Pancreas Donor Risk Index but Not Pre-Procurement Pancreas Allocation Suitability Score Predicts Pancreas Graft Survival: A Cohort Study from a Large German Pancreas Transplantation Center

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Background: The pre-procurement pancreas allocation suitability score (P-PASS) was introduced to support clinical decision-making and ultimately expand the currently insufficient pancreas donor pool. The pancreas donor risk index (PDRI) can be used at the time of organ offering to predict one-year graft survival. Thus, this study aimed to analyze the validity of the PDRI and P-PASS in a large German transplant center.

Material/Methods: From 2002 to 2015, we performed 327 pancreas transplantations at our center. P-PASS and PDRI were calculated for 322 patients. To evaluate the pancreas graft survival, the patient cohort was divided into 2 P-PASS (<17, n=115 and ≥17, n=207) and 3 PDRI groups (<1, n=87; 1–1.5, n=133; and >1.5, n=102). Kaplan-Meier and Cox regression analyses were performed. We also examined differences regarding early pancreas graft failure for both scores using the chi-square test.

Results: The PDRI was associated with pancreas graft survival in the univariate analysis (p=0.023). In the multivariate analysis, a PDRI >1.5 was associated with significantly decreased graft survival (hazard ratio=1.792, 95% confidence interval=1.10–2.90, p=0.018). The P-PASS showed no significant association (p=0.081) with pancreas graft survival in the Kaplan-Meier survival analysis. There were significantly more early pancreas graft losses in the P-PASS ≥17 group (p=0.025).

Conclusions: Our results showed an association between P-PASS ≥17 and early pancreas graft failure. However, this does not apply to long-term pancreas graft survival; the PDRI proved to be a better tool for this, and PDRI values >1.5 were associated with significantly worse outcomes after pancreas transplantation.

MeSH Keywords: Organ Transplantation • Pancreas Transplantation • Tissue and Organ Procurement

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Background

The critical shortage of pancreas donors challenges the transplant community to maximize the use of all organs from every consented deceased donor. For patients with late complications of type 1 diabetes mellitus, simultaneous pancreas-kidney transplantation (SPK) is the treatment of choice to prolong survival [1], decrease diabetes-related morbidity, and improve quality of life [2]. Therefore, defining the suitability of an organ for transplantation is a crucial step in utilizing the available organs. For this purpose, scoring systems were developed.

Several factors influence pancreas graft survival. Eurotransplant (ET) introduced the pre-procurement pancreas suitability score (P-PASS) in 2008 [3]. This score consists of 8 clinical donor factors that are available before transplantation: age, body mass index (BMI), intensive care unit (ICU) stay, cardiac arrest, serum sodium, serum amylase, serum lipase, and usage of catecholamines. The P-PASS ranges from 9 to 27. At the time of its introduction, grafts from donors with a P-PASS ≥17 were declined 3 times as often compared to grafts from donors with a lower score [3]. Nevertheless, several studies have shown that the P-PASS does not significantly correlate with pancreas graft survival [4–6]. As the P-PASS is still part of the ET donor reports, the present study includes an examination of the association between the P-PASS and pancreas graft survival.

In 2010, Axelrod et al. analyzed data from 9401 pancreas transplantations (PT) in the USA and calculated a pancreas donor risk index (PDRI) to predict one-year pancreas graft survival [7]. This risk ratio compares the one-year pancreas graft survival of the donor at hand with a reference donor from the same study. Only donors whose pancreas was indeed transplanted were included in developing the PDRI. The PDRI comprises 10 items: age, BMI, height, serum creatinine, gender, ethnicity (African-American, Asian, Caucasian), cerebral vascular accident (CVA), donation after cardiac death (DCD), transplantation type, and cold ischaemia time (CIT). The reference donor was a 28-year-old Caucasian male, with a BMI of 24, height of 173 cm, no CVA, serum creatinine less than 2.5 mg/dl, with a pancreas not donated after cardiac death, and a pancreatic CIT of 12 h [7]. As recommended by its authors, the PDRI is still under investigation in different populations to determine its usefulness. Thus, the present study analyzed the validity of the PDRI in a large German transplant center for the first time.

