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Outcomes of pancreas transplantation over two decades: a single-center retrospective cohort study

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Purpose: Pancreas transplantation (PT) is a definitive treatment for diabetes mellitus (DM), restoring endogenous insulin secretion and improving glycemic control. Despite its efficacy, PT is less common in South Korea compared to Western nations. This study aims to report the clinical outcomes of PT over 2 decades at a single center, focusing on surgical techniques, complications, and graft survival.
Methods: A retrospective analysis of 69 PT recipients at Seoul National University Hospital between January 2002 and December 2023 was conducted. Data on recipient and donor demographics, surgical details, immunosuppressive regimens, and graft outcomes were collected. Graft survival was evaluated using Kaplan-Meier analysis, with subgroup comparisons using the log-rank test. Graft failure was defined as graft removal, PT re-registration, insulin dependence exceeding 0.5 units/kg/day for more than 90 days, or patient death.
Results: Among the 69 recipients, 50 (72.5%) had type 1 DM, and 18 (26.1%) had type 2 DM. Simultaneous pancreas-kidney (SPK) transplantations comprised 84.1% (n = 58), and pancreas-after-kidney (PAK) transplantations accounted for 10.1%. The 1-year and 5-year death-censored pancreas graft survival rates were 92.7% and 89.6%, respectively, with no significant difference between SPK and PAK (P = 0.330). Graft failure occurred in 10 patients, primarily due to pancreatitis and rejection. Donor-related factors, particularly anoxic brain injury, were significantly associated with lower graft survival (P = 0.045).
Conclusion: PT outcomes in this cohort align with international standards, emphasizing the importance of donor selection and tailored immunosuppression. Expanding PT indications to include selective type 2 DM patients could benefit South Korea's PT programs with adequate resource allocation.
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Key Words: Graft survival, Immunosuppression therapy, Pancreas transplantation, Type 1 diabetes mellitus, Type 2 diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) presents significant medical, financial, and social challenges worldwide [1]. Its impact is especially pronounced in South Korea, where DM is a leading cause of end-stage renal disease (ESRD) [2]. In 2020, around 16.7% of adults aged 30 years or older and 30.1% of individuals aged 65 years or older were affected by DM, contributing

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a substantial burden on the healthcare system. Over the past decade, the prevalence of DM has steadily increased, highlighting the need for advanced management strategies to reduce long-term complications. Among these, ESRD remains a significant concern, with diabetic patients facing a 4.95-fold increased risk of developing ESRD compared to non-diabetic individuals [3]. For patients with insulin-dependent DM, pancreas transplantation (PT) represents the only definitive long-term therapeutic option that provides stable glycemic control [4]. By restoring endogenous insulin production, PT has become essential for patients unable to maintain adequate glycemic control through conventional therapies.

Kidney transplantation (KT) is recognized as a life-extending treatment for diabetic ESRD patients, with better survival outcomes compared to dialysis [5]. However, despite the success of KT, poor glycemic control posttransplant remains a major challenge, often leading to morbidity and mortality [6,7]. Furthermore, simultaneous pancreas-kidney (SPK) transplantation has been demonstrated to be the most cost-effective treatment strategy compared to dialysis or KT alone.

The aim of this study is to share our overall experience by presenting the outcomes of PT for insulin-dependent DM patients at our center, focusing on surgical procedures, complications, and graft outcomes.

METHODS

Ethics statement

This study was approved by the Institutional Review Board of Seoul National University Hospital (No. 2408-137-1565). Informed consent was waived given the retrospective nature of the study, which adheres to the Declaration of Helsinki.

Study population

A retrospective review was conducted on 69 patients who underwent PT at the Department of Transplantation and Vascular Surgery, Seoul National University Hospital, between January 2002 and December 2023. Data collected from patient medical records included recipient demographics, surgical details, deceased donor characteristics, and graft outcomes.

