NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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 (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.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in October 2015.

Procedure name

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

Specialist societies

- British Obesity and Metabolic Surgery Society
- British Society of Gastroenterology
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland.

Description

Indications and current treatment

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.

Morbid obesity is managed by lifestyle changes including exercise, diet and medication. Bariatric surgery is a treatment option in selected patients if they have not lost enough weight using non-surgical measures.

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).

What the procedure involves

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity is usually done laparoscopically with the patient under general anaesthesia.

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 200–300cm 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.

After surgery, patients are maintained on a low calorie diet. Multivitamin, calcium and iron supplements are prescribed and levels are maintained based on blood analyses.

The aim of the procedure is both restrictive (reducing the size of the stomach to restrict the amount of food a patient can eat) and malabsorptive (reducing the length of the intestine able to absorb nutrients). In patients at high risk of surgery because of extreme obesity, the procedure may be done in 2 stages: sleeve gastrectomy and then duodenal transection and duodeno-ileal anastomosis – once the patient's risks from surgery are reduced by weight loss induced by sleeve gastrectomy.

There are similarities between SADI-S and the duodenal switch (DS) procedure, which also involves sleeve gastrectomy and duodenal transection. However, gut continuity is restored with a Roux-en-Y loop, around 200 cm from the ileocaecal valve, which is anastomosed directly to the duodenal remnant at the pylorus. The proximal small bowel (that is, the bilio-pancreatic channel) arising from the divided duodenal is anastomosed to the distal ileum, 50–100 cm from the ileocaecal valve making a common channel. This procedure has 2 anastomoses but has a theoretical advantage of avoiding bile reflux into the stomach.

Outcome measures

Percentage of excess weight loss (% EWL)

Percentage of excess weight loss is a common measure for reporting weight loss after bariatric surgery. It is calculated by subtracting current weight from excess body weight (EBW; that is, preoperative weight on day of surgery minus ideal body weight [IBW]), which finds weight loss (WL); WL is then divided by EBW and converted to a percentage (% EBWL).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity. The following databases were searched, covering the period from their start to 26.10.2015: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with morbid obesity.
Intervention/test	Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 247 patients from 3 case series[1-3].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity

Study 1 Sanchez-Pernaute A [2010]

Details

Study type	**Case series**
Country	Spain
Recruitment period	2007–09
Study population and number	n=**50 patients with morbid obesity or metabolic disease** Mean BMI 44 kg/m^2, mean excess weight 51 kg. 54% (27/50) had type 2 diabetes
Age and sex	Mean age 46 years 64% (32/50) female
Patient selection criteria	Patients with morbid obesity (a BMI of 40-50 kg/m^2) and no previous bariatric operations were included. Patients with previous bariatric procedures were excluded.
Technique	Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) - performed laparoscopically (in 180 minutes) in all, except 4 in whom it was done through a laparotomy (in 90 minutes). After devascularisation of the gastric greater curvature, sleeve gastric resection was performed over a 54 F bougie. The duodenum is dissected down to the gastroduodenal artery and divided with a 60-mm linear stapler preserving the pylorus. The ileocolic junction was identified and 200 cm measured proximally. Measurement of the bowel was performed, stretching the loops at the antimesenteric border in 10 cm intervals and after infusion of hyoscine to completely relax the bowel wall and obtain the maximum length. The selected loop was descended antecolically and a side to side anastomosis completed to the proximal duodenum with a 30mm linear stapler and 2 layers of running suture. The anastomosis is tested for leaks and covered with fibrin glue. Postoperatively, patients are given liquid diet on second day and maintained on a low-calorie protein-rich diet thereafter. Multivitamin, calcium and iron supplements were prescribed and maintained based on blood analyses.
Follow-up	**1–3 years**
Conflict of interest/source of funding	None/study supported by a grant from the Medical Foundation of the Mutua Madrilena del Automovilista.

Analysis

Follow-up issues: complete follow-up for 98% of the patients.

Study design issues: prospective study at a tertiary centre.

Study population issues: cholecystectomy was performed in 11 patients simultaneously. Mean duration of type 2 diabetes was 9.6 years, 2 patients had type 1 diabetes and 27 had type 2 diabetes, of which 14 were on insulin therapy and 13 on antidiabetic drugs. Hypertriglyceridaemia was detected in 60%, hypercholesterolaemia in 43%, obstructive apnoea in 30% (17/50) and hypertension in 50% (23/50).Three patients had prior surgical revascularisation.

