

Diabetes Mellitus in Living Pancreas Donors: Use of Integrated National Registry and Pharmacy Claims Data to Characterize Donation-Related Health Outcomes

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Background. Living donor pancreas transplant is a potential treatment for diabetic patients with end-organ complications. Although early surgical risks of donation have been reported, long-term medical outcomes in living pancreas donors are not known. **Methods.** We integrated national Scientific Registry of Transplant Recipients data (1987-2015) with records from a nationwide pharmacy claims warehouse (2005-2015) to examine prescriptions for diabetes medications and supplies as a measure of postdonation diabetes mellitus. To compare outcomes in controls with baseline good health, we matched living pancreas donors to living kidney donors (1:3) by demographic traits and year of donation. **Results.** Among 73 pancreas donors in the study period, 45 were identified in the pharmacy database: 62% women, 84% white, and 80% relatives of the recipient. Over a mean postdonation follow-up period of 16.3 years, 26.7% of pancreas donors filled prescriptions for diabetes treatments, compared with 5.9% of kidney donors (odds ratio, 4.13; 95% confidence interval, 1.91-8.93; *P* = 0.0003). Use of insulin (11.1% vs 0%) and oral agents (20.0% vs 5.9%; odds ratio, 4.50, 95% confidence interval, 2.09-9.68; *P* = 0.0001) was also higher in pancreas donors. **Conclusions.** Diabetes is more common after living pancreas donation than after living kidney donation, supporting clinical consequences from reduced endocrine reserve.

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iving donor pancreas transplant is a potential treatment for patients with type I insulin-dependent diabetes mellitus complicated by end-organ damage. The first living pancreas donation took place in 1979 at the University of Minnesota and the first living donor simultaneous pancreas-kidney transplant was performed in 1994.^{1,2} Of the 8918 simultaneous pancreas-kidney transplants reported to the International Pancreas Transplant Registry (1996-2005), fewer

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¹⁰ Transplant Nephrology, Washington University School of Medicine, St. Louis, MO. than 1% were from living donors.³ The advantages of living pancreas-kidney transplant for the recipient include shorter and optimal surgical timing, minimization of immuno-suppression, and lower risk of rejection, infection, and posttransplant malignancy.⁴⁻⁶

Much of the literature on donor outcomes after living pancreas donation has focused on short-term perioperative complications, rather than long-term complications. Reassuringly, no cases of living pancreas donor perioperative deaths have

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been reported.^{2,5} Significant pancreas-related perioperative complications, such as pancreatitis, abscess, or fistula, have been reported in fewer than 5% of living pancreas donors described in case series, and reoperation and splenectomy due to bleeding, ischemia, or abscess have been noted in 5% to 15%.^{5,7-9}

In contrast, the long-term medical risk of postdonation diabetes mellitus (PDDM) in this unique patient cohort has not been well described. Candidates for living pancreas donation undergo a rigorous and thorough evaluation whereby individuals with abnormal glucose tolerance or risk factors for diabetes mellitus, such as obesity, may be excluded from donation.¹⁰ Kumar et al¹⁰ contacted 15 of the 21 living pancreas donors who had donated at the University of Minnesota between 1997 and 2003. Two had developed diabetes treated with oral agents. Of the remaining 13, metabolic testing demonstrated that 2 had impaired fasting glucose, 1 had impaired glucose tolerance, and 3 had both; 1 met the diagnostic criteria for diabetes after a mean postdonation follow-up of 5 years. The limitations of this study included the small sample size and the number of donors lost to follow-up.

Although living pancreas donation is uncommon in the United States, a better understanding of the long-term implications of this procedure is relevant to the care of previous donors and can inform consideration of future practices in the United States and other countries. Importantly, recently enacted Organ Procurement and Transplantation Network (OPTN) Policies governing living donation practices in the United States include only general requirements related to living pancreas, lung, or intestine donation due to lack of data to support organ-specific requirements for the care of these less common living donors.¹¹ A newly published series from 1 center in Korea described living pancreas donation as recently as July 2015, and recent experience from Japan illustrated the contemporary relevance of understanding postdonation outcomes and providing appropriate informed consent for living pancreas donor candidates.8,9

