

Article

Early Graft Loss in Solitary Pancreas Transplant Recipients Within Eurotransplant Region

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Abstract

Introduction: While extensive research has been conducted on specific factors affecting transplant outcomes in simultaneous pancreas-kidney recipients, less is known about outcomes following single pancreas transplantation (PTx). This study focuses on identifying factors related to early graft loss after PTx. **Patients and Methods:** A retrospective analysis was performed on a Eurotransplant (ET) registry database encompassing all consecutive solitary pancreas transplantations from 2000 to 2018. To address any missing values, multiple imputation techniques were employed. Uni and multivariable statistical analyses were performed. **Results:** The primary causes of early graft loss (<90 days) were thrombosis, bleeding, rejection, and infection. Using multivariable analysis, donor male gender (Hazard Ratio (HR) 0.62) was significantly associated with early graft survival. Of all recipient variables, recipient age (HR 0.96) and recipient cardiovascular history (HR 2.10) were associated with graft loss. A subgroup analysis PTx of female donors into female recipients showed an increased risk for early graft loss compared to male-to-male transplants (HR 2.14). The graft survival rates were 62.9% and 79.0%, respectively ($p = 0.017$). **Discussion:** This Eurotransplant registry analysis identifies various donor- and recipient-related risk factors after PTx, partly mirroring the SPK population but also identifying new factors. These findings identify PTx patients as a separate entity in pancreas transplantation and emphasize the need for tailor-made matching of donors and recipients.

Keywords: pancreas transplantation; risk factors; early graft survival



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1. Introduction

Type 1 diabetes mellitus (DM1) is the leading cause of kidney failure, nontraumatic lower limb amputations, and new cases of blindness in adults [1]. Pancreas transplantation remains the only established method to achieve sustained normoglycemic control in patients with poorly controlled diabetes and/or end-stage DM1 resulting in organ failure. Long-term pancreas graft function has improved significantly over the last three decades and successful pancreas transplantation has been demonstrated to arrest or even reverse the development and progression of secondary diabetic complications [1,2]. However, in the swiftly evolving medical landscape, the decision to pursue a single pancreas (re-)

transplantation should be carefully considered against increasingly successful alternative treatment options.

Pancreas transplantation is performed in three distinct clinical scenarios: simultaneous pancreas-kidney (SPK) transplantation, pancreas after kidney (PAK) transplantation, and pancreas transplant alone (PTA). Studies have consistently shown a higher risk of allograft failure in solitary pancreas transplantation (PTx, including both PAK and PTA) compared to SPK transplants [3].

Over the years, several Eurotransplant countries have developed robust living kidney donation programs, enabling waitlisted candidates to receive a living donor kidney transplant. These transplants are associated with superior patient and graft outcomes compared with deceased-donor kidney transplantation. PAK transplantation may further reduce kidney waiting time and mortality by facilitating access to living donor kidney transplantation while preserving deceased-donor kidneys for allocation to other recipients. In addition, Eurotransplant allocation policies prioritize local kidney transplantation, resulting in a proportion of pancreas grafts being offered without a concurrent kidney and remaining underutilized. Utilization of these isolated pancreas grafts enables timely pancreas transplantation following living donor kidney transplantation, thereby shortening effective waiting time and potentially reducing mortality in non-sensitized recipients [4].

Historically, PTx transplants have demonstrated lower pancreas allograft survival rates compared to SPK transplants (78% vs. 85% one-year graft survival, $p = 0.0001$) [5]. Despite advancements in rejection therapy, pancreas transplantation continues to face a relatively high incidence of graft loss. This can be attributed to complications such as bleeding, thrombosis, or infection-related issues [6]. This is especially pronounced in the first month(s) following transplantation and is particularly high in PTx recipients [7].

