

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg569

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 of single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity shows that there are well-recognised complications. Evidence on efficacy is limited in both quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do SADI-S for treating morbid obesity should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 Clinicians should review local clinical outcomes and enter details about all patients having SADI-S for treating morbid obesity onto the National Bariatric Surgery Registry.
- 1.4 Patient selection should be done by a multidisciplinary team experienced in managing morbid obesity.
- 1.5 Treatment should be done by surgeons with specific training in the procedure, in centres with expertise in the treatment of morbid obesity.

- 1.6 NICE encourages further research into SADI-S for treating morbid obesity, particularly research examining long-term outcomes. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Morbid obesity is defined as a body mass index of 40 kg/m² or more, or of 35 to 40 kg/m² with significant medical problems related to body weight. Comorbidities include type 2 diabetes, coronary heart disease and hypertension. Weight loss reduces the comorbidities and improves long-term survival.
- 2.2 Morbid obesity is managed by lifestyle changes including exercise and diet and medication. Bariatric surgery is a treatment option in selected patients 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), 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 Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity is usually done laparoscopically with the patient under general anaesthesia.
- 3.2 Initially, the stomach is reduced in size by a sleeve gastrectomy, which involves devascularising and excising the greater curve. This leaves a tube of stomach passing from the oesophagus to the pylorus and duodenum. The duodenum is then mobilised and divided at the level of the gastroduodenal artery using a linear stapler. This leaves a short stump of duodenum attached to the pylorus. The distal end of the duodenum is closed off permanently. A loop of small bowel, usually 200 to 300 cm from the ileocaecal valve, is anastomosed to the remnant of duodenum arising from the pylorus to restore the continuity of the gut.

This anastomosis is usually sutured in 2 layers, but may be stapled. In patients at high risk because of extreme obesity, the procedure may be done in 2 stages, first sleeve gastrectomy, and then duodenal transection and duodeno-ileal anastomosis in a subsequent procedure once the patient's risks from surgery are reduced by weight loss induced by sleeve gastrectomy.

- 3.3 After surgery, patients are maintained on a low-calorie diet. Multivitamin, calcium and iron supplements are prescribed as needed to maintain normal blood levels.

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 [interventional procedure overview](#).

- 4.1 In a case series of 100 patients with morbid obesity or metabolic disease treated with single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S), the mean excess weight loss (EWL calculated from an ideal body mass index [BMI] of 25 kg/m²) was 95% at 12 months. This was maintained for maximum of 48 months of follow-up, with no significant differences between those who had SADI-S 200 cm from the ileocecal valve and those with SADI-S 250 cm. In a case series of 97 patients with obesity and type 2 diabetes treated with SADI-S, EWL was 92% (74/80) at 2-year follow-up and 98% (425/32) at 5-year follow-up. Six percent (6/97) of patients failed to reach 50% EWL. In a case series of 123 patients with morbid obesity treated with stomach intestinal pylorus sparing (SIPS) procedure, EWL was 72% (64/102) at 1-year follow-up.
- 4.2 In the case series of 97 patients, overall weight loss was 39% at 2-year follow-up and 38% at 5-year follow-up. In the case series of 123 patients, overall weight loss was 39% and patients had an average change in BMI of 19 kg/m² at 1-year follow-up.
- 4.3 In the case series of 100 patients, the mean glycaemia level decreased from 178.2 mg/dl at baseline to 94.2 mg/dl at 1-year follow-up and to

79.6 mg/dl at 4-year follow-up. The mean glycated haemoglobin (HbA1c) level decreased from 7.9% at baseline to 5.3% at 1-year follow-up and to 5.0% at 4-year follow-up. In the case series of 97 patients, the mean glycaemia level reduced from 167.6 mg/dl at baseline to 93.0 mg/dl at 1-year follow-up and to 101.6 mg/dl at 5-year follow-up. The mean HbA1c level reduced from 7.6% at baseline to 5.1% at 1-year follow-up and to 5.5% at 5-year follow-up.

