NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Swallowable gastric balloon capsule for weight loss

In this procedure someone who is overweight or has obesity swallows a capsule containing a small inflatable balloon, which is attached to a thin tube. The capsule dissolves in the stomach and the balloon is inflated by filling it with liquid through the tube. The tube is then disconnected and removed through the mouth. The balloon stays in the stomach for around 4 months, after which it deflates and passes out naturally through the bowel. The aim is to give a feeling of fullness and temporarily restrict the size of the stomach, leading to weight loss. This procedure must be used with appropriate dietary and lifestyle changes.

NICE is looking at swallowable gastric balloon capsule for weight loss.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 23 July 2020

Target date for publication of guidance: October 2020

1 Draft recommendations

1.1 Evidence on the safety of swallowable gastric balloon capsule for weight loss shows infrequent but potentially serious adverse events.

- For people who need short-term weight loss for medical reasons, the evidence of efficacy is adequate to support the use of this procedure provided that special arrangements are in place for clinical governance, consent and audit. Find out what special arrangements mean on the NICE website.
- For people who are aiming for long-term weight loss, the evidence on efficacy is inadequate in quantity and quality and therefore the procedure should only be used in the context of research. Find out what only in research means on the NICE website.

1.2 Further research could be in the form of randomised controlled trials comparing the procedure with current standard therapies, or an observational cohort study, including using registry data. Studies should include details of patient selection such as body mass index (BMI) and other treatments such as diet and lifestyle changes. They should also report:

- short and long-term weight loss

- quality of life
- metabolic parameters
- the need for later surgery.

2 The condition, current treatments and procedure

The condition

2.1 Overweight is defined as a body mass index (BMI) of 25 kg/m^2 to 29.9 kg/m^2 and obesity as a BMI of 30 kg/m^2 or more. Overweight and obesity put people at risk of type 2 diabetes, coronary heart disease and hypertension. Weight loss reduces these risks and improves life expectancy.

Current treatments

2.2 Obesity is managed by dietary advice, physical activity and exercise, lifestyle or behavioural changes, and medication. Bariatric surgery is considered for people:

- whose BMI is over 40 kg/m^2, or over 35 kg/m^2 if they have other significant comorbidities
- who have not been able to reach or maintain a clinically beneficial weight using non-surgical measures.

  Surgical procedures include gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass or other diversion procedures.

2.3 People unable to lose weight by non-surgical measures who do not want invasive surgery can have less invasive bariatric procedures. Examples are endoscopic intragastric balloons, gastrointestinal bypass sleeves, endoscopic sleeve gastroplasty and endoluminal restrictive surgical techniques.

The procedure

2.4 A swallowable gastric balloon capsule for weight loss must be used with a nutrition and behaviour modification programme supervised by a suitably qualified and registered healthcare professional.

2.5 The procedure is usually done in an outpatient setting without endoscopy or sedation. The patient swallows a capsule containing the deflated balloon, which is attached to a fine delivery catheter, with water. If they have difficulty swallowing the capsule, a stylet can be fed through the catheter to stiffen it. This allows the doctor to help push the catheter during swallowing. After the capsule reaches the stomach this stylet is removed. The position in the stomach is confirmed by X-ray using guide marks on the catheter. The capsule disintegrates and the balloon is inflated with a fixed amount of fluid (for example distilled water and citric acid) through the connected catheter. After the balloon is inflated the catheter is detached by pulling it firmly from the patient's mouth. Imaging is done to recheck position and inflation. After a short wait to make sure the patient can tolerate the balloon, they are discharged with medication including anti-emetics, antispasmodics and proton pump inhibitors. About 4 months later, a resorbable material element of the balloon degrades, which then allows a release valve to open and expel the fluid into the stomach gradually. The deflated balloon then passes through the gastrointestinal tract to be excreted through the bowel.

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 10 sources, which was discussed by the committee. The evidence

included 1 meta-analysis, 8 case series and 1 case report. It is presented in table 2 of 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: weight loss in the short term, maintenance of weight loss in the long term, and improved comorbidities and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: gastrointestinal obstruction, perforation, early balloon deflation and expulsion.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The procedure may be useful for people who need rapid weight loss before surgery or other procedures.

3.6 The committee noted that nausea and vomiting were associated with this procedure as with other intragastric balloon procedures.

3.7 The committee was informed that the technology is evolving.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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