Other issues: There is overlap of patients with study 2 and 3.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **50**

Percentage of excess weight loss (% EWL)

	6 months	1 year	2 years	3 years
Mean % EWL	81.6	94.7	114	100

1 patient who suffered a myocardial infarction at 6 months failed to achieve 50% EWL.

Nutritional outcomes (Blood analyses)

	1 year (mean values)	percentage of patients with abnormally low values	2 years (mean values)	percentage of patients with abnormally low values	3 years (mean values)	percentage of patients with abnormally low values
Haemoglobin (g/dl)	13.6	10	13.1	12	13.4	10
Haematocrit (%)	40.5	10	39.1	12	39.5	0
Iron (mg/dl)	73.4	22	84	11	73.2	14
Proteins (g/dl)	6.7	24	6.5	25	6.3	25
Albumin (g/dl)	4	10	3.9	10	3.9	0
Vitamin B12 (pg/ml)	408.9	6	355.9	7	323.8	0
Folic acid (ng/ml)	5.3	14	6.1	14	5.1	16
Calcium (mg/dl)	9.5	2	9.4	0	9.4	0
Parathormone (pg/ml)	56.3	8	63.6	13	74.1	25
Vitamin D (ng/ml)	27.7	30	28.3	40	26.1	40

Metabolic outcomes in patients with type 2 diabetes (n=27)

	Preoperative	Abnormal percent	Postoperative	Abnormal percent
Glucose (mg/dl)	174.5	90	97	0
HbA1c (%)	7.6	60	5.4	0
Triglycerides (mg/dl)	196.5	60	109.6	16
Cholesterol (mg/dl)	187	46	134.9	0
HDL cholesterol (mg/dl)	44	-	45	-
LDL cholesterol (mg/dl)	108	-	68.3	-

Bowel movements: Mean number of bowel movements was 2.5 per day. 30% of the patients had 3 or more bowel movements per day.

Safety

	% (n)
Mortality due to progressive respiratory insufficiency at 3 months	2 (1/50)
Myocardial infarction at 6 months	2 (1/50)
Gastric leaks (1 was visible in barium swallow but uneventful, patient discharged on day 13; 1 clinical leak was managed through abdominal drain and discharged after 5 weeks)	4 (2/50)
Gastric haemorrhage (patient underwent endoscopic coagulation)	2 (1/50)
Acute trocar site herniation (patient underwent reoperation and prosthetic/mesh repair)	2 (1/50)
Subphrenic abscess (drained under radiological guidance)	2 (1/50)
Clinical hypoalbuminaemia (occurred between 6 and 12 months) 1 - due to severe diarrhoea and treated with metronidazole, 1 - due to intraabdominal infection, abscess was drained 2 - due to reduced food intake, counselling given and oral intake increased.	8 (4/50)
Sporadic vomiting	2 (1/50)
Acute cholecystitis (within 1 year, 1 had cholecystectomy and another was waiting for surgery).	4 (2/50)

Abbreviations used: EWL, excess weight loss; HDL, high density lipoprotein; LDL, low density lipoprotein; SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Study 2 Sanchez-Pernaute A [2013]

Details

Study type	**Case series**
Country	Spain
Recruitment period	2007-11
Study population and number	n=**100 patients with morbid obesity or metabolic disease** Primary operation in 93; Mean BMI 44.6 kg/m^2; mean excess weight 53 kg. Secondary operation (after previous gastrectomy) in 7; Mean BMI 48.5 kg/m^2; mean excess weight 62 kg. 59% (59/100) had type 2 diabetes.
Age and sex	Mean age 47 years 63% (63/100) female
Patient selection criteria	Patients with morbid obesity (a BMI of 40–50kg/m^2) and no previous bariatric operations were initially included. After satisfactory results, all patients consulting for surgery for obesity or metabolic disease, those with a BMI of >50kg/m^2, with major comorbidities or severe metabolic disease were included.
Technique	Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) performed laparoscopically in all but 3. In 1 case, it was converted to open laparotomy because of technical difficulties in anastomosis. In the first 50 patients anastomosis was performed at 200 cm from the ileocecal valve, and in the last 50, length was increased to 250cm. After devascularisation of the gastric greater curvature, sleeve gastric resection was performed over a 54 F bougie. The duodenum was dissected down to the gastroduodenal artery and divided with a 60-mm linear stapler. The ileocolic junction was identified and 250cm measured proximally. Measurement of the bowel was performed, stretching the loops at the antimesenteric border in 10cm intervals and after infusion of hyoscine butylbromide to completely relax the bowel wall and obtain the maximum length. The selected loop was raised in antecolic and a side to side anastomosis created to the proximal duodenum with a 30mm linear stapler and 2 layers of running suture. A vacuum drain was left in place until the patient resumed oral diet. Postoperatively, patients are maintained on a low calorie diet. Multivitamin, calcium and iron supplements were prescribed and maintained based on blood analyses.
Follow-up	**Range 0-48 months**
Conflict of interest/source of funding	None/study supported by a grant from the Medical Foundation of the Mutua Madrilena del Automovilista.

