Favorable Outcomes in Older Recipients Receiving Simultaneous Pancreas Kidney Transplantation

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INTRODUCTION

Diabetes is the leading cause of end-stage renal disease and is associated with high mortality compared with other causes of renal failure. The prevalence of diabetes and diabetic end-stage renal disease continues to be increasing.3 Successful kidney transplants improve survival and quality of life and are accepted as the standard of practice.2

Background. The objective of this study was to compare the long-term outcomes of older (50–65 y) type 1 diabetics with body mass index <35 kg/m2 and type 2 diabetics with body mass index <30 kg/m2 who received simultaneous pancreas kidney transplantation (SPKT) versus living donor kidney transplants (LDKTs). All subjects had insulin-dependent diabetes. Methods. This is a retrospective single-center study from July 2003 to March 2021 with a median follow-up of 7.5 y. Results. There were 104 recipients in the SPKT and 80 in the LDKT group. The mean age was 56 y in SPKT and 58 y in LDKT. There were 55% male recipients in the SPKT group versus 75% in LDKT. The duration of diabetes was 32 y in SPKT versus 25 y in LDKT. The number of preemptive transplants and length of dialysis were similar. However, the wait time was shorter for LDKT (269 versus 460 d). Forty-nine percent of the LDKT recipients received the organ within 6 mo of being waitlisted compared with 28% of SPKT recipients (P = 0.001). Donor age was lower in the SPKT group (27 versus 41 y). The estimated 5-y death censored kidney survival was 92% versus 98%, and 5-y patient survival was 86% versus 89% for SPKT versus LDKT. Death censored kidney and patient survival, acute kidney rejection by 1 y, and BK viremia were similar between the 2 groups. There were 17 pancreas graft losses within 1 y of transplant, the majority related to surgical complications, and it was not associated with increased mortality. Conclusions. SPKT in selected recipients aged 50 and above can have excellent outcomes similar to LDKT recipients.

Simultaneous kidney and pancreas transplant further improves the quality of life, with a better metabolic and cardiovascular profile.2,4 Although a successful pancreas transplant is associated with better glucose homeostasis and its advantages, it has a potentially increased risk of surgical complications. Most centers use a cutoff of 50 y of age as a criterion for simultaneous pancreas kidney transplantation (SPKT). SPKT can be associated with a higher risk for postoperative infections, leak, rejection, and other surgical complications, including graft thrombosis, contributing to early mortality.7 However, there has been improvement in pancreas transplant surgical techniques and better immunosuppression and thereby less complications in the recent cohorts.8-10 There has been a growing number of older subjects11 with diabetic nephropathy on insulin who may benefit from SPKT. The United States Renal Data System study by Siskind et al12 compared the outcomes among younger versus older SPKT and suggested a cutoff of <50 y for a pancreas transplant because of decreased patient and graft survival in patients >50 who received SPKT. Small retrospective studies compared the outcomes of SPKT in younger recipients versus those >50; some reported worse graft outcomes in older recipients, whereas the majority, especially more recent ones, reported similar graft outcomes.13-20

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Many centers continue to use an age cutoff of 50 y for SPKT because of concern for higher surgical complications and associated increased mortality. Insulin-dependent renal failure subjects above age 50 are often not given the option for SPKT.\textsuperscript{23}

The above studies compared the older and younger recipients of SPKT, which introduces age bias. The current study is different because it compares the living donor and SPKT recipients who were similar in age, reducing the confounding effect of age on associated mortality and graft loss.

At our center, we perform SPKT in suitable recipients <65 y of age as long as they fulfill all the other criteria. We wanted to compare the outcomes in older SPKT recipients with living donor kidney transplant (LDKT), who were similar in age and body mass index (BMI), were insulin-dependent, and would have been candidates for SPKT or LDKT. We compared the LDKT as a control because it is often considered the best option for older recipients.

The current evidence for SPKT versus LDKT is less convincing of the advantage of one over the other, especially in the older recipients.\textsuperscript{2,22-27} The previous data regarding the SPKT versus LDKT in older is based mainly on the United States Renal Data System studies that compared SPKT versus LDKT and most recipients were younger and compared data mostly from 1990s to early 2000.\textsuperscript{23,26}

We report here the long-term graft and patient survival outcomes of SPKT versus LDKT in recipients aged 50 and above at our center.

