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Successful pancreas transplantation alone is associated with excellent self-identified health score and glucose control: A retrospective study from a high-volume center in the United States

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Abstract

Background—The benefits of pancreas transplantation are often difficult to measure. Here, we sought to determine the difference in quality of life for diabetic patients with and without a functional pancreas transplant alone (PTA).

Methods—Pancreas transplant alone cases from 1993 to 2015 were considered. An IRB-approved survey inclusive of 15 questions spanning four domains was employed. Chi-square, Fisher's exact, and the *T* test were used where appropriate.

Results—A total of 137 PTAs were performed during the study period. Of those reached ($n = 32$), 94% responded to the survey. Self-reported health scores were better (2.1 vs 3.0) for those with functioning pancreata ($n = 18$) vs those with a non-functional pancreas ($n = 14$), respectively ($P = .036$). Those with a functional pancreas had a HgbA1c of 5.3, vs 7.7 for a non-functional pancreas ($P = .016$). Significant hypoglycemia was reported in two of 18 with a functional transplant vs nine of 14 patients with a failed transplant ($P = .003$). Daily frustration with blood sugar affecting quality of life was significantly higher for patients with non-functional pancreas grafts ($P < .001$).

Conclusions—Pancreas transplantation alone is associated with better glucose control than insulin. In addition, recipients of functional PTAs have improved quality of life and better overall health scores than those with failed grafts.

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AUTHORS' CONTRIBUTIONS

JRS: Wrote the paper, analyzed the data, edited the manuscript, prepared the figures, managed project; LP: Data collection, data analysis, study design; BF: Data collection, data analysis, study design; AB, data collection, data analysis, study design; AP: Data collection, data analysis, study design; MC: Data collection, data analysis, study design; JP: Data collection, data analysis, study design; NT: Data collection, data analysis, study design; ES: Data analysis, study design; STB: Data analysis, study design, edited the manuscript, idea conception.

CONFLICT OF INTEREST

None.

1 | BACKGROUND

The field of pancreas transplantation has evolved a great deal since the first successful, albeit short-lived, transplant in 1966.^{1,2} While the initial series of pancreas transplants were marked by challenging results, technical improvements and optimization of immunosuppression over the last three decades have led to excellent pancreas transplant outcomes in the modern era.^{3–5} Despite these dramatic improvements over time, the total number of pancreas transplants in the United States has declined.⁵ The reason for this decline is likely multifactorial, but includes poor referral stream, improved diabetic technologies such as the insulin pump, and insufficient access to trainee education.² Further, unlike the multi-disciplinary approaches to liver failure, kidney failure, and cancer, surgeons are somewhat disengaged from the management of the patient with severe diabetes.

Contributing to the above-mentioned reasons for the decrease in the number of pancreas transplants is the lack of knowledge regarding modern transplant outcomes, among the medical and surgical community. That is, over the last decade, the role of pancreas transplantation has become less clear, particularly for endocrinologists and nephrologists who refer patients for transplantation. While simultaneous pancreas and kidney transplantation is thought to be life-prolonging, pancreas transplantation alone is considered to be life-enhancing.^{6–9}

In the modern era, referring physicians and even surgeons may be unaware of the benefits of pancreas transplant alone (PTA). We hypothesized that a functional PTA improves a recipient's quality of life. Accordingly, we sought to determine the difference in quality of life for diabetic patients with and without a functional PTA. Using a combination of quantitative and qualitative analytics, we found that patients with a functional PTA had better glucose control and a better quality of life than those with without a functional organ.

2 | METHODS

2.1 | Patients

After approval by the institutional review board (IRB), we identified all consecutive, adult PTA procedures performed at our institution. Multiple organ transplant procedures (ie, simultaneous pancreas and kidney) were excluded, as were isolated pancreas transplants following kidney transplantation (ie, pancreas after kidney transplantation). Accordingly, we identified a total of 137 patients undergoing pancreas transplantation alone. Basic demographics were evaluated, inclusive of whether or not patients underwent portal vs systemic venous drainage of the pancreas, as both of these techniques are used at our institution. Further, our group has previously shown that portal venous drainage was associated with better rejection-free graft survival.¹⁰ Given this local experience and the possibility that this might influence our results, we chose to include this parameter in our demographic analysis. Quality of life was not defined by a single, objective value or equation. Rather, quality of life was determined based on comprehensive analysis of all data collected through our survey (see *discussion for caveats*). Graft failure was defined as transplant pancreatectomy or reinitiation of insulin use.

