NHS England

Clinical Commissioning Policy Proposition: Total Pancreatectomy with Islet Autotransplant

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1 Executive Summary

Policy Statement

NHS England proposes to not routinely commission Total Pancreatectomy with Islet Autotransplant for the treatment of recurrent acute pancreatitis (RAP) and chronic pancreatitis (CP) in accordance with the criteria outlined in this document.

In creating this policy proposition NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

This proposal addresses total pancreatectomy with islet autotransplantation for patients with recurrent acute pancreatitis and chronic pancreatitis. Recurrent acute pancreatitis and chronic pancreatitis are related progressive inflammatory conditions of the pancreas causing progressive damage with loss of function and consequent diabetes associated with complications that in many patients can be disabling and life threatening.

The primary goal of surgery is to control pain resistant to other therapies; islet autotransplantation is intended to prevent or lessen the diabetes mellitus which is an inevitable result of total pancreatectomy.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of Total Pancreatectomy with Islet Autotransplant.

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission total pancreatectomy with islet autotransplant.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether [intervention and indication] will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

Recurrent acute pancreatitis (RAP) and chronic pancreatitis (CP) are related progressive inflammatory conditions of the pancreas causing progressive damage to the parenchyma with loss of exocrine and eventually endocrine function and consequent diabetes associated with complications that in many patients can be disabling and life threatening.

Combining total pancreatectomy with an islet autotransplant (IAT) avoids the inevitability of brittle diabetes. The resected pancreas is digested and the islets are isolated and embolised into the liver via the portal vein. This technique can successfully produce insulin independence for very prolonged periods.

4 Definitions

Pancreatitis - inflammation of the pancreas.

Acute - severe

Chronic – long term

Autotransplant - the transplantation of organs, tissues, or even particular proteins from one part of the body to another in the same person.

5 Aims and Objectives

This policy proposition aims to define NHS England's commissioning position on islet autotransplantation in patients with recurrent acute pancreatitis and chronic pancreatitis.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adult patients with recurrent acute pancreatitis and chronic pancreatitis.

6 Epidemiology and Needs Assessment

Exact data are not available for the incidence in the UK, but the prevalence of chronic pancreatitis has been estimated at between 40 and 70 per 100 000. There also appears to have been a gradual increase in some countries including the UK (demonstrated by greater numbers of hospital admissions for acute and chronic pancreatitis). Very few of these patients will be eligible for TP IAT.

Severe pain is reported by 80-90% of all CP patients and leads to a poor quality of life, narcotic addiction and increased economic costs (including medical and social care). The pain is almost inevitably recurrent, intense and long lasting (episodes frequently last for days) and often requires hospital admission to enable it to be controlled. Over the lifetime of the disease this can result in dozens, and in a small subset of patients, hundreds of episodes requiring admission to hospital for days or weeks (Warshaw, Banks & Fernandez-Del Castillo 1998).

The estimate of need in the UK is 40 – rising to 80 patients per annum after 5 years.

7 Evidence Base

NHS England has concluded that there is insufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

The published literature is limited in some respects, with no randomized controlled trials and few reports of long term outcomes. However several large case series show that patients have reduced morphine requirements and reduced insulin requirement after TP IAT. Thus for example, in Sutherland's series 7 of 409 patients, 25% of adults were insulin independent at 3 years; all patients had pain before TP IAT and nearly all were on daily narcotics, whereas after TP IAT, 85% had pain improvement and by two years, 59% had ceased narcotics. There were also significant improvement in all dimensions of SF36. In Morgan's series 3 of 177 patients, 61% of patients showed a clinically important improvement in physical quality of life at three years, and 66% showed a clinically important improvement in psychological quality of life. A report on the Leicester experience 11 compared 60 patients treated with TP IAT with 37 TP alone patients; the TP IAT group fared better on all measures including survival (16.6 versus 12.9 years), pain scores, insulin use and health service use.

One report examined data from the National Surgical Quality Improvement Program in the USA (potentially including both experience and inexperienced centres) and reported higher short term morbidity with TP IAT compared to TP alone with a major complication rate of 41% versus 29%, and length of stay 13 days versus 9 days. The Leicester series 11, however, is a better guide to likely complication rates at NHS expert centres. The rate of major complications (Clavien grade III and above) was 15.0% for TP IAT and 10.8% for TP.

All authors emphasise the importance of careful selection of patients.

A single study of cost and effects indicated that the cost surgery, analgesia and

inpatient admissions over the median 16-year survival period of patients receiving TP IAT was £101 608 compared with an estimate of £110 445 if no TP + IAT had been undertaken.

The National Institute for Health and Clinical Excellence (NICE) issued full guidance in 2008 to the NHS in England, Wales, Scotland and Northern Ireland on autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy.12 The conclusion was as follows: '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.'

8 Documents That Have Informed This Policy Proposition

Not applicable.

9 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).

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