was conducted in accordance with the Declaration of Helsinki and approved by the institutional review board.

PD-ROBOSCORE calculation

For each patient, the PD-ROBOSCORE was calculated according to the original model proposed by Napoli et al. [14]. The score was reconstructed using the published regression coefficients and included six preoperative variables: 1. Sex-specific high body mass index (BMI ≥25 kg/m² in males or ≥30 kg/m² in females); 2. American Society of Anesthesiologists (ASA) physical status ≥3; 3. Tumor located in the uncinate process; 4. Presence of a replaced right hepatic artery originating from the superior mesenteric artery; 5. Pancreatic duct diameter <4 mm; 6. Borderline resectable disease.

Each variable was coded as binary (present/absent), and the continuous PD-ROBOSCORE was computed using the original weighted formula.

The score was analyzed: as a continuous variable, stratified into quartiles based on cohort distribution to evaluate risk gradients, and dichotomized using the high-difficulty threshold (PD-ROBOSCORE ≥9) as originally proposed by Napoli et al. [14], for subgroup analyses assessing the clinical impact of surgical approach.

Outcome definition

The primary endpoint of the study was the occurrence of major postoperative complications, defined as Clavien–Dindo grade ≥III after surgery [15]. For statistical purposes, the endpoint was treated as a binary variable (Clavien–Dindo <III vs ≥III).

The study was designed with four predefined analytical objectives:

1. To evaluate the association between PD-ROBOSCORE and major postoperative morbidity.
2. To assess the discriminative ability of PD-ROBOSCORE in predicting major complications.
3. To explore the impact of surgical approach (robotic vs open) in high-difficulty procedures (PD-ROBOSCORE ≥9).
4. To determine whether PD-ROBOSCORE provides incremental predictive value beyond baseline patient-related risk factors.

Additional exploratory analyses were performed to evaluate the association between PD-ROBOSCORE and reoperation risk.

Statistical analysis

Continuous variables were expressed as median with quartile rank (QR), according to data distribution, while categorical variables were reported as counts and percentages.

The association between PD-ROBOSCORE and major postoperative complications (Clavien–Dindo grade ≥III) was assessed using univariable and multivariable logistic regression analyses. Clinically relevant baseline variables and potential confounders were included a priori in the adjusted model, including sex, age, Charlson Comorbidity Index (CCI), previous abdominal surgery, neoadjuvant therapy (NAT), lesion type (PDAC vs other), surgical approach (robotic vs open), and PD-ROBOSCORE. To avoid redundancy and potential collinearity, variables already incorporated into the PD-ROBOSCORE (BMI and ASA score ≥3) were excluded from the adjusted model. Odds ratios (ORs) with 95% confidence intervals (CIs) were reported.

For trend analysis, patients were stratified into quartiles according to PD-ROBOSCORE distribution within the study cohort, and logistic regression was performed with quartiles entered as an ordinal variable (p for trend).

The discriminative ability of the PD-ROBOSCORE was evaluated using receiver operating characteristic (ROC) curve analysis, with calculation of the area under the curve (AUC) and corresponding 95% confidence intervals obtained through bootstrap resampling.

Subgroup ROC analyses were performed separately for open and robotic PD. Differences between AUCs were assessed using the DeLong test for correlated ROC curves. As a sensitivity analysis, non-parametric bootstrap resampling was additionally performed to estimate CIs for the difference between AUCs.

For the evaluation of the impact of surgical approach in high-difficulty procedures, patients were stratified according to the predefined high-difficulty threshold (PD-ROBOSCORE ≥9) [14]. Comparisons between robotic and open PD were performed within this subgroup.

The association between surgical approach and major postoperative complications was evaluated using logistic regression analysis: crude (univariable) model and multivariable model adjusted *a priori* for age, BMI, and ASA score ≥3, CCI, PD-ROBOSCORE, and lesion type (PDAC vs other) were constructed to account for baseline clinical and disease-related differences between groups. Adjusted odds ratios (aORs) with 95% CIs were reported. To explore potential effect modification, an interaction term between surgical approach and high PD-ROBOSCORE (≥9) was tested within the overall cohort using logistic regression analysis.

To assess whether PD-ROBOSCORE provides prognostic information beyond baseline patient-related risk factors, two multivariable logistic regression models were constructed:

Model 1 (clinical model) included: age, CCI, lesion type (PDAC vs other), previous abdominal surgery, preoperative chemotherapy.

Model 2 (extended model) included all variables of Model 1 plus PD-ROBOSCORE as a continuous variable.

Predicted probabilities derived from each model were used to generate ROC curves. Discriminative performance was compared by calculating the difference in AUC (ΔAUC). Statistical comparison between correlated ROC curves was performed using the DeLong test.

Exploratory logistic regression analyses were additionally performed to evaluate the association between PD-ROBOSCORE and reoperation risk.

All statistical tests were two-sided, and a p value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 26 (IBM Corp., Armonk, NY, USA) and Python (scikit-learn and statsmodels libraries).

Results

Clinico-demographic characteristics and post-operative course of the study population

A total of 381 patients undergoing PD at the Pancreatic Surgery Unit of the Fondazione Policlinico Universitario “Agostino Gemelli” IRCCS, Rome, between January 2020 and December 2025 were included in the study. Baseline clinico-demographic characteristics and postoperative outcomes are summarized in **Table 1**. Of these, 279 patients (73.2%) underwent open PD (Op-PD) and 102 (26.8%) robot-assisted PD (R-PD).

