

Summary.

From Dec. 12, 1893, through Dec. 31, 1994, a total of 244 adult islet allografts and one adult islet xenograft including historical cases have been performed at 34 Institutions worldwide including 144 at 13 institutions in North America, 97 at 20 institutions in Europe, and one elsewhere. It is assumed that to date over 2,000 fetal islet allografts and xenografts have been performed worldwide (mainly in Russia and China). Out of these, 187 fetal islet allografts have been reported to the Registry from 11 institutions.

The total number of diabetic patients reported to be insulin independent for ≥ 0.5 , ≥ 1 , ≥ 3 , ≥ 6 , ≥ 12 , ≥ 24 , ≥ 36 , and ≥ 48 month(s) after adult islet allotransplantation through Dec. 31, 1994, is 29, 28, 22, 20, 14, 4, 3, and 1, respectively.

Three fetal islet allograft recipients demonstrated periods of insulin independence post-transplant. C-peptide levels in these three patients have not been determined pretransplant. Of the 57 pretransplant C-peptide negative fetal islet allograft recipients, 8 showed clear evidence of graft function verified by basal C-peptide levels exceeding 0.5 ng/mL, lasting for periods of 2 to > 48 months.

In an analysis by era, the percentages of pretransplant C-peptide negative type 1 diabetic recipients of adult islet allografts who showed basal C-peptide levels ≥ 1 ng/mL at ≥ 1 month posttransplant and who became insulin independent for > 1 week in the 1985-89 era ($n=29$) were 21% and 7%, in the 1990-91 era ($n=37$) were 65% and 16%, and in the 1992-93 era ($n=39$) were 59% and 15%, respectively ($p=0.64$, $p=1.0$).

A detailed analysis was performed on 75 pretransplant C-peptide negative type 1 diabetic patients who received adult islet allografts between 1990 and 1993. One year patient and islet allograft survival (as defined by basal C-peptide ≥ 1 ng/mL) rates were 95% and 28%, and 11% of the recipients were insulin independent at one year follow-up. Recipient age, sex, duration of diabetes, number of donor pancreata and islet purity did not influence one-year graft survival rates. Insulin independence was achieved 1) only if islets were isolated from pancreata with a mean preservation time < 8 hrs., 2) only if $> 6,000$ islet equivalents (number of islets if all had a diameter of 150 μm) per kg b. wt. were transplanted, 3) only if islets were transplanted into the liver via the portal vein, and 4) only if induction immunosuppression comprised T-cell antibodies. In the 1990-93 period, only recipients treated with ALG/ATG but not with OKT3 remained insulin-independent at ≥ 1 yr after transplantation.

24/75 pretransplant C-peptide negative type 1 diabetic islet allograft recipients met all four aforementioned characteristics of long-term insulin independent recipients (ALG / ATG but not OKT3). Twenty of these 24 patients (83%) showed basal C-peptide levels ≥ 1 ng/mL posttransplant. At ≥ 1 -yr follow-up, 11/24 (46%) had HbA1c levels $< 7\%$, and 7/24 (29%) were insulin independent at ≥ 1 yr follow-up. In this preselected group of patients, insulin independent (8/24) and insulin dependent recipients (16/24) did not differ in regard to age, BMI, diabetes duration, pre-tx HbA1c, pre-tx insulin requirements, donor age, cold storage time, and IEQ/kg, but the former had significantly higher basal C-peptide levels at 1 month (2.7 ± 0.5 vs 1.4 ± 0.4 ng/mL, $p = 0.045$) and at 1 year (2.4 ± 0.1 vs 0.5 ± 0.2 ng/mL, $p = 0.0001$) posttransplant, respectively. The different outcome in these two subgroups seems to suggest that factors difficult to record such as islet viability and/or degree of islet implantation may determine clinical success.

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