Thrombosis is historically categorized as a 'technical failure'. Based on United Network for Organ Sharing (UNOS) data improvement in pancreas graft survival rates are not solely attributable to decreased technical failure but also to less rejection-related graft loss. The rejection loss rates at 1 year have undergone a 4–5-fold reduction from the earliest years (1988) to more recent times, registering at 8% in PTx and 2% in SPK in 2002/2003 [5]. Similar trends are observed in thrombotic loss. More recent data on this subject are scarce. Furthermore, a clear consensus regarding antithrombotic measurements is lacking, with varying protocols per center based on individual experience [6–9]. In the meantime, the potential association between rejection and thrombosis in PTx remains not fully understood.

While numerous studies on graft survival after solitary pancreas transplantation and the identification of risk factors have been performed on individual center level, there is often no clear distinction regarding factors influencing graft loss for specific types of transplantation. The available literature suggests that different processes may impact each transplant type differently. Therefore, the primary objective of this study is to investigate outcomes specifically after PTx within the Eurotransplant (ET) region, with a particular focus on early graft loss within the first 90 days.

2. Patients and Methods

2.1. Study Design

This study constitutes a retrospective cohort analysis encompassing all consecutive solitary pancreas transplantations performed within the ET region. Inclusion criteria were recipients aged >18 years of age who received a PTx between 1 January 2000, and 31 December 2018. Short-term outcome was chosen deliberately, aligning with the focus of this analysis on early pancreas graft loss (<90 days). Long-term graft survival was included as a secondary outcome parameter.

Approval for this study was obtained on behalf of Eurotransplant Pancreas Advisory Committee and with approval from the Eurotransplant Scientific Committee. Patients included in the study provided consent for use of the utilization of anonymized data upon their listing for transplantation.

2.2. Data Collection

Demographic and transplant characteristics for both recipients and donors were collected from all participating centers within the Eurotransplant region. Graft failure was defined as the removal of the pancreas graft, resumption of exogenous insulin therapy, or patient death. This determination was based on information provided by the individual centers.

2.3. Statistical Analysis

Descriptive statistics are shown for recipient, donor, and transplant characteristics. If applicable, the percentage of missing values is shown. Normal distributed continuous data were presented as means with $\pm$ Standard Deviation (SD), while skewed continuous data were presented as medians with interquartile ranges (IQR). Categorical variables were expressed as numbers and percentages.

Kaplan–Meier curves were used for survival analysis of different categorical variables, and differences between groups were compared using Log-rank tests.

Multiple imputation (MI) was used to complete the dataset in order to avoid bias due to missing values to improve the validity of the study. All variables, theoretically influencing short-term pancreas graft survival (including the outcome variable), were utilized for imputing missing baseline data to maximize information for estimating imputed values. Log-transformation was applied for non-normally distributed continuous variables. Univariate and multivariable Cox regression with calculation of pooled estimates was performed to identify factors related to early pancreas transplant loss, defined as failure during the first 90 days post-transplantation. No interactions between independent variables were studied. p -values < 0.05 were considered statistically significant. All analyses were performed using IBM SPSS statistics software (version 29).

3. Results

A total of 329 consecutive PTx were performed during the study period. In 24 (7.4%) cases, recipients underwent a subsequent pancreas transplant following any prior pancreas transplantation, regardless of the initial transplant type (PTA, PAK, or SPK). Baseline data for recipients and donors are detailed in Tables 1 and 2, while surgical factors are presented in Table 3. Enteric drainage was the most commonly performed method (82.9%), and the pancreas was transplanted with the pancreatic head in a cranial position (head up) in 57.7% of cases.

Table 1. Recipient characteristics.

Variable		N = 329	Missing (%)	Mean $\pm$ SD/%
Year of transplantation			0	
<2010		198		60.20%
2010–2014		82		24.90%
≥ 2015		49		14.90%
Age (mean $\pm$ SD)		329	0	44.2 $\pm$ 8.24
Gender	Female	126	0	38.30%
	Male	203		61.7%

Table 1. Cont.