The study population had a median age of 68 years (IQR 59.5–74). Median BMI was 24.2 kg/m² (IQR 21.85–26.97), with a median CCI of 4 (IQR 3–5). Most patients were classified as ASA 1–2 (279, 73.2%), while 102 patients (26.8%) had an ASA score ≥3. Previous abdominal surgery was reported in 98 cases (25.7%), and 79 patients (20.7%) received NAT. Pancreatic ductal adenocarcinoma represented the most common diagnosis (78.5%).

The PD-ROBOSCORE was successfully calculated for all patients using the original weighted formula proposed by Napoli et al. [14], with a median score of 5 (QR 4.5–9.44). Patients were stratified into quartiles according to PD-ROBOSCORE distribution (Q1: n=98, 25.7%; Q2: n=99, 26.0%; Q3: n=89, 23.4%; Q4: n=95, 24.9%), forming the basis for subsequent risk stratification analyses.

Major postoperative complications (Clavien–Dindo grade ≥III) occurred in 139 patients (36.5%). Clinically relevant postoperative pancreatic fistula (CR-POPF) developed in 126 cases (33%), DGE in 107 (28.1%), and PPH in 34 (8.9%). Median length of stay was 13 days (IQR 9–20), with postoperative and 90-day mortality rates of 3.7% (14 patients) and 4.7% (18 patients), respectively.

Regarding histopathological outcomes, the median tumor dimension was 28 mm (IQR 20–35). R1 resection was observed in 72 patients (18.9%). The median number of harvested lymph nodes was 20 (IQR 15–25), while the median number of positive lymph nodes was 2 (IQR 1–4).

The relationship between PD-ROBOSCORE stratification and postoperative morbidity is illustrated in **Figure 1**. A progressive increase in the incidence of major complications was observed across PD-ROBOSCORE quartiles, and trend analysis confirmed a significant increase in complication rates with increasing score categories (p for trend = 0.011).

Association and discriminative performance of the PD-ROBOSCORE

Increasing PD-ROBOSCORE values were significantly associated with a higher likelihood of major postoperative complications. At univariable logistic regression analysis, each one-point increase in PD-ROBOSCORE corresponded to an 8% increase in the odds of major complications (OR 1.08, 95% CI 1.02–1.14, p = 0.012). In multivariable logistic regression analysis, PD-ROBOSCORE remained independently associated with major postoperative complications (OR 1.12, 95% CI 1.01–1.15; p = 0.02) (**Table 2**).

ROC analysis demonstrated good discrimination of the PD-ROBOSCORE in predicting major postoperative complications, with an AUC of 0.72 (**Figure 2**).

A subgroup ROC analysis stratified by surgical approach showed comparable discriminative performance of the PD-ROBOSCORE in open and robotic PDs (AUC 0.725 vs 0.732, respectively). Comparison of AUCs using the DeLong test demonstrated no significant difference between approaches (ΔAUC = 0.007; p = 0.91). As a sensitivity analysis, non-parametric bootstrap resampling confirmed these findings, yielding a 95% CI for the difference in AUCs ranging from −0.120 to 0.125 (**Figure 3**).

In an additional exploratory analysis, higher PD-ROBOSCORE values were also significantly associated with increased odds of reoperation (OR 1.118, 95% CI 1.039–1.202; p = 0.003).

Impact of surgical approach in high-difficulty PD

To evaluate the clinical impact of surgical approach in technically demanding procedures, patients were stratified according to the high-difficulty threshold (PD-ROBOSCORE ≥9) originally proposed by Napoli et al. [14]. A total of 98 patients met this criterion, including 68 (69.4%) undergoing open PD (Op-PD) and 30 (30.6%) robotic PD (R-PD) (**Table 3**).

Major postoperative complications (Clavien–Dindo grade ≥3) occurred in 42 of 68 patients (61.8%) following Op-PD and in 17 of 30 patients (56.7%) following R-PD (p = 0.12). Histopathological outcomes were also comparable between groups. No statistically significant differences were observed in tumor dimension, R1 resection rate, number of harvested lymph nodes, or number of positive lymph nodes between Op-PD and robotic R-PD.

In crude analysis, no statistically significant difference in major postoperative complications was observed between R-PD and Op-PD (OR 0.47, 95% CI 0.19–1.16; p = 0.106).

After adjustment for age, BMI, ASA score ≥3, CCI, PD-ROBOSCORE, and lesion type, surgical approach remained not significantly associated with major postoperative complications (aOR 0.47, 95% CI 0.17–1.29; p = 0.144) (**Figure 4**).

To further explore whether the effect of surgical approach differed according to procedural difficulty, an interaction analysis between surgical approach and high PD-ROBOSCORE (≥9) was performed in the overall cohort. The interaction term was not statistically significant (interaction OR 0.51, 95% CI 0.17–1.54, $p = 0.235$), indicating no statistical evidence of effect modification across difficulty levels.

Incremental predictive value of PD-ROBOSCORE beyond baseline clinical variables

To assess whether PD-ROBOSCORE provides prognostic information beyond baseline patient-related risk factors, two multivariable logistic regression models were compared. A baseline clinical model including age, CCI, previous abdominal surgery, lesion type (PDAC vs other), and preoperative chemotherapy demonstrated good discriminative ability for predicting major postoperative complications (AUC 0.673). The addition of PD-ROBOSCORE significantly improved model performance, increasing the area under the ROC curve to 0.748 (ΔAUC = 0.075; $p = 0.003$, DeLong test) (**Figure 5**).

