

## Interventional procedure overview of endoscopic sleeve gastroplasty for obesity

### Contents

Indications and current treatment.....	2
What the procedure involves.....	4
Evidence summary .....	4
Population and studies description.....	4
Procedure technique .....	26
Efficacy.....	26
Safety .....	31
Validity and generalisability .....	35
Related NICE guidance .....	38
Interventional procedures.....	38
Technology appraisals .....	38
NICE guidelines.....	39
Professional societies .....	39
Evidence from patients and patient organisations.....	39
Company engagement.....	40
References.....	40
Methods .....	41
Other relevant studies.....	43

**Table 1 Abbreviations**

Abbreviation	Definition
ASGE	American Society for Gastrointestinal Endoscopy
% AWL	Percentage absolute weight loss
BMI	Body mass index
CI	Confidence interval
ESG	Endoscopic sleeve gastroplasty
EWL	Excess weight loss
%EWL	Percentage excess weight loss
GERD	Gastroesophageal reflux disease
GRADE	Grading Recommendations Assessment, Development, and Evaluation
IGB	Intragastric balloons
LSG	Laparoscopic sleeve gastroplasty
MD	Mean difference
NASH	Non-alcoholic steatohepatitis
OR	Odds ratio
RCT	Randomised controlled trial
RR	Risk ratio
SD	Standard deviation
SG	Sleeve gastrectomy
% TWL	Percentage total weight loss

## Indications and current treatment

Obesity is defined as a BMI of 30 kg/m<sup>2</sup> or over. The degree of obesity is classified as obesity class 1 (BMI 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>), obesity class 2 (BMI 35 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>) and obesity class 3 (BMI 40 kg/m<sup>2</sup> or more). The [NICE guideline on obesity](#) recognises that people with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean origin are prone to central adiposity and their cardiometabolic risk occurs at a lower BMI. So a lower

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

BMI of 27.5 kg/m<sup>2</sup> or above is recommended as the threshold for obesity in these groups.

Obesity is directly linked to a number of other illnesses including type 2 diabetes, hypertension, gallstones and gastro-oesophageal reflux disease, as well as psychological and psychiatric morbidities. Weight loss reduces the risk of other significant disease worsening and improves long-term survival.

The [NICE guideline on obesity](#) recommends a multicomponent approach involving dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is recommended as a treatment option in some people who have a BMI of 40 kg/m<sup>2</sup> or more (class 3 obesity), or between 35 kg/m<sup>2</sup> and 39.9 kg/m<sup>2</sup> (class 2 obesity) and other significant disease (such as type 2 diabetes) and have not lost enough weight using other methods. It is also considered at a lower BMI than in other populations in people of Asian family origin who have recent-onset type 2 diabetes.

Surgical procedures for obesity aim to help people to lose weight and to maintain weight loss by restricting the size of the stomach, decreasing the capacity to absorb food or both. 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 SG. Procedures aimed at decreasing the capacity to absorb food include biliopancreatic diversion and duodenal switch. People are also advised to modify their eating behaviour by adhering to an explicit postoperative diet.

### Clinical unmet need

Data from the Health survey of England 2019 shows that in England 28% of adults are obese (BMI 30 kg/m<sup>2</sup> or over) and a further 36% are overweight (BMI between 25 kg/m<sup>2</sup> and 30 kg/m<sup>2</sup>). There is growing unmet need for treatment for obesity. ESG is an additional endoscopic treatment option and can be used at an earlier stage in the treatment pathway to reduce the risk of progression. There may be some subgroups of people in whom ESG is useful. These include people who:

- are considered high-risk for bariatric surgery due to age or comorbidities
- refuse bariatric surgery due to fear of the associated risks and complications
- have had a previous surgical intervention in the abdomen, making bariatric surgery technically challenging and increasing the risk of surgical complications.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

**Commented [BP1]:** As we've already said "may be" at the start of the sentence, I've changed this to "is"

**Commented [BP2]:** I've changed these to bullets because there was no hierarchy in the groups - so therefore a numbered list was necessary. We also try not to use roman numerals because they can create difficulties for people who use screen readers.

- have a lower BMI (class 1: 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>; class 2: 35 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>), for whom ESG may be useful as an earlier intervention to prevent disease progression and associated comorbidities (type 2 diabetes, non-alcoholic steatohepatitis [NASH], hypertension, cardiovascular disease).

## What the procedure involves

ESG is a minimally invasive transoral endoscopic procedure that reduces the volume of the stomach and may delay gastric emptying. The aim is to reduce the volume of the stomach by about 70% to 80%, reducing the amount of food that can be eaten at one time.

The procedure is done under general anaesthesia. It may be done as a day case, but most people are kept under observation overnight and discharged the next day. A double channel scope with a procedure-specific endoscopic device attached is passed through the mouth (transorally). A series of endoluminal full-thickness suture plications (in a U, Z, square, triangle or rectangle pattern) are done along the greater curvature of the stomach (through the gastric wall, extending from the pre-pyloric antrum to the gastroesophageal junction). This involves folding the stomach in on itself and stitching it together creating a restrictive endoscopic sleeve to reduce the stomach volume by about 70% to 80%. There is no resection of the stomach and the procedure may be reversible.

## Evidence summary

### Population and studies description

This interventional procedures overview is based on over 600,000 people from 1 RCT, 4 systematic reviews and meta-analyses, 2 cohort studies and 1 retrospective non-randomised comparative study with propensity score matched analysis. There is a significant overlap of primary studies on ESG included in 3 meta-analyses (Singh 2020, Marincola 2021 and de Miranda Neto 2020). About 12,000 people had an ESG procedure. Most of the included people had SG, about 7,000 people had LSG, about 3,000 had IGB and 110 people had only lifestyle modification. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in [figure 2](#). This overview presents 8 studies as the key evidence in [table 2](#) and [table 3](#), and lists the other 71 relevant studies in [table 5](#).

Two meta-analysis (Marincola 2021, Singh 2020) pooled data from heterogenous observational studies and done an indirect comparison between ESG and LSG or

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

**Commented [JH3]:** I get 620,669. These are the studies in table 2:

1 = 2,170  
2 = 187  
3 = 2,188  
4 = 6,775  
5 = 5,004  
6 = 612  
7 = 216  
8 = 603,517

**Commented [HG4R3]:** With numbers this big, I don't think we need to report the exact number so I have changed it to 'over 600,000'.

**Commented [JH5]:** I've queried this figure earlier in the paragraph

**Commented [JH6]:** I get 15,280:

2,170  
77  
759  
3,413  
1,979  
612  
216  
6,054

**Commented [HG7R6]:** It's about 12,000 when the duplicated studies are taken into account

**Commented [JH8]:** Study 2 had 110. I haven't checked any more of this section, as I remembered that we're supposed to only check the efficacy and safety sections.

IGB. One meta-analysis done a direct comparison between ESG and LSG (Beran 2022). Another meta-analysis assessed midterm outcomes of ESG alone (de Miranda Neto 2020). Primary studies on ESG included in these analyses were mainly observational studies and are prone to risk of bias and confounding. The quality of evidence was assessed using the objective criteria from GRADE in 1 meta-analysis (de Miranda Neto 2020) and evidence was graded as low certainty (confidence in the effect estimate is limited).

One RCT compared ESG plus a lifestyle modification programme with lifestyle modification alone and people in the control group crossed over at 52 weeks to ESG. ESG procedures were done by experienced gastroenterologists or bariatric surgeons. Double blinding was not possible in the RCT. The COVID-19 pandemic affected both primary and extended follow-up periods in ESG and control groups and limited lifestyle activities and clinical visits. Crossover ESG procedures were delayed by 1 to 6 months and the loss to follow-up rate was 16%. The study was mainly funded by the device company.

Two cohort studies (Sharaiha 2021, Bhandari 2023) reported long-term outcomes on ESG. Overall follow up ranged from 1 month to 5 years.

In a large retrospective analysis of ESG, propensity score matching was done with SG cases to mitigate potential confounding bias. Data on weight loss and adverse events are limited by short-term follow up (Gudur 2023).

Most of the people (70% to 85%) included in studies were female and between a mean age range of 33 years to 47 years. Studies included people with class 1 to class 3 obesity and comorbidities, with BMI ranging between 30 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> (mean BMI ranged between 33 kg/m<sup>2</sup> and 39 kg/m<sup>2</sup>).

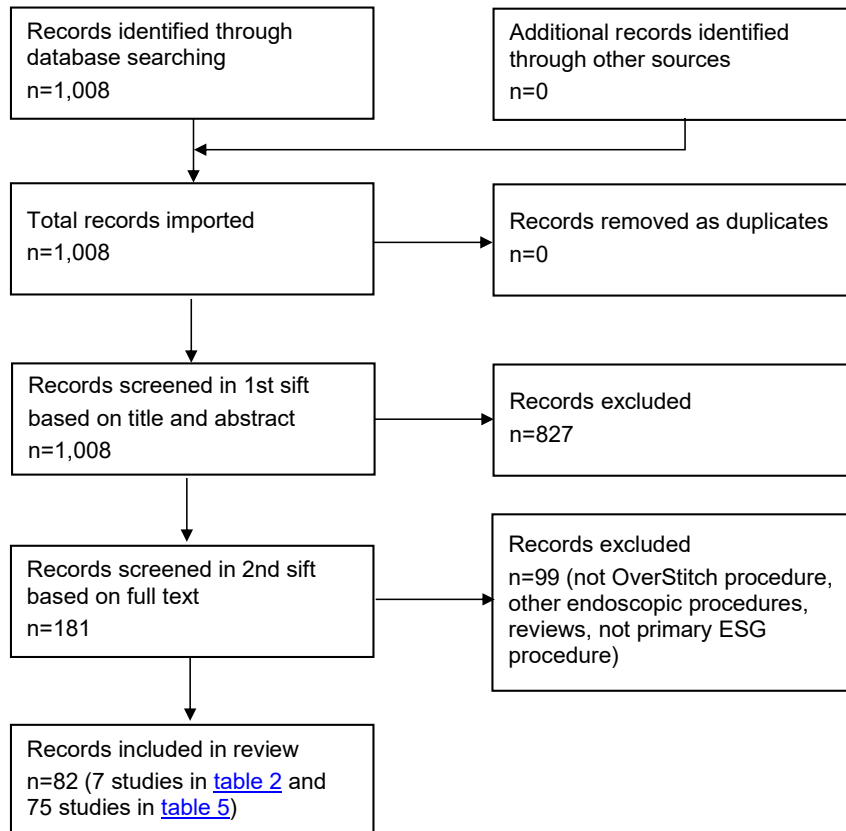
The primary outcome reported was weight loss after ESG. Weight loss was assessed as per the ASGE task force recommended threshold in studies. Studies also assessed durability of these procedures. Adverse events were classified according to the ASGE in 2 meta-analyses (Marincola 2021, de Miranda Neto 2020) and complications were graded according to Clavien-Dindo classification system in the RCT (Abu Dayyeh 2022).

Primary studies included in the meta-analyses were done in the US, Spain, Saudi Arabia, Brazil, Australia, France and India. None of the studies were done in the UK.

[Table 2](#) presents study details.

