

Implantation of a duodenal–jejunal bypass sleeve for managing obesity

Interventional procedures guidance

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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 Recommendations

- 1.1 Current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass sleeve (DJBS) for managing obesity is limited in quality and quantity. Therefore, this procedure should only be used in the context of research.
- 1.2 Clinicians should review local clinical outcomes and enter details about all patients undergoing implantation of a DJBS for managing obesity onto the National Bariatric Surgery Register.
- 1.3 Well-controlled studies are needed to support the current limited evidence on weight loss in the short term. They should document patient selection, all complications (while the device is in place and after its removal) and technical problems associated with placing and removing the device.

2 Indications and current treatments

- 2.1 Obesity is defined as a body mass index (BMI) of 30 kg per m² or more. It is a risk factor for comorbidities such as type 2 diabetes, coronary heart disease and hypertension. Weight loss reduces the risks of comorbidities and improves long-term survival.
- 2.2 Obesity is managed by dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is considered as a treatment option in selected patients whose BMI is over 40 kg per m², or over 35 kg per m² for patients with other significant comorbidities, if they have not lost enough weight using non-surgical measures.

- 2.3 Surgical procedures aim to help patients lose weight by restricting the size of the stomach (for example, gastric banding or sleeve gastrectomy) and/or by decreasing the patient's capacity to absorb food (for example, Roux-en-Y gastric bypass or biliopancreatic diversion).

3 The procedure

- 3.1 Endoscopic implantation of a duodenal–jejunal bypass sleeve (DJBS) is a minimally invasive procedure that has been used to promote weight loss in patients with obesity and with a view to improving comorbidities, including diabetes.
- 3.2 The procedure is done with the patient under general anaesthesia or sedation, using image guidance. The sleeve is positioned endoscopically (via the mouth). Using a delivery catheter, a capsule containing a single-use impermeable DJBS is positioned in the duodenal bulb just distal to the pylorus and is secured there using an integral spring metal anchor. The sleeve is advanced distally into the jejunum with the aid of a tension wire which is part of the introducer device. It extends approximately 60 cm down the small intestine and forms a barrier between food and the intestinal wall, delaying the mixing of digestive enzymes with the food.
- 3.3 After the procedure, patients are placed on a diet that typically involves progression from fluids to semi-solid foods, before returning to solid foods.
- 3.4 After a maximum of a year, the sleeve is removed under sedation, using endoscopy and image guidance. The anchor incorporates a drawstring mechanism that enables it to be collapsed and partly withdrawn into a plastic hood fitted to the endoscope. The entire device is then withdrawn.

4 Efficacy

This section describes efficacy 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](#).

- 4.1 A randomised controlled trial (RCT) of 56 patients with obesity comparing duodenal–jejunal bypass sleeve (DJBS; n=27) against sham endoscopy (n=29) reported a significantly higher percentage of excess weight loss at 12-week follow-up for the DJBS group (n=13) than for the sham endoscopy group (n=24): 11.9±1.4% and 2.7±2.0% respectively (p=0.001). A case series of 42 patients with obesity treated by DJBS reported 47.0±4.4% (p<0.0001) excess weight loss at 52-week follow-up.
- 4.2 An RCT of 18 patients with obesity and type 2 diabetes comparing DJBS (n=12) against sham endoscopy (n=6) reported that glycosylated haemoglobin (HbA1c) values decreased by 1.3±0.9% for the DJBS group and by 0.8±0.3% in the sham endoscopy group (p>0.05) at 12-week follow-up. At 24-week follow-up, the HbA1c had decreased by 2.4±0.7% in the DJBS group and by 0.8±0.4% in the sham endoscopy group (p>0.05). These differences were not statistically significant.
- 4.3 The case series of 42 patients with obesity treated by DJBS reported significant reductions from baseline in total cholesterol (from 197±7 mg/dL to 161±8 mg/dL; p<0.0001), triglycerides (from 160±16 mg/dL to 115±11 mg/dL; p=0.002) and blood pressure (systolic from 134±3 mmHg to 125±2 mmHg [p=0.01] and diastolic from 85±1 mmHg to 71±2 mmHg [p<0.0001]) at 52-week follow-up.
- 4.4 Implantation failure was reported in 20% (4 out of 25) of patients because of a short duodenal bulb (n=3) or a combination of patient anatomy and investigator inexperience (n=1) in the RCT of 56 patients.
- 4.5 The case series of 42 patients with obesity reported that, without any kind of maintenance programme, patients who completed 52 weeks of follow-up regained a mean of 4.4 kg 6 months after removal of the DJBS.
- 4.6 A case series of 22 patients with obesity and type 2 diabetes reported that improvement in HbA1c levels continued for up to 6 months after device removal in 11 patients (mean percentage decrease 1.7±0.7%).
- 4.7 The specialist advisers listed an additional key efficacy outcome measure as patient-reported quality of life.