Discussion

PD remains one of the most technically demanding procedures in abdominal surgery and continues to be associated with considerable postoperative morbidity despite advances in perioperative management and centralization of pancreatic care [1,2,19,20]. In the present study, we externally validated the PD-ROBOSCORE in a contemporary single-center cohort including both open and robotic PDs and demonstrated several clinically relevant findings. First, PD-ROBOSCORE was significantly associated with major postoperative morbidity and showed good discriminative performance. Second, comparable predictive ability was observed across open and robotic procedures, suggesting that the score captures intrinsic procedural complexity rather than approach-specific characteristics. Finally, PD-ROBOSCORE provided incremental prognostic value beyond established patient-related risk factors, supporting the concept that operative complexity represents an independent dimension of surgical risk.

Risk prediction in pancreatic surgery has traditionally relied on patient-related characteristics such as age, comorbidity burden, and physiological status [3–6]. Although these variables contribute to perioperative risk, they do not fully explain the variability in outcomes observed after PD. Increasing attention has therefore been directed toward quantifying technical difficulty as an additional determinant of surgical outcomes.

The PD-ROBOSCORE, originally proposed by Napoli et al. [14], represents one of the first structured attempts to translate anatomical and procedural complexity into a preoperative quantitative metric. In the original study, the score was developed to estimate technical difficulty in robotic PD and to assist in case selection by predicting intraoperative complexity. However, its association with clinically meaningful postoperative outcomes remained only partially explored.

In the present external validation, increasing PD-ROBOSCORE values were associated with progressively higher rates of major postoperative complications, with a significant trend observed across score quartiles. At univariable analysis, each one-point increase in PD-ROBOSCORE was associated with an 8% increase in the odds of major morbidity. Importantly, this association remained independently significant after adjustment for clinically relevant baseline variables and potential confounders, further supporting the role of PD-ROBOSCORE as an independent surrogate measure of procedural complexity associated with postoperative morbidity.

These findings indicate that anatomical determinants of operative difficulty translate into measurable postoperative risk, reinforcing the clinical relevance of procedural complexity beyond intraoperative assessment alone. The discriminative performance observed in our cohort (AUC

≈0.73) is comparable to that reported for several perioperative prediction models in pancreatic surgery, supporting the robustness and generalizability of the score. In addition, exploratory analyses demonstrated an association between higher PD-ROBOSCORE values and increased reoperation risk, further supporting the relationship between procedural complexity and severe postoperative course.

A key aspect of this study was the evaluation of PD-ROBOSCORE across both robotic and open PDs. Because the score was originally developed within the robotic setting, its applicability outside minimally invasive surgery required conceptual validation.

Our analysis demonstrated nearly identical discriminative performance between open and robotic procedures, suggesting that PD-ROBOSCORE measures intrinsic anatomical and disease-related complexity rather than technology-dependent factors. Indeed, the variables included in the model—such as borderline resectable disease, arterial variants, uncinate process involvement, pancreatic duct diameter, and patient characteristics—represent universal determinants of operative difficulty shared across surgical approaches. This observation expands the conceptual scope of PD-ROBOSCORE from a robotic case-selection tool to a broader metric of procedural complexity applicable across surgical platforms. Standardized quantification of operative difficulty may therefore facilitate more meaningful comparisons between techniques and improve interpretation of outcome variability in pancreatic surgery. However, some variables included in the score may encompass heterogeneous anatomical conditions not fully captured by binary classification alone. In particular, although based on the Comprehensive Cancer Network (NCCN) definition, borderline resectability may include varying degrees of vascular contact and anatomical complexity that are not differentiated within the current score structure. In addition, the score does not specifically account for certain extreme dimensions of technical complexity, including locally advanced pancreatic cancer and major arterial resections, which remain predominantly managed through an open surgical approach in most centers. Moreover, the score does not incorporate several clinically relevant determinants of perioperative risk, including frailty, nutritional status, and more comprehensive comorbidity assessment, which may independently influence postoperative outcomes after pancreaticoduodenectomy.

When focusing on high-difficulty procedures defined by the original PD-ROBOSCORE threshold (≥9), no statistically significant differences in major postoperative complications were observed between robotic and open PD in both crude and adjusted analyses.

Previous comparative studies between robotic and open PDs have reported heterogeneous results. Some analyses have demonstrated reduced blood loss and shorter hospitalization with robotic surgery, whereas differences in major morbidity have been inconsistent across studies [21–25].

In the present cohort, because of the limited sample size, baseline imbalances between groups, and potential selection bias in surgical allocation, subgroup comparisons between robotic and open PD should be interpreted with caution. Importantly, the absence of a significant interaction between surgical approach and procedural difficulty indicates that PD-ROBOSCORE demonstrated comparable predictive performance across surgical approaches, further supporting its interpretation as a measure of general procedural complexity rather than a technology-specific score.

The most relevant contribution of the present study lies in demonstrating the incremental predictive value of PD-ROBOSCORE beyond traditional clinical variables. When added to a baseline model including age, CCI, previous abdominal surgery, lesion type (PDAC vs other), and preoperative chemotherapy, PD-ROBOSCORE significantly improved model discrimination.

This finding supports a multidimensional interpretation of surgical risk integrating both patient frailty and procedural complexity. While traditional predictors describe physiological vulnerability, PD-ROBOSCORE appears to quantify operative challenge, representing a complementary risk domain not captured by patient-based models alone. The observed improvement in AUC, although moderate in absolute magnitude, is statistically significant and clinically meaningful, as incremental gains in discrimination are increasingly recognized as important in perioperative risk modeling. These findings further support the hypothesis that PD-ROBOSCORE may capture dimensions of procedural complexity not entirely reflected by conventional patient-related clinical variables alone.

From a clinical perspective, PD-ROBOSCORE may serve multiple roles. Preoperatively, it may assist surgeons in anticipating technical complexity and tailoring operative strategy, including selection of surgical approach. At an institutional level, objective grading of procedural difficulty could improve benchmarking and allow fairer comparisons of outcomes between centers and techniques. Furthermore, standardized complexity assessment may be particularly useful during implementation of robotic pancreatic surgery programs and in surgical training environments.