2.2 | Survey

A survey was developed as a collaborative effort between pancreas transplant surgeons, pancreas transplant nurse coordinators, inpatient providers, and biostatisticians. The survey consisted of 15 questions broken down into four domains: A) technical and demographic (eg, *when was your pancreas transplant? Is your pancreas transplant still functioning?*); B) Health score (eg, *prior to your transplant, how would you rate your health? After your transplant, how would you rate your health?*); C) Medical self-assessment (eg, *Do you have symptoms of diabetic neuropathy, such as pain or numbness in your hands or feet? Do you have symptoms of diabetic gastroparesis, such as bloating, nausea, and vomiting?*); and D) Quality of life (eg, *Do you fear leaving the house for fear of hypoglycemia? Do you fear driving a car for fear of hypoglycemia? Are you on disability?*). Patients were not offered stipends for taking the study. Each patient was called a maximum of three times, prior to coding these patients as “unreachable.” Each survey was completed in a single phone call.

2.3 | Qualitative analysis

Domain A and C questions were presented to respondents as closed-ended questions. Domain B question (health score self-identification) was presented to each respondent as a 5-level Likert scale: 1 = excellent, 2 = very good, 3 = good, 4 = fair, and 5 = poor. Domain D questions were a combination of both closed (yes/no) and open-ended questions. The primary theme of coded comments, as well as pertinent patient quotations, was included for analysis (*see results for caveats*).

2.4 | Statistical analysis

Statistical analysis was performed using IBM SPSS statistical version 24 (IBM Corp., Armonk, NY, USA). Kaplan-Meier survival analysis, chi-square, Fisher's exact, and the T test were used where appropriate.

3 | RESULTS

3.1 | Respondents

A survey of consecutive PTA patients was undertaken. Of the 137 patients, 24 (18%) expired, yielding 113 potential respondents (Figure 1). The majority of patients (n = 79; 58%) were unreachable. Two patients (1%) declined to participate in the study. Thirty-two of the remaining 34 patients (94%; 32 of 113 possible respondents, 28% overall) undertook the survey, consistent with published data regarding phone survey response rates.^{11–13} Of these 32 respondents (Table 1), 14 patients (44%) had failed grafts and required initiation of insulin and insulin dosing ranged from 30 to 90 units per day; two of 14 patients (14%) with failed grafts were using insulin pumps but did not know the total daily dose. In seven of 14 patients (50%), reinitiation of insulin was at the time of transplant pancreatectomy. No patients with functional grafts (n = 18) were on insulin (*see methods*). Both groups of patients had similar recipient and donor demographics, technical transplant procedures, and immunosuppressive regimens. Patients, as a group, had graft survivals consistent with published data (1-year graft survival of 85%), as shown in Figure 2. There was a wide range of graft survivals for those with failed grafts (18 days to 4743 days). Of those grafts which

failed, three failed in less than 1 year, and the remaining at later points; the mean time to graft failure was 1936 days, with a median time to graft failure of 1512 days.

3.2 | Self-identified health scores and glucose control

Taken together ($n = 32$), the mean self-identified pretransplantation health score reflected poor health status (score 3.6). However, posttransplantation health scores improved to 2.5. When these data were stratified by a functioning vs non-functioning pancreas (Table 2), we found that those with a functioning pancreas had a self-identified health score of 2.1 vs 3.0 for those with failed grafts ($P = .036$). Regarding glucose control, those with a functional pancreas had a mean HgbA1c of 5.3, vs 7.7 for those in the control group (ie, on insulin therapy; $P = .016$). While maintenance of body weight appeared better in the functionally transplanted group, this was not statistically significant. Of those with failed grafts, mean weight change in patients who underwent pancreatectomy was -2.4 pounds vs -18.3 pounds for those without pancreatectomy ($P = .293$).

3.3 | Complications of diabetes

Complications of diabetes were frequent in the pancreas transplant population. Symptomatic hypoglycemia was experienced by nine of 14 patients (64%) of patients on insulin whereas two of 18 patients (11%) with a functional pancreas endorsed at least one episode of hypoglycemia in the last year ($P = .003$); neither of these functionally transplanted patients was taking insulin (*see discussion for caveats*). Further, neither of these two functionally transplanted patients experienced a seizure or required intravenous glucose or dextrose. We observed no difference in the symptoms of retinopathy, neuropathy, or gastroparesis. Our center's experience with renal dysfunction in the pancreas transplant alone population was previously reported.⁷

3.4 | Quality of life

Three of 14 patients (21%) on insulin were fearful of driving an automobile. In contrast, no patients with a functional transplant were discretely fearful of driving (0%; $P = .073$), although a single patient with a functional graft stated that he/she was "occasionally" nervous about driving. Notably, this functionally transplanted patient was not receiving insulin therapy. Ten patients (71%) with failed pancreata stated they lived with frustration surrounding their blood sugar levels. In contrast, a single patient with a functional pancreas transplanted stated that he/she was concerned about blood sugar levels ($P < .001$); perhaps notably, this was the same respondent who was occasionally fearful of operating an automobile. Six of 14 patients (43%) with failed grafts were employed, in contrast to 13 of 18 patients (72%) of those with a functional graft ($P = .094$). Five of 14 patients (36%) on insulin were on medical disability vs 6 of 18 (33%) for those with a functional pancreas.

