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The Role of Pre-Procurement Pancreas Suitability Score (P-PASS) and Pancreas Donor Risk Index (PDRI) in the Outcome of Simultaneous Pancreas and Kidney or Pancreas After Kidney Transplantation

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEFG 1 Clemens Franz
ACDE 1,2 Magdalena Görtz
ACDE 1 Michael Wührl
E 1 Yakup Kulu
ACDE 1 Katrin Hoffmann
E 1 Thilo Hackert
E 3 Christian Morath
E 3 Martin Zeier
E 1 Markus W. Büchler
ACD 1 Arianeb Mehrabi

1 Department of General, Visceral and Transplantation Surgery, Ruprecht-Karls-University Heidelberg, Heidelberg, Germany
2 Department of Urology, Ruprecht-Karls-University Heidelberg, Heidelberg, Germany
3 Department of Nephrology, Ruprecht-Karls-University Heidelberg, Heidelberg, Germany

Corresponding Author: Arianeb Mehrabi, e-mail: arianeb.mehrabi@med.uni-heidelberg.de
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Background: The pre-procurement pancreas suitability score (P-PASS) and the pancreas donor risk index (pDRI) are established predictive scores for graft survival and patient outcome following pancreatic transplantation. This retrospective study aimed to evaluate the predictive value of P-PASS and pDRI following simultaneous pancreas and kidney (SPK) transplantation, or pancreas after kidney (PAK) transplantation, and the clinical impact of donor-specific factors on the postoperative graft and recipient outcome at a single transplant center.

Material/Methods: The study included 105 patients who underwent SPK (n=104) or PAK (n=4) between 2000 and 2017. Donor-specific and recipient-specific parameters were recorded. Kaplan-Meier analysis and Cox regression analysis were used to assess the outcome after transplantation.

Results: Overall, the mean 1-year and 5-year pancreas graft survival and patient survival rates were 78.7% and 93.2%, and 76.9% and 90.0%, respectively. The postoperative outcome in patients with a P-PASS score of <17 was not significantly different when compared with patients with a score of ≥17. A P-PASS score of ≥17 was significantly associated with early pancreas graft loss (p=0.04). There was no significant difference in postoperative outcome between patients with high pDRI and low pDRI. Smoking of donor (p=0.046) was a risk factor and coronary heart disease of recipient (p=0.003) had a significant effect on survival of pancreas graft.

Conclusions: This study showed that P-PASS and pDRI were not reliable predictors of outcome after pancreas transplantation and that specific characteristics of the donor and recipient must be evaluated when predicting the outcome of pancreas transplantation.

MeSH Keywords: Graft Survival • Kidney Transplantation • Pancreas Transplantation • Predictive Value of Tests

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Background

Simultaneous pancreas and kidney (SPK) transplantation has become an established treatment for patients with type I diabetes mellitus and end-stage renal disease [1,2]. In the past decade, advances in surgical techniques and more effective immunosuppression regimens have improved pancreas graft survival rates [3–7]. The increasing demand for pancreas grafts and a change in the organ donor pool towards older donors has resulted in a reevaluation of donor organ acceptability criteria [8–10].

Since 2009, the pre-procurement pancreas allocation suitability score (P-PASS) has been used within the Eurotransplant area to identify suitable pancreas donors [11]. The P-PASS was designed by the Eurotransplant Pancreas Advisory Committee as a calculated score based on nine donor-specific clinical parameters, including patient age and body mass index (BMI), the length of stay in the intensive care unit (ICU), the occurrence of cardiac arrest, and serum levels of sodium, amylase, lipase, adrenaline, and dopamine [12]. However, the predictive value of the P-PASS has not been supported by single studies and remains controversial [13,14].

The preoperative donor risk index (DRI) was developed in 2006 to quantify the risk of liver graft failure following liver transplantation. Donor-specific and logistic parameters, including the donor's age, cause of death, race, presence of a heartbeat, organ donation after cardiac death, partial or split liver graft, donor's height, distance the graft was transported, the local, regional, or national donation, and the duration of cold ischemia, were combined in a complex formula with different importance placed on each parameter [15]. The pancreas donor risk index (pDRI) is a modified version of the DRI that focuses on pancreas transplantation and was introduced in 2010 to increase organ acceptance by predicting pancreas graft outcome [16]. The pDRI is calculated based on the donor characteristics including gender, age, race, body mass index (BMI), height, cause of death, donation after cardiac death (DCD), serum creatinine, and the parameter of pancreas preservation time [16]. A large database study within the Eurotransplant area showed that the pDRI was superior to P-PASS at predicting transplant outcome [17]. However, several studies have reported conflicting results on the use of the pDRI [18–20].