Immunosuppressive regimen and postoperative protocol

The immunosuppressive regimen followed standard KT protocols and included induction therapy and triple maintenance agents. Induction therapy consisted of basiliximab (Simulect, Novartis) or rabbit anti-human thymocyte immunoglobulin (ATG) (Thymoglobulin, Sanofi). There are no absolute criteria for the choice of induction therapy. At our center, basiliximab was primarily used for SPK transplantation because these cases typically involved first-time transplants and standard-criteria donors. In contrast, ATG was generally reserved for high-risk patients. Maintenance therapy included tacrolimus, antimetabolites (mycophenolate mofetil [MMF] or mycophenolic acid [MPA]), and corticosteroids. Tacrolimus was administered twice daily, with trough concentrations maintained at 8-12 ng/mL for the first 3 months, followed by 6–10 ng/mL from 3 to 6 months. Both MMF and MPA are clinically equivalent in their therapeutic effects, with MPA demonstrating a slightly lower incidence of gastrointestinal disturbances. In clinical practice, the choice between these 2 agents is largely interchangeable and dependent on individual patient tolerance. Steroid withdrawal therapy was not adopted.

After surgery, blood sugar tests (BST) were monitored, with a target BST range of 80–110 mg/dL, and continuous regular insulin infusion was administered. On postoperative day (POD) 1, hemoglobin levels were assessed, and the characteristics of the Jackson-Pratt drain were reviewed to determine the use of low-molecular-weight heparin (Fraxiparine, Aspen Pharma). On POD 2, CT angiography was performed, and fluid replacement was managed based on urine output. Total parenteral nutrition was administered during the fasting period, which continued until POD 7. Octreotide (Sandostatin, Novartis) was administered for secretion management, and amylase, lipase, C-peptide, and drain amylase levels were regularly monitored. Hemoglobin A1c (HbA1c) and glutamic acid decarboxylase (GAD) antibodies were also followed up. Standard prophylaxis protocols were administered for antibacterial, antifungal, and antiviral protection.

Graft procurement and transplantation procedure

The pancreas graft is particularly vulnerable to ischemic damage, necessitating careful consideration of graft suitability in cases of prolonged cardiac arrest or sustained hypotensive conditions, which may result in ischemic insult. Because the exact duration of cardiac arrest that leads to significant ischemic injury is not well-established, potential ischemic damage can be inferred from elevated amylase and lipase levels, as well as physical changes in the graft, such as softening and yellowish discoloration. Ultimately, confirmation of ischemic insult relies on direct intraoperative evaluation of the graft.

The surgery followed a standard procedure. Once the pancreas was retrieved, bench preparation involved trimming excessive tissue while preserving important vascular structures. Arterial reconstruction was performed using an end-to-end anastomosis with a donor iliac artery Y-graft, connecting to the superior mesenteric artery and the splenic artery.

Venous anastomosis typically involves connecting the donor portal vein to the recipient's common iliac vein (CIV) using an end-to-side technique. The arterial anastomosis was performed at the common iliac artery. Exocrine drainage was mainly achieved through enteric drainage, connecting the donor

duodenum to a loop of the recipients' small intestine through side-to-side duodenoileostomy 150 cm proximal to the ileocecal valve depending on the position of the pancreas head. In some cases of pancreas-after-kidney (PAK) transplantation, bladder drainage was performed.

For SPK transplantation, the pancreas was implanted in the right iliac fossa and the kidney in the left. This approach optimizes space and minimizes vascular overlap. In the PAK transplantation, the kidney was first positioned on the left, allowing the subsequent placement of the pancreas graft on the right. For PT alone (PTA), the pancreas was consistently placed in the right iliac fossa. The pancreas was placed retroperitoneally with the head facing caudad for either bladder drainage or enteric drainage. In 1 case where the CIV was positioned medially due to left-sided inferior vena cava, the pancreas was located intraperitoneally and in a cephalad position. In another case, prior to Whipple's operation had led to adhesion; the pancreas was also being positioned intraperitoneally and cephalad.

Graft failure and complications

Pancreas graft failure was defined as graft removal, re-registration for pancreas or islet transplant, insulin dependence greater than 0.5 units/kg/day for more than 90 days, or patient death. Kidney graft failure was defined as graft removal, re-registration for kidney transplant, return to dialysis, or patient death [8]. Complications included postoperative complications and pancreas rejection rates (both biopsy-proven and clinical rejection). Donor characteristics such as age, sex, and cause of brain death were analyzed for their impact on graft survival.