By incorporating procedural complexity into risk assessment, PD-ROBOSCORE may contribute to more individualized surgical decision-making and improved perioperative planning.

This study has several limitations. Its retrospective single-center design may limit generalizability and introduces potential selection bias. Furthermore, although the study represents an independent cohort validation, it was conducted within the same national setting as the original PD-

ROBOSCORE study, potentially limiting heterogeneity in clinical practice patterns and patient selection criteria. Although the overall cohort size was substantial, the number of patients within the high-difficulty subgroup was relatively limited, reducing statistical power for comparisons between surgical approaches. Surgeon-related factors, including individual experience, learning-curve effects, and temporal evolution of the robotic program, could not be fully controlled and may have influenced both surgical allocation and postoperative outcomes. Moreover, because allocation to robotic or open PD was based on institutional and surgeon decision-making, with progressive implementation of robotic procedures over time rather than randomization, selection bias cannot be excluded. Finally, although incremental predictive value was demonstrated, prospective multicenter validation is required before routine clinical implementation.

Future investigations should evaluate PD-ROBOSCORE in multicenter cohorts and explore integration with composite predictive models combining patient, anatomical, and institutional variables. Prospective studies may clarify whether score-guided surgical strategy can improve outcomes and optimize allocation of minimally invasive approaches in complex pancreatic surgery.

In conclusion, PD-ROBOSCORE is significantly associated with major postoperative morbidity and demonstrates good discriminative performance after PD. The score appears to quantify procedural complexity independently of surgical approach and provides incremental predictive value beyond baseline clinical variables.

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Figure legend

Figure 1. Incidence of major postoperative complications (Clavien–Dindo grade ≥III) across PD-ROBOSCORE quartiles. Patients were stratified into quartiles according to PD-ROBOSCORE distribution within the study cohort. A progressive increase in complication rates was observed with increasing score categories. Trend analysis confirmed a significant association between higher PD-ROBOSCORE levels and major morbidity (p for trend = 0.011). Error bars represent 95% confidence intervals.

Figure 2. Receiver operating characteristic (ROC) curve evaluating the discriminative ability of PD-ROBOSCORE for predicting major postoperative complications (Clavien–Dindo grade ≥III). The model demonstrated good discrimination, with an area under the curve (AUC) of 0.727.

Figure 3. Bootstrap-based comparison of the discriminative performance of PD-ROBOSCORE between open and robotic pancreaticoduodenectomy. Non-parametric bootstrap resampling was used to estimate the distribution of the difference in area under the curve (ΔAUC) between the two approaches. The 95% confidence interval for ΔAUC ranged from −0.120 to 0.125, indicating no significant difference in predictive performance between open and robotic procedures.

Figure 4. Forest plot showing crude and adjusted odds ratios (ORs) for major postoperative complications comparing robotic versus open pancreaticoduodenectomy among high-difficulty cases (PD-ROBOSCORE ≥9). The adjusted model included age, body mass index, ASA score ≥3, CCI, PD-ROBOSCORE, and lesion type. No statistically significant differences in major postoperative complications were observed between robotic and open PD in either crude or adjusted analyses.

Figure 5. Incremental predictive value of PD-ROBOSCORE beyond baseline clinical variables. ROC curves comparing a baseline clinical model (age, CCI, lesion type (PDAC vs other), previous abdominal surgery, and preoperative chemotherapy) with and without PD-ROBOSCORE for prediction of major postoperative complications (Clavien–Dindo grade ≥III). Addition of PD-ROBOSCORE significantly improved discrimination from AUC 0.673 to 0.748 (ΔAUC = 0.075; p = 0.003, DeLong test).

Table 1. Clinico-demographic features and post-operative course of the study population	
	Study population (n=381)
Baseline features	
Sex, n (%)	
M	223 (58.5)
F	158 (41.5)
Age, median (QR)	68 (59.5-74)
BMI, median (QR)	24.2 (21.85-26.97)
CCI, median (QR)	4 (3-5)
ASA score, n (%)	
1-2	279 (73.2)
3-4	102 (26.8)
Previous abdominal surgery, n (%)	98 (25.7)
NAT, n (%)	79 (20.7)
Lesion type, n (%)	
PDAC	299 (78.5)
Other	82 (21.5)
PD-ROBOSCORE variables, n (%)	
Borderline resectable tumor, n (%)	44 (11.5)
Hepatic artery variant, n (%)	22 (5.8)
Uncinate involvement, n (%)	40 (10.5)
Small pancreatic duct, n (%)	161 (43.2)
Surgical approach, n (%)	
Open	279 (73.2)
Robot-assisted	102 (26.8)
PD-ROBOSCORE, median (QR)	5 (4.5-9.44)
PD-ROBOSCORE Quartiles, n (%)	
Q1 (range score: 1.64-4.5	98 (25.7)
Q2 (range score: 4.82-5.02)	99 (26)
Q3 (range score: 5.6-9.29)	89 (23.4)
Q4 (range score: 9.61-16.95)	95 (24.9)
Intraoperative features	
Operative time, min median (QR)	390 (324-541.5)
Vascular resection, n (%)	19 (5)
EBL, mL median (QR)	200 (150-500)
Conversion, n (%)	5 (1.3)
Post-operative course	
Clavien-Dindo≥3, n (%)	139 (36.5)
DGE, n (%)	107 (28.1)
CR-POPF, n (%)	126 (33)
POPF grade, n (%)	
B	103 (27)
C	23 (6)