Variable	N = 329	Missing (%)	Mean $\pm$ SD/%
Height (cm)	250	79 (24.0%)	172.6 $\pm$ 8.57
Weight (kg)	250	79 (24.0%)	72.1 $\pm$ 13.85
BMI (mean $\pm$ SD)	250	79 (24.0%)	24.1 $\pm$ 3.79
Transplantation type PTA	147	5 (1.5%)	45.4%
PAK	153		47.2%
Retransplantation	24		7.4%
History of cardiovascular disease No	165	70 (21.3%)	63.7%
Yes	94		36.3%
History of venous thrombosis No	158	113 (34.3%)	73.1%
Yes	58		26.9%
History of anticoagulants No	92	164 (49.8%)	55.8%
Yes	73		44.2%
Combination donor–recipient gender		0	
Male–Male	117		35.6%
Female–Male	63		19.1%
Male–Female	86		26.1%
Female–Female	63		19.1%
Patient survival (5-year follow-up)			
Patient alive		6 (1.8%)	
Yes	282		87.3%
No	41		12.7%
Patient survival	No of events (cumulative)	6 (1.8%)	Survival $\pm$ SE (%)
30 days	1		99.7 $\pm$ 0.003%
90 days	5		98.4 $\pm$ 0.007%
1 year	14		95.6 $\pm$ 0.012%
5 years	41		86.0 $\pm$ 0.020%

Table 2. Donor characteristics.

Variable	N = 329	Missing (%)	Mean $\pm$ SD/%
Age (mean $\pm$ SD)	329	0	30.3 $\pm$ 11.62
Gender Female	149	0	45.3%
Male	180		54.7%
Height (cm)	329	0	172.9 $\pm$ 12.98
Weight (kg)	329	0	69.4 $\pm$ 14.28
BMI (mean $\pm$ SD)	329	0	22.9 $\pm$ 2.88
Cause of death CVA No	131	94 (28.6%)	55.7%
Yes	104		44.3%
Donor type DBD	321	0	
DCD	8		97.6%
			2.4%
Serum creatinine (μ mol/L, mean $\pm$ SD)	321	8 (2.4%)	4.3 $\pm$ 0.48
Serum sodium (mmol/L, mean $\pm$ SD)	324	5 (1.5%)	146.2 $\pm$ 8.16

Table 3. Transplantation characteristics.

Variable		N = 329	Missing (%)	Mean ± SD/%
Warm ischemia time (minutes)		236	93 (28.3)	32.1 ± 10.64
Cold ischemia time (hours)		237	92 (28.0)	10.9 ± 3.36
Type of drainage	Bladder	46	60 (18.2)	17.1%
	Enteric	223		82.9%
Position pancreas head			81 (24.6)	
Head up (incl. Boggi)		143		57.7%
Head down (incl. bladder)		105		42.3%
Posttransplantation therapy				
Posttx anticoagulation therapy 0–1 >1			109 (33.1)	
		68 152		30.9% 69.1%
Induction therapy			68 (20.7)	
Campath		33		12.6%
ATG		145		55.6%
IL-2		56		21.5%
None/other		27		10.3%
Steroids	No	13	50 (15.2)	4.7%
	Yes	266		95.3%
Graft loss ≤ 90 days	No	226	19 (5.8)	72.9%
	Yes	84		27.1%
Early graft loss (≤90 days)		84	19 (5.8)	27.1%
(<14 days)		61		72.6%
(14–30 days)		10		11.9%
(30–90 days)		13		15.5%
Follow-up time first (90 days) (median (IQR))		310	19 (5.8)	90 (45–90)
Cause of graft loss			0	
Thrombosis		60		71.4%
Rejection		4		4.8%
Bleeding		5		6.0%
Intra-abdominal abscess/leakage		1		1.2%
Pancreatitis		7		8.3%
Duodenal Leakage		1		1.2%
Other		6		7.1%

3.1. Graft Survival

Early graft loss (<90 days) was observed in 84 (27.1%) patients. Causes of this early graft loss included thrombosis in 60 cases (71.4%), bleeding in 5 cases (6.0%), rejection in 4 cases (4.8%), infectious problems in 9 cases (10.7%), and other factors in 6 (7.1%) cases, as is shown in Table 3. No statistically significant difference was found between the different types of transplantation (Figure 1).

