NICE National Institute for Health and Care Excellence

NICE guidance

Autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance partially replaces IPG13.

1 Guidance

This document together with the interventional procedures guidance published on allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus replaces previous guidance on pancreatic islet cell transplantation (IPG13 issued in October 2003).

1.1 The current evidence on autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy shows some short-term efficacy, although most patients require insulin therapy in the long term. The reported complications result mainly from the major surgery involved in pancreatectomy (rather than from the islet cell transplantation). The procedure may be used with normal arrangements for clinical governance in units with facilities for islet cell isolation (see also section 2.5.1).

1.2 During consent, clinicians should ensure that patients understand that they may require insulin therapy in the long term. They should provide them with clear written information. In addition, the use of NICE's information for the public.

1.3 Patient selection for this procedure should involve a multidisciplinary team with experience in the management of benign complex chronic pancreatic disease.

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The procedure should be carried out by surgeons with experience in complex pancreatic surgery and clinicians with experience in islet cell isolation and transplantation.

1.4 Further audit and research should address the long-term efficacy of the procedure, quality of life, insulin independence and the management of patients' diabetes (see section 3.1).

2 The procedure

2.1 Indications and current treatments

2.1.1 Some patients with chronic pancreatitis or benign pancreatic endocrine tumours are treated by total or partial pancreatectomy, resulting in a type of insulin-dependent diabetes.

2.1.2 Post-pancreatectomy diabetes requires the daily injection of exogenous insulin and is relatively difficult to control.

2.2 Outline of the procedure

2.2.1 This procedure is performed with pancreatectomy in a single operation, with the patient under general anaesthesia. The pancreatectomy is carried out, and islet cells are isolated and prepared for transplantation. Under continuous portal vein pressure monitoring (to help prevent portal vein thrombosis), the islet cells are infused through a catheter directly into the portal vein or a tributary, and further onto the liver parenchyma, where some will remain viable.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

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2.3.1 In 4 case series of 64, 45, 40 and 13 patients treated by autologous islet cell transplantation following partial or total pancreatectomy, between 24% and 85% of patients were insulin independent at follow-up periods ranging from less than 6 months to 18 months (1 study did not state follow-up duration).

2.3.2 In a case series of 48 patients (of whom 39 were evaluated after the procedure), 15 of the 20 patients who were insulin independent at 1 month remained insulin independent at mean follow-up of 5 years, and 1 patient remained so at 10 years. In the case series of 13 patients, 38% (5 out of 13) were insulin independent after 2 years.

2.3.3 In the case series of 40 patients, all 14 patients who were followed up at 3 years were classed as either having diabetes or impaired glucose tolerance. In a case series of 24 patients, 33% (8 out of 24) required insulin within 8 years of the procedure.

2.3.4 The Specialist Advisers considered key efficacy outcomes to include quality of life, glycaemic control, glucose tolerance, avoidance of severe hypoglycaemia, long-term insulin independence and prevention of long-term diabetic complications.

2.4 Safety

2.4.1 The case series of 48 patients reported that 2 patients who also had splenectomy at the time of transplantation had 'uncontrollable' splenic hilar bleeding due to increased portal pressure. Asymptomatic portal vein thrombosis was suspected in 1 patient but the vein was not thrombosed 1 week after the operation.

2.4.2 A case series of 40 patients reported that complications in the first 24 patients included 1 case each of portal vein thrombosis, splenic infarction and splenic thrombosis requiring splenectomy. In the last 16 patients, the series reported that complications included pancreatic fistula formation and rupture and subsequent resection of the spleen (raw data not reported; timing and cause of adverse events not adequately described).

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2.4.3 A case report described a patient who developed heparin-induced thrombocytopenia following the procedure.

2.4.4 The Specialist Advisers considered theoretical and anecdotal adverse events to include portal vein thrombosis, portal hypertension, hepatic infarction, liver steatosis, liver failure, intra-abdominal haemorrhage, bile leakage, splenic rupture, disseminated intravascular coagulation, infection, intrahepatic sepsis and islet cell pulmonary emboli.

2.5 Other comments

2.5.1 The Committee noted that the National Commissioning Group (NCG), which has a remit to commission highly specialised national services for very rare conditions or treatments for the population of England, has designated centres for pancreatic islet cell isolation. Scottish residents also have access to the service under an agreement between the NCG and the National Services Division, Scotland. Health Commission Wales has a separate agreement with the provider for Welsh residents. The Regional Medical Services Consortium (RMSC) commissions specialist regional services for the population of Northern Ireland. The RMSC will commission outside the region, on an individual basis, in cases for which services are not available in Northern Ireland.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

3.2 NICE has issued guidelines on type 1 diabetes in adults, diabetes (type 1 and type 2) in children and young people and diabetic foot problems. NICE has also issued interventional procedures guidance on allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus, and technology appraisal guidance on continuous subcutaneous insulin infusion for the treatment of diabetes mellitus.

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Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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