**MATERIALS AND METHODS**

The Mayo Clinic Institutional Review Board approved this study as a retrospective, single-center study of insulin-dependent diabetic patients aged 50 and above receiving SPKT and LDKT from July 2003 to March 2021. The last follow-up was at the end of October 2021.

We included type 1 diabetic patients with BMI <35 kg/m\textsuperscript{2} and type 2 diabetic with BMI <30 kg/m\textsuperscript{2} who received SPKT or LDKT.

Eligibility criteria for SPKT at our center included renal insufficiency combined with insulin-requiring diabetes or pancreatic exocrine insufficiency. The following were exclusion criteria for SPKT: insulin requirement of >1 U/kg/d, BMI >35 for patients with type 1 diabetes, or BMI >30 kg/m\textsuperscript{2} for patients with type 2 diabetes. The type of diabetes was identified using the C-peptide level and clinical assessment by the physician seeing the recipient at the time of transplant evaluation.

Standard surgical techniques for the pancreas allotransplant included using a donor iliac artery Y-graft for arterial reconstruction, systemic venous drainage into the recipient iliac vein or vena cava, and enteric drainage of the exocrine secretions.

At our center, we encourage SPKT and take recipients with coronary artery disease, history of cerebrovascular accident, and peripheral artery disease. Subjects with a multivessel coronary disease with ischemia, decreased ejection fraction, or severe peripheral vascular disease are considered ineligible for SPKT at our center.

As comorbid conditions can affect the decision for SPKT versus LDKT and the subsequent outcomes, we examined the prevalence of cardiovascular disease, peripheral artery disease, and ejection fraction in the 2 cohorts. The decision for SPKT versus LDKT is often based on the availability of living donors and patients’ preferences. SPKT is not preferred if subjects have high insulin requirements, high BMI, dual anticoagulation, and low ejection fraction.

All patients received induction immunosuppression. Before 2011, patients received induction with rabbit antithymocyte globulin. After 2011, induction was with alemtuzumab. Patients had complete withdrawal of corticosteroids by posttransplant day 5. Steroids were maintained if they had panel reactive antibody >80% or donor-specific antibody. Maintenance immunosuppression was with tacrolimus and mycophenolate mofetil. Tacrolimus was started on posttransplant day 1, irrespective of delayed graft function. Goals for trough tacrolimus levels were 8 to 10 ng/mL for the first month and 6 to 8 ng/mL after that.

We compared the following outcomes in the 2 groups:

- Death censored graft survival and patient survival;
- Serum creatinine at 1 mo, 4 mo, and 1, 2, and 3 y and glycosylated hemoglobin A\textsubscript{1c} at 1 and 2 y posttransplant;
- Acute rejection rate by 1 y (including subclinical rejection on protocol biopsies at 4 and 12 mo) and BK viremia (BKV) infection within 1 y.

**Statistical Methods**

Descriptive statistics were reported as mean (SD) for continuous variables and frequency (percentage) for categorical variables. We compared continuous variables in 2 groups using a Student t test and dichotomous outcome using a chi-square test. Nonparametric tests compared data that were heavily skewed. We performed Kaplan-Meier survival estimates for death and death censored kidney graft loss. We used SPSS, version 27, for analysis.

**RESULTS**

**Recipient and Donor Characteristics**

The study subjects included 104 SPKT and 80 LDKT recipients with insulin-dependent diabetes (Table 1). Mean follow-up was 7.6 y (4.3 y), and median follow-up was 7.5 y (4.1–10.7 y). The mean follow-up for SPKT was 7.3 y (4.3 y) and for LDKT was 8 y (4.3; P = 0.23).

The mean age was 56 y in SPKT and 58 y in LDKT (P = 0.21). Mean BMI was 26 kg/m\textsuperscript{2} (3.6 kg/m\textsuperscript{2}) in SPKT and 27 mg/m\textsuperscript{2} (3.4 mg/m\textsuperscript{2}) in LDKT (P = 0.44). There were 55% male recipients in the SPKT group versus 75% in LDKT (P < 0.001). The majority of recipients were White. The percentage of recipients with type 1 diabetes was higher in SPKT (64% versus 21% in LDKT; P < 0.001), and the duration of diabetes was longer at 32 y (12 y) in SPKT versus 25 y (11 y) in LDKT.