Regarding pancreas graft survival, the overall 1- and 5-year survival rates were 65.2% and 49.1%, respectively. For PTA 1 and 5-year graft survival rates were 67.1% and 45.8%, respectively. For PAK these rates were 67.1% and 49.9%, and for pancreas retransplantations the survival rates were 71.8% and 62.8%, respectively. No statistically significant differences were observed by multiple comparisons (Table S2).

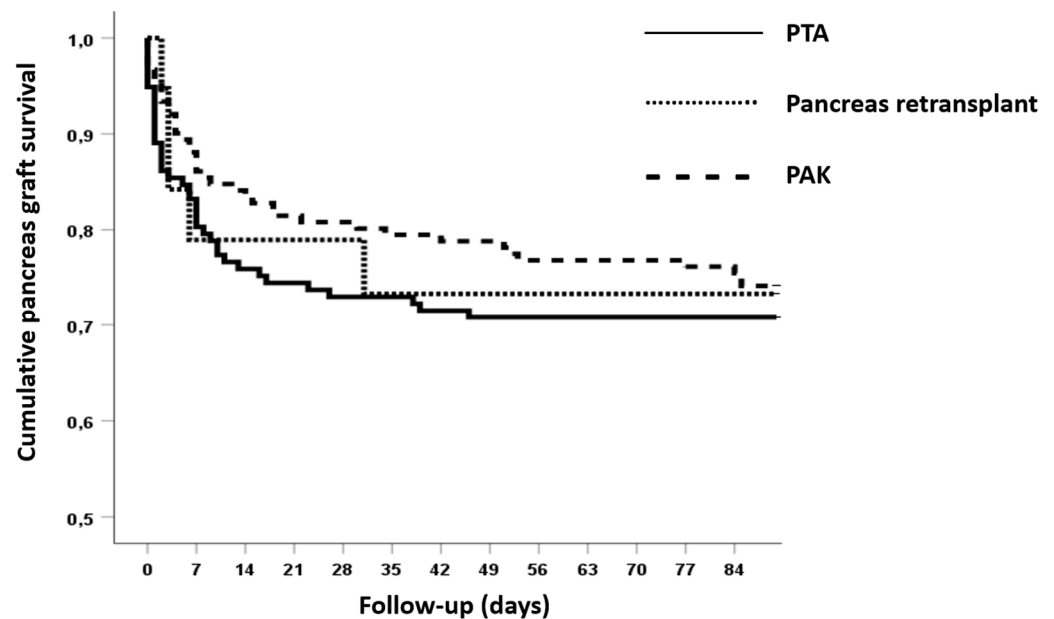


Figure 1. Short-term graft survival after different types of pancreas transplantation. Multiple comparisons showed no significant difference ($p = 0.716$).

Univariable analysis showed increased graft loss in female-to-female pancreas transplantation (HR 1.86 (95% CI 1.06–3.28) $p = 0.032$). Lower recipient age at transplantation showed a decreased risk of graft loss (HR 0.97 (95% CI 0.95–0.997) $p = 0.027$). Donor male gender (HR 0.77 (95% CI 0.44–1.03) $p = 0.07$) was considered borderline significant, as is shown in Table 4.

Table 4. Summary of parameters significantly associated with short-term graft survival (Cox regression). Full details provided in Table S1.