Analysis

Follow-up issues: short follow-up period for those who had SADI-S 250 cm, but complete follow-up for 99% of the patients. Only 61 patients had long enough follow-up.

Study design issues: prospective study at a tertiary centre. Patients with different loop lengths, those with primary and secondary operations were analysed together.

Study population issues: Study excluded patients who were non-compliant with diet, those with abnormal dietary habits, with emotional disorders, advanced age, and those with a diminished absorption capacity.

Mean duration of type 2 diabetes was 9.8 years, 42% (25/59) of them needed insulin, 72% of patients had HbA1c of 6.5%, dyslipidaemia was detected in 57 patients, obstructive apnoea in 27 and hypertension in 57.

Other issues: There is overlap of patients with study 1 and 3.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **100**

Percentage of excess weight loss (% EWL)

The mean percentage of excess weight loss was 80% 6 months after surgery and reached a mean value of 100% at 18 months and maintained during the follow-up period (48 months). There were no significant differences between SADI-S 200 cm and SADI-S 250 cm. 1 patient who suffered a myocardial infarction at 6 months failed to achieve 50% EWL.

Outcomes in patients with type 2 diabetes (n=45/49)

	preoperative	**1 year**	**2 years**	**3 years**	**4 years**
Mean glycaemia (mg/DL)	178.2	94.2	93.1	91.0	79.6
HbA1c (%)	7.9	5.3	5.2	5.4	5.0

92% of the patients had complete remission of type 2 diabetes.

Lipid profile

Lipid metabolism improved postoperatively at 2-year follow-up and there were no significant differences between SADI-S 200 and SADI-S 250 patients. Only 27% patients continued to have hypertriglyceridaemia, 27% had low levels of HDL cholesterol, 5% had high values of cholesterol, and 4% patients had abnormally high total cholesterol.

Hypertension controlled in 98% (56/57) patients, with remission in 58% of the patients. Obstructive apnoea was solved in 88% (24/27) of the patients.

Mean number of bowel movements was 2.5 per day.

Safety

	% (n)
Intraoperative complications	0
Mortality	0
Postoperative leaks (2 from gastric tube and 1 from the duodeno-ileal anastomosis, all treated conservatively - 1 leak was visible with a barium swallow but uneventful, and the patient was discharged on the thirteenth day. 1 clinical leak was managed with an abdominal drain, and the patient was discharged after 5 weeks)	3 (3/100)
Gastric haemorrhage (patient underwent endoscopic coagulation)	1 (1/100)
Acute trocar site herniation (patient underwent reoperation and prosthetic repair)	1 (1/100)
Clinical hypoalbuminaemia (occurred in patients with 200 cm common limb; in1 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 2 of the patients with recurrent hypoproteinaemia underwent revision to Roux-en-Y duodenal switch with a longer alimentary canal)	4 (4/100)

Abbreviations used: EWL, excess weight loss; HDL, high density lipoprotein; LDL, low density lipoprotein; SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Study 3 Sanchez-Pernaute A [2015]

Details

Study type	**Case series**
Country	Spain
Recruitment period	2007-11
Study population and number	n=**97 patients with obesity and type 2 diabetes** Mean BMI 44.3 kg/m^2, mean excess weight 52.7 kg. Mean duration of type 2 diabetes: 8.5 years Mean preoperative HbA1c: 7.6%
Age and sex	Mean age 50 years 54% (52/97) female
Patient selection criteria	Patients with morbid obesity (a BMI of 40-50kg/m^2) and no previous bariatric operations were initially included. After satisfactory results, all patients consulting for surgery for obesity or metabolic disease, those with a BMI of >50kg/m^2, with major comorbidities or severe metabolic disease were included.
Technique	Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) - sleeve gastrectomy performed over a 54F bougie. Duodenal division was done at the level of the gastroduodenal artery. The ileal loop was ascended antecolically and an end to side duodeno-ileal anastomosis (200 cm common limb in 25 cases and 250 cm in 69 cases) was completed either hand sewn or mechanically with a 30 mm linear stapler. A vacuum drain was systemically left. Postoperatively, on the first day patients are given oral liquids, drain removed on second day and discharged on third or fourth day. Antidiabetic treatment was managed by the endocrinologist, based on previous antidiabetic therapy. Multivitamin, calcium and iron supplements were prescribed and postoperative follow-up visits done every 3 months.
Follow-up	**5 years**
Conflict of interest/source of funding	None/study supported by a grant from the Medical Foundation of the Mutua Madrilena del Automovilista.

