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Systemic Venous *Versus* Portal Venous Drainage in Simultaneous Pancreas-Kidney Transplantation: A Matched-Pair Analysis

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Abstract

The study purpose was to evaluate outcomes in vascularized Pancreas Transplantation (PTx) with enteric exocrine drainage based on technique of venous delivery.

Methods: We retrospectively analyzed 231 Simultaneous Pancreas-Kidney Transplants (SPKTs) performed at our center between 7/2003 to 7/2019 and identified 27 that were performed with systemic venous (iliac vein) and enteric exocrine (Systemic-Enteric [S-E]) drainage. These 27 patients were compared to 27 case controls with portal venous (superior mesenteric vein) and enteric exocrine (Portal-Enteric [P-E]) drainage matched for recipient age, gender, race, and date of transplant. All patients received similar immunosuppressive regimens and underwent standardized management protocols. Intention to treat was with P-E drainage.

Results: The 2 groups were well-matched for numerous donor, preservation, recipient, and immunological characteristics. Indications for S-E drainage were central obesity/thickened mesentery, unfavorable vascular anatomy, or surgeon preference. The S-E drainage group was characterized by slightly more patients ≥ 80 kg (44% S-E *vs.* 26% P-E), with C-peptide positive diabetes (30% S-E *vs.* 18% P-E), and with diabetes onset at >20 years of age (41% S-E *vs.* 26% P-E, all p=NS), suggesting a Type 2 diabetes phenotype. Although the incidence of early pancreas thrombosis (3.7% S-E *vs.* 0% P-E), early relaparotomy rates (30% S-E *vs.* 22% P-E), and mean initial length of hospital stay (11 days S-E *vs.* 8 days P-E) were numerically higher in S-E *vs.* P-E SPKTs, none of these differences were significant. With a mean follow-up of 5 years in both groups, respective one and 3-year patient survival (100% and 96% S-E *vs.* 100% and 100% P-E), kidney graft survival (100% and 96% S-E *vs.* 100% and 89% P-E), and pancreas graft survival (96% and 96% S-E *vs.* 100% and 100% P-E) rates were comparable.

Conclusion: The method of venous delivery of insulin following PTx does not appear to influence medium-term outcomes in SPKT with enteric exocrine drainage.

Keywords: Enteric drainage; Pancreas transplantation; Portal-enteric drainage; Simultaneous pancreas-kidney transplant; Systemic-enteric drainage; Venous drainage

Abbreviations

BMI: Body Mass Index; IPTR: International Pancreas Transplant Registry; P-E: Portal-enteric PTx: Pancreas Transplant; S-E: Systemic-enteric; SMV: Superior Mesenteric Vein; SPKT: Simultaneous Pancreas-Kidney Transplant; US: United States

Introduction

Evolution in surgical techniques in the past 4 decades has had a major impact on the success of vascularized Pancreas Transplantation (PTx). Whole pancreatico-duodenal transplantation using the allograft duodenum as an exocrine conduit coupled with enteric drainage is generally regarded as the preferred technique of PTx. Enteric drainage of the exocrine secretions in combination with systemic venous (iliac vein or vena cava) delivery of insulin (systemic-enteric [S-E] technique) is currently performed in 90% of cases in the United States (US) whereas portal venous (Superior Mesenteric Vein [SMV]) delivery of insulin (Portal-Enteric [P-E] technique) accounts for only a minority of cases [1]. However, S-E drainage causes systemic hyperinsulinemia, which in the non-transplant setting may result in a number of complications such as accelerated vasculopathy,

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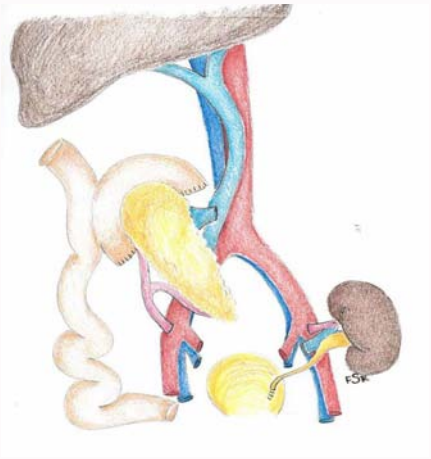

