

Author/ Year	Study Design	Demographics	Outcome measures	Results		Methodological Comments																																
				Intervention group	Control group																																	
Venstrom J, 2003	Retrospective, controlled, multicenter cohort Transplant cohort: patients on UNOS/OPTN waiting list for a pancreas transplant (PA, PAK, SPK) from Jan 1, 1995 – Dec 31, 2000 who did receive a transplant Control cohort: patients on wait list who did not receive a transplant Analysis stratified by transplant type Exclusions: on wait list for multi-organ transplant other than SPK; creatinine >2 mg/dL at time of listing; listed for PA but eventually received SPK	Total N= 11,572 Transplanted N= 6595 PA= 378 PAK= 838 SPK= 5379 For the PA group: 40% men 10% ≥50 yrs old	Unadjusted wait list and post-transplant patient survival rates Mortality risk (hazard ratio-- average risk for PA transplant patients compared to patients on wait list for comparable amount of time) assessed for 3 clinically distinct time periods in the transplant group: 0-90 days 91-365 days 366-1460 days	Results presented for PA patients only: Transplant N= 361 Baseline characteristics of transplant and wait list patients statistically indistinguishable <table border="1"> <thead> <tr> <th>Time period (days)</th> <th>Mortality Risk</th> <th>95% CI</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>0-90</td> <td>2.27</td> <td>0.84-6.13</td> <td>0.11</td> </tr> <tr> <td>91-365</td> <td>0.99</td> <td>0.41-2.39</td> <td>0.99</td> </tr> <tr> <td>366-1460</td> <td>1.70</td> <td>0.97-2.98</td> <td>0.06</td> </tr> <tr> <td>Overall (4 yrs)</td> <td>1.57</td> <td>0.98-2.53</td> <td>0.06</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Patient survival</th> <th>PA</th> </tr> </thead> <tbody> <tr> <td>At 1 yr</td> <td>96.5%</td> </tr> <tr> <td>At 4 yr</td> <td>85.2%</td> </tr> </tbody> </table> Mortality risk factors: donor death due to stroke; any complications post-transplant (includes pancreatitis, abscess, or anastomotic leak)	Time period (days)	Mortality Risk	95% CI	P value	0-90	2.27	0.84-6.13	0.11	91-365	0.99	0.41-2.39	0.99	366-1460	1.70	0.97-2.98	0.06	Overall (4 yrs)	1.57	0.98-2.53	0.06	Patient survival	PA	At 1 yr	96.5%	At 4 yr	85.2%	Results presented for PA patients only: Wait list N= 311 <table border="1"> <thead> <tr> <th>Patient survival</th> <th>Wait list</th> </tr> </thead> <tbody> <tr> <td>At 1 yr</td> <td>97.6%</td> </tr> <tr> <td>At 4 yr</td> <td>92.1%</td> </tr> </tbody> </table>	Patient survival	Wait list	At 1 yr	97.6%	At 4 yr	92.1%	Retrospective, observational nature of trial and small n are a negative. Use of a relevant control cohort is a plus. Uncertain if target population was studied-- - presume every patient added to UNOS/OPTN wait list met ADA criteria for PA Assessed patient survival/mortality risk. Short duration of study (i.e., 4 yrs post- transplant or on the wait list). Majority of study population was younger than 65 yrs. # lost to follow-up and # of cross-overs not reported.
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Gruessner R, 2004	Retrospective, controlled, multicenter cohort Transplant cohort: patients on UNOS/IPTR waiting list for a pancreas transplant (PA, PAK, SPK) from Jan 1, 1995 – May 31, 2003 who did receive a transplant Control cohort: patients on wait list who did not receive a transplant Analysis stratified by transplant type Patient with multiple listings at different transplant centers and/or who changed transplant center was counted only	For patients on the PA wait list: Total N= 1207 42% men 38.8+/- 9.2 yrs 8.3% retransplant Transplanted N= 647	Unadjusted wait list and post-transplant patient survival rates Mortality hazard ratio assessed for 3 clinically distinct time periods in the transplant group: 0-90 days 91-365 days 366 days on	Results presented for PA patients only: Transplant N= 647 Baseline characteristics of transplant v. wait list patients not stated Hazard ratio for Jan 1, 1995 – May 31, 2003 database: <table border="1"> <thead> <tr> <th>Time period (days)</th> <th>Mortality</th> <th>95% CI</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>0-90</td> <td>4.25</td> <td>1.68- 10.76</td> <td>0.002</td> </tr> <tr> <td>91-365</td> <td>1.72</td> <td>0.82-3.61</td> <td>0.15</td> </tr> <tr> <td>366 on</td> <td>0.15</td> <td>0.08-0.29</td> <td>0.0001</td> </tr> <tr> <td>Overall</td> <td>0.66</td> <td>0.39-1.12</td> <td>0.12</td> </tr> </tbody> </table> Hazard ratio for Jan 1, 1995 – Dec 31, 2000 subset of database: <table border="1"> <thead> <tr> <th>Time period (days)</th> <th>Mortality</th> <th>95% CI</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Time period (days)	Mortality	95% CI	P value	0-90	4.25	1.68- 10.76	0.002	91-365	1.72	0.82-3.61	0.15	366 on	0.15	0.08-0.29	0.0001	Overall	0.66	0.39-1.12	0.12	Time period (days)	Mortality	95% CI	P value					N= 1207 Baseline characteristics of transplant v. wait list patients not stated	Retrospective, observational nature of trial is a negative. Use of a relevant control cohort is a plus. Uncertain if target population was studied-- - presume every patient added to UNOS/OPTN wait list met ADA criteria for PA Assessed patient survival/mortality risk. Majority of study population most likely younger than 65 yrs. 8% of patients were to receive a retransplant—				
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once A patient relisted was counted only once (and all wait times summed) Exclusions: change in status from SPK/PAK/PA to KTA; listed for PA but eventually received SPK; retransplant patients				0-90	6.40	1.95-21.1	0.002			i.e., presumably these patients were not excluded from cohort prior to analysis. # lost to follow up not reported.	
				91-365	2.90	1.1-7.63	0.03				
				366 on	0.29	0.15-0.57	0.0003				
				Overall	1.45	0.83-2.55	0.19				
				Patient survival	PA						
				At 1 yr	97%						
				At 4 yr	90.5%						
				Mortality risk factors: time of listing (1995-1998); use of depleting antibody induction therapy; graft failure							
				Patient survival	Wait list						
				At 1 yr	96.6%						
				At 4 yr	87.3%						
				Mortality risk factors: time of listing (1995-1998); non-Caucasian (v. Caucasian)							

Key

CsA—cyclosporine A

TAC—tacrolimus

DM—Diabetes mellitus

Pop—population

N/A—not applicable; not available

PA—pancreas transplant alone

SPK—simultaneous pancreas-kidney transplant

PAK—pancreas after kidney transplant

CI—confidence interval

KTA—kidney transplant alone