Analysis

Follow-up issues: 95.5% (86/90) patients were followed up in first year, 92.5% (74/80) in second year, 91.6% (66/72) in third year, 86.7% (46/53) in fourth year and 78% (25/32) in the fifth year.

Study design issues: prospective study at a tertiary centre. Patients with different loop lengths, those with primary and secondary operations were analysed together.

Study population issues: study excluded patients who were non-compliant with diet, those with abnormal dietary habits, with emotional disorders, advanced age, and those with a diminished absorption capacity.

40 patients needed insulin therapy, 65% of patients had HbA1c of 6.5%, dyslipidaemia was detected in 74 patients, and hypertension in 68%.

Other issues: There is overlap of patients with study 1 and 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **97**

Weight loss

	6 months	1 year	2 years	3 years	4 years	5 years
% (n)		95 (86/90)	92 (74/80)	91 (66/72)	87 (46/53)	78 (25/32)
Percentage of excess weight loss (% EWL)	73	91	92	85	88	98
Overall weight loss (%)	31	39	39	35	37	38

6% (6/97) patients failed to reach a 50% EWL.

Glycaemic and lipid profiles

	Preoperative	1 year	2 years	3 years	4 years	5years
Patients % (n)	97/97	95 (86/90)	92 (74/80)	91 (66/72)	87 (46/53)	78 (25/32)
Mean glycaemia (mg/DL)	167.6	93	93.8	103.9	97.3	101.6
HbA1c (%)	7.6	5.1	5.07	5.25	5.43	5.52
HOMA	7.9	0.96	1.45	0.87		
QUICKI	.29	0.41	0.4	0.4		
Triglycerides (md/dL)	205	103	96	104	105	105
HDL(md/dL)	46.6	45.7	48.3	47.3	45.3	57.4
LDL(md/dL)	98.7	73.9	73.2	74.5	74.4	81.3
Cholesterol (md/dL)	185	138	142	140	139	160
Overall diabetes remission* rate %		71.6	77	75.8	63.3	52
Remission rate for patients under oral therapy %		92.5	97	96.4	85.7	75
Remission rate for patients under initial insulin therapy %		47	54	56	47.3	38.4

*when HbA1c was maintained below 6% without antidiabetic medication for >1 year.

Diabetes recurrence was reported in 8% (4/97) patients in 5 years (in 308 patient years) follow-up.

Hypertension remitted in 52% patients and improved in 44%.

Bowel movements: mean number of bowel movements was 2.5 per day.

Safety

	% (n)
Anastomotic leaks (all treated conservatively)	(1/97)
Haemoperitoneum	(1/97)
Incarcerated umbilical hernia (patient underwent reoperation)	(1/97)
Recurrent hypoproteinaemia (2 underwent revision to Roux-en-Y duodenal switch with a 200 cm common limb and a 350cm alimentary limb, 1 had division of the duodeno-ileal anastomosis and a new 1 meter proximal; 2 suffered from another episode of hypoproteinaemia due to food rejection in fear of weight gain but all patients later did well)	3 (3/97)

Hypoalbuminaemia was detected in 12% cases, low vitamin A levels in 53% and high parathormone levels in 54% cases at 3 years follow-up.

Abbreviations used: EWL, excess weight loss; HDL, high density lipoprotein; HOMA, Homeostasis Model Assessment; LDL, low density lipoprotein; QUICKI, Quantitative Insulin Sensitivity Check Index; SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Efficacy

Weight loss

Excess weight loss

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/m^2) was 95% at 12 months. This was maintained for maximum of 48 months' 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 from the ileocecal valve[2].

In a case series of 97 patients with obesity and type 2 diabetes treated with SADI-S, EWL was 73% at 6 months, 91% (86/90) at 1 year and 92%(74/80), 85% (66/72), 88% (46/53) and 98% (425/32) at 2–5 years' follow-up. Six percent (6/97) of patients failed to reach 50% EWL[3].