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

**Figure 2 Flow chart of study selection**

**Table 2 Study details**

Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
1	de Miranda Neto et al. (2020) Brazil	11 studies N=2,170 people with obesity or overweight. Average BMI pre-ESG was 35.78 kg/m <sup>2</sup> Average weight was 98.43 kg (95% CI 94.73 to 102.13) and 393 (18.11%) were males.	Mean age 42.3 years (95% CI 39.94 to 44.76)	Systematic review and meta-analysis	RCTs or observational studies, abstracts in English or Spanish, studies with at least 15 participants who underwent ESG with a minimum follow up of at least 1 month.	ESG alone. Procedure is done with endoscopic suturing system (OverStitch). Variations of procedure technique reported (the number of sutures used and the suturing patterns were described as 'Z' 'U', and triangular or rectangular). A layer of reinforcement sutures was reported in many studies.	Range 1 month to 18 months.
2	Abu Dayyeh BK et al.	N=187 people with class 1 and class 2 obesity.	ESG mean age 47.3 years.	RCT	People aged 21 to 65 years with class 1 or class 2 obesity	ESG (OverStitch device) plus moderate intensity	52 weeks: ESG n=68 Control n=89

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
	(2022) (MERIT trial) US	ESG (n=77) versus control (n=110)	Control mean age 45.7 years. ESG 88% female Control 84% female		who agreed to comply with lifelong dietary restrictions required by the procedure, with a BMI between 30 kg/m <sup>2</sup> and less than 40 kg/m <sup>2</sup> , with a history of failure with non-surgical weight loss methods.	lifestyle modifications (ESG group) versus lifestyle modifications alone (control group). People in the control group who did not reach more than 25% EWL and completed follow-up (n=72) crossed over and had ESG after 52 weeks and were followed up for an additional 52 weeks. Lifestyle modifications included low-calorie diet plan and physical activity counselling, which was customised.	Follow up of primary ESG group extended to 104 weeks to evaluate the durability of the original procedure or the effect of suture reinforcement in 5 individuals who had it at investigators discretion at 52 weeks. 104 weeks follow up: ESG n= 50 Control n=59

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).



Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
3	Marincola et al. (2021) Italy	16 studies N=2,188 people with obesity. LSG: 1,429; ESG: 759 Mean BMI 34.34 kg/m <sup>2</sup> and 34.72 kg/m <sup>2</sup> for LSG and ESG LSG: 1 RCT and 7 observational studies ESG: 8 observational studies 79.6% female	Mean age LSG 35.5 years, ESG 38.5 years	Systematic review and meta-analysis (pooled data from non-comparative studies, heterogenous study designs)	Studies with people with obesity who have a baseline BMI between 30 and 40 kg/m <sup>2</sup> with a minimum of 12 months of follow up and a rate of complications reported	ESG (with OverStitch device) versus LSG	12 months
4	Beran et al. (2022) US	7 studies N=6,775 people with obesity 3,413 ESG versus 3,362 LSG (5 retrospective cohort studies and 2	Mean age was 34.9 years (SD 10.2) 87% female	Systematic review and meta-analysis	Studies that performed a direct comparison between ESG and LSG in people with obesity	ESG (with OverStitch device) versus LSG	Range 6 months to 36 months

**Commented [BP9]:** We don't use the ± symbol because it causes problems for accessibility and people who use screen readers. Are these the standard error of the mean? In which case, I have added the abbreviation to the table and replaced - this is what has been done in previous IP overview docs.

**Commented [HG10R9]:** From the paper, they appear to be standard deviations but it is not actually specified. I have deleted from this section because I think it's OK to just report means.

IP overview: Endoscopic sleeve gastropasty for obesity

Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
		prospective cohort studies) Mean baseline BMI was 33.7 kg/m <sup>2</sup> (SD 4.8)					
5	Singh et al. (2020) US	28 studies N=5,004 people with obesity ESG patients n=1,979 (mean BMI 36.1 kg/m <sup>2</sup> ) IGB patients n=3,025 (mean BMI 41.7 kg/m <sup>2</sup> )	Not reported	Systematic review and meta-analysis	RCTs or observational studies in which people had IGB or ESG alone with or without lifestyle modification for obesity, studies reporting %TWL or %EWL with at least 12 months of follow up were included	IGB and ESG for the treatment of obesity 1 study compared ESG to IGB, 9 observational studies evaluated ESG alone, while 18 studies (4 RCTs and 14 observational studies) evaluated IGB	12 months
6	Bhandari et al. (2023) India	N= 612 people with obesity Mean BMI 34.30 kg/m <sup>2</sup> (SD 5.05) 69.3% (494 out of 612) female	Mean age 40.70 years (SD 12.66)	Prospective cohort study (single centre)	People with a BMI over 30 kg/m <sup>2</sup> (or over 27 kg/m <sup>2</sup> with comorbidities).	ESG for treatment of obesity; done by single surgeon Liquid diet for 2 weeks, followed by modified bariatric diet for 4 weeks	4 years 570 (93.1%), 1 year 552 (90.2%), 2 years 466 (81.7%) 3 years

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
							254 (81.9%) 4 years
7	Sharaiha et al. (2021) USA	N=216 people with obesity 68% (146 out of 216) female Mean BMI of 39.6 kg/m <sup>2</sup>	Mean age 46 years (SD 13)	Prospective cohort study	People with a BMI of over 30 kg/m <sup>2</sup> (or over 27 kg/m <sup>2</sup> with comorbidities), and failure of previous non-invasive weight loss measures including pharmacotherapy (if no change in weight for at least 3 months or if they were gaining weight) to achieve TWL of at least 5% People with a BMI of more than 40 kg/m <sup>2</sup> who refused bariatric surgery or were deemed to be high-risk surgical candidates	ESG for treatment of obesity in a single centre done by a single surgeon People restricted to a full-liquid diet for the first 2 weeks, then advanced to a modified bariatric diet for an additional 4 weeks Adjunct anti-obesity pharmacotherapy was given if no change in weight for at least 3 months or if they were gaining weight (before ESG n=78; after ESG n=58).	Up to 5 years 203, 96, and 68 people were eligible for 1-year, 3-year and 5-year follow up, respectively Data available 1 year 70% (142), 3 years 71% (68), and 5 years 82% (56)
8	Gudur (2021)	N=603,517	Unmatched analysis	Retrospective non-	Data on ESG and SG from 2016 to	ESG versus surgical SG.	30 days

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Study no.	First author, date, country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
	US	(6,054 people had ESG (6,053 in matched cohort) and 597,463 people had SG (30,270 in matched cohort) Most people were female (ESG 84.5% versus SG 79.8%; matched 82.3%). Unmatched analysis: mean BMI ESG 40.5 kg/m <sup>2</sup> versus SG 44.9 kg/m <sup>2</sup> ; matched: 42.8 kg/m <sup>2</sup>	ESG 47.5 years versus SG 44.2 years. Matched 44.9 years.	randomised comparative study and propensity score matched analysis	2020 the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database		

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

**Table 3 Study outcomes**

First author, date	Efficacy outcomes	Safety outcomes
de Miranda Neto et al. (2020)	<p><b>Pooled mean %TWL</b>                      1 month: 8.56 (95% CI 7.94 to 9.18, I<sup>2</sup>=0.3%, 5 studies, n=2,538)                      3 months: 11.65 (95% CI 10.76 to 12.53, I<sup>2</sup>=0%, 5 studies, n=2,296)                      6 months: 15.32 (95% CI 14.54 to 16.10, I<sup>2</sup>=15.3%, 9 studies, n=2,256)                      9 months: 16.15 (95% CI 14.94 to 17.37, I<sup>2</sup>=0%, 3 studies, n=948)                      12 months: 17.33 (95% CI 16.30 to 18.36, I<sup>2</sup>=10.8%, 9 studies, n=1,706)                      18 months: 16.80 (95% CI 13.02 to 20.56, I<sup>2</sup>=0%, 2 studies, n=252)                      Certainty of evidence was low for all time periods</p> <p><b>Pooled mean %EWL</b>                      1 month: 31.08 (95% CI 20.79 to 41.36, I<sup>2</sup>=0%, 3 studies, n=2,100)                      3 months: 46.13 (95% CI 38.79 to 53.47, I<sup>2</sup>=0%, 3 studies, n=1,838)                      6 months: 55.80 (95% CI 50.61 to 60.99, I<sup>2</sup>=15.09%, 6 studies, n=1,816)                      9 months: 66.20 (95% CI 57.54 to 74.86, I<sup>2</sup>=8.52%, 3 studies, n=912)                      12 months: 60.07 (95% CI 53.39 to 66.74, I<sup>2</sup>=18.09%, 6 studies, n=1,148)                      18 months: 73.04 (95% CI 58.94 to 87.14, I<sup>2</sup>=0%, 2 studies, n=252)                      Certainty of evidence was low for all time periods</p> <p><b>Pooled mean %AWL</b>                      1 month: 7.73 (95% CI 7.06 to 8.40, I<sup>2</sup>=16.82%, 3 studies, n=2,020)                      3 months: 10.23 (95% CI 8.44 to 12.03, I<sup>2</sup>=0%, 3 studies, n=1,768)</p>	<p>Procedure related mortality = 0</p> <p>Overall adverse events (graded according to the ASGE lexicon as mild, moderate and severe) = 2.3% (95% CI 1.2 to 4.1, I<sup>2</sup>=24.08%, 7 studies, n=38 events).</p> <ul style="list-style-type: none"> <li>Mild: 1.5% (95% CI 0.5 to 4.3, I<sup>2</sup>=0%, 2 studies, n=12 events)</li> <li>Moderate: 1.7% (95% CI 0.9 to 3.1, I<sup>2</sup>=8.16%, 6 studies, n=22 events)</li> <li>Severe: 0.8% (95% CI 0.3 to 2.0, I<sup>2</sup>=0%, 3 studies, n=4 events)</li> </ul> <p>Gastrointestinal bleeding (n=13) and perigastric collections (n=10) were the most common major adverse events reported. Other events included severe abdominal pain (n=8), fever (n=5), deep vein thrombosis (n=1) and pneumothorax (n=1).</p> <p>Most events were managed conservatively, but 2 people with gastrointestinal bleeding needed sclerotherapy and 3 people with</p>

Commented [BP11]: What are these two different n numbers?

Commented [HG12R11]: I've deleted the total number because it didn't make sense.