PPH, n (%)	34 (8.9)
Bile leak, n (%)	20 (5.2)
Chyle leak, n (%)	9 (2.4)
Sepsis, n (%)	26 (6.8)
Reoperation, n (%)	60 (15.7)
LOS, median (QR)	13 (9-20)
Post-operative mortality, n (%)	14 (3.7)
90-day mortality, n (%)	18 (4.7)
Tumor dimension, mm, median (QR)	28 (20-35)
R1 rate, n (%)	72 (18.9)
Number of lymph nodes harvested, median (QR)	20 (15-25)
Number of positive lymph nodes, median (QR)	2 (1-4)

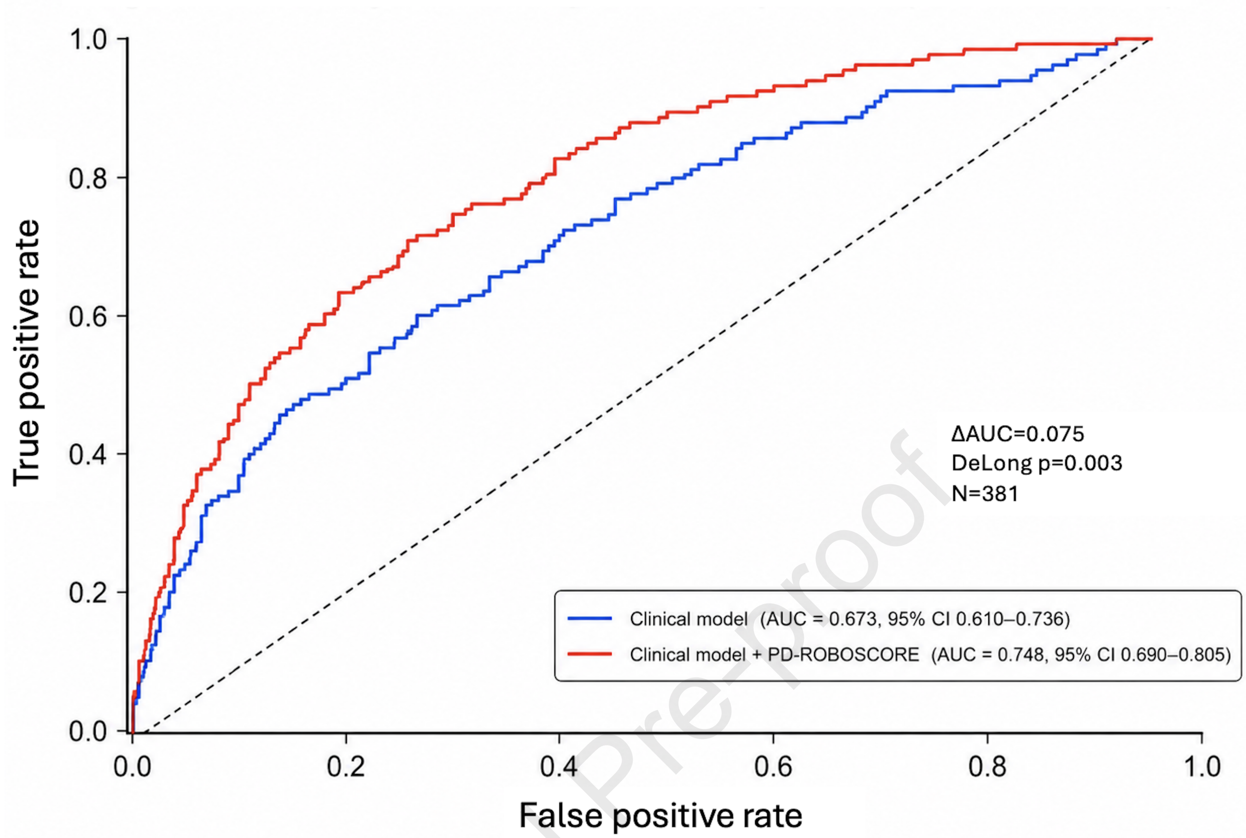
BMI: body mass index; CCI: Charlson Comorbidity Index; ASA: American Society of Anesthesiologists; NAT: neoadjuvant therapy; PDAC: pancreatic ductal adenocarcinoma; EBL: estimated blood loss; DGE: delayed gastric emptying; CR-POPF: clinically relevant post-operative pancreatic fistula; PPH: post-pancreatectomy hemorrhage; LOS: length of hospital stay