To address knowledge gaps regarding long-term outcomes in this unique population and to inform future recommendations, we integrated US transplant registry data with a nationwide pharmacy claims database to identify prescriptions for diabetes medications and supplies after living pancreas donation, as a measure of PDDM. Treatment patterns were compared with those among matched living kidney donors drawn from the same data source as controls selected for baseline good health whose donation procedure was not expected to directly affect diabetes risk.¹²

MATERIALS AND METHODS

Data Sources

We conducted a retrospective cohort study using linked healthcare databases in the United States. This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of OPTN. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight to the activities of the OPTN and SRTR contractors. Baseline demographic information ascertained for living donors from OPTN at the time of donation included age, sex, and race as reported by the transplant center.

Pharmacy fill data were assembled by linking SRTR records for living pancreas donors with billing claims from a large US pharmaceutical claims data (PCD) warehouse that maintains prescription drug fill records including self-paid fills and those reimbursed by private and public payers. The PCD comprises National Council for Prescription Drug Program format prescription claims aggregated from multiple sources including data clearinghouses, retail pharmacies, and prescription benefit managers for approximately 60% of US retail pharmacy transactions. Individual claim records include the date of a given pharmacy fill with the National Drug Code identifying agent and dosage. After institutional review board and Health Resources and Services Administration approvals, PCD records were linked with SRTR records for living donors. We applied a deterministic deidentification strategy wherein patient identifiers (last name, first name, sex, date of birth, and ZIP code of residence) were transformed before delivery to the Saint Louis University researchers with Health Information Portability and Accountability Act and HITECH-certified encryption technology from Symphony Health Solutions. The patient deidentification software uses multiple encryption algorithms in succession to guarantee that the resulting "token" containing encrypted patient identifiers can never be decrypted. However, the algorithm yields the same results for a given set of data elements, such that linkages by unique anonymous tokens are possible.

Population and Covariates

We included living pancreas donors in the SRTR registry who had donated between 1987 (the start of the national registry) and 2015 and whose records could be linked to the PCD database (2005-2015). Living pancreas donors included pancreas-only and simultaneous pancreas-kidney donors. This cohort was matched with replacement in a 1:3 ratio to living kidney-only donors (1987-2015) based on age, sex, race, donor-recipient relationship, and year of donation. Exact matches were sought, followed by iterative relaxation of the precision of age and donation year matching windows to enable selection of 3 kidney donor controls for each pancreas donor (Figure 1).

Outcomes

The primary outcome was PDDM defined by a pharmacy fill claim for a diabetes medication or diabetes supplies (Table S1, SDC, http://links.lww.com/TP/B316). Use of insulin, oral agents, and supplies were also examined separately. In secondary analyses, we computed proportions of days covered, a metric quantifying the fraction of days of identified PCD eligibility during which treatments were prescribed, among donors who received diabetes treatments. Proportion of days covered is defined as [days of treatment supplied over an observation window]/[days of observation], where the observation windows were defined as the periods of identified PCD eligibility for an individual.^{13,14}

Statistical Analyses

Data management and analyses were performed with Statistical Analysis Software (SAS) for Windows, version 9.3 (SAS Institute Inc., Cary, NC). In all outcome analyses, we interpreted 2-tailed *P* values less than 0.05 as statistically significant. Distributions of baseline traits in the living

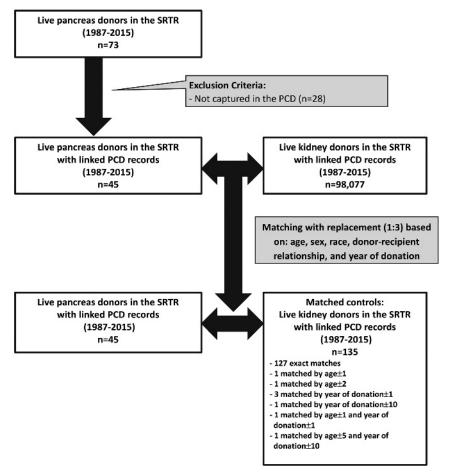


FIGURE 1. Cohort selection.

pancreas and kidney donors were compared by McNemar test for paired proportions and paired *t* tests. We compared pharmacy fills for diabetes medications and supplies in living pancreas donors and matched living kidney donors using conditional logistic regression. Distributions of baseline traits among living pancreas donors with and without PDDM were compared by Fisher exact test for categorical variables and *t* tests for continuous variables.