Therefore, this retrospective study aimed to evaluate the predictive value of P-PASS and pDRI following SPK transplantation, or pancreas after kidney (PAK) transplantation, and the clinical impact of donor-specific factors on the postoperative graft and recipient outcome at a single transplant center.

Material and Methods

Study population

Between July 2000 and April 2017, the clinical data of 105 consecutive patients undergoing simultaneous pancreas and kidney (SPK) transplantation, or pancreas after kidney (PAK) transplantation, at the University Hospital Heidelberg, were retrospectively studied. The indications for transplantation were in accordance with national guidelines and the German Organ Transplantation Act. Eurotransplant allocated the organs.

Surgical technique

All organs were prepared before transplantation, and the arterial supply was reconstructed using a Y-graft from the donor's iliac arterial bifurcation. The donor's superior mesentery artery and splenic artery were anastomosed with the internal and external iliac artery, respectively. During transplantation, the pancreatic graft was implanted in the right iliac fossa, and the kidney graft was implanted in the left iliac fossa, thereby connecting the kidney to the iliac vessels and the pancreas to the iliac artery and inferior vena cava. Intestinal drainage of pancreatic secretions was achieved by duodenojejunostomy [5].

Follow-up

Patients were followed up at the outpatient clinic of the Kidney Center at the Ruprecht-Karls University of Heidelberg. If patients were lost to follow-up or died, the relatives or general practitioner were interviewed to obtain the last survey results and the documented date of death.

Patient data

Transplant recipient-specific or donor-specific quantitative variables included age, waiting time, time from the first diagnosis to transplantation, body mass index (BMI), distance the graft was transported, duration of cold ischemia, P-PASS, pDRI, time from donor hospital admission until brain death, and time from brain death until organ retrieval were expressed as medians with the interquartile range (IQR). Nominally scaled variables, including gender, race, cause of death, donation after cardiac death (DCD), smoking history, coronary heart disease (CHD), dialysis, and insulin use were presented as percentages.

P-PASS values were obtained from donor reports in the Eurotransplant database. The pDRI was calculated, as previously described by Axelrod et al. [16]. Graft survival from the day of transplantation onwards was the main outcome parameter. Graft survival was defined as the time from transplantation until graft removal. Analysis of graft survival was death-censored, and death with a functioning graft was not

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Table 1. Patient characteristics.

Gender:		
Male	71	(65.7%)
Female	37	(34.3%)
Dialysis before operation:		
Yes	86	(79.6%)
No	22	(20.4%)
Type of operation:		
SPK	104	(96.3%)
PAK	4	(3.7%)
Insulin administration during/at last follow-up:		
Yes	33	(30.6%)
No	75	(69.4%)
Pancreatic graft removal due to:	n=27	
Pancreatitis	11	(40.7%)
Rejection	7	(25.9%)
Thrombosis	3	(11.1%)
Primary non-function	3	(11.1%)
Necrosis	2	(7.4%)
Bleeding	1	(3.7%)
Kidney graft explantation due to:	n=8	
Rejection	6	(75%)
Primary non-function	1	(12.5%)
Thrombosis	1	(12.5%)

counted as graft failure. Uncensored overall survival was evaluated, including early postoperative mortality.

Statistical analysis

Statistical analysis was performed using SPSS version 22 statistical software (IBM Corp., Armonk, NY, USA). Survival rates and the median survival time were calculated using the Kaplan-Meier method. Differences between the survival curves for subgroups of the study population were analyzed using the log-rank test. Univariate and multivariate Cox regression analysis were used for donor and recipient risk factors. The non-parametric variables of P-PASS and pDRI were compared using the Mann-Whitney U test. Follow-up data were presented as the mean follow-up time after transplantation. Non-parametric correlations were analyzed using Spearman's correlation coefficient because the P-PASS and pDRI values were not normally distributed, as determined by Kolmogorov-Smirnov normality testing. A p-value ≤0.05 was considered as statistically significant.