Table 1. Characteristics of pancreas transplantation recipients

Characteristic	Data
No. of patients	69
Age (yr)	44.7 ± 10.5
Sex, male:female	38 (55.1):31 (44.9)
Body mass index (kg/m^2)	23.3 ± 4.1
Comorbidity	
Hypertension	34 (49.3)
HBV	4 (5.8)
Tuberculosis	4 (5.8)
Follow-up duration (mo)	
Pancreas	297.3 ± 180.2
Kidney	324.3 ± 240.4
DM duration (yr)	19.40 ± 7.03
Waiting duration (mo)	64.4 ± 42.4
Preoperative HbA1c (%)	7.81 ± 1.61
Preoperative creatinine (mg/dL)	8.58 ± 3.81
Preoperative insulin demand (IU)	35.11 ± 20.65
No. of HLA mismatches	3.87 ± 1.03
Cause of pancreas transplantation	
Type 1 DM	50 (72.5)
Type 2 DM	18 (26.1)
Others	1 (1.4)

Values are presented as number only, mean ± standard deviation, or number (%).
DM, diabetes mellitus; HbA1c, hemoglobin A1c; HLA, human leukocyte antigen.

Statistical analysis

Continuous variables were represented as mean ± standard deviation, and categorical variables were expressed as percentages. Kaplan-Meier survival curves were constructed to evaluate overall graft survival among PT patients and compare graft survival between SPK and PAK transplantations through a log-rank test. Additionally, graft survival is based on donor age, donor sex, cause of death, and reason for PT. All analyses were conducted using IBM SPSS Statistics ver. 26 (IBM Corp.) and R software ver. 4.4.1 (The R Foundation). A P-value of <0.05 was considered statistically significant.

RESULTS

Patient and donor characteristics

From January 2002 to December 2023, a total of 69 patients underwent PT. The mean follow-up period was 390.2 ± 161.3 months. All recipients were of Korean ethnicity, and their demographic data is summarized in Table 1. Preoperative HbA1c level was 7.8% ± 1.6%, with a total daily insulin requirement of 35.1 ± 20.7 IU. Type 1 DM was classified based on the following criteria: diagnosis under the age of 35 years, C-peptide <0.6 ng/mL, or GAD antibody positivity [9]. Of the recipients, 50 (72.5%) had type 1 DM, while 18 (26.1%) had type 2 DM. One patient underwent PT following a total pancreatectomy for the ampulla of Vater cancer.

Donor characteristics are summarized in Table 2. The mean donor age was 30.5 ± 8.6 years. The 3 leading causes of brain death were head trauma, cerebrovascular accidents, and anoxic injury. Head trauma and cerebrovascular accidents each accounted for 22 donors (31.9%). Anoxic injury, which resulted from drowning or suicide, contributed to 21 donors (30.4%).

Table 2. Characteristics of pancreas transplantation donor

Characteristic	Data
Age (yr)	30.5 ± 8.6
Sex, male:female	50 (72.5):19 (27.5)
Donor BMI (kg/m^2)	22.1 ± 3.1
Cause of brain death	
Head trauma	22 (31.9)
Cerebrovascular accident	22 (31.9)
Anoxic death	21 (30.4)
Unknown	4 (5.8)

Values are presented as mean ± standard deviation or number (%).
BMI, body mass index.

Surgical procedures and postoperative complications

Basiliximab was the most commonly used induction agent, administered in 65 patients (94.2%). The majority of surgeries were SPK transplantations (n = 58, 84.1%), followed by PAK transplantations (n = 7, 10.1%). PTA was performed in 3 patients (4.3%), and simultaneous pancreas and living KT (SPLK) was performed in 1 patient (1.4%). Enteric drainage was used in most patients (n = 66, 95.6%), with 3 patients (4.4%) initially receiving bladder drainage. Of these, 2 patients required conversion to enteric drainage due to recurrent urinary tract infections and pancreatitis (Table 3).

Postoperative complications included bleeding, thrombosis, pancreatic juice leakage, pancreatitis, and other conditions requiring readmission, such as acidosis, ileus, hematuria, ureteral complications, urinary tract infection, and pneumonia. Complications were categorized as minor if they required observation only, or as major if they necessitated therapeutic intervention. Reoperation for bleeding control was required in 12 patients (17.4%). For thrombosis, 9 patients (13.0%) were treated with medical therapy including anticoagulation or antiplatelet agents, while 1 patient (1.5%) required open thrombectomy and 5 patients (7.3%) underwent interventional procedures (Table 4).