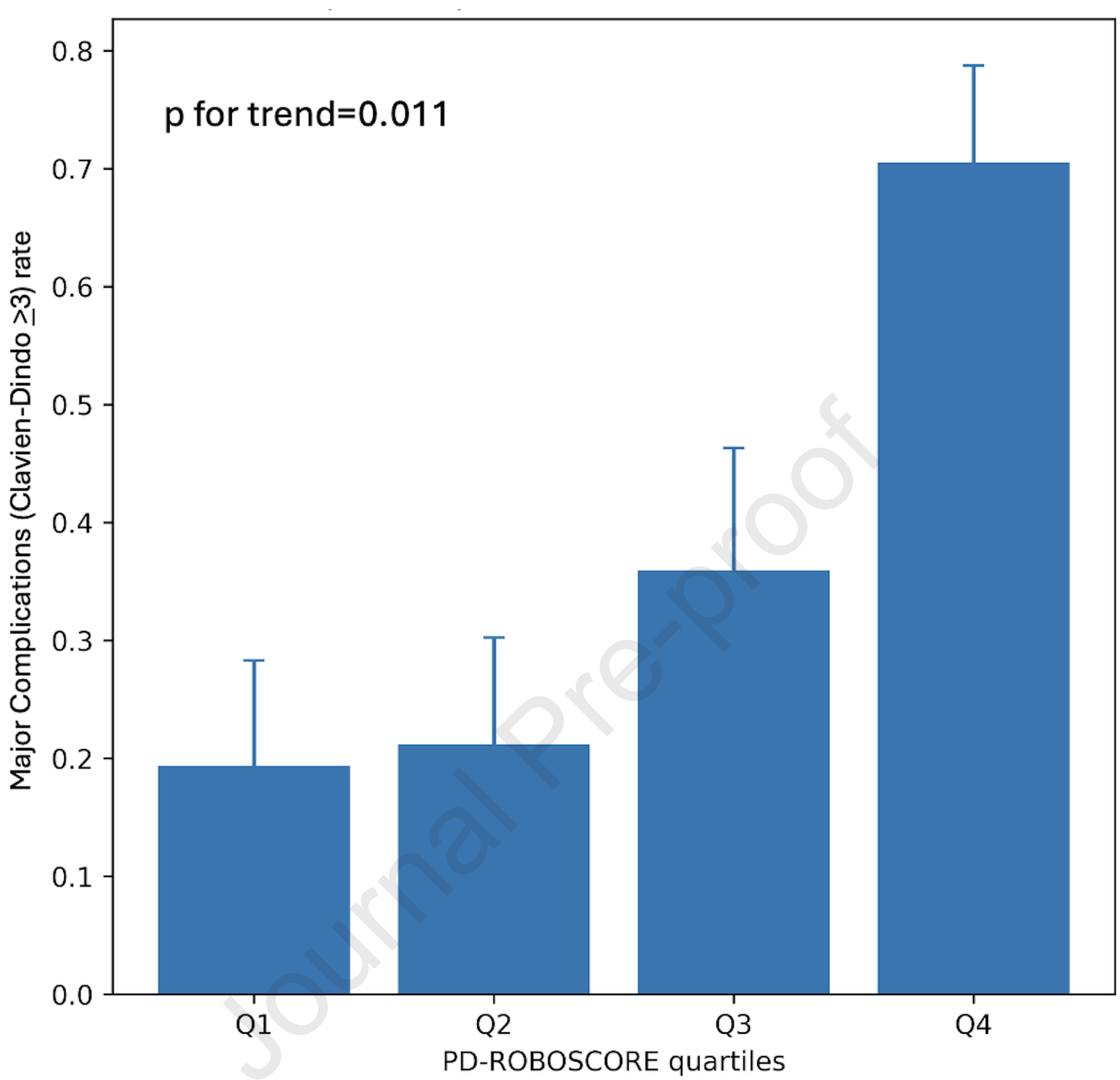
Table 2. Univariable and multivariable logistic regression analyses for major postoperative complications						
Variables	**Univariable analysis**			**Multivariable analysis**		
	OR	**CI 95%**	**p**	**OR**	**CI 95%**	**p**
Female gender	0.42	0.27-0.66	<0.001	0.60	0.37-0.98	0.044
Age	1.00	0.98-1.02	0.956			
CCI	1.03	0.90-1.18	0.578			
Previous abdominal surgery	1.01	0.52-1.15	0.458			
NAT	0.40	0.22-0.72	0.002	0.38	0.20-0.72	0.003
PDAC vs Other	0.61	0.38-0.97	0.039	0.80	0.51-1.25	0.337
Robotic vs Open approach	0.68	0.43-1.07	0.101			
PD-ROBOSCORE	1.08	1.02–1.14	0.012	1.12	1.01-1.15	0.02

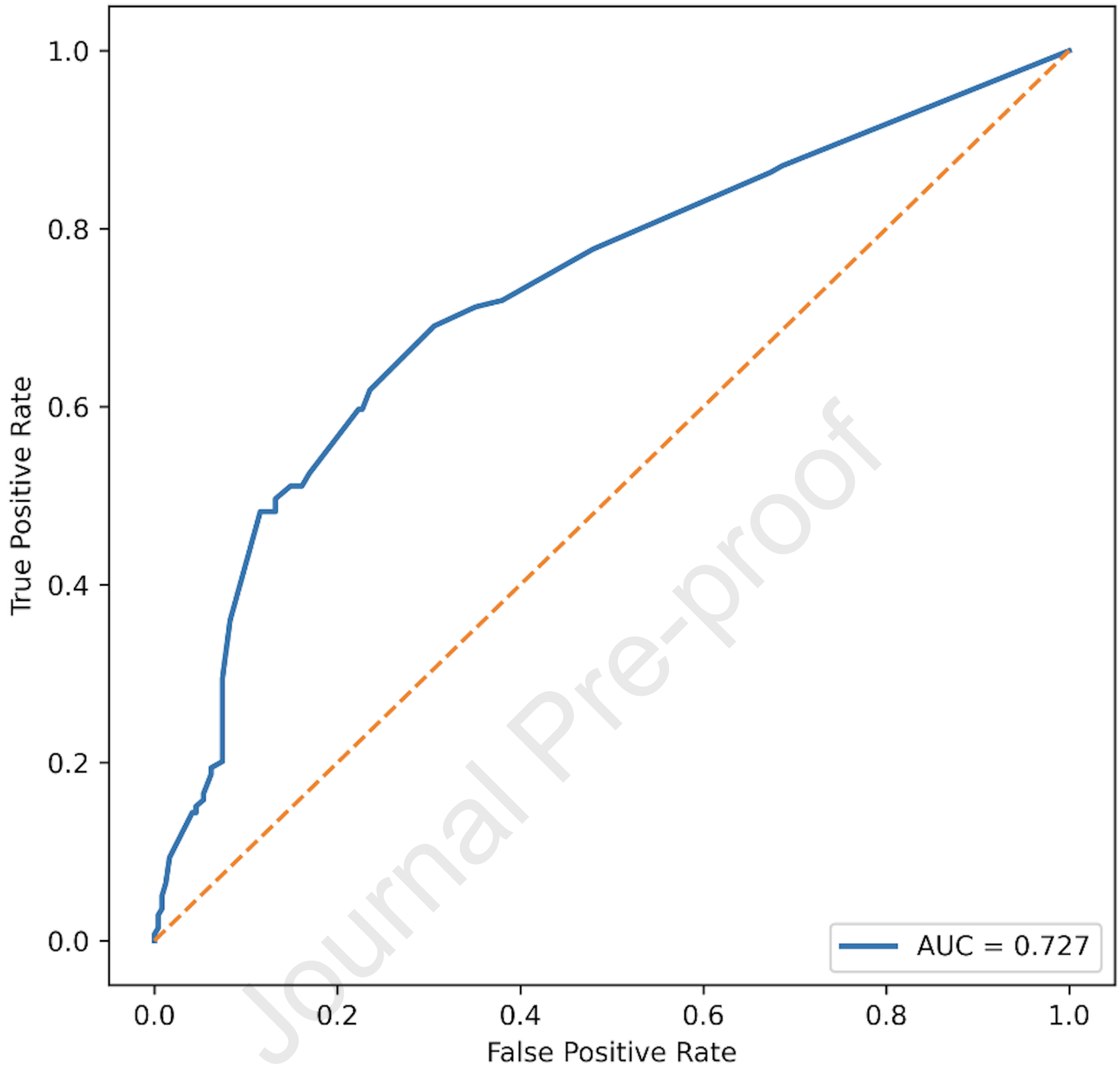
BMI and ASA score ≥3 were excluded from the multivariable model because they are incorporated within the PD-ROBOSCORE