Results

Patient characteristics

One hundred and eight pancreas transplantations from 105 patients were included in the retrospective study. Simultaneous pancreas and kidney (SPK) transplantation was performed in 104 cases (96.3%) and pancreas after kidney (PAK) transplantation was performed in four cases (3.7%). Eight cases (7.4%) were re-transplantations and included PAK after previous SPK followed by removal of the transplanted pancreas (n=4), repeat SPK after previous SPK followed by graft failure of kidney and pancreas (n=1), and SPK after previous kidney transplant alone (KTA) followed by transplant nephrectomy (n=3). The gender distribution was unequal with 65.7% (n=71) male transplant recipients and 34.3% (n=37) female transplant recipients. The median age at transplantation was 44.3 years (IQR, 38.2–50.4 years; range, 21–64 years). The median waiting time until transplantation was 14.8 months (IQR, 7.9–26.7 months) and the median follow-up time after transplantation was 51 months (IQR, 26–80 months). Preoperative dialysis was required in 79.6% of all patients (Table 1).

Table 2. Donor and recipient characteristics.

Variable	Median	IQR
Recipient characteristics		
Age at transplantation [years]	44.3	38.2–50.4
BMI [kg/m²]	23.1	21.5–25.6
Time on waiting list [months]	14.8	7.9–26.7
Time on dialysis [years]	2.5	1.3–4.2
Follow-up [months]	51	26–80
Donor characteristics		
Age at explantation [years]	35	20–42
BMI [kg/m²]	23.3	21–25
Graft travel distance [km]	156	91–284
Cold ischemia time [hours]	12.0	10–14.1
P-PASS	17	14–20
pDRI	1.198	0.961–1.382

The gender distribution of the donors was almost equal with 53.7% (n=58) male and 46.3% (n=50) female donors, and the median body mass index (BMI) was 23.3 kg/m² (IQR, 21–25 kg/m²). The average distance the graft was transported between the site of donor organ harvesting and transplantation was 156 kilometers (IQR, 91–284 kilometers). The median cold ischemia time was 12.0 hours (IQR, 10–14.1 hours). The median pDRI was 1.198 (IQR, 0.961–1.382), and the median P-PASS was 17 (IQR, 14–20) (Table 2).

Operative course

In all the cases of SPK transplantation, the pancreas was sited in the right iliac fossa, and the kidney was sited in the left iliac fossa. In 80.8% of cases (n=84), the donated kidney was from the donor's right side and was sited in the left iliac fossa.

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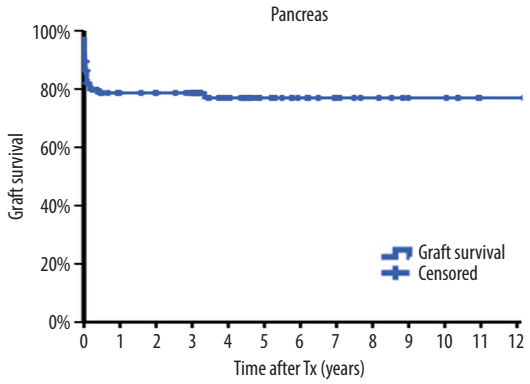

Figure 1. Pancreas graft survival in 105 patients following transplantation (Tx). Simultaneous pancreas and kidney (SPK) transplantation (n=104) or pancreas after kidney (PAK) transplantation (n=4).

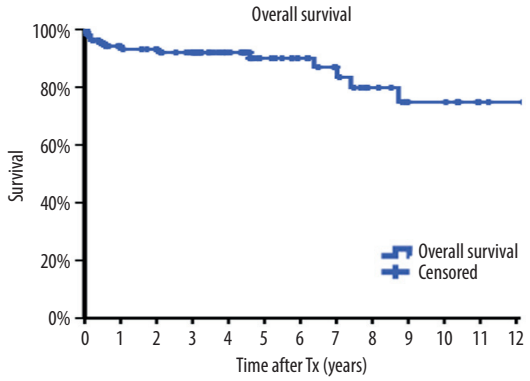

Figure 2. Overall survival of 105 patients following transplantation (Tx). Simultaneous pancreas and kidney (SPK) transplantation (n=104) or pancreas after kidney (PAK) transplantation (n=4).