Figure 1: Technique of portal-enteric pancreas transplantation with donor portal vein anastomosis to recipient SMV followed by donor duodenal drainage to recipient small bowel.

macroangiopathy, lipid dysmetabolism, and insulin resistance. Consequently, to improve the physiology of PTx, an innovative surgical technique of intraperitoneal portal venous drainage using an anterior approach to the SMV was introduced by Shokouh-Amiri, et al. [2] and subsequently refined to a lateral or "retroperitoneal" approach by Boggi et al. [3]. The P-E technique merges portal venous delivery of insulin with enteric drainage of the exocrine secretions, which mimics the physiology of the native pancreas. However, the potential of P-E drainage has not been attained because it is performed in only 10% of Simultaneous Pancreas-Kidney Transplants (SPKTs) in the US [1]. Previous reports have shown similar outcomes for enteric-drained PTxs with either systemic or portal venous drainage [4-8]. Although the preferred technique is widely debated, it is reasonable to assume that surgical team experience with a given technique coupled with anatomic considerations play an important role in the surgical approach and decision-making [9,10]. At our center, we perform P-E drainage preferentially but have confidence with either technique of PTx [11,12]. The study purpose of was to analyze our outcomes in SPKT with S-E drainage compared to P-E drainage in a matched-pair analysis.

Methods

Study design

The PTx program at Wake Forest originally started in 1995 (one SPKT with systemic-bladder drainage was performed in the 1990s). However, the program was resumed in November 2001 and 283 PTxs have been performed as of October 2019. For purposes of this study, we retrospectively reviewed 231 SPKTs performed at our center between 7/2003 to 7/2019 and identified 27 that were performed with S-E drainage. These 27 patients were compared to 27 SPKT case controls with P-E drainage matched for recipient age, gender, race, and date of transplant. All patients received similar management strategies and intention to treat was with P-E drainage in most cases [11-15].

Recipient selection

Indications for SPKT were the presence of diabetes requiring insulin therapy, either Type 1 or Type 2, with complications from diabetes (including chronic kidney disease). A comprehensive medical assessment was performed to determine whether the patient could predictably recover from the surgical procedure. In addition, a detailed psychosocial assessment was mandatory to establish that patients and their support systems could cope with the obligatory immunosuppressive and supportive medications in consort with intensive outpatient follow-up [12-14]. Indications for SPKT included stage 4/5 chronic kidney disease or end stage renal disease and the absence of any contraindications. Exclusion criteria included age >65 years; insufficient cardiovascular reserve; current substance abuse; active infection or recent malignancy; major ongoing psychiatric illness, recent noncompliance, or lack of adequate social support; significant obesity or unfavorable anatomy; severe vascular disease; or inability to either understand or commit to the more intense follow-up associated with SPKT compared to kidney transplantation alone. In patients with a type 2 diabetes phenotype, indications for SPKT included age <55 years, Body Mass Index (BMI) <30 kg/m^2, continuous need for daily insulin therapy for at least 3 years, total insulin dose <1 u/kg/day, a fasting C-peptide level <12 ng/ml, and absence of any exclusion criteria as noted above [12-16].

Technical aspects

For most cases, the intent-to-treat approach was P-E drainage using the proximal ileum in the recipient for exocrine drainage (side-to-side duodeno-ileostomy, Figure 1) without a diverting Roux limb [11-14]. The arterial anatomy of the pancreas was reconstructed on the back bench with a donor common iliac bifurcation graft (Figure 2), after which the recipient's right common iliac artery was used to re-establish arterial inflow [17,18]. If the SMV was <6 mm in diameter, deep in the mesentery, or difficult to access, then venous drainage to the right common iliac vein or distal inferior vena cava was considered. In patients with central obesity or a BMI >30 kg/m^2, the SMV might be inadequate for safe P-E drainage. In addition, in patients with either severe proximal right common iliac artery calcifications or a short arterial "Y" graft, S-E drainage was contemplated if the arterial graft supplying the pancreas would not reach a soft target either on the iliac artery or aorta [11-14]. In these cases, S-E drainage was performed to simplify the procedure (Figure 3). In both groups, the majority of SPKTs were performed with ipsilateral placement of the kidney and pancreas to the right iliac vessels through a midline intraperitoneal approach in order to reduce operating time and to preserve the left iliac vessels for future transplantation.