Variable	Univar HR (95% CI)	<i>p</i> -Value	Multivar HR (95% CI)	<i>p</i> -Value
Donor gender				
Female	1		1	
Male	0.77 (0.44–1.03)	0.07	0.62 (0.40–0.96)	0.032
Recipient age	0.97 (0.95–0.997)	0.027	0.96 (0.94–0.99)	0.008
Recipient cardiovascular disease				
No	1		1	
Yes	1.48 (0.92–2.38)	0.109	2.10 (1.23–2.57)	0.007
Gender combination:				
Donor–recipient				
Male to male	1		1	
Male to female	1.21 (0.65–2.26)	0.546	1.32 (0.68–2.55)	0.412
Female to male	1.40 (0.80–2.47)	0.243	1.51 (0.85–2.70)	0.162
Female to female	1.86 (1.06–3.28)	0.032	2.14 (1.19–3.83)	0.011

Multivariable analysis revealed that several factors were found to be significantly associated with early graft survival: recipient age (HR 0.96 (95% CI 0.94–0.99) $p = 0.008$), recipient cardiovascular history (HR 2.10 (95% CI 1.23–2.57) $p = 0.007$), and male donor gender (HR 0.62 (95% CI 0.40–0.96) $p = 0.032$). No significant perioperative risk factors could be identified (Table 4, with additional details available in Supplementary Table S3).

3.2. Patient Survival

During the first year 14 patients were deceased (survival rate 95.6%) and after 5 years a total of 41 patients were deceased (survival rate 86.0%).

3.3. Gender

Pancreas transplantation of female donor to female recipient showed a significant increase in risk for early pancreas graft loss in comparison to male donor to male recipient pancreas transplantation (HR 2.14 (1.19–3.83) $p = 0.011$). For female grafts to male recipient and male graft to female recipient, no significant difference in graft survival was found (Table 4, Figure 2).

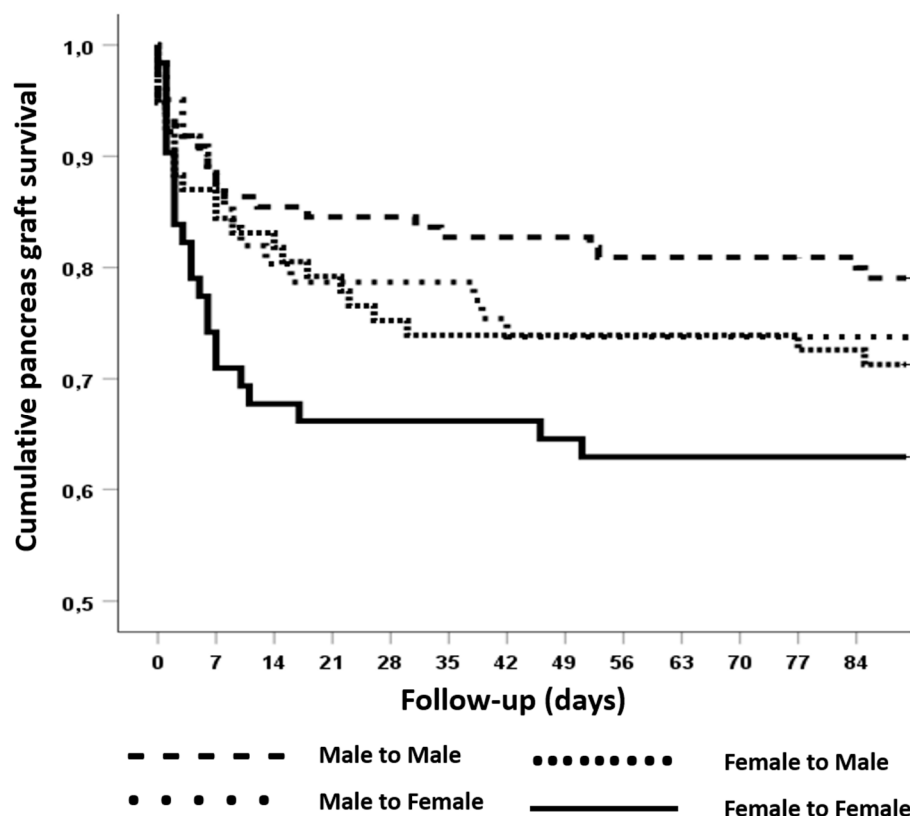


Figure 2. Short-term graft survival after pancreas transplantation with different donor–recipient gender matches. $p = 0.017$, F-F vs. M-M transplantation (log rank).