Graft survival and rejection rates

The 1-year and 5-year pancreas graft survival rates were 92.7% and 89.6% respectively (Fig. 1A). There was no significant difference in pancreas graft survival between SPK and PAK transplantations (P = 0.330). In patients who underwent SPK transplantation, kidney graft survival was higher than pancreas graft survival up to 124 months, with 1-year and 5-year survival rates of 100% and 96.3%, respectively. However, after 124 months, pancreas graft survival remained higher, although this difference was not statistically significant (P = 0.870) (Fig. 1B). Ten patients experienced pancreas graft failure due to pancreatitis in 4 patients (40.0%), pancreas rejection in 3 patients (30.0%), or in 1 patient each, pancreatitis with acute rejection, thrombus due to hyperacute rejection, and bleeding (Fig. 2). Pancreas rejection occurred in 18 patients (26.1%), with 15 patients (21.7%) experiencing clinical rejection and 3 patients (4.3%) experiencing biopsy-proven rejection (Fig. 2). Of these, 15 patients (21.7%), including 14 patients (20.3%) who responded to steroid pulse therapy and 1 patient (1.4%) who required a combination of steroid pulse and ATG therapy. Among the patients initially treated for suspected rejection, 2 patients subsequently experienced graft failure due to recurrent rejection. Overall, graft failure due to rejection was observed in 3 patients.

While most factors did not show significant differences in graft survival, donors who died due to anoxic injury showed a significantly lower graft survival rate compared to those with other causes of death (P = 0.045) (Fig. 3).

Table 3. Characteristics of pancreas transplantation procedure

Variable	Data
Induction	
No	2 (2.9)
ATG	2 (2.9)
Basilixumab	65 (94.2)
Operation type	
SPK	58 (84.1)
PAK	7 (10.1)
PTA	3 (4.3)
SPLK	1 (1.4)
Drainage method	
Enteric drainage	66 (95.6)
Bladder drainage	3 (4.4)
Pancreas weight (g)	181.11 ± 37.36
Pancreas cold ischemic time (min)	453.34 ± 152.11
Kidney weight (g)	165.76 ± 41.51
Kidney cold ischemic time (min)	308.28 ± 130.85

Values are presented as number (%) or mean ± standard deviation.
ATG, rabbit anti-human thymocyte immunoglobulin; SPK, simultaneous pancreas and kidney transplantation; PAK, pancreas-after-kidney transplantation; PTA, pancreas transplantation alone; SPLK, simultaneous pancreas and living kidney transplantation.

Table 4. Complications after pancreas transplantation

Variable	Data
Bleeding	
Observation	3 (4.3)
Operative bleeding control	12 (17.4)
Thrombosis	
Observation	9 (13.0)
Open thrombectomy	1 (1.5)
Intervention	5 (7.3)
Pancreas juice leakage[a]	
Minor	2 (2.9)
Major	6 (8.7)
Pancreatitis need to readmission[a]	
Minor	5 (7.3)
Major	12 (17.4)
Acidosis	4 (5.8)
Ileus	7 (10.1)
Hematuria	10 (12.5)
Ureter complication	3 (4.3)
Urinary tract infection	10 (12.5)
Pneumonia	8 (11.6)

Values are presented as number (%).
[a]Complications were categorized as minor if they required observation only, or as major if they necessitated therapeutic intervention.