The prevalence of coronary artery disease, peripheral artery disease, and the mean ejection fraction in SPKT versus LDKT was similar.

The 2 groups were similar in the number of preemptive transplants (30% versus 21%) and length of dialysis (441 versus 408 d). SPKT recipients waited longer on the waitlist (460 versus 269 d; P < 0.001). Forty-nine percent of the LDKT recipients received the organ within 6 mo of being waitlisted compared with 28% of SPKT recipients (P = 0.001).

The number of previous transplants (4% versus 7%) was similar; however, there were more HLA mismatches in the SPKT group. Two LDKT recipients received pancreas after kidney transplant.
Donor age was significantly lower in the SPKT group (27 versus 41 y; \( P < 0.001 \)), and cold ischemia time was longer (7.8 versus 2.4 h; \( P < 0.001 \)). More female donors were in the LDKT group (70% versus 30%; \( P < 0.001 \)).

The mean Kidney Donor Profile Index in SPKT groups was 16.4 (13.9).

Graft and Patient Survival

Death censored kidney graft survival (Figure 1) was similar between SPKT versus LDKT (\( P = 0.09 \)). The estimated 1-y death censored kidney survival was 92% versus 98% for SPKT versus LDKT.

On multivariate analysis for death censored kidney graft survival, duration of diabetes (0.96–1.06; \( P = 0.74 \)) and type of diabetes (0.72 (0.26–2.02; \( P = 0.54 \)) were not associated with kidney graft loss. The longer dialysis (d) length was associated with an increased graft loss risk 1.001 (1.00–1.002; \( P = 0.017 \)). The male gender was associated with a lower risk of graft loss of 0.3 (0.1–0.9; \( P = 0.03 \)).

There was no significant difference in mortality between the 2 groups (log-rank \( P = 0.25 \)). The estimated 1-y patient survival was 95% versus 98%, and the estimated 5-y patient survival was 86% versus 89% for SPKT versus LDKT (Figure 2). There were 2 (2.5%) deaths in the LDKT group and 5 deaths (5%) in the SPKT group within 1 y (\( P = 0.7 \)).

Fourteen patients had pancreas graft failure in the first 30 d (14%). Causes of pancreas graft loss in the first 30 d include graft thrombosis in 11, bleeding in 1, primary nonfunction in 1, and vascular complication in 1 patient. The pancreas graft loss was 8 of 59 (13.6%) until 2011; in the last decade, from 2012 to 2021, it was 6 of 45 (13%). Because of the small numbers, we could not conclude regarding the trends. Three more subjects lost the pancreas graft after 1 mo but within 1 y from thrombosis, infection, and leak.

Of the 5 deaths within the first year in the SPKT group, 3 were in the group with no pancreas graft loss (1 each from a cardiac event, cardiovascular accident, and pneumonia), and 2 were in the group with pancreas loss (lymphoma and unknown cause) (\( P = 0.19 \)).