RESULTS

Baseline Characteristics of the Living Donor Sample

Through 2015, 73 living US pancreas donors were recorded in SRTR data, with the last donation occurring in 2013. Of these, 45 (61.6%) were identified in the linked pharmacy database. The baseline characteristics of the study sample are presented in Table 1. There were no significant differences in the distribution of baseline characteristics among living pancreas donors who were captured in the PCD data versus those who were not (all P > 0.05) (Table S2, SDC, http://links.lww.comTP/B316). Most donors in our study sample (68.9%) underwent a simultaneous pancreas-kidney donation procedure. The mean age at the time of donation was 39.0 years (standard deviation [SD], 10.4 years); 62.2% of donors were women, 84.4% were white, and 8.9% were African American. Most (80.0%) were biological relatives of their recipients, including 75.6% first-degree relatives. The mean time from donation to end of follow-up was 16.3 years (SD, 5.0 years; maximum, 26.0 years).

Results of the process for matching 3 living kidney donors as controls to each pancreas donor are summarized in Figure 1. From the pool of living kidney donors with linked PCD data in the study period, 127 exact matches were identified based on age, sex, race, donor-recipient relationship, and year of donation. To provide 3 matches for each pancreas donor, an additional 5 kidney donor controls were identified by relaxing the precision of age or donation year criteria by ± 2 . Finally, 3 more kidney donor controls were identified by allowing an age difference of up to 5 years and/or a difference in donation year of up to 10 years. Distributions of matching factors among the final cohorts were statistically and numerically similar in the living pancreas and kidney donors. Compared with the pancreas donors, fewer kidney donors had human leukocyte antigens (HLA) DR3, DQ2, or DQ8. Mean follow-up time for the living kidney donors (16.0 years, SD, 5.4 years) was similar to that for the living pancreas donors (P = 0.74).

Comparison of PDDM in Living Pancreas Donors and Living Kidney Donors

During the follow-up period, 26.7% of living pancreas donors filled prescriptions for diabetes medications or supplies, compared with 5.9% of living kidney donors (odds ratio, 4.13, 95% confidence interval, 1.91-8.93; P = 0.0003) (Table 2). Use of insulin (11.1% vs 0%) and oral agents (20.0% vs 5.9%; odds ratio, 4.50, 95% confidence interval,

TABLE 1.

Comparison of baseline traits of living pancreas donors and matched living kidney donor controls

Baseline characteristics	Living pancreas donors (n = 45)	Living kidney donor controls (n = 135)
Age at donation (SD), y	39.0 (10.4)	39.2 (10.1)
Female	62.2	62.2
Race/ethnicity		
White	84.4	85.9
African American	8.9	9.6
Hispanic	4.4	4.4
Other	2.2	0
Donor/recipient relationship		
First-degree relative	75.6	75.6
Other biological relative	4.4	4.4
Spouse	11.1	11.1
Unrelated	8.9	8.9
Blood type		
0	73.3	65.9
А	17.8	25.9
В	6.7	7.4
AB	0	0.7
Missing	2.2	0
Donor HLA		
Antigen DR3	33.3*	14.8
Antigen DR4	33.3	26.7
Antigen DR3 or DR4	55.6	40.0
Antigen DQ2	60.0*	28.9
Antigen DQ8	13.3*	2.2
Antigen DQ2 or DQ8	64.4*	31.1

Data are presented as percentages (%) except for age, which is presented as mean and SD. * P < 0.05 for difference in distribution of baseline factors among living pancreas compared with matched living kidney donors.

2.09-9.68; P = 0.0001) were also higher in pancreas than in kidney donors. Average times to first captured pharmacy fills for diabetes supplies, insulin, and oral agents were 12.9, 13.7, and 13.3 years, respectively (maximum, 21 years for all). Among treated patients, the proportion of observed follow-up days covered by diabetes supplies was 70.4% for pancreas donors and 41.9% for kidney donors. Among the pancreas donors who received insulin or an oral agent, the proportion of observed days covered by diabetes medication was 66.8%, compared with 37.2% for the treated kidney donors.

