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CADTH RAPID RESPONSE REPORT: REFERENCE LIST

Islet Cell Transplantation for Patients with Unstable or Uncontrollable Diabetes Mellitus: Clinical Effectiveness, Cost-Effectiveness and Guidelines

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Authors: Christopher Freige, Suzanne McCormack, Caitlyn Ford

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Questions or requests for information about this report can be directed to **requests@cadth.ca**

Research Questions

1. What is the clinical effectiveness of islet cell transplantation in patients with unstable diabetes mellitus?
2. What is the cost-effectiveness of using islet cell transplantation in patients with unstable diabetes mellitus?
3. What are the evidence-based guidelines associated with the use of islet cell transplantation in patients with unstable diabetes mellitus?

Key Findings

Three health technology assessments, one randomized controlled trial, and three non-randomized studies were identified regarding the clinical effectiveness of islet cell transplantation in patients with unstable diabetes mellitus. In addition, one economic evaluation was identified regarding the cost-effectiveness of using islet cell transplantation in patients with unstable diabetes mellitus. Lastly, one evidence-based guideline associated with the use of islet cell transplantation in patients with unstable diabetes mellitus was identified.

Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were islet cell transplantation and type 1 diabetes. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and February 25, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with unstable, uncontrollable, or unawareness type I diabetes mellitus (DM)
Intervention	Islet cell transplantation
Comparator	Standard treatment with insulin and insulin related devices (i.e., injection, insulin pumps)
Outcomes	Q1: Clinical effectiveness (e.g., stabilization of blood sugar levels [HbA1c], regression of DM, decreased use of insulin/devices) Q2: Cost-effectiveness (e.g., cost per quality-adjusted life-year [QALY]) Q3: Recommendations regarding the use of islet cell transplantation for patients with unstable or uncontrolled DM (e.g., is there any specific criteria to be eligible for this procedure)
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports and systematic reviews are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

Three health technology assessments,[1-3] one randomized controlled trial,[4] and three non-randomized studies[5-7] were identified regarding the clinical effectiveness of islet cell transplantation in patients with unstable diabetes mellitus. In addition, one economic evaluation[8] was identified regarding the cost-effectiveness of using islet cell transplantation in patients with unstable diabetes mellitus. Lastly, one evidence-based guideline[9] associated with the use of islet cell transplantation in patients with unstable diabetes mellitus was identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

1. Health Policy Advisory Committee on Technology. New and emerging health technologies for diabetes; Herston (AU): HealthPACT; 2015: https://www.coaghealthcouncil.gov.au/Portals/0/December%202015_New%20and%20Emerging%20Health%20Technologies%20for%20Diabetes.pdf

2. Pancreas Islet Transplantation for Patients With Type 1 Diabetes Mellitus: A Clinical Evidence Review; Ont Health Technol Assess Ser. 2015;15(16):1-84: https://www.hqontario.ca/Portals/0/Documents/evidence/reports/eba-pancreas-islet-transplantation-1509-en.pdf

3. Xie X, Rich B, Dendukuri N. Islet transplantation in patients with Type 1 Diabetes Mellitus. (Report No. 66). Montreal (QC): Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC); 2014: https://muhc.ca/sites/default/files/micro/m-TAU/muhc_tau_2014_66_islet_transplantation.pdf

Systematic Reviews and Meta-Analyses

No literature identified.

Randomized Controlled Trials

4. Lablanche S, Vantyghem MC, Kessler L, et al. Islet transplantation versus insulin therapy in patients with type 1 diabetes with severe hypoglycaemia or poorly controlled glycaemia after kidney transplantation (TRIMECO): a multicentre, randomised controlled trial. *Lancet Diabetes Endocrinol*. 2018 Jul;6(7):527-537. PubMed: PM29776895

Non-Randomized Studies

5. Foster ED, Bridges ND, Feurer ID, Eggerman TL, Hunsicker LG, Alejandro R. Improved Health-Related Quality of Life in a Phase 3 Islet Transplantation Trial in Type 1 Diabetes Complicated by Severe Hypoglycemia. *Diabetes Care*. 2018 May;41(5):1001-1008.
PubMed: PM29563196