Material and Methods

A total of 327 adult patients underwent PT at our center between January 2002 and August 2015. SPK transplantation was performed in 296 patients, pancreas after kidney (PAK) transplantation in 24 patients, and PT alone (PTA) in 7 patients.

All patients were type 1 diabetics. The P-PASS and PDRI were calculated in 322 (98.5%) cases. We excluded 5 patients because of insufficient data needed to compute their scores. The PDRI was calculated using the original model proposed by Axelrod et al. [7]. We utilized the iOS app "Pancreas Transplant Donor Risk Index" developed by Marc L. Melcher. Ethnicity is not mentioned in ET donor reports; therefore, the ethnicity box in the app was routinely set to Caucasian. For analysis, the patient collective was divided into 2 P-PASS (P-PASS <17, n=115 and P-PASS ≥17, n=207) and 3 PDRI (PDRI <1, n=87; PDRI 1–1.5, n=133; and PDRI >1.5, n=102) groups. To allow comparisons with other studies (e.g., Amaral et al. with the same groups [8] or Axelrod et al. with >1.57 as the highest group [7]), we chose these 3 PDRI groups. Patient and graft survivals were calculated for each group using the Kaplan-Meier method with the log-rank test. A p<0.05 was considered statistically significant. Pancreas graft failure was defined by return to exogenous insulin therapy, explant of organ, or patient death. Early pancreas graft failure was defined as pancreas graft failure within 1 month after transplantation. Kidney graft failure was defined as transplant nephrectomy, return to hemodialysis, or patient death.

For the statistical analysis of patient characteristics, the *t* test, Mann-Whitney U test, and chi-square test were used in both P-PASS groups. Analysis of variance, chi-square test, Kruskal-Wallis H test, and Bonferroni correction were used in the 3 PDRI groups.

The analysis was performed with IBM SPSS Statistics 24 (IBM, Armonk, NY). The protocol of this study was approved by the local ethics board of the Faculty of Medicine, Ruhr-University of Bochum (No. 16-5642) and performed in accordance with the principles of the Declaration of Helsinki.

Results

Demographics

Tables 1 and 2 detail the demographics of the study population. There were significant differences (*p*<0.001) between the 2 donor P-PASS groups in terms of age, donor age category, BMI, and cause of death. Although the gender distribution among the 2 donor P-PASS groups differed, with more female patients in the P-PASS ≥17 group (114 *vs.* 93 male patients), this difference was not statistically significant (*p*=0.46). The recipients showed no significant differences in terms of the investigated variables (Table 2). Important recipient factors, such as age, BMI, diabetes duration, and dialysis duration, were not significantly different, nor were several procedure factors such as CIT, operation time, and period of hospitalization. Moreover, there were more female patients in the PDRI ≥1.5 donor group than in the PDRI <1 group (*p*<0.001) and more donors in the

Table 1. Donor characteristics in the P-PASS and PDRI groups.

	P-PASS <17	P-PASS ≥17	PDRI <1	PDRI 1–1.5	PDRI >1.5
Patients (n)	115 (35.7)	207 (64.3)	87 (27)	133 (41.4)	102 (31.6)
PDRI	1.06±0.32	1.45±0.35	0.85±0.08	1.25±0.1	1.77±0.21
P-PASS	14.2±1.6	18.5±1.4	15.1±2.2	17.2±2.6	18.1±1.7
Age category (in years)					
<15	26 (22.6)	1 (0.5)	14 (16.1)	13 (9.8)	0
15–35	65 (56.6)	40 (19.3)	72 (82.8)	33 (24.8)	0
36–50	18 (15.6)	144 (69.6)	1 (1.1)	86 (64.7)	75 (73.5)
>50	6 (5.2)	22 (10.6)	0	1 (0.7)	27 (26.5)
Gender					
Male	65 (56.5)	93 (44.9)	55 (63.2)	65 (48.9)	38 (37.3)
Female	50 (43.5)	114 (55.1)	32 (36.8)	68 (51.1)	64 (62.7)
BMI	21.4±3.3	24.3±2.5	22.4±3.5	23.3±3.2	24.1±2.4
Age (years)	25.6±13.2	41.7±8.7	21.2±5.9	35.8±10.6	48.6±3.7
COD					
Traumatic	42 (36.5)	36 (17.4)	41 (47.1)	25 (18.8)	12 (11.8)
Non-traumatic	73 (63.5)	171 (82.6)	46 (52.9)	108 (81.2)	90 (88.2)

