

Complete Summary

GUIDELINE TITLE

Pancreas transplantation in type 1 diabetes.

BIBLIOGRAPHIC SOURCE(S)

Robertson P, Davis C, Larsen J, Stratta R, Sutherland DE. Pancreas transplantation in type 1 diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S105. [1 reference] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

The guideline was originally approved in November 1999.

American Diabetes Association (ADA) position statements are reissued annually.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Type 1 diabetes mellitus

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Internal Medicine

INTENDED USERS

Health Plans
Physicians

GUIDELINE OBJECTIVE(S)

To review the safety, efficacy, and indications for pancreas and islet cell transplantation for patients with diabetes mellitus

TARGET POPULATION

- Adults with diabetes mellitus with imminent or established end-stage renal disease who have had or plan to have a kidney transplant
- Adults with diabetes mellitus who meet the following criteria for pancreas-only transplantation: 1) a history of frequent acute severe metabolic complications requiring medical attention, 2) clinical and emotional problems associated with exogenous insulin therapy that are so severe as to be incapacitating, and 3) consistent failure of insulin-based management to prevent acute complications

INTERVENTIONS AND PRACTICES CONSIDERED

1. Pancreas after kidney transplant (PAK)
2. Pancreas transplant alone (PTA)
3. Simultaneous pancreas and kidney transplant (SPK)
4. Pancreatic islet cell transplant

MAJOR OUTCOMES CONSIDERED

- 1- and 3-year patient and graft survival
- Metabolic results (i.e., independence from exogenous insulin therapy, blood glucose concentrations, HbA_{1c}, glucose counterregulation)
- Effects on the chronic complications of diabetes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This paper was peer-reviewed and approved by the Professional Practice Committee and the Executive Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. Pancreas transplantation should be considered an acceptable therapeutic alternative to continued insulin therapy in diabetic patients with imminent or established end-stage renal disease who have had or plan to have a kidney transplant, because the successful addition of a pancreas does not jeopardize patient survival, may improve kidney survival, and will restore normal glycemia. Such patients also must meet the medical indications and criteria for kidney transplantation and not have excessive surgical risk for the dual transplant procedure. Medicare and other third-party payers of medical care should include coverage for pancreas transplant procedures meeting these criteria. The pancreas transplant may be done simultaneous with, or subsequent to, a kidney transplant. Pancreas graft survival is better when done simultaneously with a kidney transplant.
2. In the absence of indications for kidney transplantation, pancreas transplantation should only be considered a therapy in patients who exhibit these three criteria: 1) a history of frequent, acute, and severe metabolic complications (hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention, 2) clinical and emotional problems with exogenous insulin therapy that are so severe as to be incapacitating, and 3) consistent failure of insulin-based management to prevent acute complications. Program guidelines for ensuring an objective multidisciplinary evaluation of the patient's condition and eligibility for transplantation should be established and followed. Third-party payer coverage is appropriate only where such guidelines and procedures exist.
3. Pancreatic islet cell transplants hold significant potential advantages over whole-gland transplants. However, at this time, islet cell transplantation is an experimental procedure, also requiring systemic immunosuppression, and should be performed only within the setting of controlled research studies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Successful pancreatic transplantation may result in:

- Independence from exogenous insulin therapy, normal blood glucose concentrations, and normal or near-normal HbA_{1c}.
- Improved quality of life primarily due to elimination of daily insulin injections and frequent daily blood glucose measurements
- Reduced episodes of acute complications experienced by patients with type I diabetes (e.g., hypoglycemia, hyperglycemia)

- Partial reversal of the long-term renal and neural complications
- Prolonged life expectancy of diabetic patients with autonomic insufficiency

POTENTIAL HARMS

Risks associated with pancreatic transplantation include clinical complications caused by the surgery and by chronic immunosuppressive drugs, as well as death.

- *Surgical complications:* Perioperative complications leading to relaparotomy occur in approximately 30% of patients and include intra-abdominal infections and abscess, vascular graft thrombosis, anastomotic leak, and duodenal stump leak.
- *Side effects associated with life-long immunosuppressive therapy:* The combination of immunosuppressive agents most frequently used (e.g., cyclosporine, azathioprine, and prednisone) have numerous and varied significant adverse effects including nephrotoxicity, infection, hypertension, and gingival hyperplasia.
- *Mortality risk:* The mortality rate 1 and 3 years after pancreas transplant alone (PTA), simultaneous pancreas and kidney transplant (SPK), or pancreas after kidney transplant (PAK) is approximately 7%. The mortality rate 1 year after the much less invasive procedure of pancreatic islet transplantation is 5%. Thus, it seems likely that the mortality rates are related more to chronic diabetes than to pancreas transplantation itself.

QUALIFYING STATEMENTS

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Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Nov (republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors of Position Statement, Initial Draft: R. Paul Robertson, MD; Connie Davis, MD; Jennifer Larsen, MD; Robert Stratta, MD; David E.R. Sutherland, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The recommendations in this paper are based on the evidence reviewed in the following publication:

- Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DER: Pancreas and islet transplantation for patients with diabetes (Technical Review). Diabetes Care 2000;23:112-6.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 1, 1998. The information was verified by the guideline developer on December 15, 1998. This summary was updated by ECRI on April 1, 2001, January 29, 2002, April 21, 2003, and April 1, 2004.

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