



Endoscopic sleeve gastroplasty for obesity

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www.nice.org.uk/guidance/ipg783

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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Use endoscopic sleeve gastroplasty as an option to treat obesity in adults with standard arrangements in place for clinical governance, consent and audit.
- Patient selection, assessment, and monitoring should be done by a multidisciplinary team within a specialist weight management service experienced in managing obesity (see the section on initial assessment and discussions with the multidisciplinary team in the NICE guideline on obesity).
- 1.3 This procedure should only be done in specialist weight management centres by clinicians with specific training and experience in the procedure.
- Details about everyone having endoscopic sleeve gastroplasty for obesity should be submitted into the <u>National Bariatric Surgery Registry</u>.

Why the committee made these recommendations

Evidence on safety shows this procedure is safe in the short and long term. Evidence on efficacy shows that, when combined with lifestyle changes, people with a body mass index (BMI) over 30 kg/m² who have the procedure lose weight. So, it can be used with standard arrangements.

2 The condition, current treatments and procedure

The condition

- Obesity is defined as a body mass index (BMI) of 30 kg/m² or over. The degree of obesity is classified as:
 - obesity class 1 (BMI 30 kg/m² to 34.9 kg/m²)
 - obesity class 2 (BMI 35 kg/m² to 39.9 kg/m²) and
 - obesity class 3 (BMI 40 kg/m² or more).

The <u>NICE guideline on obesity</u> recognises that people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnicity are prone to central adiposity and their cardiometabolic risk occurs at a lower BMI. So, a lower BMI of 27.5 kg/m² or above is recommended as the threshold for obesity in these groups.

Obesity is directly linked to a number of other illnesses including type 2 diabetes, hypertension, gallstones and gastro-oesophageal reflux disease, as well as psychological and psychiatric morbidities. Weight loss reduces the risk of comorbidities and improves long-term survival.

Current treatments

The <u>NICE guideline on obesity</u> recommends a multicomponent approach involving dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is recommended as an option in some people who have class 3 obesity, or class 2 obesity and other significant disease (such as type 2 diabetes) and have not lost enough weight using other methods. It is also considered at a lower BMI threshold than in other populations in people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnicity. This is because these groups are prone to central adiposity and cardiometabolic risk

occurs at a lower BMI.

Surgical procedures for obesity aim to help people to lose weight and to maintain weight loss by restricting the size of the stomach, decreasing the capacity to absorb food, or both. Procedures that reduce the size of the stomach (gastric volume) limit the capacity for food intake by producing a feeling of satiety with a smaller ingested volume of food. They include laparoscopic gastric banding and sleeve gastrectomy. Procedures that aim to decrease the capacity to absorb food include biliopancreatic diversion and duodenal switch. People are also advised to modify their eating behaviour by adhering to an explicit postoperative diet advised by specialist dieticians.

The procedure

- 2.5 Endoscopic sleeve gastroplasty is a minimally invasive transoral endoscopic procedure that reduces the volume of the stomach and may delay gastric emptying. It creates a sensation of fullness and reduces the amount of food that can be eaten at one time.
- The procedure is done under general anaesthesia. It may be done as a day case, but most people are kept under observation overnight and discharged the next day. A single or a double channel scope with a procedure-specific endoscopic device attached is passed through the mouth (transorally). A series of endoluminal full-thickness suture plications (in a U, Z, square, triangle or rectangle pattern) are done along the greater curvature of the stomach (through the gastric wall, extending from the pre-pyloric antrum to the fundus). This involves folding the stomach in on itself and stitching it together, creating a restrictive endoscopic sleeve to reduce the stomach volume by about 70% to 80%. There is no resection of the stomach and the procedure may be reversible in the early stages.

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 8 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 4 systematic reviews and meta-analyses, 2 cohort studies and 1 propensity score matched 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.
- The professional experts and the committee considered the key efficacy outcomes to be: weight loss (percentage total weight loss and percentage excess weight loss) in the short and long term, quality of life, improvement in comorbidities (diabetic control, blood pressure, obstructive sleep apnoea score and liver health), nutritional status and technical success of the procedure.
- The professional experts and the committee considered the key safety outcomes to be: perioperative complications including pain, rate of gastroesophageal reflux disease, rate of readmissions, damage to adjacent structures, gastric perforation and need for further procedures.
- Five commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- The committee noted that evidence included people with obesity (a body mass index [BMI] over 30 kg/m²) for whom non-surgical weight loss treatments had not worked, and people with class 3 obesity for whom invasive bariatric surgery would be considered high risk.
- 3.6 The committee considered that this procedure may particularly benefit people:

- with class 3 obesity for whom invasive bariatric surgery would be considered high risk
- who decline bariatric surgery because of the associated risks and complications
- who have class 1 or class 2 obesity, for whom the procedure may prevent progression of obesity and associated comorbidities.
- 3.7 The committee suggested that a lower BMI threshold of 27.5 kg/m² or above should be used for people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnicity.
- 3.8 The committee noted that this procedure is not used in children.
- The committee noted that some people experience self-limiting side effects immediately after the procedure and there is a high incidence of readmission for abdominal pain when the procedure is done as a day case.
- The committee noted that more than one device is available for doing this procedure and the exact suture technique may vary.
- The committee noted that more detailed data collection on the exact type of procedure technique used and nutritional status would be useful for the <u>National Bariatric Surgery Registry</u>.
- The committee noted the importance of multidisciplinary team training for wider introduction into the NHS, particularly around malabsorption post-procedure.
- 3.13 The committee noted that gastro-oesophageal reflux disease is not a contraindication for this procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