Values are given as mean ± standard deviation or n (% of group). PDRI – pancreas donor risk index; P-PASS – pre-procurement pancreas allocation suitability score; BMI – body mass index; COD – cause of death.

Table 2. Recipient characteristics in the P-PASS and PDRI groups*.

	P-PASS <17	P-PASS ≥17	p	PDRI <1	PDRI 1–1.5	PDRI >1.5	p
Patients (n)	115 (35.7)	207 (64.3)		87 (27)	133 (41.4)	102 (31.6)	
Age category (in years)			0.673				0.668
<30	6 (5.2)	7 (3.4)		2 (2.3)	7 (5.3)	4 (3.9)	
30–39	30 (26.1)	54 (26.1)		23 (26.4)	37 (27.8)	24 (23.5)	
40–49	50 (43.5)	80 (38.6)		35 (40.3)	57 (42.9)	38 (37.3)	
50–59	25 (21.7)	59 (28.5)		23 (26.4)	30 (22.5)	31 (30.4)	
≥60	4 (3.5)	7 (3.4)		4 (4.6)	2 (1.5)	5 (4.9)	
Gender			0.865				0.966
Male	70 (60.9)	124 (59.9)		53 (60.9)	79 (59.4)	62 (60.8)	
Female	45 (39.1)	83 (40.1)		34 (39.1)	54 (40.6)	40 (39.2)	
BMI	24.5±3.4	24.3±3.5	0.587	24.7±3.4	23.9±3.5	24.8±3.6	0.80
Age (years)	43.2±8.4	44.8±8.8	0.112	44.0±8.3	43.8±8.1	45.6±9.5	0.144
Diabetes duration (years)	30±9	31±9	0.453	30±9	30±9	31±9	0.336
Dialysis duration (months)	34±24	38±30	0.604	38±27	37±31	34±25	0.791

Table 2 continued. Recipient characteristics in the P-PASS and PDRI groups*.

	P-PASS <17	P-PASS ≥17	p	PDRI <1	PDRI 1–1.5	PDRI >1.5	p
Dialysis type			0.322				0.319
Pre-terminal (no dialysis)	15 (13)	40 (19.3)		13 (14.9)	22 (16.5)	20 (19.6)	
Haemodialysis	79 (68.7)	128 (61.9)		54 (62.1)	90 (67.7)	61 (59.8)	
Peritoneal dialysis	21 (18.3)	39 (18.8)		20 (23)	21 (15.8)	21 (20.6)	
HLA mismatch			0.844				0.416
0–2	11 (9.6)	14 (6.7)		8 (9.2)	10 (7.5)	7 (6.9)	
3–4	41 (35.7)	79 (38.2)		32 (36.8)	44 (33.1)	44 (43.1)	
5–6	63 (54.7)	114 (55.1)		47 (54)	79 (59.4)	51 (50)	
Transplantation type			0.005				0.594
SPK	94 (81.8)	186 (89.9)		72 (82.8)	116 (87.2)	92 (90.4)	
PAK	10 (8.7)	2 (1)		5 (5.7)	6 (4.5)	1 (0,9)	
Re-SPK	3 (2.6)	9 (4.3)		3 (3.5)	6 (4.5)	3 (2.9)	
PTA	2 (1.7)	5 (2.4)		2 (2.3)	2 (1.5)	3 (2.9)	
Re-PTA	6 (5.2)	5 (2.4)		5 (5.7)	3 (2.3)	3 (2.9)	
Preservation solution			0.615				0.542
HTK	76 (66.1)	131 (63.3)		57 (65.5)	81 (60.9)	69 (67.6)	
UW	39 (33.9)	76 (36.7)		30 (34.5)	52 (39.1)	33 (32.4)	
CIT (min)							
Pancreas graft	708±146	684±168	0.202	705±147	691±160	684±172	0.676
Kidney graft	799±173	784±183	0.505	794±179	780±181	795±179	0.799
Operation time (min)	301±90	317±83	0.115	311±97	303 ±78	322 ±84	0.250
Venous drainage			0.971				0.759
Systemic	78 (67.8)	140 (67.6)		60 (69)	87 (65.4)	71 (69.6)	
Portal	37 (32.2)	67 (32.4)		27 (31)	46 (34.6)	31 (30.4)	
Duration of hospitalisation (days)	39±23	41±25	0.987	38±25	43±27	39±19	0.342
Early pancreas graft loss (within 1 month)	10 (9.7)	37 (17.9)	0.025	12 (13.8)	14 (10.5)	21 (20.6)	0.093
Pancreas graft thrombosis	3 (30)	16 (43)		5 (42)	6 (43)	8 (38)	