Overall weight loss

In the case series of 97 patients, the overall weight loss was 31% at 6 months after surgery, 39% at 1 year and 2 years, 35% at 3 years, 37% at 4 years and 38% at 5 years follow-up[3].

Metabolic outcomes

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 years' follow-up. The mean glycated haemoglobin (HbA1c) decreased from 7.9% at baseline to 5.3% at 1-year follow-up and to 5.0% at 4 years' follow-up[2].

In the case series of 97 patients, the mean glycaemia, HbA1c, insulin resistance and sensitivity indices decreased. Mean glycaemic level reduced from 167.6 mg/dl at baseline to 93.0 mg/dl at 1-year follow-up and to101.6 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[3].

Diabetes control

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 72% at 1 year after surgery, 77% at 2 years, 76% at 3 years, 63% at 4 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) (92% versus 47% at 1 year; 97% versus 54% at 2 years; 96% versus 56% at 3 years; 86% versus 47% at 4 years and 75% versus 38% at 5 years[3].

Diabetes recurrence

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)[3].

Bowel movements

The case series of 100 patients reported that the mean number of bowel movements was 2.5 per day[2].

Safety

Mortality

Mortality due to progressive respiratory insufficiency occurred at 3 months in 1 patient in a case series of 50 patients[1].

Myocardial infarction

Myocardial infarction occurred at 6 months in 1 patient in the case series of 50 patients[1].

Bleeding

Gastric haemorrhage occurred in 1 patient in a case series of 100 patients. Patient had endoscopic coagulation[2].

Gastric leaks

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 thirteenth day. One clinical leak was managed with an abdominal drain and the patient was discharged after 5 weeks[2].

Anastomosis leaks

Duodenal anastomotic leak (treated conservatively) occurred in 1 patient in the case series of 100 patients[2].

Herniation

Acute trocar site herniation occurred in 1 patient in the case series of 100 patients. The patient had another operation and prosthetic/mesh repair[2].

Incarcerated umbilical hernia occurred in 1 patient in the case series of 97 patients. The patient had another operation[3].

Subphrenic abscess

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

Hypoproteinaemia

Clinical hypoalbuminaemia occurred in 4% (4/100) patients between 6 and 12 months in a 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 intraabdominal 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 alimentary canal[2]. Hypoalbuminaemia was detected in 12% of patients, low vitamin A levels in 53% and high parathormone levels in 54% at 3 years follow-up in a case series of 97 patients[3].

Vomiting

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

Cholecystitis

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 report[1].

Haemoperitoneum

Haemoperitoneum occurred in 1patient in a case series of 97 patients. Further details were not reported[3].

Validity and generalisability of the studies

- Most of the studies published were small and there is lack of long-term evidence.
- The evidence is mainly from one center in Spain (none from the UK).
- There are no randomised controlled trials comparing with other bariatric procedures such as gastric bypass and standard duodenal switch.
- There is overlap of patients between the Sanchez-Pernaute A[1–3] studies.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Implantation of a duodenal–jejunal bypass sleeve for managing obesity. NICE interventional procedure guidance 471 (2013) Available from http://www.nice.org.uk/guidance/IPG471
- Laparoscopic gastric plication for the treatment of severe obesity. NICE interventional procedure guidance 432 (2012) Available from http://www.nice.org.uk/guidance/IPG432

NICE guidelines

- Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. NICE guideline 189 (2014). Available from http://www.nice.org.uk/guidance/CG189
- Obesity: Guidance on the prevention of overweight and obesity in adults and children. NICE guideline 43 (2006). Available from http://www.nice.org.uk/guidance/CG43
- Managing overweight and obesity in adults – lifestyle weight management services. NICE public health guideline 53 (2014). Available from http://www.nice.org.uk/guidance/PH53

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. 3 Specialist Advisor Questionnaires for Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent xxx questionnaires to xxx NHS trusts for distribution to patients who had the procedure (or their carers). NICE received xxx completed questionnaires.

Section to be inserted if there is no patient commentary

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Section to be inserted if patient commentators raised no new issues

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Section to be inserted if patient commentators raised new issues

The patient commentators raised the following issues about the safety/efficacy of the procedure, which did not feature in the published evidence or the opinions of specialist advisers, and which the Committee considered to be particularly relevant:

- [insert additional efficacy and safety issues raised by patient commentators and highlighted by IPAC, add extra rows as necessary].
- [Last item in list].