4 | DISCUSSION

Pancreas transplantation remains the only long-term treatment for glucose homeostasis in diabetic patients, without the risks of hypoglycemia.^{2,14–16} Despite this, the total number of pancreas transplants in the United States has decreased steadily since 2004.^{2,5} This decrease has been most striking for PTA and PAK.⁵ Leaders in the field have suggested that the

decrement in transplant volume is likely the result of a combination of factors including poor referral stream, lack of sufficient training, and improvement in non-surgical glucose management techniques.² Indeed, as non-surgical therapies for the management of diabetes have improved, it has become less clear (to providers—and possibly surgeons), as to whether patients really benefit from a PTA. Unfortunately, there is a paucity of high-quality data to help answer this question. Further, there are no previous reports of which we are aware that compare the quality of life of patients with failed vs functioning PTAs.^{17,18} We observed improved quality of life metrics for those with a functional PTA. These data indicate that PTA remains an important, if not critical, part of the continuum of care of patients with severe diabetes. Accordingly, rather than relying solely on medical therapies, surgeons are obliged to play a larger role in the evaluation and treatment of these challenging patients.

There are good data to suggest that quality of life, overall health status, and cognition improve with combined kidney-pancreas transplantation as compared to kidney transplantation alone.^{19–21} In a recent study of 126 patients who underwent combined kidney-pancreas transplantation, authors observed improved post-transplantation gastrointestinal quality of life indices, psychological status, and social function when compared with pretransplantation assessments.²² Further, investigators found lower rates of unemployment (36.5% from 50.8%) after combined kidney-pancreas transplants. Patients with two functional grafts had better quality of life when compared with patients with only a single functional graft.²² Perhaps importantly, patients who are awaiting combined kidney-pancreas transplantation (and who tend to be younger and fitter than the standard dialysis population) have poorer health-related quality of life scores prior to transplantation, perhaps reflecting that young, fitter patients are more emotionally and socially vulnerable to illness. This is important, because it is plausible that these patients stand to gain the most quality of life after transplantation.²³ There is a paucity of quality of life survey data in recipients of pancreas transplants alone; however, pancreas transplantation alone likely improves health-related quality of life through improvement in retinopathy and nephropathy.^{24–26} Taken together, pancreas transplantation provides recipients with improved overall health and autonomy.

This study is unique because we chose to compare quality of life using a survey of patients with and without a functional PTA. This is in contrast, for example, to comparing functionally transplanted patients with those patients who remain on the waiting list, as has been performed previously.^{6,8,18} Our rationale for choosing this control group (ie, failed pancreas transplants) was based on the notion that this group would most closely mirror those in the transplanted group, beyond basic demographics. Specifically, both groups underwent the preoperative testing, both groups were considered transplant candidates, and both groups received a major operation (as well as having assumed the risks for surgical complications). In addition, both groups were subject to immunosuppression and were treated by the same group of physicians at a single institution. As such, this unique control group makes the present, granular study an important contribution to the literature.

Patients with a PTA had better glucose control than did patients with a failed PTA ($P = .016$). This implies that not only was our control group appropriate (ie, these patients “needed”

pancreas transplants), but that the PTA itself was beneficial, medically. Two patients in the functional pancreas group stated that they experienced a hypoglycemic episode in the last year; however, these patients had HgbA1c levels of 4.3 and 5.5, neither patient was on insulin, and both were vigilant about their care after experiencing years of diabetic complications. As such, these self-reported “hypoglycemic episodes” may have been overstatements by insightful patients very involved in their care. Supporting this argument, neither patient experienced a seizure or required intravenous dextrose. We observed no difference in the self-reported presence of retinopathy, neuropathy, or gastroparesis. Because it likely takes many years to observe changes in these symptoms, our data regarding diabetic complications (retinopathy, etc.) are difficult to interpret in the context of small numbers and variable graft survival and follow-up.²⁷

Our observed improvement in quality of life spanned multiple survey domains. We found a trend toward improved likelihood of gainful employment and freedom to travel independently (operate a motor vehicle) for those patients who were functionally transplanted, vs those with failed grafts. While the data are not arguable (lack of statistical significance), it stands to reason that the ability to provide for one’s family and to travel independently is contributory to a higher quality of life. With a larger study, it is quite possible that these factors would have reached statistical significance. Nonetheless, it was more than clear that patients with a functional transplant lived with markedly less frustration on a day-to-day basis resulting from improved glucose homeostasis ($P < .001$), than did the cohort with failed grafts.