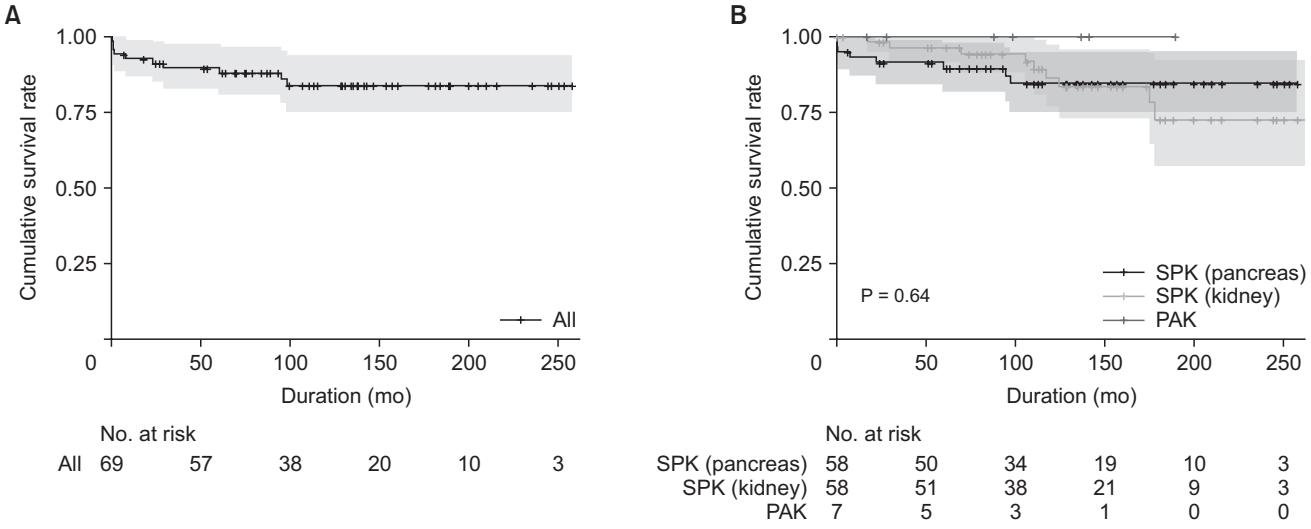

Fig. 1. Kaplan-Meier curve for pancreas graft survival rates in patients who underwent pancreas transplantation. (A) For all patients. (B) Comparison of pancreas graft survival between simultaneous pancreas-kidney (SPK) and pancreas-after-kidney (PAK) transplantations, and comparison of pancreas and kidney graft survival in SPKs.

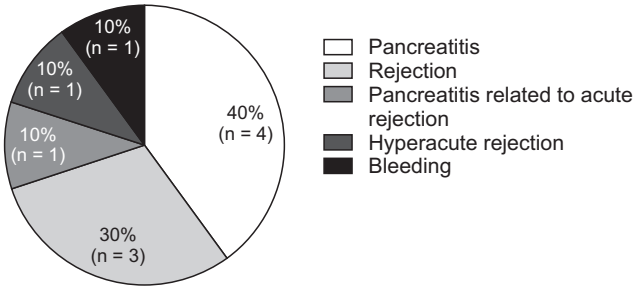

Fig. 2. Causes of pancreas graft failure.

DISCUSSION

PT addresses the limitations of insulin therapy by replacing dysfunctional pancreatic tissue with a healthy donor organ. Since Kelly et al. [8] performed the first partial PT at the University of Minnesota in 1966, advancements in immunosuppressive agents, surgical techniques, and postoperative management have facilitated the widespread adoption of PT worldwide [10,11]. In South Korea, the first successful SPK transplantation occurred in July 1992 in a patient with type 1 DM and renal failure. Since then, approximately 800 PTs have been performed [12,13]. Despite these advancements, PT in South Korea remains significantly less active compared to Western countries. Currently, only 7 centers in South Korea (15.6% of academic medical centers) perform PT compared to 147 out of 216 academic centers (68.1%) in the United States [14,15].

Furthermore, the increasing age of brain-dead donors has contributed to the reduced availability of suitable donors. However, our study demonstrated favorable 1-year, and 5-year graft survival rates of 92.7% and 89.6%, respectively, compared to 90.4% and 81.2% reported in the United States [16]. Additionally, although it has been well-established that graft survival rates are lower in PAK compared to SPK due to factors such as the immunological consistency provided by the simultaneous kidney and PT and better maintenance of blood flow to both grafts in SPK [17], our results demonstrated no significant difference between these approaches. Additionally, for SPK transplantation, it has been reported that the pancreas graft is more susceptible to rejection and has a higher risk of surgical complications compared to the kidney graft. Generally, it often leads to a higher survival rate for kidney grafts. In our study, the kidney graft survival rate remained higher only up to 124 months. However, with prolonged posttransplant duration and well-managed immunosuppressive therapy, the immune system can stabilize, increasing the long-term survival potential of the pancreas graft. Conversely, kidney grafts can experience graft failure due to factors such as calcineurin-induced nephropathy, and the progression of atherosclerosis and hypertension.

