Long-Term Follow-Up of the Edmonton Protocol of Islet Transplantation in the United States.

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Abstract

We report the long-term follow-up of the efficacy and safety of islet transplantation in seven type 1 diabetic subjects from the United States enrolled in the multicenter international Edmonton Protocol who had persistent islet function after completion of the Edmonton Protocol. Subjects were followed up to 12 years with serial testing for sustained islet allograft function as measured by C-peptide. All seven subjects demonstrated continued islet function longer than a decade from the time of first islet transplantation. One subject remained insulin independent without the need for diabetic medications or supplemental transplants. One subject who was insulin-independent for over 8 years experienced graft failure 10.9 years after the first islet transplant. The remaining six subjects demonstrated continued islet function upon trial completion, although three had received a supplemental islet transplant each. At trial completion, five subjects were receiving insulin and two remained insulin independent, although one was treated with liraglutide. The median hemoglobin A1c was 6.3% (45 mmol/mol). All subjects experienced progressive decline in the C-peptide/glucose ratio. No patients experienced severe hypoglycemia, opportunistic infection, or lymphoma. Thus, although the rate and duration of insulin independence was low, the Edmonton Protocol was safe in the long term. Alternative approaches to islet transplantation are under investigation.

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