| TABLE 1. Recipient and donor characteristics |
|---------------------------------------------|
| SPKT (104) | LDKT (80) | \( P \) |
| **Recipient and donor characteristics** |
| Age (y) | 56 (4.3) | 58 (4.7) | 0.21 |
| Sex (male) | 57 (55%) | 60 (75%) | <0.01 |
| BMI (kg/m²) | 26 (3.6) | 27 (3.4) | 0.44 |
| Race (White/AA/Hispanic/other) | 67%/3%/26%/4% | 56%/4%/27%/13% | <0.001 |
| Type 1 diabetes | 66 (64%) | 17 (21%) | <0.001 |
| Diabetes duration (y) | 32 (12) | 25 (11) | 0.01 |
| Coronary stent | 16 (15%) | 14 (18%) | 0.84 |
| Coronary artery bypass graft | 10 (10%) | 11 (14%) | 0.49 |
| Cardiac ejection fraction (%) | 61 (7) | 59 (8) | 0.09 |
| Cerebrovascular accident including transient ischemia attack | 9 (9%) | 8 (10%) | 0.8 |
| Peripheral vascular disease | 11 (11%) | 9 (11%) | 1 |
| Length on dialysis (d) | 441 (526) | 408 (426) | 0.32 |
| Months on dialysis | | | |
| <6 mo | 44 (42%) | 28 (35%) | 0.002 |
| 6 mo to 1 y | 9 (9%) | 23 (29%) | |
| 1–2 y | 30 (29%) | 12 (15%) | |
| >2 y | 21 (20%) | 17 (21%) | |
| Preemptive | 31 (30%) | 17 (21%) | 0.2 |
| Days on waitlist | 460 (397) | 269 (246) | <0.001 |
| Months on dialysis | | | 0.001 |
| <6 mo | 29 (28%) | 39 (49%) | |
| 6 mo to 1 y | 23 (22%) | 22 (28%) | |
| 1–2 y | 37 (26%) | 17 (21%) | |
| >2 y | 15 (14%) | 2 (2%) | |
| Peak PRA (%) | 12 (28) | 7 (15) | 0.09 |
| HLA mismatch (mean) | 4.6 (1.2) | 3.2 (1.4) | 0.01 |
| Previous kidney transplant | 3 (2%) | 5 (6%) | 0.26 |
| Previous pancreas transplant | 1 (1%) | 1 (1%) | 0.85 |
| **Donor characteristics** |
| Donor race (White/AA/Hispanic/American Indian/other) | 68%/6%/19%/7% | 58%/4%/25%/13% | 0.05 |
| Donor age (y) | 27 (8.4) | 41 (13.6) | <0.001 |
| Donor sex (male) | 73 (70%) | 24 (30%) | <0.001 |
| Kidney Donor Profile Index | 16.4 (13.9) | | |
| Cold ischemia time (h) | 7.8 (3.4) | 2.4 (3) | <0.001 |

For continuous variables, we have included mean (SDs), and for dichotomous variables, we have included number (percentage). AA, African American; BMI, body mass index; LDKT, living donor kidney transplant; PRA, panel reactive antibody; SPKT, simultaneous pancreas kidney transplantation.
Graft Function

The rate of delayed graft function (8% versus 2%; \(P = 0.04\)) and length of initial hospital stay (8.1 d [4.8 d] versus 3.3 d [1.3 d]; \(P < 0.001\)) were higher in the SPKT cohort than the LDKT cohort (Table 2).

The rate of BKV was similar between the 2 groups (13% versus 16%; \(P = 0.67\)). The rate of acute rejection, including subclinical rejection on protocol biopsies within 1 y, was comparable (10% versus 14%).

Serum creatinine was similar in the 2 groups at 1 and 4 mo and 1, 2, and 3 y. The factors associated with higher creatinine at 1 y on regression analysis included higher donor age (0.015 [0.003–0.026; \(P = 0.013\)]) and recipient male gender (0.29 [0.07–0.51; \(P = 0.009\)]).
Glycosylated hemoglobin was lower in SPKT versus LDKT (5.4 versus 7.8; \( P < 0.001 \)) at 1 y and (5.4 versus 7.9; \( P < 0.001 \)) 2 y.

**DISCUSSION**

A successful pancreas transplant is associated with long-term survival advantages because of insulin independence, metabolic control, and stabilization or improvement of secondary complications. It is unclear if older recipients would benefit from SPKT because they often have more vascular disease, comorbidities, and a potentially higher risk of complications.\(^\text{21}\) We studied the cohort of insulin-dependent diabetic recipients \( >50 \) who received SPKT versus LDKT. The BMI cutoff at our center for SKPT is 35 kg/m\(^2\) for recipients with type 1 diabetes and 30 kg/m\(^2\) for those with type 2 diabetes. To match the recipients of SKPT, we excluded those LDKT recipients above these BMI cutoffs. The mean age was 56 y in SPKT and 58 y in LDKT. The average duration of diabetes was 32 y in SPKT and 25 y in LDKT. Both groups were similar with respect to the duration of dialysis and pretransplant cardiovascular morbidity. However, most SPKT recipients (64%) had type 1 diabetes, whereas most LDKT recipients (79%) had type 2 diabetes. We report equivalent graft and patient survival among our recipients \( >50 \) y of age, with 5-y death censored kidney graft survival of 92% versus 98% and 5-y patient survival of 86% versus 89% for SPKT versus LDKT cohort. The longer dialysis (d) length was associated with an increased risk of graft loss of 1.001 (1.00–1.002; \( P = 0.017 \)). Faster access to transplants is associated with improved graft survival.