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	6 months: 14.88 (95% CI 13.33 to 16.42, I <sup>2</sup> =0%, 6 studies, n=1,730) 9 months: 15.44 (95% CI 12.70 to 18.17, I <sup>2</sup> =0%, 2 studies, n=878) 12 months: 17.32 (95% CI 15.65 to 18.99, I <sup>2</sup> =0%, 7 studies, n=1,218) 18 months: 15.95 (95% CI 10.95 to 20.95, I <sup>2</sup> =0%, 2 studies, n=252) Certainty of evidence was low for all time periods	perigastric collections needed surgical interventions (including closure of a gastric fistula and 1 reversal of ESG).  Nausea, vomiting, and mild abdominal pain were not considered as adverse events.
Abu Dayyeh et al. (2022)	<p><b>Mean %EWL at 52 weeks in primary ESG and control groups</b>                      ESG group 49.2% (SD 32.0) and 3.2% (SD 18.6) for control group-lifestyle modification programme alone (p&lt;0.0001).                      Crossover group (n=72) achieved mean 44.1% (SD 35.7) EWL at 52 weeks from crossover.                      Mean EWL of all people who had the ESG procedure (both primary ESG and crossovers) at week 52 post procedure was 46.7% (SD 33.8).                      81% (55 out of 68) of people reached the primary endpoint (25% or more EWL) at 52 weeks, compared with 72% (46 out of 64) in the crossover ESG group with 52 weeks follow up (p=0.21).</p> <p><b>Mean %TWL at 52 weeks</b>                      ESG group 13.6% (SD 8.0) and 0.8% (SD 5.0) for control group (p&lt;0.0001).                      After adjusting for age, sex, type 2 diabetes, hypertension, and baseline BMI in a modified intention to treat analysis with mixed-effects models, people in the ESG group had a MD of 44.7% (95% CI 37.5 to 51.9) EWL and 12.6% (95% CI 10.7 to 14.5) TWL, compared with the control group at 52 weeks (p &lt;0.0001 using last observation carried forward and p&lt;0.0001 using mixed-model imputations for missing data).</p> <p><b>Proportion of people with 25% or more EWL at 52 weeks</b></p>	<p><b>Primary safety endpoint at 104 weeks</b>                      5% or less device or procedure related serious adverse events (in primary and crossover ESG groups).  <b>Total adverse events:</b> n=927 events in 92% (138 out of 150)  <b>Serious adverse events: 2% (3 out of 131)</b>                      Abdominal abscess, grade 3 managed endoscopically (n=1); upper gastrointestinal bleed, managed conservatively without transfusion (n=1); malnutrition requiring endoscopic reversal of the ESG (n=1).                      ESG reversal (requested by patient) n=1  <b>Minor adverse events, 66% (612 out of 927)</b>                      Gastrointestinal symptoms including pain, heartburn, nausea, and vomiting (symptoms resolved within 1 week)</p>

Commented [BP13]: Can this be changed to SD, rather than the symbol? Taken from here: <https://www.sciencedirect.com/science/article/abs/pii/S0140673622012806>

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p>ESG group 77% (59 out of 77) versus control group 12% (13 out of 110; p&lt;0.0001).</p> <p><b>Proportion of people with 25% or more EWL at 104 weeks (in ESG group only)</b> 68% (41 out of 60); 41% EWL, 11.4% TWL.</p> <p><b>Change in at least 1 obesity comorbidity at 52 weeks</b>                      ESG group: improved in 80% (41 out of 51) and worsened in 12% (6 out of 51)                      Control group: improved in 45% (28 out of 62) and worsened in 50% (31 out of 62)</p> <p><u>Diabetes</u>                      Improved: ESG 92% (12 out of 13), control 15% (4 out of 27), MD -77.5 (10.1; 95% CI -91.4 to -47.4) p&lt;0.0001.                      Worsened: ESG 0% (0 out of 13), control 44% (12 out of 27), MD 44.4 (9.6; 95% CI 16.1 to 60.2) p=0.0041.</p> <p><u>Hypertension</u>                      Improved: ESG 67% (24 out of 36) control 40% (19 out of 48), MD -27.1 (10.6; 95% CI -46.1 to 5.5) p=0.014                      Worsened: ESG 6% (2 out of 36), control 23% (11 out of 48), MD 17.4 (7.2; 95% CI 1.5 to 30.7) p=0.029</p> <p><u>Metabolic syndrome</u>                      Improved: ESG 83% (24 out of 29), control 35% (10 out of 29), MD -48.3 (11.3; 95% CI -67.0 to -23.3) p=0.0002                      Worsened: ESG 0% (0 out of 29), control 38% (11 out of 29), MD 37.9 (9.0; 95% CI 17.2 to 53.7) p=0.0002</p>	<p>Hospital admission for management of accommodative symptoms: 4% (6 out of 150).</p>

Commented [JH14]: 12%

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p><b>Hyperlipidaemia</b>  Improved: ESG 40% (6 out of 15), control 32% (8 out of 25), MD -8.0 (15.7; 95% CI -37 to -22) p=0.61  Worsened: ESG 27% (4 out of 15), control 28% (7 out of 25), MD 1.3 (14.9; 95% CI -28 to 28) p=0.93</p> <p>Authors state that quality of life, eating behaviours, improvement in depression, and patients' satisfaction were all superior in the ESG group compared with the control group.</p>	
Marincola et al. (2021)	<p><b>Pooled mean % EWL at 12 months</b>  ESG (n=759): 62.2% (95% CI 57.8 to 66.6; I<sup>2</sup>=65.52, Tau<sup>2</sup>=24.68; Cochran's Q test p=0.005).  LSG (n=1,429): 80.32% (95% CI 68.1 to 92.5; I<sup>2</sup>=98.88, Tau<sup>2</sup>=56.62; Cochran's Q test p=0.001).</p> <p>Absolute difference=18.1% (p=0.0001)</p>	<p><b>Pooled mean peri-procedural major or minor adverse events</b>  ESG (n=1,778): 0.15% (Cochran's Q test p=0.0001, I<sup>2</sup>=42.81).  LSG (n=1,929): 0.30% (Cochran's Q test p=0.0001, I<sup>2</sup>=62.26).</p> <p>Difference in mean rate of major or minor adverse events was 0.19% (χ<sup>2</sup>=1.602, p=0.2056).</p>
Beran et al. (2022)	<p><b>Pooled %TWL (meta-analysis of 7 studies)</b>  ESG: 6 months: 15.2 (SD 6.3); 12 months 19.1 (SD 7.9); 24 months 16.4 (SD 10.1)  LSG: 6 months 18.8 (SD 7.5); 12 months 28.9 (SD 8.2); 24 months 22.3 (SD 8.3)</p> <p><b>Pooled %EWL</b></p>	<p><b>Overall adverse events</b>  <b>Pooled analysis of 7 studies</b>  ESG 0.7% (24 out of 3,250) versus LSG 1.7% (52 out of 3,104); RR 0.51; 95% CI 0.23 to 1.11; p=0.09, I<sup>2</sup>=50%.</p>

Commented [BP15]: Should this be a negative number?

Commented [HG16R15]: The paper reports is a positive number, but I agree that it should be negative.

Commented [BP17]: Changed to the word rather than the symbol because they can cause problems for accessibility.

Commented [BP18]: Is this SEM or SD? Please remove the symbol and change to "15.2 (SEM/SD 6.3)" (or whichever term is appropriate) for each use here



Commented [BP19]: As above

First author, date	Efficacy outcomes	Safety outcomes
	<p>ESG: 6 months 66.7% (SD 28.7) and 12 months 71.04% (SD 24.6)                      LSG 6 months 76.6% (SD 31.3) and 12 months 94.9% (SD 20.6)</p> <p><b>%TWL</b>                      6 months: MD -7.48 (95% CI -10.44 to -4.52; p&lt;0.0001, I<sup>2</sup> = 94%),                      7 studies (n=5,516), ESG n=2,882 versus LSG n=2,634                      12 months: MD -9.90; (95% CI -10.59 to -9.22; p&lt;0.00001, I<sup>2</sup>=9%),                      4 studies (n=5,113), ESG n=2,542 versus LSG n=2,571                      24 months: MD -7.63 (95% CI -11.31 to -3.94; p&lt;0.0001, I<sup>2</sup> = 85%),                      2 studies (n=5,260), ESG n=2,641 versus LSG n=2,619</p> <p><b>%EWL</b>                      6 months: MD -10.23 (95% CI -11.90 to -8.56; p&lt;0.00001, I<sup>2</sup>=0%),                      3 studies (n=4,884), ESG n=2,526 versus LSG n=2,358                      12 months: MD -23.99 (95% CI -25.30 to -22.68; p&lt;0.00001, I<sup>2</sup>=0%),                      2 studies (n=4,642), ESG n=2,252 versus LSG n=2,390</p> <p><b>Improvement or remission of diabetes mellitus</b>                      2 studies, LSG 81.9% (73 out of 114) versus ESG 64% (289 out of 353),                      RR 0.78, 95% CI 0.68 to 0.91, p=0.001, I<sup>2</sup>=0%</p> <p><b>Improvement or remission of hypertension</b>                      2 studies, ESG 51% (53 out of 104) versus LSG 45.6% (57 out of 125),                      RR 1.12, 95% CI 0.86 to 1.47, p=0.39, I<sup>2</sup>=0%</p>	<p><b>Pooled analysis of 6 studies</b>                      (Excluding 1 large study Alqahtani 2019, which caused significant between study heterogeneity)                      ESG 2.5% (10 out of 395) versus LSG 12.2% (42 out of 344); RR 0.39 (95% CI 0.18 to 0.83), p=0.01, I<sup>2</sup>=23%</p> <p><b>New onset GERD (2 studies)</b>                      ESG 1.3% (1 out of 77) versus LSG 17.9% (19 out of 106); RR 0.10, (95% CI 0.02–0.53), p=0.006, I<sup>2</sup>=0%</p>
Singh et al. (2020)	<p><b>ESG</b>  <b>Mean %TWL</b></p>	<p><b>ESG</b>  <b>Overall adverse events 1.52%</b></p>

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

First author, date	Efficacy outcomes	Safety outcomes
	<p>6 months: 15.34 (95% CI 14.33 to 16.35, I<sup>2</sup>=92.23, 9 studies)                      12 months: 17.51 (95% CI 16.44 to 18.58, I<sup>2</sup>=88.35, p=0.004, 9 studies)                      18 to 24 months: 17.85 (95% CI 15.85 to 19.86, I<sup>2</sup>=69.57, p=0.025, 4 studies)</p> <p><b>Mean %EWL</b>                      6 months: 55.61 (95% CI 50.28 to 60.95, I<sup>2</sup>=83.38, 6 studies)                      12 months: 60.51 (95% CI 54.39 to 66.64, I<sup>2</sup>=66.67, p=0.22, 6 studies)                      18 to 24 months: 66.77 (95% CI 57.54 to 76.00, I<sup>2</sup>=67.72, p=0.047, 4 studies)</p> <p><b>IGB</b>  <b>Mean %TWL (4 RCTs and 5 observational studies)</b>                      6 months: 12.16 (95% CI 10.37 to 13.95, I<sup>2</sup>=91.32%, 9 studies)                      12 months: 10.35 (95% CI 8.38 to 12.32, I<sup>2</sup>=89.80%, p=0.13, 9 studies)                      18 to 24 months: 6.89 (95% CI 3.78 to 10.01, I<sup>2</sup>=96.50%, p=0.003, 3 studies)</p> <p><b>Mean %EWL (2 RCTs and 13 observational studies)</b>                      6 months: 34.83 (95% CI 30.97 to 38.69, I<sup>2</sup> = 97.71%, 15 studies)                      12 months: 29.65 (95% CI 25.40 to 33.91, I<sup>2</sup>=97.51%, p=0.10, 13 studies)                      18 to 24 months: 23.88 (95% CI 17.41 to 30.33, I<sup>2</sup>=87.05%, p=0.001, 5 studies)</p>	<p>Severe abdominal pain (2.2%)                      Mild to moderate abdominal pain (50.65%)                      Nausea, managed with medications (32.31%)                      Gastrointestinal bleeding (0.61%)                      Perigastric fluid collection (0.45%)                      Perforation (0.10%)                      Post-procedure fever (0.25%)                      Pulmonary embolism and DVT (0.10%)                      Reversal of ESG (because of persistent symptoms; 0.15%, n=3).                      Mortality=0</p> <p><b>IGB</b>                      Overall adverse events in 4% of people.                      Abdominal pain (32.51%)                      Nausea (55.09%)                      Balloon hyperinflation (0.03%)                      Balloon resting in antrum (0.10%)                      Severe dehydration (0.77%)                      Esophagitis (2.33%)                      Gastrointestinal bleeding (0.21%)                      Obstruction (0.10%)                      Perforation (0.10%)</p>

