

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Endoscopic duodenal mucosal resurfacing for insulin resistance in type 2 diabetes

Type 2 diabetes can occur when the cells in the body do not respond properly to insulin (insulin resistance). The duodenum (the first part of the small intestine) plays an important role in insulin sensitivity and the regulation of blood sugar. One factor thought to contribute to insulin resistance is the duodenum not working properly.

In this procedure, an endoscope (a long, thin, flexible tube with a small camera and light on the end) is passed through the mouth into the second section of the duodenum. A balloon catheter is passed through the endoscope and inflated to expand the duodenal mucosa (lining). Then heat is used to destroy the lining. This encourages a new lining to grow (resurfacing). The aim is to make the duodenum work better by making the mucosa more sensitive (less resistant) to insulin.

NICE is looking at endoscopic duodenal mucosal resurfacing for insulin resistance in type 2 diabetes.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 31 January 2024

Target date for publication of guidance: May 2024

## 1 Draft recommendations

- 1.1 More research is needed on endoscopic duodenal mucosal resurfacing for insulin resistance in type 2 diabetes.
- 1.2 This procedure should only be done as part of a formal research study, and a research ethics committee needs to have approved its use.

### More research

- 1.3 More research, which should ideally be adequately powered randomised controlled trials, analysis of registry data or other suitably designed studies, is needed on:

- patient selection
- procedure used
- quality of life
- blood sugar control
- change in antidiabetic medication (including insulin)
- complications
- long-term outcomes.

### Why the committee made these recommendations

The evidence on the efficacy and safety of this procedure is limited, and comes mainly from 1 randomised controlled trial with a follow up of only 24 weeks. This trial found that, compared with a sham procedure, duodenal mucosal resurfacing statistically significantly (that is, the results are reliable and unlikely to be due to chance) reduced HbA1c (a measure of average blood sugar level) in the European subgroup, but not in the whole trial group or the Brazilian subgroup. Overall, there are uncertainties about the safety and long-term outcomes of the procedure. So, this procedure should only be used in research.

## **2 The condition, current treatments and procedure**

### **The condition**

- 2.1 Type 2 diabetes is a chronic metabolic condition characterised by insulin resistance and insufficient pancreatic insulin production, resulting in hyperglycaemia. The condition is commonly associated with obesity, physical inactivity, raised blood pressure, periodontitis, disturbed blood lipid levels and a tendency to develop thrombosis. It is recognised to lead to an increased cardiovascular and stroke risk.

### **Current treatments**

- 2.2 Dietary control is the mainstay of type 2 diabetes treatment. Weight loss and being active are also recommended to help manage the condition. In addition to lifestyle modification, type 2 diabetes is controlled using metformin, insulin or other medicines, with the aim of keeping a person's blood sugar levels within a healthy range. These treatments have varying efficacy and can sometimes cause side effects, including hypoglycaemia.

### **The procedure**

- 2.3 Endoscopic duodenal mucosal resurfacing is a minimally invasive procedure. It involves endoscopic exploration under general anaesthesia or deep sedation. This is followed by submucosal expansion with saline, and then hydrothermal ablation of the duodenal mucosa under direct vision with fluoroscopic guidance. The aim is for mucosal regeneration, and so to treat the duodenal dysfunction that is thought to contribute to insulin resistance.

### 3 Committee considerations

#### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 2 prospective cohort studies (1 study with 2 publications) and 1 proof of concept study. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: quality of life, improved blood sugar control and reduced use of antidiabetic medication, in particular insulin.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: perforation, duodenal stenosis and gastrointestinal symptoms.
- 3.4 Patient commentary was sought but none was received.

#### Committee comments

- 3.5 The committee was informed that this procedure:
- is used in addition to dietary control and other lifestyle modifications
  - may reduce the need for insulin and other antidiabetic medications, as well as improving blood glucose control
  - uses technology that is evolving, which may affect its safety profile

- uses advanced endoscopic technique, so clinicians need specialised training and experience to carry it out, including in using fluoroscopy and guidewires
- could be done as a day-case procedure.

3.6 Registry data may be helpful in determining the safety and long-term efficacy of the procedure.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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