In 19.2% of cases (n=20), the donated kidney was from the donor's left side and was transplanted to the same side. In cases of re-transplantation, PAK after SPK, SPK after SPK, or SPK after KTA, the graft was transplanted in the same side as the primary SPK transplantation by either removal of the transplanted pancreas or transplant nephrectomy before or during re-transplantation.

Survival analysis

The mean pancreas graft survival time was 12.5 years (95% CI, 11.1–13.9 years) and 25% (n=27) of pancreas grafts were removed during the follow-up period, with an upper limit of 16.2 years. The 1-year and 5-year pancreas graft survival rates were 78.7% and 76.9%, respectively (Figure 1). The mean

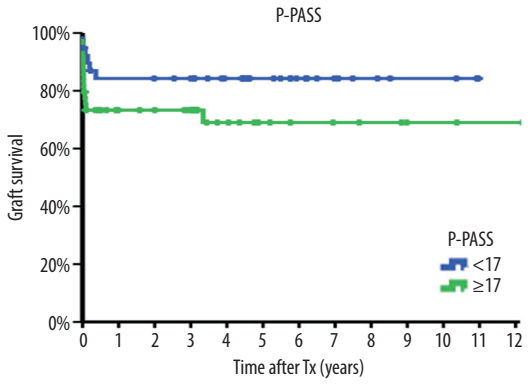

Figure 3. The effect of the pre-procurement pancreas suitability score (P-PASS) on pancreas graft survival. No significant difference was found between the pre-procurement pancreas suitability score (P-PASS) <17 and ≥17 (p=0.111).

overall survival was 13.4 years (95% CI, 11.9–14.9 years) with a 1-year overall survival rate of 93.2% and a 5-year overall survival rate of 90.0% (Figure 2).

Postoperative insulin treatment was required in 30.6% of cases (n=33), whereas 69.4% (n=75) of patients did not require postoperative insulin up to the last follow-up appointment. The reasons for pancreas graft loss included pancreatitis (40.7%; n=11), rejection (25.9%; n=7), thrombosis (11.1%; n=3), primary non-functional graft (11.1%; n=3), graft necrosis (7.4%; n=2), and bleeding (3.7%; n=1) (Table 1).

The mean kidney graft survival was 15.3 years (95% CI, 14.5–16.1 years) with a 1-year kidney graft survival rate of 95.8% and a 5-year kidney graft survival rate of 94.0%. Overall, 7.4% (n=8) of recipients developed kidney graft insufficiency and required regular dialysis. In 5.6% of cases (n=6), the kidney graft was explanted because of rejection, and in 0.9% of cases (n=1), the graft was explanted because of thrombosis or primary non-function. A further 9.3% of transplant recipients (n=10) developed partial kidney graft insufficiency. Intermittent dialysis was required in eight cases without the need to explant the kidney graft.

Outcome prediction for the pre-procurement pancreas suitability score (P-PASS) and the pancreas donor risk index (pDRI)

Univariate analysis showed that a P-PASS ≥17 was not significantly better or worse at predicting pancreas graft survival or overall survival when compared with a score <17 (pancreas graft survival, p=0.111; overall survival, p=0.337; data not shown) (Figure 3). The mean pancreas graft survival was

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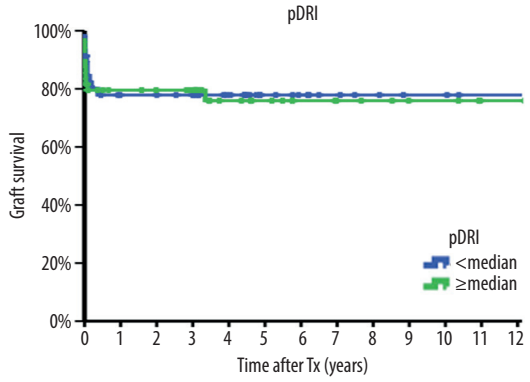

Figure 4. The effect of pancreas donor risk index (pDRI) on pancreas graft survival. No significant difference was found between the median pancreas donor risk index (pDRI) <1.198 and ≥1.198 (p=0.843).