One notable finding of our study is the relatively high percentage of PTs performed in patients with type 2 DM (n = 18, 26.1%). PT has been traditionally considered suitable only for type 1 DM to replace destroyed β-cell mass and prevent autoimmune destruction with immunosuppression. Conversely, type 2 DM patients, who were thought to primarily have insulin resistance with residual β-cell function, were not recommended as ideal candidates. However, type 2 DM is now recognized as a diverse condition involving varying degrees of β-cell mass and insulin resistance. Identifying factors that predict good outcomes after PT in type 2 DM is crucial for

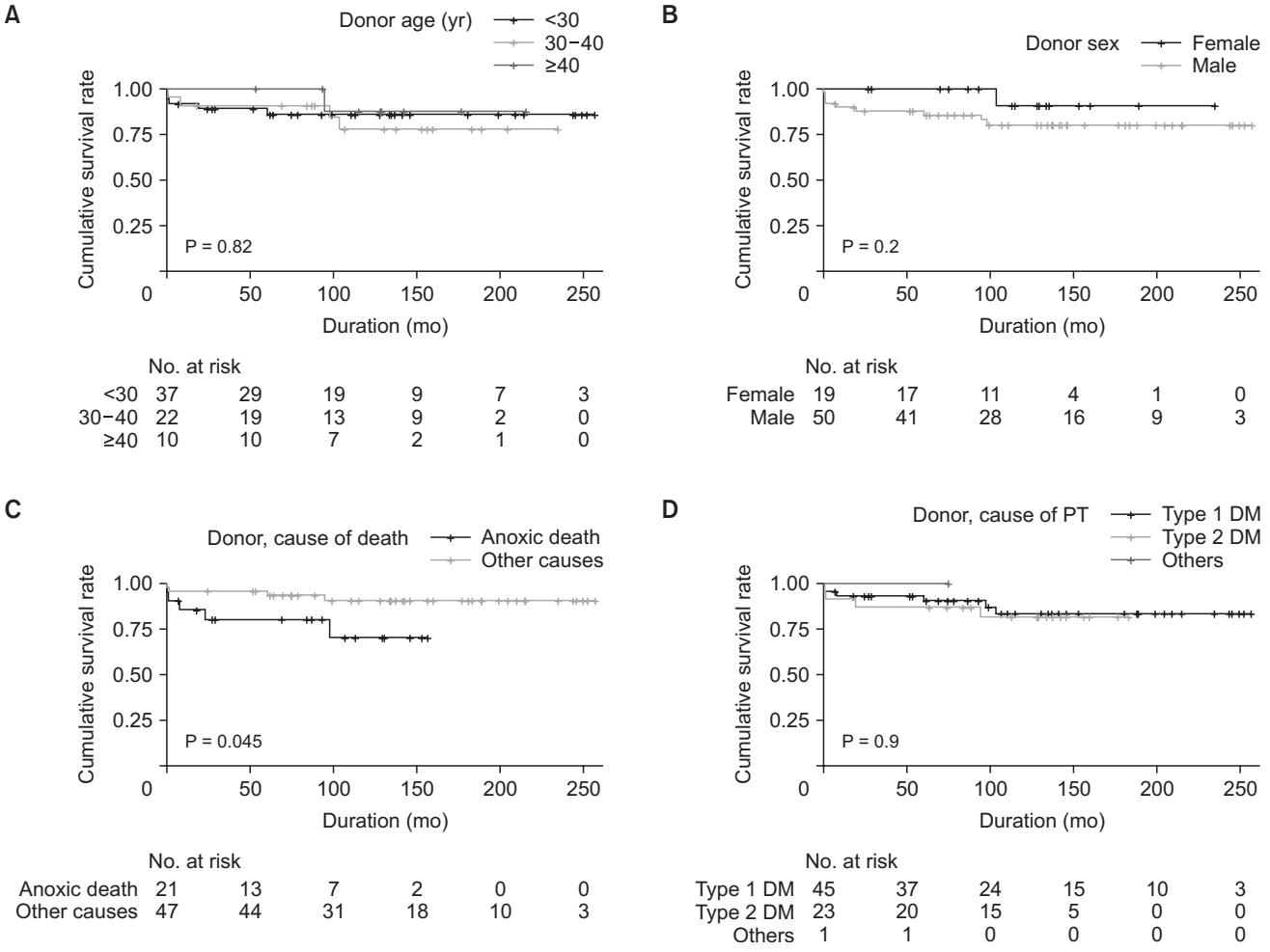

Fig. 3. Impact of characteristics of graft survival. (A) Donor age, (B) donor sex, (C) cause of brain death, (D) cause of pancreas transplantation (PT). DM, diabetes mellitus.