Anti-coagulation

Anti-coagulation was administered peri-operatively in selected SKPT recipients. For patients with a prior history of thrombosis, diseased or small recipient or donor vessels, or pancreas cold ischemia times exceeding 16 h, an intravenous heparin bolus of 2000 to 3000

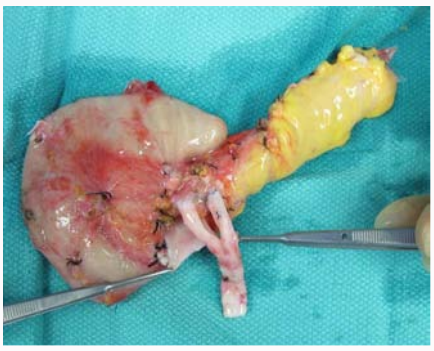

Figure 2: Back bench reconstruction of pancreas transplant with donor common iliac artery bifurcation "Y"-graft.

Table 1: Donor and Recipient Characteristics and Outcomes According to Surgical Technique.

Mean ± SD	Systemic-enteric N=27	Portal-enteric N=27	p-value
Donor age (years)	23.3 ± 8.2	22.3 ± 8.6	NS
Donor weight (kg)	74.5 ± 15.2	67.5 ± 18.3	NS
Donor BMI (kg/m^2)	24.3 ± 4.8	23.3 ± 4.2	NS
Pancreas cold ischemia (hours)	13.5 ± 4.6	13.7 ± 3.9	NS
HLA-mismatch	4.7 ± 1.0	4.5 ± 1.2	NS
PRA >10%	2 (7.4%)	4 (14.8%)	NS
CMV D+/R-	5 (18.5%)	8 (29.6%)	NS
Retransplant	1 (3.7%)	2 (7.4%)	NS
Kidney Donor Profile Index (%)	15.2 ± 17.5	19 ± 15.7	NS
Organ import	3 (11.1%)	7 (26%)	0.29
Recipient age (years)	44.9 ± 10	45.1 ± 9	NS
Recipient gender: Male	19 (70.4%)	19 (70.4%)	NS
Recipient: African American	11 (40.7%)	11 (40.7%)	NS
Recipient weight (kg)	77.2 ± 10.3	71.8 ± 12.8	NS
Recipient weight ≥ 80 kg	12 (44.4%)	7 (26.0%)	0.25
Recipient BMI (kg/m^2)	25.6 ± 3.2	23.7 ± 3.1	NS
Hemodialysis Peritoneal Dialysis None (preemptive)	16 (59%) 5 (19%) 6 (22%)	15 (56%) 9 (33%) 3 (11%)	NS
Duration of dialysis (months)	32.5 ± 64	25 ± 27	NS
Duration of diabetes (years)	25.5 ± 10.8	28 ± 9.7	NS
Age of diabetes onset >20 years	11 (40.7%)	7 (26%)	NS
Pretransplant HbA1c level (%)	8.5 ± 1.5	8.75 ± 2.1	NS
Daily insulin dose (units)	41 ± 20	36 ± 14.5	NS
C-peptide positive pretransplant	8 (29.6%)	5 (18.5%)	NS
Time on waiting list (months)	8.1 ± 8	9.8 ± 10	NS
Patient survival	24 (88.9%)	25 (92.6%)	NS
Death with functioning grafts	2 (7.4%)	1 (3.7%)	NS
Kidney graft survival	23 (85.2%)	18 (67%)	0.2
Death-censored kidney graft survival	23/24 (95.8%)	18/26 (69.2%)	0.02
Pancreas graft survival	22 (81.5%)	19 (70.4%)	NS
Death-censored pancreas graft survival	22/25 (88%)	19/26 (73.1%)	0.29
One year kidney graft survival	27 (100%)	27 (100%)	NS
One year pancreas graft survival	26 (96.3%)	27 (100%)	NS
Five year kidney graft survival	25 (92.6%)	23 (85.2%)	NS
Five year pancreas graft survival	26 (96.3%)	23 (85.2%)	NS
Follow-up (months)	58 ± 50	68 ± 57	NS
Early relaparotomy (<3 months)	8 (29.6%)	6 (22.2%)	NS
Early thrombosis (<1 month)	1 (3.7%)	0	NS
Days of initial hospital stay	10.8 ± 6.8	8 ± 2.9	NS