Issues for consideration by IPAC

- The procedure is also known as stomach intestinal pyloric sparing surgery (SIPSS) or proximal duodenal-ileal end to side bypass, or loop duodenal switch.
- Papers related to modified duodenal switch techniques have been added to Appendix A as outcomes might vary. These include:

  - Single-loop anastomosis duodeno-jejunal bypass with sleeve gastrectomy (SADJB-SG)
  - SADI as a second step after SG
- Ongoing trials
  - NCT01463904: Single-Anastomosis Duodeno-Ileal Bypass With Sleeve Gastrectomy (SADI-S) for the Treatment of Morbid Obesity and Its Metabolic Complications (SADI-S 250). Study type: prospective observational-cohort study; n=250; patient population: Morbid obesity patients and patients with obesity and type 2 diabetes; location: Spain; study completion date: April 2015. The status of this study is unknown.
  - NCT01685177: Prospective Randomized Trial Comparing Single-Anastomosis Duodeno-Ileal Bypass With Standard Roux-en-Y Duodenal Switch as a Second Step After a Sleeve Gastrectomy in the Super-Morbid Obese Patient. Study type: prospective observational-cohort study; n=30; primary outcome: weight loss, excess weight loss based on an ideal BMI of 25; location: Spain; study completion date: not reported. Recruitment status of this study is unknown.

References

1. Sánchez-Pernaute A, Herrera MA, Pérez-Aguirre ME et al (2010). Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S). One to three-year follow-up. Obes Surg. 20(12):1720–6.
2. Sánchez-Pernaute A, Rubio MA et al (2013). Single-anastomosis duodenoileal bypass with sleeve gastrectomy: metabolic improvement and weight loss in first 100 patients. Surgery for Obesity & Related Diseases 9 (5) 731–735.
3. Sánchez-Pernaute A, Rubio MÁ, Cabrerizo L et al (2015). Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) for obese diabetic patients. Surg Obes Relat Dis. Feb 7. pii: S1550-7289(15)00029-5. doi: 10.1016/j.soard.2015.01.024. [Epub ahead of print]

Appendix A: Additional papers on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Sanchez-Pernaute A, Rubio Herrera MA, et al (2007). Proximal duodenal-ileal end-to-side bypass with sleeve gastrectomy: proposed technique. Obesity Surgery 17 (12) 1614-1618.	Proximal duodenal-ileal end-to-side bypass with sleeve gastrectomy is a new bariatric technique based on the biliopancreatic diversion with duodenal switch in which after the sleeve gastrectomy, the duodenum is anastomosed to the ileum in a Billroth-II fashion. A 200-cm common channel-alimentary limb is devised.	Anticipating an appropriate weight loss, at least similar to that obtained after gastric bypass, theoretical benefits for operated patients are a shorter operative time, the performance of only one anastomosis, and no mesentery opening. A prospective trial is now being conducted to find out the results of the procedure and to compare them to those obtained with gastric bypass and standard duodenal switch.	Describes technique
Sanchez-Pernaute A, Rubio MA et al (2015). Single-anastomosis duodenoileal bypass as a second step after sleeve gastrectomy. Surgery for Obesity & Related Diseases 11 (2) 351-355.	Case series n=16 BMI 56.4 kg/m(2) Mean excess weight loss of 39.5% after a sleeve gastrectomy. (SADI) single-anastomosis duodenoileal bypass with a 250-cm common channel. Follow-up: 2 years	There were no postoperative complications. The mean excess weight loss was 72% 2 years after the second-step surgery. The complete remission rate was 88% for diabetes, 60% for hypertension, and 40% for dyslipidaemia. The mean number of daily bowel movements was 2.1. One patient suffered an isolated episode of clinical hypoalbuminemia. SADI is a safe operation that offers a satisfactory weight loss for patients subjected to a previous sleeve gastrectomy. The side effects are well tolerated, and complications are minimal.	SADI was done as a second step operation. The mean time for the second operation was 24 months (range 16-38) after initial operation.
Lee WJ, Lee KT et al (2014). Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG): short-term result and comparison with gastric bypass. Obesity Surgery 24 (1) 109-113.	Retrospective comparative case series n=50 morbid obese patients Single-loop anastomosis duodeno-jejunal bypass with sleeve gastrectomy (SADJB-SG) compared with historical data of other gastric bypass surgeries (50 RYGB, 50 MGB). Follow-up:1 year.	All procedures were completed laparoscopically. The mean operative time was 181.7 +/- 38.4 min, and the mean hospital stay was 3.8 days. Three minor early complications (6 %) were encountered but no major complication was noted. There was no significant difference in perioperative parameters between the SADJB-SG and gastric bypass except a longer operation time. The mean BMI decreased from 38.4 to 25.4 at 1 year after surgery with a mean weight loss of 32.7 % which is higher than gastric bypass. Laparoscopic SADJB-SG appears to be an ideal metabolic/bariatric surgery, whereas the efficacy is non-inferior to gastric bypass.	SADJB-SG not SADI-S. Another modified duodenal switch technique.