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p><b>Comparative analysis</b>                      ESG achieved statistically significantly higher %TWL and %EWL than IGB.                      The difference in mean %TWL between ESG and IGB was 3.07 at 6 months (95% CI 1.46 to 4.67, p=0.002), 7.33 at 12 months (95% CI 5.22 to 9.44, p=0.0001), and 11.51 at 18 to 24 months (95% CI 5.33 to 17.69, p=0.0003).                      The difference in mean %EWL between ESG and IGB was 20.80 at 6 months (95% CI 12.50 to 29.10, p=0.0001), 30.99 at 12 months (95% CI 22.81 to 39.16, p=0.0001), and 43.78 at 18 to 24 months (95% CI 35.98 to 51.58, p=0.0001).</p>	<p>Ulcers (0.24%)                      Severe GERD (0.17%)                      Early removal of IGB because of intolerance (6%)                      Mortality (3 people; 2 due to acute gastric perforation, 1 due to cardiac arrest at 4 weeks).</p>
<p>Bhandari et al. (2023)</p>	<p><b>Mean %TWL</b>                      6 months: 12.6% (95% CI 9.28 to 19.06, p&lt;0.001) with 94% (575 out of 612) of people achieving 5% or more TWL                      1 year: 21.20% (95% CI 20.81 to 21.59, p&lt;0.001) with 98% (558) of people achieving 5% or more TWL                      2 years: 20.05% (95% CI 19.61 to 20.48, p&lt;0.001) with 93% (513) of people achieving 5% or more TWL                      3 years: 18.74% (95% CI 18.31 to 19.12, p&lt;0.001) with 91% (425) of people maintaining 5% or more TWL                      4 years: 18.19% (95% CI 17.72 to 18.57, p&lt;0.001) with 90% (229) of people maintaining 5% or more TWL                      People's %TWL at their nadir weight after ESG had a mean of 18.9% (95% CI 18.5 to 19.3). People's mean weight gain after nadir was 3.5 kg until the end of the follow-up period (95% CI 3.1 to 3.3)</p>	<p><b>Adverse events % (n)</b>                      Post-operative complications included:                      Nausea 35.45% (217)                      Vomiting 17.6% (108)                      Bloating 12.25% (75)                      Abdominal pain 46.6% (284)                      Generalised weakness 2.6% (16)</p> <p><b>Revision or redo surgery</b>                      0.3% (2) of people underwent revision to SG after 12 months of primary ESG, due to weight regain.                      0.4% (3) of people had reversal redo-ESG</p>

**Commented [JH20]:** This is an error: it should say 18.19%, according to the efficacy section (and supported by the CI values)

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p><b>Mean %EWL</b>                      1-year 56.9% (95% CI 56.51 to 57.30, p&lt;0.001) with 90% (513) of people achieved 25% or more EWL                      2 years, 54.4% (95% CI 54.03 to 54.80, p&lt;0.001) with 442 and 80% of people maintained 25% or more EWL                      3 years, 50.1% (95% CI 49.71 to 50.08, p&lt;0.001) with 327 and 70% (327) of people maintained 25% or more EWL                      4 years, 49.3% (95% CI 48.91 to 49.68, p&lt;0.001) with 70% (177) of people maintained 25% or more EWL                      People's %EWL at their nadir weight after ESG had a mean of 57.2% (95% CI 56.8 to 57.5)</p> <p>Mean duration of surgery was 61.96 minutes (SD 2.1; range 45.2 to 121.1) and hospital length of stay was 3 days (range 2 to 4 days)</p> <p><b>Resolution or improvement of comorbidities within 90 days</b>                      Diabetes 51.2% (121 out of 236)                      Hypertension 65.8% (216 out of 328)                      Dyslipidaemia 73.6% (302 out of 410)                      Obstructive sleep apnoea 89.9% (401 out of 446)</p>	
Sharaiha 2021	<p><b>Mean %TWL</b>                      1 year: 15.6% (95% CI 14.1 to 17.1; p&lt;0.001)                      3 years: 14.9% (95% CI 12.1 to 17.7; p&lt;0.001)                      5 years: 15.9% (95% CI 11.7 to 20.5; p&lt;0.001)                      At nadir weight: 16.7% (95% CI 15.6 to 17.7, p&lt;0.0001)</p>	<p><b>Mild adverse events</b> in 32% of people.                      Heartburn (up to 3 weeks) 25% (n=54)                      Nausea or vomiting (managed with medications) 25% (n=43)</p>

**Commented [BP21]:** Is this SEM or SD ? Please change format to "61.96 (SEM 2.1 minutes; range 45.2 to 121.1)" or "...(SD 2.1 minutes..." as appropriate

**Commented [JH22]:** Should this be Sharaiha?

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p><b>Percentage of people achieving 5% or more TWL</b>  1 year: 89% (n=118)  3 years: 85% (n=50)  5 years: 90% (n=28)  At nadir weight: 96% (207 out of 216)</p> <p><b>Percentage of people achieving 10% or more TWL</b>  1 year: 77% (n=103)  3 years: 63% (n=37)  5 years: 61% (n=19)  At nadir weight: 80% (172 out of 216)</p> <p><b>Mean weight gain after ESG</b>  2.9 kg from nadir until the end of the follow-up period (95% CI 2.3 to 3.7)</p> <p><b>Mean EWL</b>  1 year: 47.9% (95% CI 42.4 to 53.3; p&lt;0.001)  3 years: 45.1% (95% CI 34.9 to 55.2; p&lt;0.001)  5 years: 45.3% (95% CI 32.9 to 57.7; p&lt;0.001)  At nadir weight: 53.5% (95% CI, 49.1 to 57.9, p value not reported).</p> <p><b>Percentage of people achieving 25% EWL</b>  1 year: 80%  3 years: 68%</p>	<p>Epigastric pain (beyond 24 hours, managed with medications) 31% (n=65)  Constipation (managed with laxatives) 29% (n=63)  Superficial oesophageal tear (from the over tube with the device, managed endoscopically) n=1  Asymmetric paraesthesia n=1  Spinal white-matter plaques and low serum thiamine (vitamin B1) n=1</p> <p><b>Moderate adverse events 1.3% (n=3)</b>  Pain, n=1 (in left upper quadrant 18 months after ESG, scan showed sutures with bridging fibrosis bands. ESG sutures were released leading to increased gastric volume and improvement in pain)  Perigastric leak n=2 (after dietary indiscretion, managed with antibiotics and percutaneous drainage in 1)  Bariatric surgery or SG (for inadequate weight loss) 1% (n=2).</p> <p><b>Revision procedures</b></p>

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

First author, date	Efficacy outcomes	Safety outcomes
	<p>5 years: 74%</p> <p><b>Adjunct pharmacotherapy</b> (in 58 cases with TWL of 5% or more and weight regain at a median 5 months) Adjunct pharmacotherapy was not associated with a significant difference in mean TWL compared with people who did not have it. Weight stabilised but no additional weight loss noted.</p> <p><b>Repeat ESG in those with weight regain (n=13 with mean 2.6 kg weight regain)</b> Average TBWL of 21.5% before second ESG was stabilized at 24.2% at 1 year after the second ESG.</p> <p><b>Predictors of TWL</b> The amount of weight loss at 1 month after the procedure, patient's compliance with follow up, and endoscopist's experience are independent predictors of weight loss.</p>	<p>Repeat ESG (for mean 2.6 kg weight gain) 6% (13 out of 216). Average TWL after 1 year was 24.2%. Laparoscopic SG (due to inadequate weight loss after ESG) 1% (n=2)</p>
Gudur 2023	<p><b>Mean% TWL within 30 days follow up (propensity score matched cohort)</b></p> <p>ESG 4.0% (SD 6.7) versus SG 5.4% (SD 4.3); p&lt;0.001.</p> <p><b>Mean change in BMI from pre-operative to post-operative</b> ESG -1.77 kg/m<sup>2</sup> (SD 2.89) versus SG -2.36 kg/m<sup>2</sup> (SD 1.78); p&lt; 0.001</p>	<p><b>Overall adverse events</b> SG 1.1% (340 out of 30,270) versus ESG 1.4% (86 out of 6,053); p=0.058</p> <p><b>Factors impacting adverse events</b> Propensity score matched analysis demonstrated that black ethnicity associated with a higher risk of adverse events in SG compared with ESG (OR, 1.23; 95% CI, 1.13 to 1.35). Multivariate regression noted that people with a</p>

**Commented [BP23]:** Is TBWL different to TWL? If not, please change TBWL to TWL throughout. If it is different, please add it to the abbreviations table at the top of the document.

**Commented [BP24]:** Please add the range in brackets with the appropriate acronym (e.g., SD or SEM etc.)

**Commented [BP25]:** As above

**Commented [BP26]:** Please add in brackets as above

**Commented [BP27]:** And again

IP overview: Endoscopic sleeve gastroplasty for obesity

First author, date	Efficacy outcomes	Safety outcomes
	<p><b>Procedure time</b> ESG 62.9 minutes versus SG 72.4 minutes, p&lt;0.001.</p> <p><b>Length of stay</b> ESG 0.87 days versus SG 1.45 days, p&lt;0.001.</p>	<p>higher BMI were less likely to have an adverse event after ESG.</p> <p>In the ESG cohort, albumin, BMI, renal insufficiency, age, therapeutic anticoagulation, non-insulin-dependent diabetes, chronic steroid use, and female gender were statistically significant patient factors. These variables were also associated with adverse events in the SG cohort. Additional variables associated with adverse events in the SG cohort were GERD, insulin-dependent diabetes, previous surgery, hypertension, black ethnicity, history of pulmonary embolism, previous cardiac surgery, independent preoperative functional status, sleep apnoea, smoking, history of myocardial infarction, chronic obstructive pulmonary disease, dialysis, and hyperlipidaemia</p> <p><b>Readmission within 30 days</b> ESG 3.8% (231 out of 6,053) versus SG 2.6% (794 out of 30,270); p&lt;0.001</p> <p><u>Causes of readmission for ESG</u> Nausea, vomiting, fluid or electrolyte disturbance 26% (n=72) Abdominal pain 17% (n=47)</p>

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

First author, date	Efficacy outcomes	Safety outcomes
		<p>Gastrointestinal leak 6% (n=16)                      Gastrointestinal bleeding 5% (n=15)</p> <p><u>Causes of readmission for SG</u>                      Nausea, vomiting, fluid or electrolyte disturbance 31% (n=5,686)                      Abdominal pain 12% (n=2,097)                      Gastrointestinal leak 6% (n=1,063)</p> <p><b>Reoperation within 30 days</b>                      ESG 1.4% (86 out of 6,053) versus SG 0.8% (238 out of 30,270), p&lt;0.001</p> <p><u>Main causes of reoperation for ESG</u>                      Abdominal re-exploration 13% (n=10),                      Obstruction or GI perforation or pain 10%</p> <p><u>Main causes of reoperation for SG</u>                      Abdominal re-exploration 27% (n=1,315)                      Gastrointestinal bleeding 25% (n=1,217)                      Staple line leak 15% (n=1,217)</p> <p><b>Reintervention within 30 days</b>                      ESG 2.8% (171 out of 6,053) versus SG 0.7% (209 out of 30,270); p&lt;0.001.</p>

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).



First author, date	Efficacy outcomes	Safety outcomes
		<p data-bbox="1100 456 1518 505"><u>Common endoscopic interventions after ESG</u></p> <p data-bbox="1100 513 1518 594">Therapeutic endoscopy (was mainly for stent placement or dilatation) ESG 48% (n=52) versus SG 32% (n=1,714)</p> <p data-bbox="1100 634 1518 716"><b>Treatment for dehydration</b> ESG 2.4% (147 out of 6,053) versus 3.3% (993 out of 30,270); p=0.001</p> <p data-bbox="1100 756 1518 837"><b>Emergency visit with no admission</b> ESG 4.9% (294 out of 6,053) versus 5.9% (1,786 out of 30,270); p=0.002.</p>

## Procedure technique

ESG procedures were done with an endoscopic suturing system (OverStitch) and authors of the meta-analyses reported that the procedure technique varied across included primary studies. The differences reported were the variable number of sutures used, the suturing patterns ('Z', 'U,' or triangular, rectangular or square patterns, in running or interrupted fashion) and a layer of reinforcement sutures.