- 4.4 In the case series of 97 patients, the overall diabetes remission rate (defined as HbA1c below 6% without antidiabetic medication for more than 1-year) was 77% at 2 years and 52% at 5 years. Remission rates were higher for those having oral therapy (n=14) than for those having insulin therapy (n=40) (97% versus 54% at 2 years; 75% versus 38% at 5 years).
- 4.5 In the case series of 97 patients, type 2 diabetes recurred in 8% (4/97) of patients within 5 years (308 patient-years follow-up).
- 4.6 In the case series of 123 patients, mean values for the nutritional data (Vitamin A, B1, B12, D and albumin) were at normal levels at 1-year follow-up.
- 4.7 The specialist advisers listed key efficacy outcomes as weight loss, remission of type 2 diabetes, resolution of obesity-related comorbidities and improvement in 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 [interventional procedure overview](#).

- 5.1 Mortality due to progressive respiratory insufficiency occurred at 3 months in 1 patient in a case series of 50 patients.
- 5.2 Myocardial infarction occurred at 6 months in 1 patient in the case series of 50 patients.

- 5.3 Gastric haemorrhage occurred in 1 patient in a case series of 100 patients (timing not stated). Patient had endoscopic coagulation but further details were not reported.
- 5.4 Postoperative gastric leaks occurred in 2% (2/100) of patients in the case series of 100 patients. One leak was visible with a barium swallow but uneventful, and the patient was discharged on the thirteenth day. One clinical leak was managed with an abdominal drain, and the patient was discharged after 5 weeks. Duodenal anastomotic leak (treated conservatively) occurred in 1 patient in the case series of 100 patients.
- 5.5 Haemoperitoneum occurred in 1 patient in a case series of 97 patients. Further details were not reported. Abdominal haematoma occurred in 3% (4/123) of patients in the case series of 123 patients. Further details were not reported.
- 5.6 Acute trocar site herniation occurred in 1 patient in the case series of 100 patients. The patient had another operation and prosthetic/mesh repair. Incarcerated umbilical hernia occurred in 1 patient in the case series of 97 patients. The patient had another operation.
- 5.7 Subphrenic abscess (drained under radiological guidance) occurred in 1 patient in the case series of 50 patients.
- 5.8 Stricture in the gastric sleeve (which led to dysphagia) needing dilatation occurred in 1 patient in the case series of 123 patients.
- 5.9 Reoperation due to early postoperative ulcer was needed in 1 patient in the case series of 123 patients.
- 5.10 Acute cholecystitis occurred within 1 year of the procedure in 4% (2/50) of patients in the case series of 50 patients. One patient had cholecystectomy and another patient was waiting to have surgery at the time of the report.
- 5.11 Clinical hypoalbuminemia occurred in 4% (4/100) patients in the case series of 100 patients. In 1 patient, it was related to severe diarrhoea and treated with metronidazole. In another patient it was due to intra-

abdominal infection and the abscess was drained. In 2 other patients, it was due to reduced food intake; the patients were given counselling and their oral intake increased. Because of recurrent hypoproteinaemia, 2 of the patients had revision to the Roux-en-Y duodenal switch with a longer gut. Hypoalbuminemia was detected in 12% of patients, low vitamin A levels in 53% and high parathormone levels in 54% at 3 years follow-up in the case series of 97 patients.

- 5.12 Sporadic vomiting occurred in 1 patient in the case series of 50 patients. Further details were not reported.
- 5.13 Diarrhoea was reported in 2% (2/123) of patients in the case series of 123 patients. Further details were not reported.
- 5.14 Constipation was reported in 2% (2/123) of patients in the case series of 123 patients. Further details were not reported.
- 5.15 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers reported no anecdotal adverse events. They considered that the following were theoretical adverse events: malnutrition, vitamin and mineral deficiencies.

6 Committee comments

- 6.1 The committee noted that there is the potential for serious metabolic complications after this procedure.
- 6.2 The committee noted that there may be a need for revision procedures.
- 6.3 The committee noted that much of the evidence in the overview came from a single centre.

7 Further information

7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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](#).