5 Safety

This section describes 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](#).

- 5.1 Gastrointestinal bleeding with haematemesis was reported in 14% (3 out of 21) of patients at 11, 25 and 43 days after the procedure in the duodenal–jejunal bypass sleeve (DJBS) group of the randomised controlled trial (RCT) of 56 patients. The devices were removed. One patient needed sclerotherapy and endoscopic clips and 2 did not need further interventions to stop the bleeding.
- 5.2 Device migration was reported in 41% (5 out of 12) of patients in the DJBS group (4 because of anchor migration and 1 because of 'device turning or migration') during 12 weeks of follow-up in the RCT of 18 patients. All the devices were removed. Three patients presented with symptoms (1 with moderate pain, 1 with nausea, and 1 with vomiting and abdominal pain). Two patients had no symptoms, but device migration was noted at follow-up endoscopy (n=1) and at time of device removal (n=1).
- 5.3 Sleeve obstruction with severe nausea and vomiting on day 30 was reported in 1 patient in the RCT of 40 patients. Symptoms resolved after removal of the device.
- 5.4 One pharyngeal mucosal tear and 1 oesophageal mucosal tear occurred during device removal in a case series of 12 patients. Further intervention was not needed.
- 5.5 Nausea and upper abdominal pain were reported in 77% (20 out of 26) and 50% (13 out of 26) of patients respectively (mainly in the first week after the procedure) in the DJBS group of the RCT of 41 patients. All events resolved with medication. Continuous epigastric pain was reported in 1 patient in the RCT of 41 patients. This resolved after removal of the device at 3 months.
- 5.6 Pseudopolyp formation and implant site inflammation were noted during explantation or at follow-up endoscopy in 50% (13 out of 26) and 38% (10 out of 26) in the DJBS group of the RCT of 41 patients.

- 5.7 The specialist advisers listed anecdotal adverse events as multiple linear ulcerated areas with perforation in the proximal jejunum, erosion of the duodenal wall, device malplacement, misplacement of the endoscope hood in the pharynx during endoscopic removal of the device, and inability to remove an obstructed and migrated device endoscopically (needing a laparotomy for removal). The specialist advisers listed theoretical adverse events as implantation failure; perforation of the oesophagus, stomach, duodenum or proximal jejunum and consequent laparotomy; and reduced absorption of dietary calcium and iron.

6 Committee comments

- 6.1 The Committee considered that the quality of randomised controlled trials was poor, with substantial loss of patients to follow-up and potential for bias.
- 6.2 The Committee was advised that appropriate indications for implantation of a duodenal–jejunal bypass sleeve (DJBS) are uncertain. The specialist advisers stated that it might be used for improvement of control of diabetes in patients with obesity (but not in patients with diabetes who are not obese); for weight loss alone (but the durability of its effects may be limited); or for weight reduction before planned bariatric surgery. The literature reported heterogeneous outcomes relevant to these various indications, and also reported improvements in control of hypertension and blood lipid levels. The Committee was also advised that the device used in some of the studies was a prototype rather than a device that has been introduced into clinical practice.
- 6.3 The Committee noted specialist advice that this procedure should only be used in units specialising in the treatment of obesity, as one of a range of treatment options and as part of a package of care.

7 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](#).