

# Laparoscopic gastric plication for the treatment of severe obesity

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg432](http://www.nice.org.uk/guidance/ipg432)

## 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.

# 1 Guidance

- 1.1 The evidence on laparoscopic gastric plication for severe obesity raises no major safety concerns in the short term. There is inadequate evidence about safety in the long term, specifically with regard to the reversibility of the procedure and how it affects the safety of any further gastric surgery that may be necessary. There is limited evidence of efficacy in the short and medium term, but more evidence is needed about the long-term efficacy of the procedure. Therefore, laparoscopic gastric plication for the treatment of severe obesity should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake laparoscopic gastric plication for the treatment of severe obesity should take the following actions.
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients understand the uncertainties about the procedure's long-term efficacy and about how the procedure may affect the safety of any further gastric surgery that they may need. Clinicians should provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 Laparoscopic gastric plication for severe obesity should only be carried out in units specialising in bariatric surgery that can offer the procedure as one of a range of treatment options. This recommendation is consistent with NICE's guideline on obesity prevention.

- 1.4 Clinicians should submit data on all patients undergoing laparoscopic gastric plication for severe obesity to the [National Bariatric Surgery Registry](#). Data should be entered into the register under the 'other' procedure category. Clinicians should also collect and review these data as part of local audit.
- 1.5 NICE encourages further research on laparoscopic gastric plication for severe obesity, which should include information about long-term efficacy and safety, and specifically how the procedure influences further gastric surgery. Comparison with alternative procedures would be useful.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Severe obesity is defined as a body mass index (BMI) of 40 kg per m<sup>2</sup> or more, or between 35 kg per m<sup>2</sup> and 40 kg per m<sup>2</sup> in association with significant comorbidities such as hypertension or diabetes. Weight loss reduces the risk of comorbidities worsening and improves long-term survival.
- 2.1.2 Severe obesity is managed by dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is considered as a treatment option in selected patients who have not lost enough weight using these measures.
- 2.1.3 Surgical procedures for severe obesity aim to help patients to lose weight and to maintain weight loss by restricting the size of the stomach and/or by decreasing the capacity to absorb food. 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. Patients are also advised to modify their eating behaviour by adhering to an explicit postoperative diet.

## 2.2 Outline of the procedure

- 2.2.1 Laparoscopic gastric plication aims to help patients lose weight by reducing the size of the stomach. It is usually done by plicating the greater curve of the stomach, although anterior plication has also been reported. Because none of the stomach is removed, it is potentially a reversible procedure.
- 2.2.2 The procedure is done with the patient under general anaesthesia, using several (usually 5 or 6) small incisions in the abdomen for the placement of a camera and ports for instruments. Greater curvature plication involves freeing the greater curve of the stomach by dissecting it from the greater omentum and short gastric vessels. Plication is done by folding the gastric wall inward along the greater curvature and securing this fold using rows of running sutures. Modifications of the technique may include a double or triple plication of the greater curve, and this may need extra rows of sutures.
- 2.2.3 Patients are placed on a postoperative diet that typically involves progression from fluids to semi-solid foods, avoiding intake of solid foods for approximately 6 weeks.

## 2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 A case series of 135 patients reported mean excess weight loss of 65% at a mean follow-up of 23 months (the number of patients followed up was not given). The study reported a significantly higher mean excess weight loss of 70% for patients with a BMI of less than 45 kg per m<sup>2</sup> (110 out of 135) compared with 56% for patients with a BMI of more than 45 kg per m<sup>2</sup> (25 out of 135; p=0.006). A case series of 100 patients reported mean excess weight loss of 54% after 6 months and 60% after 24 months (72 and 50 patients respectively).
- 2.3.2 The case series of 135 patients reported inadequate excess weight loss (defined as excess weight loss of less than 50%) in 21% (29 out of 135) of patients and

failure of the procedure (defined as excess weight loss of less than 30%) in 6% (8 out of 135) of patients at a mean follow-up of 23 months.