## Efficacy

### Weight loss

#### Percentage total weight loss

##### ESG alone

In a systematic review and meta-analysis of 11 studies (with 2,170 people who had ESG), the pooled mean %TWL at 1 month was 8.56 (95% CI 7.94 to 9.18,  $I^2=0.3%$ , 5 studies), at 3 months was 11.65 (95% CI 10.76 to 12.53,  $I^2=0%$ , 5 studies), at 6 months was 15.32 (95% CI 14.54 to 16.10,  $I^2=15.3%$ , 9 studies), at 9 months was 16.15 (95% CI 14.94 to 17.37,  $I^2=0%$ , 3 studies), at 12 months was 17.33 (95% CI 16.30 to 18.36,  $I^2=10.8%$ , 9 studies), and at 18 months was 16.80 (95% CI 13.02 to 20.56,  $I^2=0%$ , 2 studies). [The certainty of evidence was low] (de Miranda Neto 2020).

In a [systematic review] and meta-analysis of 28 studies on endobariatric therapies with a follow up of at least 12 months, meta-analysis of 9 studies on ESG alone (with a mean BMI of 36.1 kg/m<sup>2</sup>) reported that the pooled mean %TWL at 6 months, 12 months and between 18 months and 24 months follow-up was 15.34, 17.51 and 17.85. Pooled analysis of IGB alone studies showed that mean %TWL at 12 months was 10.35. This was significantly decreased at between 18 months and 24 months (6.89) indicating weight regain after IGB removal. An

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Commented [JH28]: I couldn't find this stated in table 3

Commented [HG29R28]: I have added to T3

Commented [JH30]: 'Systematic review and meta-analysis', according to table 2

Commented [JH31]: I haven't seen this in either table

Commented [HG32R31]: I have added mean BMIs to table 2

Commented [JH33]: I haven't seen this in either table

indirect comparison of ESG to IGB (non-comparative studies) showed that ESG achieved significantly superior weight loss (difference in mean %TWL was 3.07 at 6 months, 7.33 at 12 months [ $p=0.0001$ ], and 11.51 at between 18 months and 24 months; Singh 2020).

In a prospective cohort study of 612 people who had ESG for treatment of obesity, the mean %TWL was 18.19 (95% CI 17.72 to 18.57) with 90% of participants maintaining a percentage of total weight loss of 5% or more (Bhandari 2023).

In a prospective cohort study of 216 people with mean BMI of 39.6 kg/m<sup>2</sup>, who had ESG, mean %TWL was 15.6 (95% CI 14.1 to 17.1;  $p<0.001$ ) at 1 year with 89% and 77% of people achieving 5% or more and 10% or more TWL, respectively. At 3 years mean TWL was 14.9% (95% CI 12.1 to 17.7;  $p<0.001$ ) and 85% and 63% of people maintained 5% or more and 10% or more TWL, respectively. At 5 years mean TWL was 15.9% (95% CI 11.7 to 20.5;  $p<0.001$ ) and 90% and 61% of people maintained 5% or more and 10% or more TWL, respectively. Mean %TWL at nadir weight was 16.7 (95% CI 15.6 to 17.7,  $p<0.0001$ ; Sharaiha 2023).

### ESG plus lifestyle modification versus lifestyle modification alone

In a multicentre RCT (MERIT trial) of 187 people with class 1 or 2 obesity comparing ESG plus intensive lifestyle modification ( $n=77$ ) with intensive lifestyle modification alone ( $n=110$ ) at 52 weeks, the %TWL was 13.6 for the ESG group and 0.8 for the control group ( $p<0.0001$ ; Abu Dayyeh 2022).

### ESG versus LSG

A meta-analysis of 7 studies (6,775 people) that directly compared ESG ( $n=3,413$ ) with LSG ( $n=3,362$ ) reported that there were significant differences in %TWL at 6 months (MD -7.48; 95% CI -10.44 to -4.52;  $p<0.00001$ ), 12 months

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Commented [JH34]: Can't find

Commented [HG35R34]: I have added to table 3

Commented [JH36]: Can't find

Commented [HG37R36]: I have added to T3

Commented [JH38]: Or greater,  $\geq$  according to table 3

Commented [BP39]: Is this different to total weight loss? If not, please change TBWL to TWL throughout for consistency. If it is different, please add TBWL to the abbreviations table at the top.

Commented [JH40]: Or greater,  $\geq$  according to table 3

Commented [JH41]: Or greater,  $\geq$  according to table 3

Commented [JH42]: According to table 3

Commented [JH43]: It doesn't say this in table 3; it just says MD

(MD -9.90; 95% CI -10.59 to -9.22;  $p < 0.00001$ ), and 24 months (MD -7.63; 95% CI -11.31 to -3.94;  $p < 0.0001$ ) showing superiority of LSG over ESG (Beran 2022).

### ESG versus SG

In a propensity score matched analysis of 6,054 people who had ESG and 30,270 people who had SG, mean %TWL was higher in the SG group compared with ESG group (5.4 versus 4.0,  $p < 0.001$ ). A greater mean reduction in BMI within the initial 30 days after the procedure was also reported in the SG group compared with ESG group, (-2.36 versus -1.77,  $p < 0.001$ ) (Gudur 2023).

Commented [JH44]: Table 2 says 597,463

### Percentage excess weight loss

#### ESG alone

In the systematic review and meta-analysis of 11 studies (with 2,170 people who had ESG), the pooled mean %EWL at 1 month was 31.08 (95% CI 20.79 to 41.36,  $I^2 = 0\%$ , 3 studies), at 3 months was 46.13 (95% CI 38.79 to 53.47,  $I^2 = 0\%$ , 3 studies), at 6 months was 55.80 (95% CI 50.61 to 60.99,  $I^2 = 15.09\%$ , 6 studies), at 9 months was 66.20 (95% CI 57.54 to 74.86,  $I^2 = 8.52\%$ , 3 studies), at 12 months was 60.07 (95% CI 53.39 to 66.74,  $I^2 = 18.09\%$ , 6 studies), and at 18 months was 73.04 (95% CI 58.94 to 87.14,  $I^2 = 0\%$ , 2 studies). The certainty of evidence was low (de Miranda Neto 2020).

Commented [JH45]: I haven't seen this

Commented [HG46R45]: Added to T3

In a prospective cohort study of 612 people who had ESG for treatment of obesity (mean BMI 34.30 kg/m<sup>2</sup>), mean %EWL was 49.30 (95% CI 48.91 to 49.68) with 70% of people maintaining an EWL of 25% or more at 4 years (Bhandari 2023).

In the prospective study of 216 people who had ESG, at 1 year mean EWL was 47.9% (95% CI 42.4 to 53.3;  $p < 0.001$ ) with 80% of people achieving 25% EWL. At 3 years, mean EWL was 45.1% (95% CI 34.9 to 55.2;  $p < 0.001$ ) and 68% of

people maintained 25% EWL. At 5 years, mean EWL was 45.3% (95% CI 32.9 to 57.7;  $p < 0.001$ ) and 74% of people maintained 25% EWL. Mean EWL at nadir weight was 53.5% (95% CI 49.1 to 57.9,  $p$  value not reported; Sharaiha 2023).

### ESG plus lifestyle modification versus lifestyle modification alone

In the multicentre RCT (MERIT trial) of 187 people with class 1 or 2 obesity comparing ESG plus intensive lifestyle modification ( $n=77$ ) with intensive lifestyle modification alone ( $n=110$ ) at 52 weeks, the mean %EWL (primary endpoint) was 49.2 for the ESG group and 3.2 for the control group ( $p < 0.0001$ ). Additionally, 77% (59 out of 77) of people in the ESG group achieved 25% or more %EWL at 52 weeks compared with 12% (13 out of 110) in the control group ( $p < 0.0001$ ). The crossover ESG group ( $n=72$ ) achieved a mean 44.1% EWL at 52 weeks from crossover. The mean %EWL of all participants who underwent the ESG procedure (both primary ESG and crossovers) at week 52 post procedure was 46.7%. A %EWL of 25% or more was maintained in 68% (41 out of 60) people in the ESG group at 104 weeks. In the primary ESG group, 81% (55 out of 68) of people reached the primary endpoint (25% or more EWL) at 52 weeks, compared with 72% (46 out of 64) in the crossover ESG group with a similar follow-up period ( $p=0.21$ , no statistically significant difference; Abu Dayyeh 2022).

### ESG versus LSG

In a systematic review and meta-analysis of 16 studies comparing ESG with LSG, the mean %EWL was 80.3 (95% CI 68.1 to 92.5;  $p=0.001$ ;  $I^2=98.9\%$ ,  $\text{Tau}^2=56.62$ ) for the LSG group and 62.2 (CI 57.8 to 66.6;  $p=0.005$ ;  $I^2=65.52$ ,  $\text{Tau}^2=24.68$ ) for the ESG group, corresponding to an absolute difference of 18.1% ( $p=0.0001$ ; Marincola 2021).

A meta-analysis of 7 studies (with 6,775 people) that directly compared ESG ( $n=3,413$ ) with LSG ( $n=3,362$ ) reported that there significant differences in EWL% at 6 months (MD  $-10.23$ ; 95% CI  $-11.90$  to  $-8.56$ ;  $p < 0.00001$ ;  $I^2=0\%$ , 3 studies)  
IP overview: Endoscopic sleeve gastroplasty for obesity

Commented [JH47]: '25% or more', according to table 3

Commented [JH48]: Table 3 says 55

Commented [JH49]: Not written in table 3

Commented [HG50R49]: Added to T3

Commented [JH51]: Not written in table 3

Commented [HG52R51]: Added to T3

Commented [JH53]: Not written (unless it's the  $p$  value in table 3, which is  $p=0.001$ )

Commented [HG54R53]: Added to T3

and at 12 months (MD  $-23.99$ ; 95% CI  $-25.30$  to  $-22.68$ ;  $p < 0.00001$ ;  $I^2 = 0\%$ , 2 studies) showing superiority of LSG over ESG (Beran 2022).

### ESG versus IGB

In the systematic review of 28 studies on endobariatric therapies with at least 12 months follow up, overall pooled mean %EWL after ESG alone (in 9 studies) was 55.6 at 6 months, 60.5 at 12 months, and 66.8 between 18 months to 24 months. Weight loss slightly increased at 12 months and 24 months compared with 6 months. Pooled analysis of IGB alone studies showed that mean %EWL was 34.8 at 6 months (15 studies) and 29.7 at 12 months (13 studies). This significantly decreased at 18 months or 24 months (%EWL 23.9,  $p = 0.001$ , 5 studies) indicating weight regain after IGB removal. An indirect comparison of ESG to IGB, showed that ESG achieved significantly superior weight loss (the difference in mean %EWL at 6 months, 12 months, and 18 months to 24 months was 20.8, 31.0, and 43.8, respectively; Singh 2020).

Commented [JH55]: This isn't needed; it already appears at the end of this paragraph.

(or, alternatively, a new paragraph is needed after the citation).