4. Discussion

This Eurotransplant registry analysis is one of the largest studies on single pancreas transplantation known in the literature. The key findings are that in the context of PTx, recipient age, donor sex, and recipient history of cardiovascular disease emerge as relevant factors associated with outcome.

Additionally, this study shows that thrombosis stands out as the predominant cause of early graft failure. However, it remains unclear whether this issue is solely technical or if immunological factors also play a role in this specific patient group. At present, no uniform recommendations exist regarding postoperative anticoagulation therapy after pancreas transplantation. In our cohort, no association between postoperative anticoagulation therapy and patient survival was observed. However, data on the specific type of anticoagulant therapy (e.g., antiplatelet agents or low-molecular-weight heparin) were not available in our database, which limits the conclusions that can be drawn from these observations.

Overall graft survival observed in our study corresponds with the existing literature. The 5-year overall graft survival rate in our cohort was 49.1% (SD 3.1%). A study by Humar et al. reported 3-year graft survival of 61.7% after PAK [10]. In a previous study by our group (partially overlapping with the current cohort), death-censored pancreas graft survival was 66.0% at 1 year and 55.0% at 5 years for PAK recipients [8].

A subsequent study, with a mean follow-up of 45.1 months, reported a graft failure rate of 33.4% (313 of 937). Remarkably, this study highlighted that for SPK recipients, technical failure was the most common cause of graft loss, followed by rejection. In contrast, for PAK and PTA recipients, rejection was the primary cause followed by technical failure [11]. In our study cohort, technical failure (e.g., thrombosis) emerged as the leading cause both in overall graft loss and early graft loss for patients undergoing their first pancreas transplant or pancreas retransplant. While it remains challenging to determine the extent to which rejection may have contributed to a thrombotic cascade, the possibility of such a connection cannot be ruled out.

Our ET registry patient survival rates correspond with the existing literature. The 1-year and 5-year overall survival rates were 95.6% and 86.0%, respectively. Fridell et al. reported a 1-year and 5-year patient survival in PAK recipients ($n = 65$) of 98% and 82.9% [4,12]. A small subgroup analyzed by Genzini et al. from the early 2000s described a one-year patient survival of 85% in a group of 20 pancreas re-transplantations [13]. Gasteiger et al. found a 5-year overall patient survival rate of 89% and 88% (28 of 32) for single pancreas re-transplantation recipients [14]. These numbers closely mirror our findings.

Different combinations of donor and recipient gender are generally not considered a significant risk factor in pancreas transplantation and may not play a decisive role in graft acceptance. However, our results suggest that female-to-female transplantation should be considered a potential risk. Our database did not provide a clear mechanistic explanation for this finding. However, prior studies support a potential influence of donor sex on graft outcomes. In particular, Coffman et al. reported an increased risk of relaparotomy, pancreas thrombosis, and lower overall survival in recipients of female donor organs, regardless of recipient sex [15]. These findings suggest that female donor organs may be associated with higher early graft complications, which could contribute to reduced graft survival. The underlying mechanisms may include differences in organ size, vascular anatomy, or immunological factors, but these remain incompletely understood. Further studies are warranted to investigate the risk of thrombosis and graft failure in female recipients, particularly when receiving female donor organs, to better elucidate the role of sex-related factors in pancreas transplantation outcomes.