The current evidence for SPKT versus LDKT is less convincing of the advantage of one over the other, especially in the older recipients.\(^\text{2,22-27}\) The data regarding the SPKT versus LDKT in older recipients are based mainly on the United States Renal Data System and the studies that compared SPKT versus LDKT. Most recipients were younger, and compared data were mainly from the 1990s to early 2000.\(^\text{23-26}\)

Using the United Network for Organ Sharing (UNOS) registry for transplants from 1987 to 1996, Reddy et al\(^\text{23}\) reported that SPKT was associated with a higher risk of death versus living donors in the first 18 mo (hazard ratio of 2.2) but associated with decreased relative risk thereafter (relative risk, 0.86; \( P = 0.02 \)). In this study, at a 10-y time point, the SPKT group had a slight survival advantage (67% versus 64%, not statistically significant) compared with the LDKT group. Later, in another study using UNOS data for transplants from 2000 to 2007, Young et al\(^\text{25}\) reported lower kidney graft survival for SPKT versus LDKT but similar patient survival. This study had a shorter follow-up of around 72 mo. A registry study of people with type 2 diabetes utilizing the UNOS database reported the survival advantage for SPKT versus deceased donor kidney transplants (DDKTs) was related to the younger donor and recipient ages in the SPKT cohort versus DDKTs, and outcomes were superior with LDKT compared with SPKT.\(^\text{26}\)

Other studies have reported improved long-term survival in SPKT recipients with functioning pancreas grafts compared with LDKT, possibly related to the improved cardiac and metabolic profile.\(^\text{3,6}\) Morath et al\(^\text{2}\) reported the advantage of SPKT over LDKT after 10 y, likely due to decreased cardiovascular disease and better metabolic profile. Weiss et al\(^\text{27}\) examined SPK-waitlisted patients from 1997 to 2005 who underwent either an SPKT, an LDKT, or a DDKT. The SPKT cohort with functioning pancreas grafts had better survival throughout the following 7 y than the other 2 groups. Early pancreas graft failure was not detrimental to kidney and patient survival rates, similar to kidney-alone transplant recipients.

The present study’s rate of pancreas graft loss was 14% at 30 d and 17% at 1 y. This is somewhat higher than the average graft loss rate of around 5% to 10% reported recently.\(^\text{10}\) However, pancreas graft loss was not associated with higher mortality or inferior kidney graft survival, unlike previous registry studies that have reported higher mortality with pancreatic graft loss.\(^\text{24,29}\)

Renal function and risk of BKV infection at 1 y were similar. The rate of acute rejection within 1 y was also similar between the 2 cohorts. We use a similar immunosuppression regimen for SPKT and LDKT <65. Induction consists of depleting agents and maintenance with tacrolimus and mycophenolate.\(^\text{30,31}\)

As a limitation to this study, we recognize that it is a retrospective single-center study, and there is an inherent bias.
associated with recipient selection for SPKT. Because of the patient data spanning >18 y and changes in the medical records storage, we could no longer review the medical chart physician note for the specific reason subjects received LDKT over SPKT. Forty-nine percent of the LDKT recipients received the organ within 6 mo of being waitlisted compared with 28% of SPKT recipients (P = 0.001), suggesting the common reason to proceed with LDKT was the availability of living donors. The prevalence of comorbid cardiovascular disease, peripheral vascular disease, and ejection fraction was similar in the 2 groups.

We compared the LDKT as a control, often considered the best option for older recipients, and debated if SPKT should be offered to older recipients. Our study had similar kidney graft and patient outcomes in SPKT recipients versus age-controlled recipients with diabetic nephropathy who received LDKT. The above results encourage the community to rethink the age cutoff of 50 y.

SPKT should be considered in older subjects who are insulin-dependent diabetics with kidney failure, especially those who do not have living donors. The choice between LDKT and DDKT versus SPKT should include a decision with individual patient circumstances, preferences, and comorbidities.

**CONCLUSIONS**

We conclude that older recipients (>50 y of age) receiving SPKT had similar outcomes to those receiving LDKT. Although they had a 14% rate of early pancreatic loss, this was not associated with increased mortality.

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