Commented [JH56]: Can't find

Commented [HG57R56]: Added to T3

### Percentage absolute weight loss

#### ESG alone

In the systematic review and meta-analysis of 11 studies (with 2,170 people who had ESG), the pooled mean AWL at 1 month was 7.73 kg (95% CI 7.06 to 8.40,  $I^2 = 16.82\%$ , 3 studies), at 3 months was 10.23 kg (95% CI 8.44 to 12.03,  $I^2 = 0\%$ , 3 studies), at 6 months was 14.88 kg (95% CI 13.33 to 16.42,  $I^2 = 0\%$ , 6 studies), at 9 months was 15.44 kg (95% CI 12.70 to 18.17,  $I^2 = 0\%$ , 2 studies), at 12 months was 17.32 kg (95% CI 15.65 to 18.99,  $I^2 = 0\%$ , 7 studies), and at 18 months was 15.95 kg (95% CI 10.95 to 20.95,  $I^2 = 0\%$ , 2 studies). The certainty of evidence was low (de Miranda Neto 2020).

Commented [JH58]: I haven't seen this in table 3

Commented [HG59R58]: Now added

### Improvement in comorbidities

#### ESG alone

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

In a prospective cohort study of 612 people who had ESG for treatment of obesity, resolution or improvement of comorbidities was reported in 51% cases of diabetes, 66% cases of hypertension, 74% cases of dyslipidaemia and 90% of people with obstructive sleep apnoea (Bhandari 2023).

### **ESG plus lifestyle modification versus lifestyle modification alone**

In the multicentre RCT (MERIT trial) of 187 people with class 1 or 2 obesity comparing ESG plus intensive lifestyle modification (n=77) with intensive lifestyle modification alone (n=110) at 52 weeks, 80% (41 out of 51) of people in the ESG group had improvement in 1 or more metabolic comorbidities, while 12% (6 out of 51) worsened. 45% (28 out of 62) of people in the control group showed improvement, while 50% (31 out of 62) worsened (Abu Dayyeh 2022).

### **ESG versus LSG**

A meta-analysis of 7 studies (with 6,775 people) that directly compared ESG (n=3,413) with LSG (n=3,362) reported that the improvement or remission of diabetes mellitus was significantly higher with LSG compared with ESG (82% versus 64% respectively; RR 0.78, 95% CI 0.68 to 0.91, p=0.001, I<sup>2</sup>=0%). The improvement or remission of hypertension was similar between the ESG and LSG groups (51% versus 46% respectively; RR 1.12, 95% CI 0.86 to 1.47, p=0.39, I<sup>2</sup>=0%; Beran 2022).

## **Safety**

### **Adverse events**

#### **ESG alone**

In a systematic review and meta-analysis of 11 studies, the overall pooled rate of adverse events was 2.3% (95% CI 1.2 to 4.1, I<sup>2</sup>=24%, 7 studies). Of these, a rate of 1.5% (95% CI 0.5 to 4.3, I<sup>2</sup>=0%, 2 studies) for mild, 1.7% (95% CI 0.9 to 3.1,

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Commented [JH60]: Table 3 says n=3,698

Commented [HG61R60]: The denominators don't make sense, so I have deleted them and just left the rates with 95% CIs.

Commented [JH62]: Table 3 says n=2,050

Commented [JH63]: Table 3 says n=3,232

$I^2=8.16\%$ , 6 studies) for moderate, and  $0.8\%$  (95% CI 0.3 to 2.0,  $I^2=0\%$ , 3 studies) for severe adverse events was observed. No procedure-related mortality was reported in any of the included studies. The most common major adverse events were gastrointestinal bleeding ( $n=13$ ) and perigastric fluid collection ( $n=10$ ). Most events were managed conservatively, but 2 of the gastrointestinal bleeding cases needed sclerotherapy, and 3 of the cases with perigastric fluid collection needed surgical interventions. These included 1 person who developed a gastric fistula, which needed closure and reversal of the ESG. Other adverse events included severe abdominal pain ( $n=8$ ), fever ( $n=5$ ), deep vein thrombosis ( $n=1$ ) and pneumothorax ( $n=1$ ) (de Miranda Neto 2020).

Commented [JH64]: Table 3 says  $n=1,108$

The prospective cohort study of 612 people reported post-operative complications such as nausea in 36% (217) of people, vomiting in 18% (108), bloating in 12% (75), abdominal pain in 47% (284) and generalised weakness in 3% (16) of people (Bhandari 2023).

Commented [JH65]: Not found in table 3

Commented [HG66R65]: Now added

The prospective study of 216 people reported moderate adverse event rate of 1% ( $n=3$ ). These events included pain at sutures after 18 months (managed by releasing suture lines to increase gastric volume); 2 cases of perigastric leak (after dietary indiscretion, managed with antibiotics, and percutaneous drainage in 1 case). Minor adverse events reported include nausea or vomiting (managed with medications) in 25% ( $n=43$ ), epigastric pain (beyond 24 hours, managed with medicines) in 31% ( $n=65$ ), constipation (managed with laxatives) in 29% ( $n=63$ ), superficial oesophageal tear in 1 (from the device; managed endoscopically), asymmetric paraesthesia in 1, and thiamine deficiency in 1. SG (for inadequate weight loss) was reported in 1% ( $n=2$ ) of people (Sharaiha 2023).

Commented [JH67]: 12.3 (rounded up from 12.25)

Commented [HG68R67]: Changed to whole number

### ESG plus lifestyle modification versus lifestyle modification alone

A multicentre RCT (MERIT trial) of 187 people with class 1 or 2 obesity comparing ESG plus intensive lifestyle modification ( $n=77$ ) with intensive lifestyle

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).



modification alone (n=110) and a crossover to ESG at 12 months for those people not losing 25% of EBW (n=72) reported serious adverse events in 2% (3 out of 131) of people at 104 weeks follow up. These include abdominal abscess, managed endoscopically; upper gastrointestinal bleed, managed conservatively without transfusion; and a case of malnutrition requiring endoscopic reversal of the ESG. 927 events were reported in 93% (138 out of 150) of people in the primary and crossover ESG group. 66% (612 out of 927) of reported adverse events were gastrointestinal symptoms, including pain, heartburn, nausea, and vomiting. Most of these symptoms resolved within 1 week (Abu Dayyeh 2022).

### ESG versus LSG

In a systematic review and meta-analysis of 16 studies comparing ESG with LSG, the pooled mean periprocedural complication rate in the ESG group was 0.15% (Cochran's Q test p=0.0001), with a moderate grade of heterogeneity ( $I^2=42.81$ ). The pooled mean periprocedural complication rate in the LSG group was 0.30% (Cochran's Q test p=0.0001), with a moderate grade of heterogeneity ( $I^2=62.26$ ). The difference in mean rate of adverse events was 0.19% (between study heterogeneity  $\chi^2=1.602$ ; p=0.2056; Marincola 2021).

In the meta-analysis of 7 studies (with 6,775 people) that directly compared ESG (n=3,413) with LSG (n=3,362), there was a lower rate of adverse events with ESG compared with LSG, but this was not statistically significant (RR 0.51, 95% CI 0.23 to 1.11, p=0.09). The rate of new-onset GERD was significantly lower after ESG compared with LSG, 1.3% versus 17.9% respectively (RR 0.10, 95% CI 0.02 to 0.53, p=0.006; Beran 2022).

### ESG versus IGB

In a systematic review of 28 studies on endobariatric therapies with at least 12 months of follow up, 9 studies on ESG reported severe abdominal pain in 2.2% of people, mild to moderate abdominal pain in 51% of people, and nausea

Commented [JH69]: Table 3 says 92% (138/150)

Commented [HG70R69]: amended

Commented [JH71]: Table 3 says 0.11%

Commented [HG72R71]: Amended T3

Commented [JH73]: Table 3 says 0.9%

Commented [HG74R73]: Amended T3

in 32% of people. Reversal of ESG because of persistent symptoms was needed in 0.15% (3) of people. Serious adverse events included gastrointestinal bleeding (0.61%), perigastric fluid collection (0.45%), perforation (0.10%), post-procedure fever (0.25%), and pulmonary embolism and DVT (0.10%). Overall, these adverse events were seen in 1.5% of people. No deaths associated with the procedure were reported (Singh 2020).

In studies with IGB, adverse events were reported in 4% of people. These include abdominal pain (32.5%), nausea (55.1%), balloon hyperinflation (0.03%), balloon resting in antrum (0.10%), severe dehydration (0.77%), esophagitis (2.3%), gastrointestinal bleeding (0.2%), obstruction (0.1%), perforation (0.1%), ulcers (0.2%), and severe GERD (0.2%). Early removal of IGB because of intolerance was reported in 6% of people. Mortality was reported in 3 people. Two deaths were due to acute gastric perforation, and 1 due to cardiac arrest at 4 weeks (Singh 2020).

### ESG versus SG

A propensity score matched analysis of 6,054 people who had ESG and 30,270 people who had SG reported that adverse events were low and there was no significant difference in major adverse events between the groups within 30 days follow up (1.4% versus 1.1%,  $p=0.058$ ). People in the ESG group had more readmissions (3.8% versus 2.6%), reoperations (1.4% versus 0.8%), and reinterventions (2.8% versus 0.7%) within 30 days compared with the SG group ( $p<0.001$ ). In the ESG group, readmission was mainly because of nausea, vomiting, fluid or electrolyte disturbance (26%), abdominal pain (17%), gastrointestinal leak (6%), or gastrointestinal bleeding (5%). In the SG group, readmission was due to nausea, vomiting, fluid or electrolyte disturbance (31%), abdominal pain (12%), or gastrointestinal leak (6%). The most commonly performed reoperation after both ESG and SG was abdominal re-exploration. The most common reason for reoperation after ESG was suspicion for obstruction or

IP overview: Endoscopic sleeve gastropasty for obesity

**Commented [JH75]:** The table only says that the nausea was managed with medications (it doesn't say that the abdominal pain was).

**Commented [JH76]:** Table 2 says 597,463

**Commented [HG77R76]:** 597,463 is the total number, 30,270 is the number in the matched cohort

**Commented [JH78]:** Table 3 says  $p=0.05$

**Commented [HG79R78]:** Amended T3

**Commented [JH80]:** Not sure that this is needed, as all reasons for readmission have been listed.

**Commented [JH81]:** In table 3, this word is missing for SG

**Commented [HG82R81]:** Amended T3

**Commented [JH83]:** 'The next most common reason'?

(The most common reason is abdominal re-exploration)

**Commented [HG84R83]:** I think abdominal re-exploration includes reoperation.

gastrointestinal perforation, whereas gastrointestinal bleeding and staple line leak were the most common reasons after SG. Therapeutic endoscopy was the most common reintervention after ESG (48%) and SG (32%), with stent placement or dilatation representing the most common endoscopic interventions. Black ethnicity was associated with a higher risk of adverse events in SG compared with ESG (OR 1.23; 95% CI 1.13 to 1.35; Gudur 2023).

Commented [JH85]: 'next'? (the most common reason was abdominal re-exploration)

### **Anecdotal and theoretical adverse events**

Expert advice was sought from consultants who have been nominated or ratified by their professional society or Royal College. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might occur, even if they had never happened (theoretical).

They listed the following anecdotal adverse events:

- gallbladder problems (full thickness suture placed into gallbladder) requiring successful cholecystectomy
- abdominal abscess.

They listed future bariatric surgery being more complex as a theoretical adverse event.

Six professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the [specialist advice questionnaires for this procedure](#).

### **Validity and generalisability**

- In this overview we only considered studies on ESG (in which stomach capacity is reduced by making full-thickness sutures along the greater

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

curvature using the OverStitch endoscopic suturing system) as a primary obesity procedure.