Earlier studies have suggested that donor variables such as age, BMI, and length of ICU stay may negatively impact graft success [16,17]. In our study cohort, focusing on early graft loss, only donor male gender (HR 0.62 (95% CI 0.40–0.96) $p = 0.032$) appeared to be protective. Donor BMI is well known as a risk factor for transplant outcome; for instance, a donor BMI of 30 kg/m² was found to be a risk factor (RR 1.66, $p = 0.06$) in an earlier study [11]. In our study, very few donors and recipients with BMI > 25 were included, which probably explains why we did not find this known risk factor in our cohort. Furthermore, pre-existing cardiovascular disease in the recipient showed a significant impact on the prevalence of postoperative complication rates after pancreas transplantation [18]. Our study corroborates these findings as we observed a negative association between cardiovascular history of the recipient and early graft loss (HR 2.10 (95% CI 1.23–2.57) $p = 0.007$). Other risk factors associated with technical failure described by Humar et al. were preservation time < 24 h (RR 1.87, $p = 0.04$), donor cause of death other than trauma (RR 1.58, $p = 0.04$), and enteric drainage of the pancreas (RR 1.68, $p = 0.06$). In line with other studies [19], our study did not indicate enteric drainage as a risk factor after multivariable analysis.

Unfortunately, our database did not provide sufficient information regarding the potential effects of antithrombotic therapy. Centers employ different protocols, with a tendency towards more aggressive therapy in high-risk transplants. While successful international protocols exist, the absence of multicenter prospective data emphasizes the

need for further study, as recently stated by the World Consensus Conference on pancreas transplantation [20–22]. The recently established European Pancreas Transplant Research Consortium (EPTRC) platform aims to meet this need.

Successful pancreas transplantation has demonstrated the ability to slow or even halt the progression of diabetic retinopathy and nephropathy, offering the potential to increase quality of life and patient survival. However, the decision-making process regarding pancreas (re-) transplantation, islet allotransplantation, or continuous insulin therapy treatment using modern devices remains a subject of debate. Treatment strategies should be individualized, taking into account patient preferences, surgical considerations, and immunological factors. It is essential to recognize that a pancreas used for pancreas re-transplantation with suboptimal outcome may also be viewed as a missed opportunity for another patient awaiting a first transplantation. Therefore, the indication for re-transplantation should be carefully considered and made judiciously.

The current study has several limitations. First, this study is of a retrospective design, and despite its status as a large cohort from the ET region on this topic, the relatively low patient numbers may introduce bias. The registry cohort itself represents a heterogeneous group, encompassing various transplant types, center experiences, and perioperative care practices. Nevertheless, this contributes to a real-life portrayal of pancreas transplantation. A second limitation pertains to the presence of missing data, a common challenge in epidemiologic studies. How they are handled is critical, as results may be biased, and precision may be overestimated if inappropriate methods are used. Our approach to the handling of missing data was detailed in the Section 2, adhering to the literature standards [23]. Unfortunately, this limitation precluded conclusions on antithrombotic therapy and rejection.

From this large retrospective registry analysis, we may conclude that early graft survival after single pancreas transplantation is adequate and in line with earlier studies from United Kingdom and United States of America cohorts. As shown elsewhere, survival is lower than after SPK. To a certain extent, similar risk factors and treatment strategies apply as for SPK, but immunological factors may exert a more prominent role. Thrombosis is more prevalent in PTx cohorts compared to SPK, but determining whether this is associated with a rejection process remains elusive. The benefit of single pancreas (re-) transplantation should be carefully weighed against other treatment options that are demonstrating increasing success. Continuous prospective follow-up of PTx within registries is imperative to monitor treatment success in the future.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/transplantology7010003/s1>, Table S1: Cox-regression analysis of parameters related to donor; Table S2: Cox-regression analysis of parameters related to recipient; Table S3: Cox-regression analysis of parameters related to peri-operative care.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. All patients receiving a transplant within the Eurotransplant region automatically consent with this anonymized used when placed on the waiting list.

Data Availability Statement: The original contributions presented in this study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding authors.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

BMI	body mass index
CI	confidence interval
DM1	type 1 diabetes mellitus
ETPRC	European pancreas Transplant Research Consortium
ET	Eurotransplant
HR	hazard ratio
IQR	interquartile range
MI	multiple imputation
PAK	pancreas after kidney transplantation
PTA	pancreas transplantation alone
PTx	single pancreas transplantation
SD	standard deviation
SPK	simultaneous pancreas-kidney transplantation
UNOS	United Network for Organ Sharing

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