Values are given as mean ±SD or n (% of group). SD – standard deviation; P-PASS – pre-procurement pancreas allocation suitability score; PDRI – pancreas donor risk index; BMI – body mass index; TX – transplantation; HLA – human leucocyte antigen; SPK – simultaneous pancreas-kidney transplantation; PAK – pancreas after kidney transplantation; Re-SPK – repeated simultaneous pancreas kidney transplantation; PTA – pancreas transplantation alone; Re-PTA – repeated pancreas transplantation alone; HTK – histidine-tryptophane-ketoglutarate; UW – University of Wisconsin; CIT – cold ischaemia time.
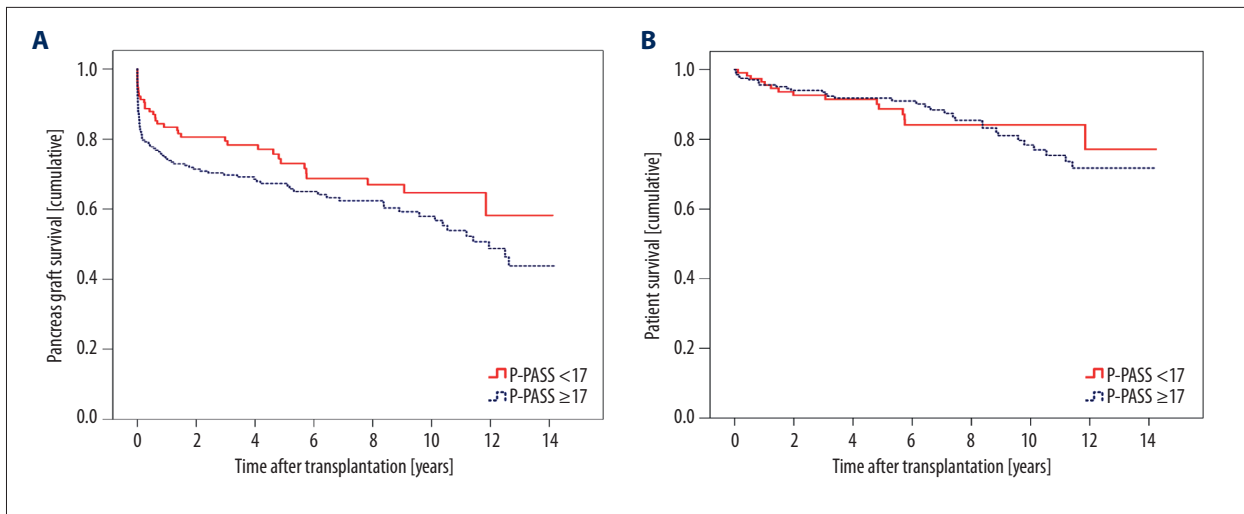
Figure 1. (**A**) Kaplan-Meier curves depicting pancreas graft survival in the P-PASS groups. (**B**) Kaplan-Meier curves depicting patient survival in the P-PASS groups.
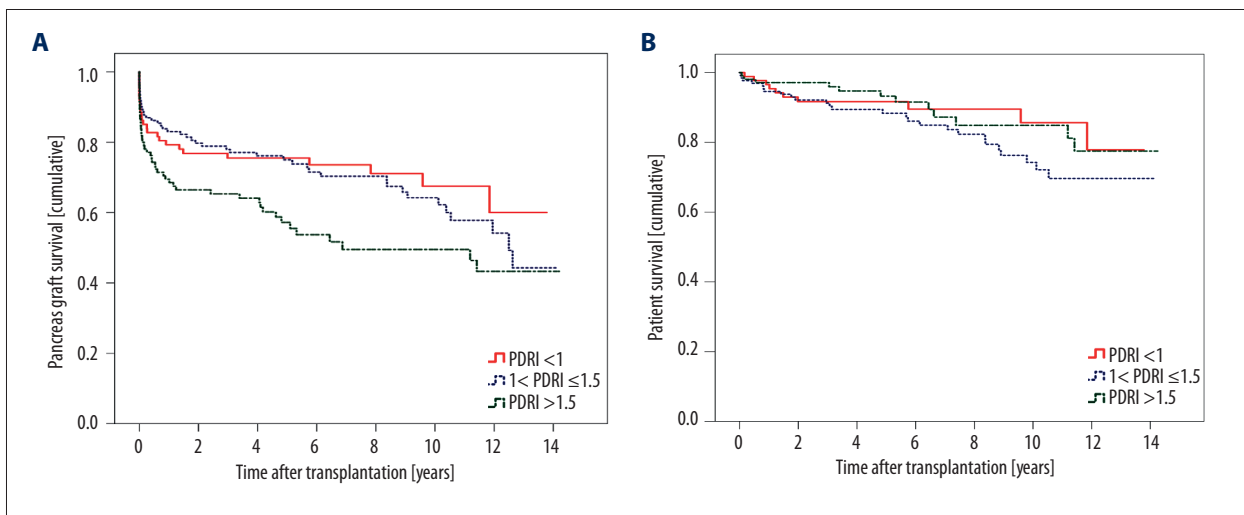