- All other ESG techniques (Primary obesity surgery endoluminal [POSE™], Endoscopic sutured gastroplasty [E-ESG, Endomina system], Endoluminal vertical gastroplasty [EVG], Transoral gastric volume reduction [TGVR- sequel of EVG], Transoral vertical gastroplasty [TOGA], Articulating circular endoscopic stapler [ACE], Endozip) are not considered in this evidence summary as 2 of these procedures (POSE and E-ESG) are not undertaken in the NHS and the remaining systems are not currently available for commercial use in the UK.
- Evidence on ESG performed after other treatments is also not considered in this overview.
- Most of the studies included people with obesity (a BMI between 30 to 39.9 kg/m<sup>2</sup>), those with a history of failure with non-surgical weight loss treatments, those refused to undergo bariatric surgery or not eligible or considered to be at high risk of surgery. Therefore, the indication in the title has been amended to 'obesity'.
- Studies were heterogenous, in terms of study designs, sample sizes, procedure technique, length of follow-up, and outcome measures.
- Postoperative rehabilitation (including guidance on water or food intake and exercise) varied between the studies.
- The RCT comparing ESG plus lifestyle modification with lifestyle modification alone was funded by the device company presenting some possibility of bias.
- Two cohort studies reported follow-up from 4 to 5 years.
- The technique of ESG is evolving. One small retrospective study (Glaysher 2019) done in the UK reported a modified gastroplasty suture pattern (longitudinal compression sutures). This has been added to the appendix.
- Ongoing trials:

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

1. NCT04060368: Efficacy and safety of endoscopic sleeve gastroplasty (using OverStitch Endoscopic Suture System) versus laparoscopic SG in obese subjects with NASH (Non-Alcoholic Steatohepatitis). RCT, n=30; ESG plus lifestyle modifications versus LSG plus lifestyle modifications; primary outcome: proportion of subjects undergoing ESG relative to LSG achieving resolution of NASH without worsening of fibrosis, Proportion of subjects undergoing ESG relative to LSG with cardiovascular and liver-related death events; study location: Spain; study completion June 2023.
2. NCT03705416: Long term outcomes of bariatric patients treated with surgery (surgical reduction or bypass) or endoscopy (ESG). Observational prospective cohort study, n=250, ESG versus surgery (vertical SG or a Roux-en-Y gastric bypass); Primary outcome: percentage of participants with GERD based on symptoms, and abnormal acid exposure time and/or reflux esophagitis; location USA; study completion March 2028.
3. Jamie Kelly, Vinod Menon, Frank O'Neill et al. UK cost-effectiveness analysis of endoscopic sleeve gastroplasty versus lifestyle modification alone for adults with class 2 obesity (BMI 35.0-39.9 kg/m<sup>2</sup>) based on results from the MERIT RCT (pre-print) <https://doi.org/10.21203/rs.3.rs-2616584/v1>
  - A UK cost-effectiveness study sponsored by Apollo Endosurgery and under review as a full manuscript at the International Journal of Obesity. According to the authors, the cost-utility analysis was done in line with the NICE reference case and methodologies and is the first cost-effectiveness of ESG versus LM alone in adults with class 2 obesity (BMI 35.0-39.9 kg/m<sup>2</sup>) from a national healthcare system perspective in England. The model was informed by patient level data from the MERIT study and demonstrates that ESG (in addition to lifestyle modification) is highly cost-effective compared with lifestyle modification alone. According to the authors, the base-case ICER was £2,453/QALY and ESG remained cost-effective at the NICE willingness to pay threshold in all sensitivity analyses.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

4. Wilson E, O'Neill F et al. Short term cost savings with endoscopic sleeve gastroplasty; a 30 day US cost consequence analysis (presentation at DDW 2023 conference)
  - A 30-day comparison of LSG and ESG from the US perspective. According to the authors, this demonstrated significant cost-savings with ESG. Savings were driven by a reduced OR time (\$871) and length of stay (\$2,776) between the procedures. After 30 days there was an increased incidence of GERD (6.6%) in the LSG compared with ESG (0.4)( $p < 0.01$ ). All other adverse events contributed to a cost saving with ESG after 30 days.

## Related NICE guidance

### Interventional procedures

- NICE interventional procedures guidance 569 [Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity](#) (2016).  
Recommendation: special arrangements
- NICE interventional procedures guidance 471 [Implantation of a duodenal-jejunal bypass sleeve for managing obesity](#) (2013).  
Recommendation: research
- NICE interventional procedures guidance 432 [Laparoscopic gastric plication for the treatment of severe obesity](#) (2012).  
Recommendation: special arrangements

### Technology appraisals

- NICE technology appraisal guidance TA494 [Naltrexone-bupropion for managing overweight and obesity](#) (2017).
- NICE highly specialised technologies guidance HST21 [Setmelanotide for treating obesity caused by LEPR or POMC deficiency](#) (2022).

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

- NICE technology appraisal guidance [TA664] [Liraglutide for managing overweight and obesity](#) (2020).

## NICE guidelines

- NICE guideline CG189 [Obesity: identification, assessment and management](#) (2014, updated 2022).
- NICE guideline in development [GID-NG10182] [Weight Management: preventing, assessing and managing overweight and obesity \(update\)](#), expected publication date: 27 March 2024.
- NICE guideline PH42 [Obesity: working with local communities](#) (2012, updated 2017).
- NICE guideline NG7 [Preventing excess weight gain](#) (2015).
- NICE guideline PH53 [Managing overweight and obesity in adults – lifestyle weight management services](#) (2014).
- NICE guideline PH47 [Weight management: lifestyle services for overweight or obese children and young people](#) (2013).
- NICE guideline on CG43 [Obesity prevention](#) (2006).

## Professional societies

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

## Evidence from patients and patient organisations

NICE received 5 questionnaires from patients who had the procedure.

Patients' views on the procedure were consistent with the published evidence and the opinions of the professional experts. See the [patient commentary summary](#) for more information.

IP overview: Endoscopic sleeve gastropasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

## Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 2 completed submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

## References

1. de Miranda Neto AA, de Moura DTH, Ribeiro IB, et al. (2020) Efficacy and safety of endoscopic sleeve gastroplasty at mid term in the management of overweight and obese patients: a systematic review and meta-analysis. *OBES SURG.* 370 (30), 1971-1987.
2. Abu Dayyeh BK, Bazerbachi F, Vargas EJ et al. (2022) Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. *Lancet* 2022; 400: 441–51.
3. Marincola G, Gallo C, Hassan C, et al. (2021) Laparoscopic sleeve gastrectomy versus endoscopic sleeve gastroplasty: a systematic review and meta-analysis. *Endosc Int Open.* 09(01):E87-E95.
4. Beran A, Matar R, Jaruvongvanich V et al. (2022) Comparative Effectiveness and Safety Between Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: a Meta-analysis of 6775 Individuals with Obesity. *Obesity Surgery.* 32:3504–3512.
5. Singh S, de Moura DT, Khan A et al. (2020) Intra-gastric Balloon Versus Endoscopic Sleeve Gastroplasty For The Treatment Of Obesity: A Systematic Review And Meta-Analysis. *Obes Surg.* 30(8): 3010–3029.
6. Bhandari M, Kosta S, Reddy M, Mathur W, Neto MG, Bhandari M. Four-year outcomes for endoscopic sleeve gastroplasty from a single centre in India. *J Minim Access Surg.* 2023;19(1):101-106. doi:10.4103/jmas.jmas\_3\_22
7. Sharaiha RZ, Hajifathalian K, Kumar R et al. (2021) Five-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity. *Clinical Gastroenterology and Hepatology*;19:1051–1057.
8. Gudur AR, Geng CX, Kshatri S et al. (2023) Comparison of endoscopic sleeve gastroplasty versus surgical sleeve gastrectomy: a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database analysis. *Gastrointest Endosc;* 97:11-21.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).



## Methods

NICE identified studies and reviews relevant to endoscopic sleeve gastroplasty for obesity from the medical literature. The following databases were searched between the date they started to 22.02.2023: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the [table 4 literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following inclusion criteria were applied to the abstracts identified by the literature search:

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
- Patients with obesity.
- Intervention or test: endoscopic sleeve gastroplasty.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in the section on [other relevant studies](#).

Find out more about [how NICE selects the evidence for the committee](#).

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

**Table 4 literature search strategy**

Databases	Date searched	Version/files
MEDLINE (Ovid)	22/02/2023	1946 to February 21, 2023
MEDLINE In-Process (Ovid)	22/02/2023	1946 to February 21, 2023
MEDLINE Epubs ahead of print (Ovid)	22/02/2023	February 21, 2023
EMBASE (Ovid)	22/02/2023	1974 to February 21, 2023
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	22/02/2023	Issue 2 of 12, February 2023
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	22/02/2023	Issue 2 of 12, February 2023
International HTA database (INAHTA)	22/02/2023	-

## Trial sources searched

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

## Websites searched

- 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)
- 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.

**MEDLINE search strategy**

The MEDLINE search strategy was translated for use in the other sources.

```

1  Gastroplasty/ 4564
2  Gastroplast*.tw. 1962
3  or/1-2 5313
4  Endoscopy/ 58464
5  endoscop*.tw. 204478
6  4 or 5 221821
7  3 and 6 683
8  ((Endoscopic adj4 sleeve adj4 (gastroplast* or (gastr* adj4 surger*))) or
ESG).tw. 487
9  (Endoscopic adj4 (gastroplast* or (gastr* adj4 surger*))).tw. 433
IP overview: Endoscopic sleeve gastroplasty for obesity

```

10	(endoscopic adj4 sutur*).tw.	703
11	((endosleeve or endolum?nal) adj4 (procedure* or surger*)).tw.	371
12	POSE-2.tw.	12
13	or/7-12	2253
14	Obesity, Morbid/	25562
15	((Obese or Obesity or obesities) adj4 (Morbid* or sever*)).tw.	26378
16	Body Mass Index/	147081
17	("body mass index" or BMI).tw.	266185
18	Weight Loss/	42821
19	(weight adj4 (loss* or reduc*)).tw.	127413
20	or/14-19	436184
21	13 and 20	564
22	Overstitch.tw.	59
23	Endomina.tw.	1
24	or/21-23	606
25	Animals/ not Humans/	5060243
26	24 not 25	595

## Other relevant studies

Other potentially relevant studies to the IP overview that were not included in the main evidence summary (tables 2 and 3) are listed in table 5.