units was given intra-operatively prior to clamping the vessels and a low dose continuous heparin infusion was continued post-operatively (300 units/h for 24 h, then 400 units/h for 24 h, and then 500 units/h until post-operative day 5) in the absence of bleeding [11-13,18,19]. All patients also received baby aspirin (81 mg) daily.

Immunosuppression

All patients received triple maintenance daily immunosuppression with twice daily tacrolimus (target 12 h trough levels of 8-10 ng/ml initially, then 6-8 thereafter), full dose mycophenolate mofetil (1000 mg twice daily) or mycophenolic acid (720 mg twice daily), with either early steroid withdrawal or a rapid prednisone taper (dose reduction to 5 mg/day by 1 month following SPKT) [12-15,20]. In addition, depleting anti-T cell induction therapy with either single dose alemtuzumab (30 mg intravenous intra-operatively) or rabbit anti-thymocyte globulin (1.5 mg/kg/dose, total 3-5 doses) was administered to all SPKT recipients [15,20]. A first-generation cephalosporin (cefazolin) was administered for 24 h for surgical

site prophylaxis. In addition, anti-fungal, anti-viral, and anti-pneumocystis prophylaxis consisted of fluconazole (50 mg/d for one month), valganciclovir (450 mg/d for 3-6 months contingent on donor and recipient cytomegalovirus serologic status), and trimethoprim-sulfamethoxazole (one single strength tablet every Monday, Wednesday, and Friday), respectively.

Statistical analysis

We queried both retrospective and prospective databases to review data. In addition, using local Institutional Review Board approval and guidelines, any missing or questionable data elements were confirmed by review of the medical record. The chi-square test was used for categorical variables, when data were sparse; Fisher's exact test was applied. Continuous data were summarized as means and standard deviations whereas categorical data were summarized as proportions and percentages. Significance was ascribed when the two-tailed p-value was <0.05.

Results

From 7/1/03 through 7/1/19, we performed 231 SPKTs at our center and identified 27 that were performed with S-E drainage. These 27 patients were compared to 27 case-matched SPKT controls with P-E drainage. Indications for S-E drainage were central obesity/thickened mesentery (n=10), unfavorable vascular anatomy/small SMV (n=11), and surgeon preference (n=6). In the 27 cases of SPKT with S-E drainage, the choice to abandon P-E drainage and switch to S-E drainage was made during the procedure. Comparison of recipient and donor characteristics between the two groups is depicted in Table 1. The two groups were well-matched for numerous donor, preservation, recipient, and immunological characteristics. The S-E drainage group was characterized by slightly more patients ≥ 80 kg (44% S-E *vs.* 26% P-E), with C-peptide positive diabetes (30% S-E *vs.* 18% P-E), and with diabetes onset at >20 years of age (41% S-E *vs.* 26% P-E, all p=NS), suggesting a Type 2 diabetes phenotype. Although the incidence of early pancreas thrombosis (3.7% S-E *vs.* 0% P-E), early relaparotomy rates (30% S-E *vs.* 22% P-E), and mean initial length of hospital stay (11 days S-E *vs.* 8 days P-E) were numerically higher in S-E *vs.* P-E SPKTs, none of these differences were significant. Indications for early relaparotomy were unexplained fever, bleeding, or pancreatitis (3 each); thrombosis (2); and one case each of enteric leak, partial small bowel obstruction, and ureteral revision. With a mean follow-up of 5 years in both groups, respective one and 3-year patient survival (100% and 96% S-E *vs.* 100% and 100% P-E), kidney graft survival (100% and 96% S-E *vs.* 100% and 89% P-E), and pancreas graft survival (96% and 96% S-E *vs.* 100% and 100% P-E) rates were comparable (Table 1).