6. Holmes-Walker DJ, Gunton JE, Hawthorne W, et al. Islet Transplantation Provides Superior Glycemic Control With Less Hypoglycemia Compared With Continuous Subcutaneous Insulin Infusion or Multiple Daily Insulin Injections. *Transplantation*. 2017 Jun;101(6):1268-1275.
PubMed: PM27490410

7. Hering BJ, Clarke WR, Bridges ND, et al. Phase 3 Trial of Transplantation of Human Islets in Type 1 Diabetes Complicated by Severe Hypoglycemia. *Diabetes Care*. 2016 Jul;39(7):1230-1240.
PubMed: PM27208344

Economic Evaluations

8. Wallner K, Shapiro AM, Senior PA, McCabe C. Cost effectiveness and value of information analyses of islet cell transplantation in the management of 'unstable' type 1 diabetes mellitus. *BMC Endocr Disord*. 2016 Apr 9;16:17.
PubMed: PM27061400

Guidelines and Recommendations

9. Senior PA, AlMehthel M, Miller A, Paty BW. Diabetes and Transplantation. *Can J Diabetes*. 2018;42: S145-S149: https://guidelines.diabetes.ca/docs/cpg/Ch20-Diabetes-and-Transplantation.pdf

Appendix — Further Information

Previous CADTH Reports

10. Islet Cell Transplantation in Patients with Unstable Diabetes: A Review of Clinical- and Cost-Effectiveness and Guidelines. (CADTH Rapid response report: summary with critical appraisal). Ottawa (ON): CADTH; 2014: https://www.cadth.ca/islet-cell-transplantation-patients-unstable-diabetes-review

Non-Randomized Studies

Alternative Comparator

11. Vantyghem MC, Chetboun M, Gmyr V, et al. Ten-Year Outcome of Islet Alone or Islet After Kidney Transplantation in Type 1 Diabetes: A Prospective Parallel-Arm Cohort Study. *Diabetes Care*. 2019 Nov;42(11):2042-2049. PubMed: PM31615852

12. Lablanche S, Borot S, Wojtusciszyn A, et al. Five-Year Metabolic, Functional, and Safety Results of Patients With Type 1 Diabetes Transplanted With Allogenic Islets Within the Swiss-French GRAGIL Network. *Diabetes Care*. 2015 Sep;38(9):1714-1722. PubMed: PM26068866

No Comparator

13. Anazawa T, Saito T, Goto M, et al. Long-term outcomes of clinical transplantation of pancreatic islets with uncontrolled donors after cardiac death: a multicenter experience in Japan. *Transplant Proc*. 2014 Jul-Aug;46(6):1980-1984. PubMed: PM25131088

Clinical Practice Guidelines

14. Clinical guidelines for pancreatic islet transplantation. Vancouver (BC): BC Transplant; 2014 http://www.transplant.bc.ca/Documents/Health%20Professionals/Clinical%20guidelines/Clinical%20Guidelines%20for%20Pancreatic%20Islet%20Transplantation_01Sept2014_0.pdf

Review Articles

15. Maffi P, Secchi A. Islet Transplantation Alone Versus Solitary Pancreas Transplantation: an Outcome-Driven Choice? *Curr Diab Rep*. 2019 Apr 25;19(5):26. PubMed: PM31025188

16. Rickels MR, Robertson RP. Pancreatic Islet Transplantation in Humans: Recent Progress and Future Directions. *Endocr Rev*. 2019 Apr 1;40(2):631-668. PubMed: PM30541144

Additional References

17. Wojtusciszyn A, Branchereau J, Esposito L, et al. Indications for islet or pancreatic transplantation: Statement of the TREPID working group on behalf of the Societe francophone du diabete (SFD), Societe francaise d'endocrinologie (SFE), Societe francophone de transplantation (SFT) and Societe francaise de nephrologie - dialyse - transplantation (SFNDT). *Diabetes Metab*. 2019 Jun;45(3):224-237. PubMed: PM30223084