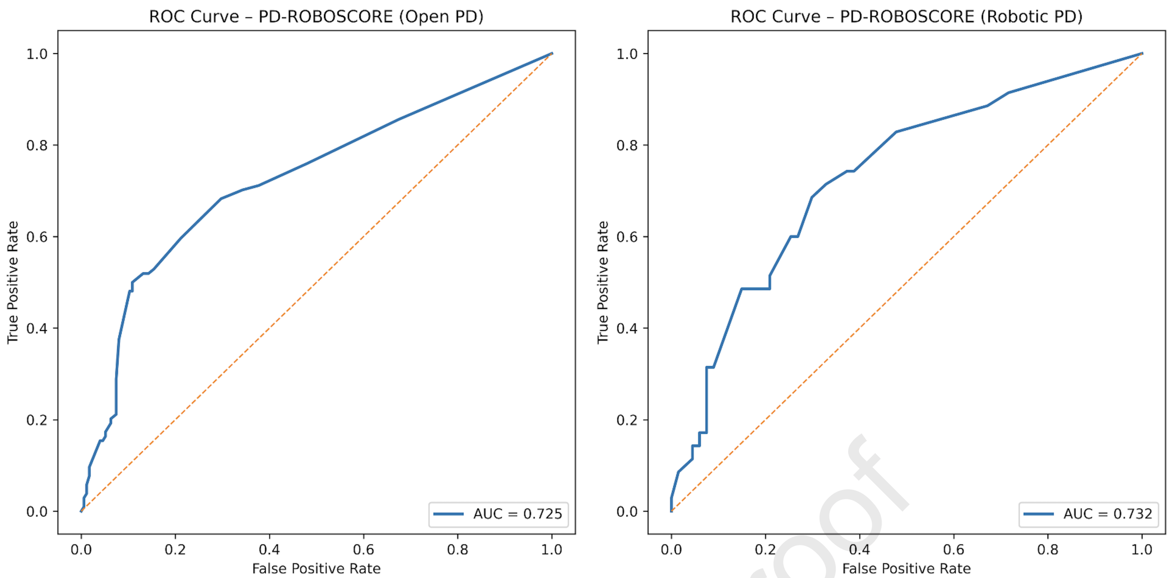
Table 3. Comparison between open and robotic PDs in high-difficulty cases (PD-ROBOSCORE ≥9)			
	Op-PD (n=68)	**R-PD (n=30)**	**p**
Baseline features			
Sex, n (%)			
M	59 (86.8)	23 (76.7)	0.21
F	9 (13.2)	7 (23.3)	
Age, median (QR)	68 (61.2-72.7)	61 (53-71)	**0.04**
BMI, median (QR)	27.7 (25.9-29)	27 (26.3-30.8)	0.71
CCI, median (QR)	4 (3-5)	3.5 (3-5)	**0.04**
ASA score, n (%)			
1-2	34 (50)	18 (60)	0.33
3-4	34 (50)	12 (40)	
Previous abdominal surgery, n (%)	13 (19.1)	6 (20)	0.24
NAT, n (%)	16 (23.5)	9 (30)	0.31
Lesion type, n (%)			
PDAC	53 (77.9)	19 (63.3)	0.09
Other	15 (22.1)	11 (36.7)	
PD-ROBOSCORE, median (QR)	11.4 (9.6-12.7)	9.8 (9.6-12.5)	0.07
Intraoperative features			
Operative time, min median (QR)	378.5 (325-432.2)	533 (479-626)	**<0.0001**
Vascular resection, n (%)	6 (8.8)	1 (3.3)	0.28
EBL, mL median (QR)	200 (150-450)	200 (150-300)	0.55
Post-operative course			
Clavien-Dindo≥3, n (%)	42 (61.8)	17 (56.7)	0.12
DGE, n (%)	24 (35.3)	8 (26.7)	0.4
CR-POPF, n (%)	27 (39.7)	14 (46.7)	0.55
PPH, n (%)	4 (5.8)	2 (6.7)	0.65
Bile leak, n (%)	4 (5.8)	2 (6.7)	0.82
Chyle leak, n (%)	0	1 (3.3)	0.7
Sepsis, n (%)	7 (10.3)	4 (13.3)	0.17
Reoperation, n (%)	14 (20.6)	9 (30)	0.31
LOS, median (QR)	12 (9-25)	13 (8.7-19.5)	0.63
Post-operative mortality, n (%)	4 (6)	1 (3.3)	0.85
90-day mortality, n (%)	5 (7.3)	2 (6.7)	0.83
Histopathological features			
Tumor dimension, mm, median (QR)	30 (28-35)	29 (27-37)	0.84
R1 rate, n (%)	12 (17.6)	4 (13.3)	0.59
Number of lymph nodes harvested, median (QR)	20 (18-23)	17 (17-22)	0.63
Number of positive lymph nodes, median (QR)	1 (1-3)	1 (1-4)	0.46