candidate selection [17,18]. In type 2 DM, insulin dependency is considered a valid indication. Notably, within the Korean population, a high prevalence of adult-onset DM has been reported to involve progressive islet β-cell destruction, resulting in insulin dependency [19]. SPK transplantation is increasingly recognized as a safe and effective procedure for type 2 DM patients, with shorter waiting times for deceased donor kidneys compared to isolated kidney transplants [20]. Our study demonstrated no significant difference in survival rates between PT recipients with type 1 and type 2 DM (Fig. 3).

Secondly, it is noteworthy that graft survival was significantly lower when the donor's cause of death was anoxic injury compared to other causes of death ($P = 0.045$). Oxygen deprivation leads to significant cellular apoptosis or necrosis, which is particularly detrimental in organs like the pancreas, which are sensitive to ischemia, thereby impairing islet cells and compromising insulin production [21]. Anoxia also triggers an inflammatory response through ischemia-reperfusion injury. When blood supply is restored, reactive oxygen species generated during ischemia-reperfusion injury further compromise graft viability. Additionally, anoxic injury impacts the endothelium, leading to thrombosis and impaired graft perfusion, as well as heightened immune responses that increase the risk of rejection [22,23]. This highlights the importance of careful donor selection, especially concerning the cause of death.

One notable case involved a patient who underwent PT following a total pancreatectomy for ampulla of Vater cancer. Typically, patients with malignancies are excluded from transplantation candidacy due to the heightened risk of cancer recurrence associated with immunosuppression. Consequently, PT after total pancreatectomy is generally restricted to cases of chronic pancreatitis or benign neoplasms [24]. However, this patient experienced no recurrence 4 years after pancreatectomy, and PT was pursued due to recurrent hypoglycemia and difficulty managing insulin doses. Seven years after transplant, the patient remains in sustained remission on a standard triple immunosuppressive regimen.

Another notable case concerns a patient who maintained stable renal and pancreas graft function, along with consistent tacrolimus levels, for 31 months following SPK transplantation. The patient presented with persistent tremors, leading to the conversion from Prograf (Astellas Pharma) to Advagraf (Astellas Pharma) at the standard dose ratio of 1:1.1 [25]. Advagraf, as an extended-release formulation, provides equivalent exposure to tacrolimus with therapeutic drug monitoring when administered repeatedly. However, it is absorbed more slowly than the conventional, twice-daily, immediate-release formulation. As a result, initially, it may produce lower exposure when administered at the same daily dose. In this case, the patient exhibited persistent low tacrolimus trough levels following conversion from Prograf to Advagraf, which led to rejection with thrombosis, leading to irreversible pancreatic damage. As a fast metabolizer (concentration/dose, <1.05 ng/mL/mg), achieving sufficient immunosuppressive trough levels was particularly challenging [26]. For such patients, the standard 1.1-fold increase in dosage during conversion may be inadequate, and more frequent monitoring of trough levels is essential to prevent rejection and related complications.

This study has several limitations. First, it is based on a retrospective and single-center design, with a relatively small sample size, which limits the generalizability of the findings. Additionally, the limited number of PAK cases reduced the statistical power to compare SPK and PAK outcomes.

Nevertheless, the PT program of our center has demonstrated comparable or even favorable outcomes to international data, particularly in terms of 1-year and 5-year graft survival rates. Despite the limited availability and fewer performing centers in South Korea compared to Western countries, our results underscore the success and feasibility of PT. Careful donor selection and meticulous postoperative immunosuppressive therapy remains essential for optimizing graft survival outcomes. This study supports expanding PT indications to include carefully selected type 2 DM patients and highlights the need for increased resources dedicated to PT programs in South Korea.

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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