Discussion

Data from the International Pancreas Transplant Registry (IPTR) and the United Network for Organ Sharing have documented steadily improving success rates in SPKT in each successive era [1,21]. For primary, deceased donor SPKTs performed in the US between 2014 and 2018, one-year patient, kidney, and pancreas graft survival (insulin-free) rates are 97%, 94%, and 89.6%, respectively, according to IPTR data [1,22]. The unadjusted five-year patient, kidney, and pancreas graft survival rates are 88%, 82%, and 76%, respectively. For patients with functioning grafts at one year, the conditional kidney and pancreas graft half-lives exceed 13 years following SPKT in the most recent era [1,22,23]. At present, vascularized PTx is the most effective way to prevent wide glycemic excursions while maintaining an insulin-free state as patients with functioning pancreas grafts are truly "ex-diabetic".

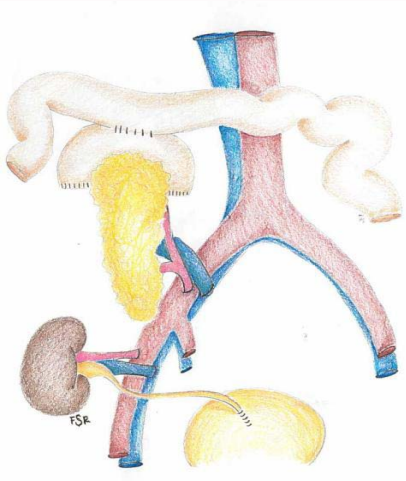

Figure 3: Technique of systemic-enteric pancreas transplantation with donor portal vein anastomosis to recipient right common iliac vein followed by donor duodenal drainage to recipient small bowel.

Analysis of data from the IPTR suggests that there are no differences in outcomes according to method of venous delivery (systemic *vs.* portal vein drainage) in patients with enteric exocrine drainage [1,21]. Consequently, the preferred technique of implantation is debated. Shared aspects of all techniques include appropriate selection of donors and their optimal management, meticulous pancreas assessment and recovery, minimizing warm and cold ischemia, and careful bench reconstruction [9-18]. Having familiarity with more than one implantation technique is helpful for intra-operative planning because of singular differences in anatomy. In the past, the P-E technique was attributed to having distinctive advantages from an immunologic, metabolic, and surgical perspective [2-12]. Unfortunately, many of these purported benefits have not been proven by either randomized controlled studies, prospective cohort reports, or IPTR database analyses [1-12,24]. On the other hand, none of these papers have found any major shortcomings associated with portal venous drainage although there is a perception that the procedure is technically more complex and may have a higher complication rate. In this study, we chose to focus on technical considerations and analyzed our experience with S-E drainage as a "rescue" or secondary technique of PTx when P-E drainage was not deemed appropriate. An advantage of portal venous outflow is that the PTx is primarily a mid-abdominal rather than a pelvic procedure, which is beneficial in patients who have had previous pelvic transplants or other lower abdominal procedures. However, a potential disadvantage of the mid-abdominal or anterior approach to the SMV is that the arterial anastomosis may be difficult and require a long interposition "Y" graft (especially in patients with central, omental, or mesenteric obesity or in patients with severe proximal iliac vascular disease). For this reason, even though we controlled for recipient age, gender, and race; compared to the P-E group, the S-E group had numerically more patients with a phenotype associated with type 2 diabetes (shorter duration and older age of onset of diabetes, detectable pretransplant C-peptide levels ≥ 2.0 ng/ml, higher body weight). For patients with technical challenges or unusual anatomy, several newer techniques using SMV drainage have been introduced in recent years including exocrine drainage using

the recipient's stomach, third portion of the duodenum, and small bowel (± a diverting Roux limb or venting jejunostomy) [10,11,25-32]. Based on these study findings, we conclude that comparable overall technical results can be achieved in SPKT with either S-E or P-E drainage. Having experience with different PTx techniques allows a surgeon to tailor the implantation procedure to the recipient. In addition to recipient and donor anatomic factors, the confidence level and experience of the surgical team with a given technique is an important consideration for planning purposes. Variations on a theme and nuances will continue to be reported in the literature, suggesting that "one size does not fit all" with respect to the technical aspects of PTx.

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