Distribution of Clinical Traits Among Living Pancreas Donors With and Without PDDM

Among the living pancreas donors, PDDM was not significantly associated with sex, race, ethnicity, blood type, or donor-recipient relationship, although power was limited by the sample size (Table 3). There were no differences in the distributions of HLA DR3, DR4, DQ2, or DQ8 antigens among live pancreas donors who did and did not develop PDDM.

DISCUSSION

Living pancreas donation has been performed in the United States as a treatment for diabetic patients with end-organ complications. Perioperative risks have been described, and observed rates of bleeding and the risk of splenectomy range from 5% to 15%.^{5,7-9} However, less is known about the long-term medical outcomes of living pancreas donation. By linking the national US donor registry with pharmaceutical fill records, we found that 26.7% of living pancreas donors filled diabetes medications or supplies over a mean postdonation follow-up period of 16 years, including use of insulin or an oral agent in 20%. The rate of PDDM after living pancreas donation was 4 times the rate in a matched cohort of living kidney donors, a group selected for baseline good health whose donation procedure was not expected to directly affect diabetes risk.¹²

In our study, 11.1% of living pancreas donors required insulin therapy postdonation. This is higher than the 6.5% (3/46) rate reported by Gruessner et al¹⁵ for donors at the University of Minnesota from 1978 to 2000; however, importantly, outcome information could not be obtained for 58% (69/115) of living pancreas donors from this center and follow-up information was collected by survey. Of the 3 donors who developed PDDM treated with insulin therapy in the center's report, 1 had a history of gestational diabetes and the other 2 were obese. These observations led to changes in the center's criteria for acceptance of living pancreas donors in 1997, with incorporation of abnormal predonation glucose tolerance tests, a history of gestational diabetes mellitus, or elevated body mass index at the time of donation as exclusion criteria.7 In a more recent study from the same institution after this policy change, Kumar et al¹⁰ reported that 20% (3/15) of living pancreas donors between 1997 and 2003 had developed PDDM after a mean follow-up period of 5 years by evaluation including glucose tolerance testing; however, only 13% were receiving diabetes medications at the time of follow-up, and 28% (6/21) of the original cohort were lost to follow-up. An additional 46% (6/15) of the followed pancreas donors were found to have impaired fasting glucose and/or impaired glucose tolerance after metabolic assessment and 1 met metabolic criteria for diabetes. In a group of 20 living pancreas donors at 1 center in Korea through 2015, PDDM was identified in 10% (2/20) with diagnosis times ranging from 1 month to 7.5 years, but the approach to follow-up encounters, loss-to-follow-up rate, and details of treatment are not described.⁸ These estimates are notably higher than the less than 3% long-term risk of diabetes in living pancreas donors suggested by Boggi et al⁶ in a review, and contrast with the report of no PDDM cases among 12 living pancreas donors in Japan after follow-up ranging from 6 months to 5 years.⁹ In our study, among living pancreas

TABLE 2.

Comparison of postdonation diabetes treatments in living pancreas donors and matched living kidney donors

Diabetes treatment	Living pancreas donors, %	Living kidney donor controls, %	Odds ratio (95% Cl)	Р
Any	26.7	5.9	4.13 (1.91-8.93)	0.0003
Insulin or oral agent	20.0	5.9	4.50 (2.09-9.68)	0.0001
Insulin	11.1	0	_	_
Oral agent	20.0	5.9	4.50 (2.09-9.68)	0.0001
Diabetes supplies	20.0	4.4	6.00 (2.53-14.24)	<0.0001

Cl, confidence interval

TABLE 3.

