NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic sleeve gastroplasty for obesity

Obesity is a body mass index (BMI) of 30 and over, or 27.5 and over for people with South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean origin. BMI is a measure of whether someone is a healthy weight for their height. In this procedure, an endoscope (a thin, flexible tube with a camera on the end) and a special stitching device are inserted through the mouth into the stomach. Using the stitching device, 1 or more large folds are made in the stomach wall and sewn together (sleeve gastroplasty). There is no cutting or stapling, and none of the stomach is removed, so the procedure is potentially reversible. People can usually go home on the same day as the procedure. The aim is to reduce the volume of the stomach by about 70% to 80%, and so reduce the amount of food that can be eaten before you feel full.

NICE is looking at endoscopic sleeve gastroplasty for obesity.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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.

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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: 26 October 2023

Target date for publication of guidance: February 2024

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1 Draft recommendations

1.1 Endoscopic sleeve gastroplasty for obesity may be used if standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.1 Patient selection should be done by a multidisciplinary team experienced in managing obesity.

1.2 This procedure should only be done in specialist centres by a clinician with specific training and experience in the procedure.

1.3 Details about everyone having endoscopic sleeve gastroplasty for obesity should be submitted into the National Bariatric Surgery Registry.

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 BMI over 30 kg/m^2 who have the procedure lose weight. So, it can be used with standard arrangements.

2 The condition, current treatments and procedure

The condition

2.1 Obesity is defined as a body mass index (BMI) of 30 kg/m^2 or over. The degree of obesity is classified as:

- obesity class 1 (BMI 30 kg/m^2 to 34.9 kg/m^2)
- obesity class 2 (BMI 35 kg/m^2 to 39.9 kg/m^2) and
- obesity class 3 (BMI 40 kg/m^2 or more).

The NICE guideline on obesity recognises that people with a

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South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean origin are prone to central adiposity and their cardiometabolic risk occurs at a lower BMI. So, a lower BMI of 27.5 kg/m^2 or above is recommended as the threshold for obesity in these groups.

2.2 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

2.3 The NICE guideline on obesity recommends a multicomponent approach involving dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is recommended as a treatment option in some people who have a BMI of 40 kg/m^2 or more (class 3 obesity), or between 35 kg/m^2 and 39.9 kg/m^2 (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 than in other populations for people of Asian family background who have recent-onset type 2 diabetes.

2.4 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 aimed at decreasing 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.

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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. The aim is to reduce the volume of the stomach by about 70% to 80%, reducing the amount of food that can be eaten at one time.

2.6 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 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 gastroesophageal junction). 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.

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.

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3.2 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 apnea score, liver health), and technical success of the procedure.

3.3 The professional experts and the committee considered the key safety outcomes to be: peri-operative complications including pain, rate of gastroesophageal reflux disease, rate of readmissions, damage to adjacent structures, gastric perforation and need for further procedures.

3.4 Five commentaries from people who have had this procedure were discussed by the committee.

Committee comments

3.5 The committee noted that evidence included people with obesity (a body mass index [BMI] over 30 kg/m^2) for whom non-surgical weight loss treatments had not worked, and people with severe obesity for whom invasive bariatric surgery would be considered high risk.

3.6 The committee suggested that a lower BMI threshold of 27.5kg/m^2 or above should be used for people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background.

3.7 The committee noted that this procedure is not used in children.

3.8 The committee noted that some people experience self-limiting side effects immediately after the procedure and there was a high incidence of readmission for abdominal pain where the procedure was done as day case.

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3.9 The committee noted that more than one device is available for doing this procedure and the exact suture technique may vary.

3.10 The committee noted that more detailed data collection on the exact type of procedure technique used would be useful for the National Bariatric Surgery Registry.

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Chair, interventional procedures advisory committee
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