Figure 2. (**A**) Kaplan-Meier curves depicting pancreas graft survival in the PDRI groups. (**B**) Kaplan-Meier curves depicting patient survival in the PDRI groups.

PDRI <1 donor group died due to trauma than in the other 2 PDRI donor groups ($p<0.001$).

P-PASS

The median P-PASS value of all patients was 17 (range, 9–23). In the P-PASS <17 (n=115) group, pancreas graft survival rates at 1, 5, and 10 years were 84%, 73%, and 65%, respectively, compared to 74%, 67%, and 58%, respectively, among the P-PASS ≥17 group (n=207). The log-rank test showed no significant statistical association between the P-PASS and pancreas graft survival ($p=0.08$) (Figure 1A), kidney graft survival ($p=0.76$), or patient survival ($p=0.68$) (Figure 1B).

PDRI

The median PDRI value of all patients was 1.30 (range, 0.54–2.40). In the PDRI <1 group, 1, 5, and 10-year pancreas graft survival rates were 79%, 75%, and 68%, respectively. In the PDRI 1–1.5 group, they were 83%, 75%, and 64%, respectively, and in the PDRI >1.5 group, they were 69%, 57%, and 50%, respectively (Figure 2A). In the univariate analysis, the PDRI showed a statistically significant association with pancreas graft survival ($p=0.02$). However, kidney graft survival after SPK ($p=0.88$) and patient survival ($p=0.25$, Figure 2B) showed no significant statistical association with the PDRI in the log-rank test. In the Cox regression analysis, the PDRI >1.5 group showed a significantly increased risk for pancreas graft failure [hazard ratio (HR)=1.79, 95% confidence interval (CI)=1.10–2.90,

p=0.018)]. The PDRI 1–1.5 group also showed an increased risk for pancreas graft failure, but this difference was not statistically significant (HR=1.14, 95% CI=0.70–1.86, p=0.60).