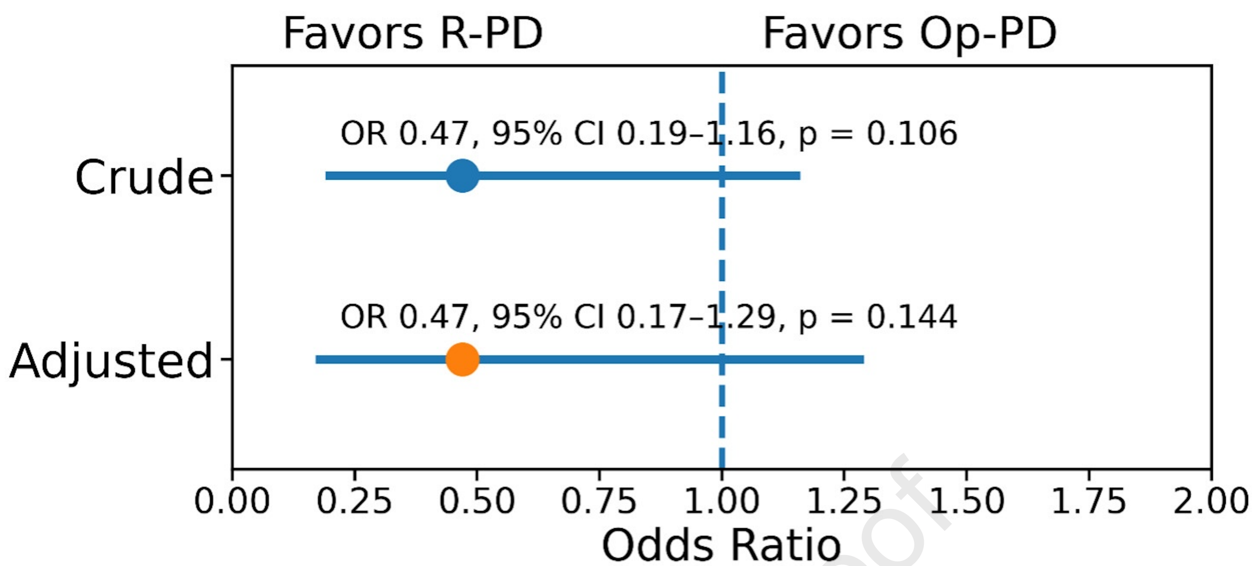
BMI: body mass index; CCI: Charlson Comorbidity Index; ASA: American Society of Anesthesiologists; NAT: neoadjuvant therapy; PDAC: pancreatic ductal adenocarcinoma; EBL: estimated blood loss; DGE: delayed gastric emptying; CR-POPF: clinically relevant post-operative pancreatic fistula; PPH: post-pancreatectomy hemorrhage; LOS: length of hospital stay


True positive rate
False positive rate
0.0
0.2
0.4
0.6
0.8
1.0
ΔAUC=0.075
DeLong p=0.003
N=381
Clinical model (AUC = 0.673, 95% CI 0.610–0.736)
Clinical model + PD-ROBOSCORE (AUC = 0.748, 95% CI 0.690–0.805)


p for trend=0.011
Major Complications (Clavien-Dindo ≥3) rate
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
Q1
Q2
Q3
Q4
PD-ROBOSCORE quartiles


1.0
0.8
0.6
0.4
0.2
0.0
True Positive Rate
0.0
0.2
0.4
0.6
0.8
1.0
False Positive Rate
AUC = 0.727


ROC Curve – PD-ROBOSCORE (Open PD)
True Positive Rate
False Positive Rate
AUC = 0.725
ROC Curve – PD-ROBOSCORE (Robotic PD)
True Positive Rate
False Positive Rate
AUC = 0.732


Favors R-PD
Favors Op-PD
OR 0.47, 95% CI 0.19–1.16, p = 0.106
Crude
OR 0.47, 95% CI 0.17–1.29, p = 0.144
Adjusted
0.00
0.25
0.50
0.75
1.00
1.25
1.50
1.75
2.00
Odds Ratio

Two-Sentence Article Summary

We externally validated the PD-ROBOSCORE in patients undergoing pancreaticoduodenectomy, demonstrating its association with major postoperative morbidity and its incremental predictive value beyond established clinical risk factors. The importance of this finding is that it underscores the role of procedural complexity as an independent dimension of surgical risk, with potential implications for preoperative stratification and operative planning.