Appendix B: Related NICE guidance for single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity

Guidance	Recommendations
Interventional procedures	**Implantation of a duodenal–jejunal bypass sleeve for managing obesity. NICE interventional procedure guidance 471 (2013).** **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 when the facility for this is available. 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. **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. **Implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes. NICE interventional procedure guidance 518 (2015).**

	1. Recommendations Current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes is limited in quality and quantity. Therefore the procedure should only be used in the context of research. 1.2 Further research should give details of patient selection, including information about use of the procedure in patients with different levels of BMI. The research should provide information on complications; reasons for early removal of the device; medication used for treating type 2 diabetes, both when the device is in place and after its removal; and control of type 2 diabetes after device removal. NICE may update the guidance on publication of further evidence.
NICE guidelines	**Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. NICE guideline 189 (2014). Available from http://www.nice.org.uk/guidance/CG189** This guideline updates and replaces section 1.2 of NICE guideline CG43 (published December 2006). It offers evidence-based advice on the care and treatment of Obesity. New recommendations have been added about low-calorie and very-low-calorie diets, bariatric surgery and follow-up care. **1.10 Surgical interventions** 1.10.1 Bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled: • They have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight. • All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss. • The person has been receiving or will receive intensive management in a tier 3 service[10]. • The person is generally fit for anaesthesia and surgery. • The person commits to the need for long-term follow-up. See recommendations 1.10.12 and 1.10.13 for additional criteria to use when assessing children, and recommendation 1.10.7 for additional criteria for adults. See also recommendations 1.11.1–1.11.3 for additional criteria for people with type 2 diabetes. **[2006, amended 2014]** 1.10.2 The hospital specialist and/or bariatric surgeon should discuss the following with people who are severely obese if they are considering surgery to aid weight reduction: • the potential benefits • the longer-term implications of surgery • associated risks

- complications
- perioperative mortality.

The discussion should also include the person's family, as appropriate. **[2006, amended 2014]**

1.10.3 Choose the surgical intervention jointly with the person, taking into account:

- the degree of obesity
- comorbidities
- the best available evidence on effectiveness and long-term effects
- the facilities and equipment available
- the experience of the surgeon who would perform the operation. **[2006]**

1.10.4 Provide regular, specialist postoperative dietetic monitoring, including:

- information on the appropriate diet for the bariatric procedure
- monitoring of the person's micronutrient status
- information on patient support groups
- individualised nutritional supplementation, support and guidance to achieve long-term weight loss and weight maintenance. **[2006]**

1.10.5 Arrange prospective audit so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term.[11] **[2006, amended 2014]**

1.10.6 The surgeon in the multidisciplinary team should:

- have had a relevant supervised training programme
- have specialist experience in bariatric surgery
- submit data for a national clinical audit scheme.[11] **[2006, amended 2014]**

Adults

1.10.7 In addition to the criteria listed in 1.10.1, bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m^2 when other interventions have not been effective. **[2006, amended 2014]**

1.10.8 Orlistat may be used to maintain or reduce weight before surgery for people who have been recommended surgery as a first-line option, if it is considered that the waiting time for surgery is excessive. **[2006, amended 2014]**

1.10.9 Surgery for obesity should be undertaken only by a multidisciplinary team that can provide:

- preoperative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- information on the different procedures, including potential weight loss and associated risks
- regular postoperative assessment, including specialist dietetic

