NICE National Institute for Health and Care Excellence

NICE guidance

Endoscopic duodenal mucosal resurfacing for insulin resistance in type 2 diabetes

HealthTech guidance
Published: 16 May 2024

www.nice.org.uk/guidance/htg721

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.

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.

Contents

This guidance replaces IPG787.

1 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, progressive 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. NICE's guideline on type 2 diabetes in adults describes its management.

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 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, reduced use of antidiabetic medication (in particular insulin) and weight loss.

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 and other metabolic disturbances
- uses technology that is evolving
- should be done by healthcare professionals with experience of advanced endoscopic technique and specific training in the duodenal mucosal resurfacing procedure

- 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.

3.7 There are ongoing studies. The guidance will be considered for review when new key evidence is published.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 787 has been migrated to HealthTech guidance 721. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8976-8

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.