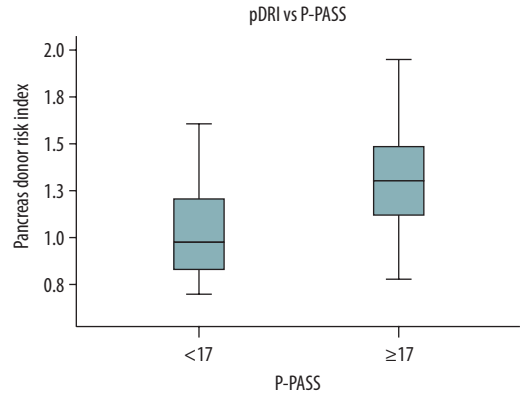

Figure 5. There was a positive correlation between the pancreas donor risk index (pDRI) and the pre-procurement pancreas suitability score (P-PASS). The pre-procurement pancreas suitability score (P-PASS) (<17 or ≥17) had a significant effect on the pancreas donor risk index (pDRI) (p<0.001).

8.6 years (95% CI, 7.0–10.3 years) in patients with a P-PASS of ≥17 compared with 9.3 years (95% CI, 8.0–10.5 years) in patients with a P-PASS <17. Restriction of graft survival analysis to the early postoperative 30 days showed a significantly worse pancreas graft survival for P-PASS ≥17 (p=0.04) (Figure 3, left).

A median pDRI of 1.198 was not significantly better or worse at predicting pancreas graft survival rates (p=0.843) (Figure 4) and overall survival rates (p=0.175) (data not shown) than pDRI values lower than the median.

Spearman's correlation analysis showed a significant correlation between P-PASS and pDRI values (correlation coefficient=0.48;

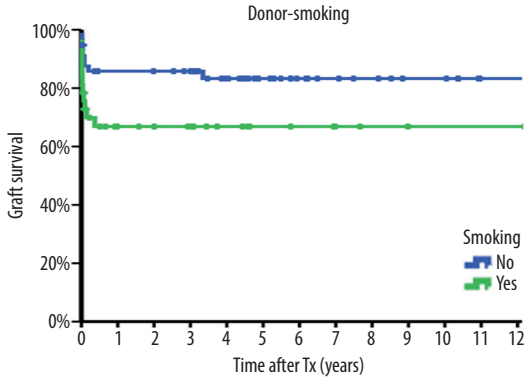

Figure 6. There was a significant effect of donor smoking (p=0.046) on pancreas graft survival.

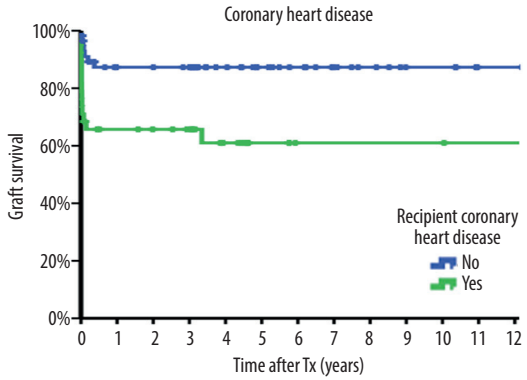

Figure 7. There was a significant effect of recipient coronary heart disease (CHD) (p=0.003) on pancreas graft survival.

p<0.001). Cases with a P-PASS ≥17 had significantly different pDRI values (mean pDRI, 1.31; 95% CI: 1.25–11.38) than those with a P-PASS <17 (mean pDRI, 1.04; 95% CI, 0.96–1.11) (p<0.001) (Figure 5).

Univariate analysis showed that the donor risk factor of smoking (p=0.046) (Figure 6) and the recipient risk factor of coronary heart disease (CHD) (p=0.003) (Figure 7) significantly affected pancreas graft survival. Multivariate analysis confirmed that recipient CHD was an independent prognostic factor for grafts survival (p=0.005) (Table 3).

Discussion

A significant concern in solid organ transplantation is the availability of reliable scores to predict acceptance of the transplant and postoperative outcome after transplantation. Because of

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Table 3. Multivariate Cox regression analysis.

Variable	HR*	95% CI**	p Value#
Donor risk factor			
Smoking yes *vs.* no	1.97	0.82–4.74	0.128
Recipient risk factor			
CHD## yes *vs.* no	3.73	1.49–9.33	**0.005**

* Hazard ratio; ** confidence interval; # likelihood ratio test p<0.001; ## coronary heart disease.

the increasing lack of availability of transplant organs, transplant teams have extended their donor criteria to include more high-risk donors. However, these new inclusion criteria may increase the risk of transplant rejection and reduce patient survival following transplantation [12,15,21]. Therefore, many patients are analyzed in a central database to define the organizational and donor-specific variables that affect the postoperative outcome that are then included in a weighted scoring system to predict transplant outcome [22].

