

Common Characteristics of Insulin-Independent Cases

It is evident that many unknown factors might have operated in the type 1 diabetic recipients listed on page 13 who became C-peptide positive and insulin independent following adult islet allotransplantation.

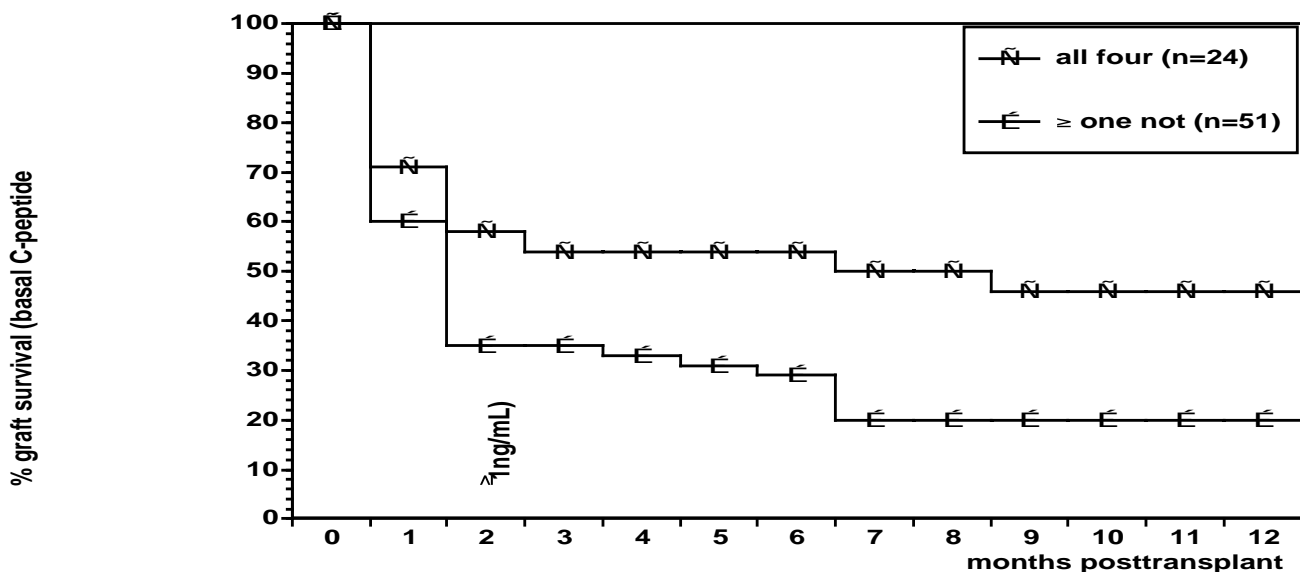
However, four common characteristics can be identified when the individual protocols that have been applied in these successful cases are being compared.

These four common characteristics are as follows:

1. Mean preservation time of the donor pancreas (pancreata): < 8 h
2. Islet mass: 6,000 IEQ / kg bodyweight
3. Implantation site: liver via portal vein
4. Induction immunosuppression: ALG/ATG but not OKT3

When all four criteria were met, the number (percentage) of patients who had basal C-peptide 1 ng/ml and who were insulin independent at one year posttransplant was 11 (46%) and 7 (29%) in contrast to 10(20%) and 1 (1%, p=0.001), respectively, when at least one criterion was not fulfilled (see page 18 and this page).

**One-Year Islet Allograft Survival
in 75 Pre-Tx C-Peptide Negative IDDM-Recipients (1990-1993) according to
Common Characteristics**



| Islet Transplantation - Experiences Worldwide 1990 - 93 Results in 24 C-peptide Negative IDDM-Recipients (and only ALG/ATG but not OKT3) fulfilling the four common characteristics of insulin independent recipients | | |
|--|---------------|-------------|
| | ≥ 1 month | ≥ 1 year |
| | post islet tx | |
| Basal C-Peptide ≥ 1 ng/ml | 83 % | 46 % |
| HbA1c < 7 % | | 46 % |
| Insulin Independent | 33 % | 29 % |

**Comparison of Insulin Dependent and Insulin Independent
Islet Allograft Recipients
(1990 - 93, only patients who met all 4 criteria)**

| | Off Insulin (n=8/ 24) (mean ± SEM) | On Insulin (n=16/ 24) (mean ± SEM) | p* |
|--------------------------------|---|---|-----------|
| Age (yrs) | 41.5±1.84 | 42.0± 1.97 | NS |
| BMI (kg/m²) | 22.6±0.83 | 22.6± 0.77 | NS |
| Diab. Duration (yrs) | 29.7±3.02 | 28.7± 1.85 | NS |
| Pre-Tx HbA1c (%) | 7.4±0.48 | 7.7± 0.36 | NS |
| Pre-Tx Insulin (U/kg/d) | 0.8±0.07 | 0.7± 0.11 | NS |

**Comparison of Insulin Dependent and Insulin Independent
Islet Allograft Recipients
(1990 - 93, only patients who met all 4 criteria)**

| | Off Insulin (n=8/ 24) (mean ± SEM) | On Insulin (n=16/ 24) (mean ± SEM) | p* |
|--------------------------------|---|---|---------------|
| Av. Donor Age (yrs) | 32.8 ± 2.99 | 33.1 ± 2.48 | NS |
| Av. Pres. Time (min) | 198.6 ± 39.1 | 206.4 ± 25.03 | NS |
| IEQ / kg | 10174 ± 1127 | 12234 ± 2041 | NS |
| basal C-P 1 mo. (ng/ml) | 2.7 ± 0.47 | 1.4 ± 0.37 | 0.0448 |
| basal C-P 1 yr. (ng/ml) | 2.2 ± 0.11 | 0.48 ± 0.19 | 0.0001 |

* nonparametric two-tailed Mann-Whitney test