Comparison of baseline traits in living pancreas donors with and without PDDM

Baseline characteristics	Living pancreas donors with PDDM (n = 12)	Living pancreas donors without PDDM $(n = 33)$
Concomitant kidney donor	66.7	69.7
Age at donation (SD), y	37.7 (8.2)	39.5 (11.1)
Female	50.0	66.7
Race/ethnicity		
White	83.3	84.9
African American	8.3	9.1
Hispanic	0	6.1
Other	8.3	0
Donor/recipient relationship		
First-degree relative	75.0	75.8
Other biological relative	0	6.1
Spouse	8.3	12.1
Unrelated	16.7	6.1
Blood type		
0	66.7	75.8
А	8.3	21.2
В	25.0	0
AB	0	0
Missing	0	3.0
Donor HLA		
Antigen DR3	25.0	36.4
Antigen DR4	33.3	33.3
Antigen DR3 or DR4	50.0	57.6
Antigen DQ2	50.0	63.6
Antigen DQ8	16.7	12.1
Antigen DQ2 or DQ8	58.3	66.7

Data are presented as percentages (%) except for age, which is presented as mean and SD. P > 0.05 for comparison of distribution of baseline factors among living pancreas donors with and without PDDM.

donors who received diabetes medications, use was sustained, with medication covering 67% of observed days.

Current OPTN policies effective February 2014 for the informed consent and evaluation of living donors include organ-specific requirements related to kidney and liver donors, but only general recommendations related to living pancreas, lung, or intestine donors due to lack of data to support requirements for the care of these less common living donors.¹¹ Our findings support that the risk of PDDM should be considered in the informed consent of living pancreas donors, and also illustrate the value of integrated national registry and pharmacy fill data in defining health outcomes in small but important patient groups.^{16,17} These databases also allowed estimation of risk specifically attributable to pancreas donation through comparison of the rates of PDDM in living pancreas donors to the rates in living kidney donors, a population with similar baseline good health. Predonation diabetes mellitus is an exclusion to living kidney donation in US policy¹¹ and in many international clinical practice guidelines.¹⁸⁻²¹

There are limitations to our study. Some baseline health information, such as donor health insurance, physical examination measurements such as body mass index, and laboratory values such as hemoglobin A1c and oral glucose tolerance test results were not available in our databases.

We included use of diabetes supplies in the primary outcome measure in an effort to capture diet-controlled diabetes. Use of supplies alone may reflect monitoring, but as the average time from donation to the first captured fill for diabetes supplies was 12.9 years (maximum, 21 years), the observed use of diabetes supplies in this study does not dominantly reflect early postpancreatectomy monitoring. Regardless of supply fills, the 4.5-fold difference in the use of insulin or oral agents among pancreas compared with kidney donors was large and significant. We were also unable to ascertain evidence of prediabetes, such as impaired fasting glucose or impaired glucose tolerance, after donation in our study sample. These conditions may also be exacerbated by living pancreas donation. Although we are unable to determine the additive risk of PDDM in the presence of risk factors in the current study, we endorse rigorous clinical evaluation of donor candidates and cautious selection to mitigate risk. Some HLA antigens associated with diabetes in the general population (HLA DR3, DQ2, and DQ8)²² were more common in live pancreas donors compared with matched live kidney donors, likely reflecting common familial relationships to patients with type 1 diabetes mellitus. Importantly, however, there were no differences in the distributions of these antigens among live pancreas donors who did and did not develop PDDM. Further study is warranted to better define the impact of family history on the risk of diabetes after both types of live organ donation. Last, our sample represents a subset of the US national experience, and outcomes may differ for the donors not identified in the PCD. The nature of the available data does not allow distinction of donors who are not captured in the study PCD from those who did not fill any medications at any pharmacy. However, as the average time from donation to the end of pharmacy data was 16 years (maximum, 26 years), exclusion from the study PCD data is unlikely to be driven by absence of any pharmacy fill activity due to young age throughout follow-up. Notably, there were no significant differences in the distributions of baseline characteristics among living pancreas donors who were and were not captured in the PCD.

In summary, linkage of the national US donor registry with pharmacy claims data enabled characterization of a clinically relevant long-term medical outcome after living pancreas donation. This methodology can complement reports of center experience and surveys by circumventing some of the difficulties inherent in long-term follow-up by transplant centers. Our findings suggest that after an average of 16 years postdonation, 26.7% of living pancreas donors may require diabetes medications or supplies, including use of insulin or an oral agent in 20%, rates that are more than 4 times that of living kidney donors. This information can be used to guide consideration of future practices and informed consent related to this procedure in the United States and in other countries.

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