Eurotransplant now recommends that pancreas grafts from donors with a pre-procurement pancreas suitability score (P-PASS) <17 should be considered for organ transplantation because they have a three-times higher acceptance rate than grafts with a P-PASS ≥17 [12]. In liver transplant surgery, the donor risk index (DRI) was developed to predict postoperative liver graft failure before transplantation [15]. The pancreas donor risk index (pDRI) is a modified version of the DRI and is specific for pancreas transplantation [16]. P-PASS and pDRI were developed to determine whether or not an organ is acceptable for transplantation in individual cases [12,16]. In the present retrospective study, we analyzed the value of P-PASS and pDRI in predicting pancreas graft survival in a typical German transplant center.

In this study, the P-PASS of the graft donor (<17 or ≥17) did not significantly affect the overall survival or the graft survival of the pancreas and kidney. This finding was supported by the results from previous studies that showed no correlation between the P-PASS and long-term graft outcome after pancreas transplantation [13,14,23,24]. When long-term follow-up was omitted, and only early graft failure was analyzed, we found a significant association for the P-PASS ≥17 and early graft loss within 30 days postoperatively. This finding was supported by those of Ayami et al. [25], who described a significant association between P-PASS and early graft failure but did not show a significant difference in long-term pancreas graft survival.

In the present study, the pDRI did not show a significant effect on overall survival or graft survival rates, and a low pDRI did not increase the graft survival. This finding was supported by those of Salamanca-Bustos et al., who did not find a significant correlation between pDRI and graft survival after simultaneous pancreas and kidney (SPK) transplantation [19]. However, in 2015, a correlation between graft outcome and pDRI was reported in a UK transplantation population [26]. Recently, Blok et al. [23], who showed a significant difference in pancreas graft outcome between low and high pDRI (median cutoff value, 1.24). At our center, the median pDRI was lower at 1.198, but even when using the cutoff pDRI of Blok et al., the outcome of the graft did not differ significantly. We found a positive correlation between P-PASS values and pDRI values, but this did not significantly affect graft survival or patient survival.

Unlike the established scoring systems, the donor-specific risk factor of smoking, and the recipient risk factor coronary heart disease (CHD) were significant prognostic parameters following transplantation. Multivariate analysis confirmed recipient CHD as an independent prognostic parameter. Khambalia et al. [27] investigated factors that predict the length of hospital stay following SPK transplantation surgery and found that the Waterlow score correlated with the total length of hospital stay and the length of stay in the intensive care unit (ICU) [27]. The Waterlow score includes the transplant recipient's body mass index (BMI), skin integrity, sex, age, nutritional status, continence, mobility, morbidity, neurological deficit, type of surgery, length of surgery, and medications [27]. However, in this previous study, the correlation between the Waterlow score and graft survival were not evaluated [27].

Previously, there have been conflicting results regarding the correlation between pDRI and P-PASS with graft survival between transplant centers, which may be explained by the omission of recipient criteria from pDRI and P-PASS calculations. Recipient criteria are also an important part of transplant surgery and should be included when evaluating the postoperative outcome. This hypothesis should be validated by multicenter studies within Eurotransplant to include donor-specific and recipient-specific parameters and graft survival and patient survival as the major endpoints.

Conclusions

Although the pre-procurement pancreas suitability score (P-PASS) and the pancreas donor risk index (pDRI) are well-established predictive scores in pancreas transplant surgery, the findings from this study showed that they had no impact on graft outcome in this patient cohort. A P-PASS ≥17 had a significant effect on early postoperative pancreas graft survival, but patients who received pancreas grafts with a P-PASS of ≥17 or a high pDRI still had good long-term clinical outcome.

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This finding questions the concept of predicting the postoperative outcome based exclusively on donor criteria. Patient outcome after pancreas transplantation may be more complex, and so both donor-specific and recipient-specific parameters should be considered. This study showed that a history of smoking in the donor and coronary heart disease (CHD) in the recipient had a negative effect on graft survival. Combining donor and recipient characteristics may enhance the predictive impact of preoperative scores, which should be studied further within the Eurotransplant area. From the findings of this retrospective study, we recommend that transplant surgeons consider donor, recipient, and environmental parameters when assessing individual cases of pancreas transplantation.

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Conflict of interest

None.

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