Early pancreas graft failure and pancreas graft thrombosis

In the examined population, there were 118 pancreas graft failures. Out of these 118 graft failures, 47 (39.8%) were early pancreas graft failures. Moreover, 32 recipients lost their pancreas grafts due to graft thrombosis in total, and 19 (59.4%) of them were lost within 1 month after transplantation. As demonstrated in Table 2, there were significantly more early pancreas graft losses in the P-PASS ≥17 group (p=0.025). In contrast, the PDRI groups showed no significant differences regarding early pancreas graft loss (p=0.093).

Discussion

Currently, 2 scoring systems (P-PASS and PDRI) have been proposed for evaluating the suitability of pancreas grafts. ET has incorporated P-PASS to help identify a suitable pancreas donor. Vinkers et al. previously stated that an ideal pancreas donor should have a P-PASS <17, concluding that this score could be used in screening for potential pancreas donors [3]. Furthermore, Ziaja et al. conducted a study analyzing the results of 46 SPKs and reported an association between the P-PASS and a higher incidence of surgical complications, which could impair both graft and patient survival rates [9]. However, most of the initial enthusiasm about the reliability of P-PASS as a predictor of pancreas graft quality has waned over time. Most of the existing studies regard its clinical utility to be marginal. More specifically, Woeste et al. presented the results of their single-center analysis of 52 PTs [6]. They found that the P-PASS could not significantly predict pancreas graft survival, postoperative morbidity, or severity of ischemia-reperfusion injury [6]. In another study by our working group, Schenker et al. [4] demonstrated that a P-PASS ≥17 was indeed associated with significantly higher rates of graft thrombosis and re-laparotomies, and longer hospitalization. Nevertheless, no association between P-PASS and pancreas graft survival rates was found. Thus, utilization of grafts from donors with a P-PASS ≥17 could reliably expand the organ donor pool. Finally, after the analysis of 349 pancreas transplants at the University of Leiden, Blok et al. stated that the P-PASS could not predict graft survival and should therefore not be used in clinical decision-making [5].

The results of our present study are in line with the above-mentioned findings [4–6] and show that the P-PASS is not reliable in predicting pancreas graft survival. Furthermore, the P-PASS was not correlated with either patient or kidney graft survival (in cases of SPK).

The outcomes of PTs in general are also highly recipient-dependent. To exclude a possible bias related to unequal recipient characteristics in our 2 examined P-PASS groups, we analyzed and compared important recipient data. The statistical analysis showed no significant differences between recipients of the P-PASS <17 and P-PASS ≥17 groups.

Taking into consideration all published data, the former recommendation of preferring pancreas grafts with a P-PASS <17 should be critically re-examined. So far, according to a study by Kopp et al., its utility in predicting acceptance by transplantation surgeons appears to be inferior to the PDRI [10]. This large ET registry-study analyzed the allocation outcome of 10 444 pancreata reported for transplantation and showed that the PDRI predicts the allocation outcome (acceptance or refusal by transplant surgeons) more accurately than the P-PASS [10].

The clinical significance of the PDRI to predict the outcome of PT has also been investigated. A small number of studies showed controversial results. On the one hand, Amaral et al. analyzed the outcome in 154 PTs in a Brazilian population with regard to the predictive value of the PDRI. They performed a subgroup analysis based on the same PDRI intervals as in our study, and concluded that there is no association between PDRI and 1-year pancreas graft survival [8]. Salamanca-Bustos et al. reported similar results after the evaluation of 126 SPKs in a Spanish population [11].

