INAHTA Brief

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Title Islet transplantation for the treatment of type 1 diabetes

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Aim

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- To assess the safety and efficacy/effectiveness of islet transplantation (IT), compared with whole organ pancreas transplantation or intensive insulin therapy (IIT), in adults with type 1 diabetes mellitus (T1DM).
- To estimate the costs and cost-effectiveness of IT, compared with intensive insulin therapy (IIT), and the potential economic impact of IT in Alberta.

A social and system demographic analysis was also conducted.

Conclusions and results

Safety and efficacy/effectiveness
Six comparative and 13 case series studies of 10 or more patients followed up for at least one year were identified. The comparative studies showed that IT was associated with a higher risk of procedure-related adverse events than IIT, but that IT produced significantly fewer and less severe procedure-related complications than whole organ pancreas transplantation. Significantly fewer patients achieved insulin independence after IT, compared with pancreas transplantation, and this improvement was usually not sustained over the long term. However, the lower demand for insulin among patients receiving IT meant that they were able to maintain a level of glycemic control similar to that provided by pancreas transplantation, thereby avoiding severe hypoglycemia. Four case series studies reported improvements in disease-specific quality of life scores, but not in generic scores.

Limited data indicated a potentially positive effect of IT on some diabetic complications, such as retinopathy, but these findings were inconclusive. None of the identified studies compared: IT with IIT in patients with severe hypoglycemia or hypoglycemia unawareness; IT with pancreas transplantation in non-uremic patients; or islet after kidney transplantation with simultaneous pancreas and kidney (SPK) transplantation in uremic patients. Therefore, no conclusions could be drawn about the superiority of any of these interventions over another.

Economic outcomes
IT is not cost-saving compared with IIT. A prohibitive factor in the value of IT is its high cost per additional quality-adjusted life-year (QALY) gained. If the opportunity cost of IT for the health system is greater than the value for money associated with it (that is, >C$181,847 per additional QALY gained), IT would be considered cost-effective. While IT was associated with cost savings from reduced health service utilization for general diabetes management, the savings were dominated by the cost increases associated with transplantation. The budget impact of IT is approximately C$5.9 million per year.

Recommendations

SPK transplantation is the treatment of choice for patients with T1DM and end-stage renal failure, whereas IT is an option for patients who have T1DM, a history of severe hypoglycemia under IIT, and unstable glycemic control, but without end-stage renal failure. The role of IT in the long-term treatment of patients with T1DM has yet to be determined because of the potential risk of immunosuppression-related side effects, the absence of data on long-term treatment effects, and the insufficient supply of donor pancreata.

Methods

Please refer to the full report for details of the methods.

Further research/reviews required

Larger, better designed comparative studies are required to clarify the true impact of IT on long-term clinical outcomes. In addition, insulin independence may not be an appropriate primary outcome for IT; rather IT should aim to reduce the insulin requirement and frequency of severe hypoglycemia, thereby improving quality of life and glycemic control and preventing long-term diabetic complications in patients with T1DM.

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