NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

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

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy is a type of weight loss surgery used to treat people with morbid obesity (also known as bariatric surgery). The left side of the stomach is removed (sleeve gastrectomy), and the exit point of the stomach is cut and re-joined to the gut further down. The aim is to reduce the size of the stomach to restrict the amount of food a patient can eat, and to make the gut smaller so that less food is absorbed.

The National Institute for Health and Care Excellence (NICE) is examining single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 20 May 2016

Target date for publication of guidance: September 2016

1 Draft 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.

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 [URL to be added at publication] is recommended.
- Audit [URL to audit tool to be added at publication] and review clinical outcomes of all patients having SADI-S for treating morbid obesity (see section 7.1).

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 surgical 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/m^2 or more, or of 35–40 kg/m^2 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 200–300 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 and nutrition levels are maintained based on blood analyses.

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 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.

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.

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 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. Patient had endoscopic coagulation but further details were not reported.

5.4 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.

5.5 Duodenal anastomotic leak (treated conservatively) occurred in 1 patient in the case series of 100 patients.

5.6 Hemoperitoneum occurred in 1 patient in a case series of 97 patients. Further details were not reported.

5.7 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.

5.8 Subphrenic abscess (drained under radiological guidance) occurred in 1 patient in the case series of 50 patients.

5.9 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.

5.10 Sporadic vomiting occurred in 1 patient in the case series of 50 patients. Further details were not reported.

5.11 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.

5.12 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 published evidence came from a single centre.

7 Further information

7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

7.2 For related NICE guidance, see the NICE website.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
April 2016