On the other hand, several studies indicate that the PDRI does correlate with pancreas graft survival. First, Axelrod et al. retrospectively analyzed data from PTs performed during a 7-year period in the USA and recorded by the Scientific Registry of Transplant Recipients (n=9401) [7]. The authors concluded that a higher PDRI score (≥1.57) is associated with a significant reduction in 1-year pancreas graft survival and that the use of this score could potentially enhance the allocation and utilization of higher-risk organs [7]. Another large study, from the UK, examined data from 1021 PTs and confirmed an association between PDRI and graft survival. Interestingly, these results were confined only to SPKs and were not applicable to PTAs or PAKs [12]. In the aforementioned study by Blok et al., PDRI values above a cut-off point set at 1.24 were associated with impaired graft survival. The authors stated that the PDRI is a predictor of pancreas graft survival, although good outcomes can also be achieved with grafts from high-PDRI donors [5]. The use of the PDRI in decision making was recommended by another large retrospective study from the USA that evaluated the data and results from 9916 registered SPKs [13] to determine the impact of BMI on outcomes. The data analysis showed a significantly worse 1-year outcome in cases with a PDRI >2.12 [13].

In our study, the PDRI >1.5 group showed lower 1-, 5-, and 10-year survival rates compared to the other 2 PDRI groups. Compared to the PDRI <1 group to the PDRI >1.5 group, the

1-year survival rate was 10% worse, and the 5- and 10-year survival rates were each 18% worse in the latter. The survival rates between the PDRI <1 and PDRI 1–1.5 groups did not differ significantly. The slightly better 1-year survival in the PDRI 1–1.5 group (83% *vs.* 79%) could be ascribed to one of the several factors that may influence graft survival in the first year (e.g., graft thrombosis, pancreatitis, postoperative bleeding, and rejection episodes). It is possible that these causes of graft failure occurred more frequently in the PDRI <1 group. Altogether, it seems that high PDRI scores, such as >1.5, are associated with worse graft survival.

To exclude the influence of recipient or procedural factors on graft survival, we have shown that there were no significant differences between the PDRI recipient groups in all tested variables and the data are demonstrated in Table 2. In contrast to the USA population (median donor with a PDRI=1.0), the median PDRI of our pancreas donors was 1.3. Although this study produced clear results, it has the limitation of incorporating a relatively small number of patients (n=322). Some of the previously mentioned studies that evaluated the role of the PDRI are multi-centric and analyzed a much larger population.

Applying the PDRI to a population belonging to the ET network necessarily excludes ethnicity and DCD in its calculation as these factors are not recorded in ET transplant protocols. The formula shows that African-American ethnicity increases the calculated PDRI by 0.27 when all other parameters are held constant for the median donor [7]. Similarly, Asian ethnicity adds 0.17 and the DCD 0.39 each to the PDRI [7]. In summary, this limits the comparability of the PDRI to the way it is used in the USA and the ET area. However, a comparison between German centers is possible as they use the same protocols and none include ethnicity or DCD in the PDRI calculation.

Interestingly, studies indicate that pancreas and kidney survival from donors after brain death (DBD) and DCD does not differ significantly in SPK [14,15]. Further studies of this kind with the same results could lead to also considering DCD in Germany to expand the donor pool further and meet the growing demand for grafts.

Nevertheless, our single-center study is the first to evaluate the PDRI regarding pancreas graft survival in a German population. Our findings are in line with recent large studies reporting the association between PDRI and pancreas graft survival [5,12,13].

However, the role of risk scores in the decision-making process has so far only been supportive. This applies not only to the P-PASS, but also to the PDRI. The decision of whether to accept or decline a pancreas graft should be based on the evaluation of several variables. A study by Loss et al. demonstrated that the selection process is highly inconsistent [16] and is characterized by discrepancies in the accepted cut-off values of important donor factors such as age, laboratory findings, and ICU stay [16].

Conclusions

Our study, performed in a German population, showed that PDRI values >1.5 are associated with a significantly worse outcome after PT. Additional studies in other populations with a larger number of patients could further validate the PDRI. Furthermore, to compare the quality of pancreas grafts and SPK outcomes in different transplant centers, the PDRI could be useful. Although the P-PASS showed an association with early graft failure, it failed to show a similar result regarding long-term pancreas graft survival.

Conflict of interest

None.

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