This report’s results should be approached carefully. One way to improve this analysis would be to prospectively study patients’ quality of life before and after PTA, and then to again compare those patients with failed vs functional grafts. This, however, would be resource-heavy given the low rate of PTA graft failure in 2017. An additional, and perhaps interesting, comparator would be islet transplantation; however, there are too few patients who have undergone this procedure at our institution to perform a meaningful analysis.

Limitations to this study largely relate to sample size. Indeed, we captured 32 of 111 possible respondents. This low rate percentage of respondents introduces the possibility of sampling error. Nevertheless, 94% of those contacted, responded to the survey. Our overall data are consistent with the, generally, low response rates to surveys. Given the large number of non-responders, and the severity of diabetes in this population, it is likely that a significant proportion the “unreachable” patients have expired from their disease. We chose to speak directly with the patients (by phone, rather than using a stipend-influenced mailer) so we could learn more about their personal experiences. It is possible that our yield of survey respondents may have been higher with the use of email, other electronic means, or a combination of techniques; however, there are data to suggest otherwise.^{11–13} Despite the inherent challenges of a survey study, we retained a reasonable cohort of patients from whom we were able to learn a great deal. Beyond sample size, the study included patients transplanted over a long period of time. Because operative and perioperative care evolved, this long duration may have introduced bias. It should also be noted that early pancreas failures (eg, less than a year) may affect patients differently than a pancreas which failed more than 10 years ago. All but three pancreas recipients in this study had grafts which

failed later, suggesting that these patients were able to experience the benefits of an insulin-free lifestyle prior to graft failure.

In the opinion of the authors, consideration for PTA should include a comprehensive evaluation which focuses on not just glucose control, but autonomy, social well-being, and overall health. Indeed, PTA holds an important place in the management of the severely diabetic.

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FIGURE 1.
Diagram of survey respondents

FIGURE 2.
Graft survival of survey respondents

TABLE 1

Demographics of survey respondents

	All (n = 32)	Functioning (n = 18)	Failed (n = 14)	P*
Age (y)	53	52	54	.4
Age at Txp (y)	40	40	41	.6
Donor age (y)	25	25	24	.4
Gender, n (%); Female	14 (43)	8 (44)	6 (43)	.6
Race, n (%); Caucasian	32 (100)	18 (100)	14 (100)	c
PVD vs SVD, n (%); PVD	21 (66)	14 (78)	7 (50)	.1
TCD?, n (%); Yes	28 (88)	16 (89)	12 (86)	.8
CI?, n (%); Yes	29 (91)	17 (94)	12 (84)	.1
Steroids?, n (%); Yes	19 (59)	11 (61)	8 (57)	.5
Graft survival (y)	6.4	7.6	4.6	.4

PVD, portal venous drainage; SVD, systemic venous drainage; TCD, T-cell depletion; CI, calcineurin inhibition.

* Comparison of Functional with Failed pancreas transplant alone parameters. Graft survival presented as comparison of means. Kaplan-Meier analysis shown in Figure 1; c, constant.

TABLE 2

Differences in quality of life based on 4-domain (A–D) survey of pancreas transplant alone (PTA) recipients

	Functional (n = 18)	Failed (n = 14)	P
Domain A: Technical and demographic			
Demographics	See table 1	See table 1	N/A
Domain B: Health score			
Prior to transplant	3.7	3.4	.7
After transplant	2.1	3	.036
Domain C: Medical			
HgbA1c	5.3	7.7	.016
Weight loss	0.1 pound weight loss	9.8 pound weight loss	.514
Retinopathy symptoms? Yes, n (%)	14 (78)	8 (57)	.194
Neuropathy symptoms? Yes, n (%)	9 (50)	6 (43)	.59
Gastroparetic symptoms? Yes, n (%)	5 (28)	4(29)	.496
Do you have episodes of hypoglycemia? Yes, n (%)	2 (11)	9 (64)	.003
Domain D: Quality of life			
Employed, n (%)	13 (72)	6 (43)	.094
Employed full time? Yes, n (%)	9 (50)	5 (36)	.328
On disability? Yes, n (%)	6 (33)	5 (36)	.59
Do you live in frustration of your blood sugars? Yes, n (%)	1 (6)	10 (71)	<.001
Fearful of socializing? Yes, n (%)	0 (0)	2 (14)	.183
Fearful of driving? Yes, n (%)	0 (0)	3 (21)	.073
Do you drive? Yes, n (%)	16 (89)	10 (71)	.212