	and surgical follow up (see 1.12.1) • management of comorbidities • psychological support before and after surgery • information on, or access to, plastic surgery (such as apronectomy) when appropriate • access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and seating suitable for people undergoing bariatric surgery, and staff trained to use them. **[2006]** 1.10.10 Carry out a comprehensive preoperative assessment of any psychological or clinical factors that may affect adherence to postoperative care requirements (such as changes to diet) before performing surgery. **[2006, amended 2014]** 1.10.11 Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive experience because of the high rate of complications and increased mortality. **[2006]** **Children** 1.10.12 Surgical intervention is not generally recommended in children or young people. **[2006]** 1.10.13 Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity. **[2006]** 1.10.14 Surgery for obesity should be undertaken only by a multidisciplinary team that can provide paediatric expertise in: • preoperative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s) • information on the different procedures, including potential weight loss and associated risks • regular postoperative assessment, including specialist dietetic and surgical follow up • management of comorbidities • psychological support before and after surgery • information on or access to plastic surgery (such as apronectomy) when appropriate • access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and seating suitable for children and young people undergoing bariatric surgery, and staff trained to use them. **[2006]** 1.10.15 Coordinate surgical care and follow-up around the child or young person and their family's needs. Comply with the approaches outlined in the Department of Heath's A call to action on obesity in England. **[2006, amended 2014]** 1.10.16 Ensure all young people have had a comprehensive psychological, educational, family and social assessment before

undergoing bariatric surgery. **[2006, amended 2014]**

1.10.17 Perform a full medical evaluation, including genetic screening or assessment before surgery to exclude rare, treatable causes of obesity. **[2006]**

1.11 Bariatric surgery for people with recent-onset type 2 diabetes

1.11.1 Offer an expedited assessment for bariatric surgery to people with a BMI of 35 or over who have recent-onset type 2 diabetes[12] as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). **[new 2014]**

1.11.2 Consider an assessment for bariatric surgery for people with a BMI of 30–34.9 who have recent-onset type 2 diabetes[12] as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). **[new 2014]**

1.11.3 Consider an assessment for bariatric surgery for people of Asian family origin who have recent-onset type 2 diabetes[12] at a lower BMI than other populations (see recommendation 1.2.8) as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). **[new 2014]**

1.12 Follow-up care

1.12.1 Offer people who have had bariatric surgery a follow-up care package for a minimum of 2 years within the bariatric service. This should include:

- monitoring nutritional intake (including protein and vitamins) and mineral deficiencies
- monitoring for comorbidities
- medication review
- dietary and nutritional assessment, advice and support
- physical activity advice and support
- psychological support tailored to the individual
- information about professionally-led or peer-support groups. **[new 2014]**

1.12.2 After discharge from bariatric surgery service follow-up, ensure that all people are offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management. **[new 2014]**

[Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE clinical guideline 43 (2006). Available from http://www.nice.org.uk/guidance/CG43

1.2 Clinical recommendations (This section has been replaced by Obesity: Identification, assessment and management of overweight and obesity in children, young people and adults (2014) NICE guideline CG189).

	Managing overweight and obesity in adults – lifestyle weight management services. NICE public health guideline 53 (2014). Available from http://www.nice.org.uk/guidance/PH53 Guideline covers only lifestyle weight management recommendations.

Appendix C: Literature search for single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	26/10/2015	Issue 10 of 12, October 2015
HTA database (Cochrane Library)	26/10/2015	Issue 3 of 4, July 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	26/10/2015	Issue 9 of 12, September 2015
MEDLINE (Ovid)	23/10/2015	1946 to October Week 3 2015
MEDLINE In-Process (Ovid)	23/10/2015	October 22, 2015
EMBASE (Ovid)	23/10/2015	1974 to 2015 Week 42
PubMed	26/10/2015	n/a
BLIC	26/10/2015	n/a

Trial sources searched on 22 September 2015

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 22 September 2015

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 exp Obesity/

2 obes*.tw.

3 diabetes mellitus/

4	diabet*.tw.
5	or/1-4
6	gastrectomy/
7	exp bariatric surgery/
8	(bariatric adj4 surg*).tw.
9	(sleeve adj4 gastrectom*).tw.
10	or/6-9
11	exp small intestine/su
12	(duodenum adj4 (surg* or bypass*)).tw.
13	(ile* adj4 (surg* or bypass*)).tw.
14	(duodenoile* or duodeno ile*).tw.
15	11 or 12 or 13 or 14
16	single anastomos*.tw.
17	SADIS.tw.
18	SADI-S.tw.
19	(loop* adj4 DS).tw.
20	(loop adj4 duoden* adj4 switch*).tw.
21	SIPS.tw.
22	(Stomach adj4 Intestinal adj4 Pylor* adj4 Preserv* adj4 Surg*).tw.
23	(Pylor* adj4 Preserv* adj4 Surg*).tw.
24	SADJB-SG.tw.
25	sanchez-pernaute*.au.
26	or/16-25
27	10 or 15
28	5 and 26 and 27
29	animals/ not humans/
30	28 not 29