- 2.3.3 A case series of 42 patients who had mean excess weight loss of 20% at 1 month follow-up reported no regaining of weight at 18-month follow-up.
- 2.3.4 In the case series of 100 patients, 38 patients had comorbidities such as hypertension, diabetes, low back pain and sleep apnoea. Improvements were reported for 71% (15 out of 21) of patients with low back pain, 61% (8 out of 13) of patients with diabetes, 67% (6 out of 9) of patients with hypertension, and 100% (3 out of 3) of patients with sleep apnoea, 6 months after the operation.
- 2.3.5 A case series of 15 patients reported a significant improvement in the overall quality of life score (Impact of Weight on Quality of Life-Lite [IWQOL-Lite]; range 0 to 100, higher score indicating better quality of life) in 6 patients after greater curvature plication ( $p=0.009$ ) but not in 9 patients treated by anterior gastric plication ( $p=0.38$ ) at 12-month follow-up (numerical scores not reported).
- 2.3.6 The Specialist Advisers listed additional key efficacy outcomes as excess weight loss at 3, 5 and 10 years and durability of plication as assessed by endoscopic evaluation or contrast swallow at 12 months.

## 2.4 Safety

- 2.4.1 Partial jejunal necrosis due to portomesenteric thrombosis was reported in 1 patient in the case series of 135 patients 24 days after the procedure. This was treated by small bowel resection at laparotomy.
- 2.4.2 Gastric perforation in the prepyloric area was reported in 1 patient in the case series of 100 patients 3 days after the procedure (repaired at laparotomy).
- 2.4.3 Gastric obstruction due to herniation of the 'gastric fundus between 2 distal fasteners of the suture line' was reported in 1 patient in the case series of 135 patients 14 months after the procedure. This was treated by surgical reduction of the herniated fundus and reinforcement of the suture line using a laparoscopic approach.

- 2.4.4 Micro leak at the suture line was reported in 2 patients in the case series of 135 patients (timing not stated). Both patients were readmitted 7 days after the procedure and were treated conservatively. Gastric leak causing peritonitis was reported in 1 patient in the case series of 120 patients 3 days after the procedure. This was treated laparoscopically by suturing the leak hole, performing looser plication, cleaning the whole peritoneum cavity and antibiotic treatment for 3 weeks. Gastric leak with pain secondary to forceful vomiting was reported in 1 patient in a case series of 100 patients 2 days after the procedure. This was treated by repairing the suture line.
- 2.4.5 Intracapsular liver haematoma with abscess was reported in 1 patient in the case series of 100 patients 6 months after the procedure. This was treated by drainage of the abscess using a laparoscopic approach.
- 2.4.6 Intra-gastric seroma that resulted in gastric obstruction was reported in 2 patients in the case series of 135 patients 3 months after the procedure. This was treated by revision of plication.
- 2.4.7 Gastrointestinal bleeding was reported in 2 patients in the case series of 135 patients. The patients were readmitted 5 and 30 days after the procedure and were treated conservatively.
- 2.4.8 Non-obstructive jaundice was reported in 2 patients in the case series of 100 patients for more than 2 weeks after the procedure; it 'disappeared spontaneously'.
- 2.4.9 Hypocalcaemia was reported in 1 patient in the case series of 100 patients (no further details reported).
- 2.4.10 Prolonged nausea and vomiting (attributed to mucosal oedema caused by venous stasis) was reported for 2 to 20 days in 'most' of the 93 patients treated with single plication but only for 'a few hours' in 42 patients treated with multiple plication (exact figures not reported) in the case series of 135 patients who had laparoscopic greater curvature plication.
- 2.4.11 'Permanent' vomiting and discomfort due to adhesions between liver and stomach was reported in 1 patient in the case series of 100 patients. This

resolved after an operation to divide the adhesions 8 months after the procedure.

- 2.4.12 The Specialist Advisers listed an anecdotal event as disruption of plication due to 'broken suture causing weight regain'. They listed theoretical events as bleeding during dissection of omentum from the greater curvature of the stomach, injury to spleen, ischaemia or infarction of the plicated stomach and dysphagia.

## 3 Further information

### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

### Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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### Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).