**Table 5 additional studies identified**

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Alexandrea F, Lapergolaa A, Vannucci M et al. (2023) Endoscopic management of obesity: Impact of endoscopic sleeve gastropasty on weight loss and co-morbidities at six months and one year. Journal of Visceral Surgery 160, S38—S46.	Prospective case series. N=99 patients had ESG. BMI 42.7 ± 7.8 kg/m <sup>2</sup> Follow-up 12 months.	ESG is a well-tolerated and safe surgical procedure that is effective in terms of weight loss and reduction of obesity-related comorbidities at 6 months and 1 year.	Higher level evidence included in evidence summary
Abu Dayyeh BK, Acosta A, Camilleri M, et al. (2017) Endoscopic sleeve	Observational study (prospective)	ESG delays gastric emptying, induces early	Included in systematic reviews added

**Commented [HG86]:** I haven't accepted any changes to titles of published papers

IP overview: Endoscopic sleeve gastropasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
gastroplasty alters gastric physiology and induces loss of body weight in obese individuals. Clin Gastroenterol Hepatol; 15: 37–43	N=25 patients with BMI between 30 and 40 kg/m <sup>2</sup> had ESG. Follow-up 20 months	satiating, and significantly reduces body weight. ESG could be an alternative to bariatric surgery for selected patients with obesity.	to evidence summary.
Abu Dayyeh B, Rajan E, Gostout C.J. (2017) Gastric endoscopic remodeling techniques. Techniques in Gastrointestinal Endoscopy. 19(1):22-26.	Descriptive review of the various techniques to remodel the stomach, with an emphasis on safety and efficacy.	ESG is a well-tolerated outpatient intervention, with most patients returning to a functional status within 24 to 48 hours after the intervention. To date, 2 endoscopic bariatric techniques (ESG and POSE) seem to be safe, reproducible, cost effective and produce 25% excess weight loss at 1 year.	Review
Alqahtani A, Al-Darwish A, Mahmoud AE, et al. (2019) Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients. Gastrointest Endosc; 89(6):1132–8.	Observational study (prospective). N=1,000 patients with BMI > 40 kg/m <sup>2</sup> or 35 kg/m <sup>2</sup> with comorbidities had ESG.	ESG appears to be well tolerated, safe, and effective. Significant weight loss occurs during the first 18 months without mortality or significant morbidity. Some patients need revision or	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	Follow-up 18 months	reversal during the first year.	
Alqahtani AR, Elahmedi M, Aldarwish A et al. (2022) Endoscopic Gastroplasty Versus Laparoscopic Sleeve Gastrectomy: A Non-Inferiority Propensity Score Matched Comparative Study. <i>Gastrointest Endosc</i> (2022) doi:10.1016/j.gie.2022.02.050	Propensity score matched study of patients who underwent ESG or LSG. 3,180 pairs. Average 33.3 kg/m <sup>2</sup> . Follow-up 36 months.	Mean %EWL at 1, 2, and 3 years after ESG was 77%, 75% and 60% respectively. Mean %EWL at 1, 2, and 3 years after LSG was 95%, 94%, and 74% respectively. The mean difference in %TWL was 9.7% (p<0.001), 6.0% (p<0.001), and 4.8% (p<0.001) at 1, 2, and 3 years, respectively. 14 ESG patients developed adverse events (0.5%) versus 10 LSG patients (0.3%). Comorbidity remission rates after ESG versus LSG were 64% versus 82% for diabetes, 66% versus 64% for dyslipidaemia, and 51% versus 46% for hypertension, respectively. 80 ESG patients (3%) had revision to LSG for insufficient weight	Study included in a meta-analysis added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		loss or weight regain, and 28 had resuturing after primary ESG (1%).	
Asokkumar R, Hong Lim C, Tan AS et al. (2021) Safety and early efficacy of endoscopic sleeve gastroplasty (ESG) for obesity in a multi-ethnic Asian population in Singapore. Journal of gastroenterology and hepatology 5, 1351–1356	Retrospective case series. N=35 patients who had primary ESG for obesity. Mean BMI 34 kg/m <sup>2</sup> . Chinese ethnicity 51%. Follow-up 6 months.	21 patients completed 3 months of follow-up, and 10 patients 6 months. The mean TBWL at 3 and 6 months were 15% and 16%, respectively. Improvement in diabetes mellitus (87%), fatty liver (86%), and hypertension (58%) was also reported.	Larger and more comprehensive studies included in evidence summary.
Lavín-Alconero L, Fernández-Lanas T, Iruzubieta-Coz P et al. (2021) Efficacy and safety of endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy in obese subjects with NonAlcoholic SteatoHepatitis (NASH): study protocol for a randomized controlled trial (TESLA-NASH study). Trials; 22:756.	RCT protocol. N=30 patients with obesity with or without metabolic syndrome and NASH. endoscopic sleeve gastroplasty (ESG) versus laparoscopic sleeve gastrectomy (LSG).	This clinical trial will help us apply different tactics to the treatment of obesity and NASH.	Protocol only
Badurdeen D, Farha J, Fayad L et al. (2022) The Attitude of Practitioners Towards Endoscopic Sleeve	Survey of 1,200 bariatric endoscopists trained to perform	ESG practice trends remain heterogenous among practitioners in	Survey on clinical practice.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastroplasty . J Clin Gastroenterol;56:756–763.	endoscopic suturing using the Apollo OverStitch suturing device.	regard to indication, technique, and preprocedural and postprocedural management. Specific ESG guidelines are warranted.	
Barrichello S, Hourneaux de Moura DT, Hourneaux de Moura EG, et al. (2019) Endoscopic sleeve gastroplasty in the management of overweight and obesity: an international multicenter study. Gastrointest Endosc. 90 (5), 770-780.	Observational study (prospective). N=193 overweight or obese patients who failed diet and lifestyle modifications and had ESG. Follow-up 12 months.	All groups had more than 10% TWL and more than 25% EWL at 6 months. On average, %TWL was 14% and 15%, and the %EWL 56% and 59%, at 6 months and 1 year. ESG appears to be feasible, safe, and effective in the treatment of patients with overweight and obesity according to ASGE/ASMBS thresholds.	Included in systematic reviews added to evidence summary.
Bhandari M, Jain S, Mathur W, Kosta S, Neto MG, Brunaldi VO, et al. (2020)Endoscopic sleeve gastroplasty is an effective and safe minimally invasive approach for treatment of obesity: first Indian experience. Dig Endosc; 32 (4), 541-546.	Observational retrospective study. N=53 patients with mean BMI 34.8 kg/m <sup>2</sup> had ESG. Follow-up 12 months.	Average %TWL was 8%, 12%, 14%, and 20% at 1, 3, 6, and 12 months, respectively. 88% of patients achieved more than 15% TWL at 12 months. Younger and female patients	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		had greater %TWL.	
Balint IB, Csordas J, and Csaszar F. (2023) Is endoscopic approach superior to laparoscopic surgery for gastric plication in terms of complications and efficacy? A systematic review including meta-analysis. <i>Minerva Surgery</i> , 78, 1-10.	Systematic review and meta-analysis. 18 endoscopic bariatric metabolic therapies (EBMT) studies (2 techniques 14 ESG studies and 4 POSE studies are assessed, n=3585) LGCP 29 studies, N=2350 6 months to 5 years follow-up.	EBMTs appeared to be superior to LGCP regarding safety but differences did not reach statistical threshold. Weight loss outcomes were favourable after each method. EBMTs imitating LGCP are promising safe and effective methods.	Results not analysed separately for different EBMTs.
Boškosi I, Pontecorvi V, Gallo C et al. (2020). Redo endoscopic sleeve gastroplasty: technical aspects and short-term outcomes. <i>Ther Adv Gastroenter</i> . 13,1-6.	Retrospective analysis of prospective data. N=120 patients who underwent ESG	at 12 months mean %EWL was 44%, mean %TBWL was 18%. 4 patients had ESG revisions within 12 months. No adverse events were reported during redo-ESG. 6 month follow-up for 3 patients reported that mean %EWL and %TBWL were 44% and 20%.	Not primary ESG. Revisions of ESG. Higher level evidence included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity



Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Carr P, Keighley T, Petocz P, et al. (2022) Efficacy and safety of endoscopic sleeve gastroplasty and laparoscopic sleeve gastrectomy with 12+ months of adjuvant multidisciplinary support. <i>Bmc Prim Care</i> . 23(1):26.	Prospective study (2 arm). N=61 patients with obesity who received ESG or LSG with 12+ months of adjuvant multidisciplinary pre- and postprocedural support. N=16 ESG (BMI 35.5 kg/m <sup>2</sup> ) N=45 LSG (BMI 40.5 kg/m <sup>2</sup> ) Follow up 12 months.	ESG and LSG were safe and effective weight loss treatments for obese adults along- side multidisciplinary support. Patients who elected the ESG maintained fat-free mass at 6-months but both cohorts lost fat-free mass at 12-months post procedure. Patients who elected the LSG had large and significant improvements to weight-related quality of life. Further well-powered studies are required to confirm these findings.	Large studies included in evidence summary.
Cheskin LJ, Hill C, Adam A et al. (2020) Endoscopic sleeve gastroplasty versus high-intensity diet and lifestyle therapy: a case-matched study. <i>Gastrointest Endosc</i> ; 91: 342–349.e1	Observational case-matched study. Patients with mean BMI 40 kg/m <sup>2</sup> 105 ESG and high-intensity diet and lifestyle therapy (HIDLT) versus 281 patients	Mean %TBWL at 1, 3, 6, and 12 months was significantly higher in patients undergoing ESG than patients undergoing HIDLT. Specifically, at 3 months, the mean %TBWL in the ESG cohort was 14%	Included in systematic reviews added to evidence summary

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	with HIDLT alone. Follow-up 12 months	compared with 11% in the HIDLT cohort ( $p < 0.011$ ) and at 12 months the mean %TBWL in the ESG cohort was 21% versus 14% in the HIDLT cohort ( $p < 0.001$ ).	
Cohen RV, Oliveira da Costa MV, Charry L et al. (2019) Endoscopic gastroplasty to treat medically uncontrolled obesity needs more quality data: A systematic review. Surg Obes Relat Dis. 1-6.	Systematic review (included both ESG and POSE endoscopic gastroplasty (EG) technique - plication of the fundus). (2 RCTs on POSE, 14 observational studies, 9 case reports were included).	The case series reported 16% to 19% total weight loss, but few had more than 6 months of follow-up. Serious adverse events ranged from 2% to 10%. Review concluded that endoscopic gastroplasty does not have enough quality scientific evidence regarding long-term weight loss and the procedure's safety to recommend the use in current clinical practice.	More recent comprehensive studies included in the evidence summary.  Review combined ESG with other endoscopic gastroplasty techniques, including plication of the fundus, that uses different devices and mechanism of action.
Currie AC, Galysher MA, Blencowe NS et al. (2021) Systematic Review of Innovation Reporting in Endoscopic Sleeve Gastroplasty. Obesity Surgery. 31:2962–2978	Systematic review. 16 retrospective cohort studies, 17 prospective cohort studies and 3 case reports included.	The number of patients in the included studies ranged from 1 to 1000. The lower BMI limit ranged from 27 to 35 kg/m <sup>2</sup> . Research approvals were	Recent meta-analyses included in the evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		reported in 26 studies. Two studies reported on the learning curve. All studies reported some aspect of technical implementation, but many variations were noted. Suturing device used and suture pattern were the most commonly reported aspects (32 studies). Follow-up ranged from 1 to 24 months but was 12 months or less in 28 studies. 48 different outcomes were reported across all studies.	
Dayyeh BKA, Rajan E, Gostout CJ. Endoscopic sleeve gastropasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. <i>Gastrointest Endosc.</i> 2013;78(3):530-535	Prospective case series. N=4 patients with BMI between 30-40 kg/m <sup>2</sup> had ESG.	Early results are encouraging and suggest that endoscopy-based intraluminal therapies may provide the next major treatment advance in this area.	Larger studies included in evidence summary.
de Souza TF, Neto ACM, Coronel MA et al. The First Study Evaluating Effectiveness and Safety of the Endoscopic Sleeve	Retrospective case series. N=7 patients with HIV had ESG	After 6 months, absolute weight loss, percentage of excess weight loss, percentage	Larger studies included in evidence summary.

IP overview: Endoscopic sleeve gastropasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastroplasty in HIV Patients. Obesity Surgery (2020) 30:1159–1162.	Mean BMI 33.7 kg/m <sup>2</sup>	total weight loss, and BMI reduction were 20.2 kg, 86%, 21%, and 7.1 kg/m <sup>2</sup> , respectively. No patients presented severe adverse events.	
Espinete-Coll E, Nebreda-Durán J, Galvão-Neto M, et al. (2020) Suture pattern does not influence outcomes of endoscopic sleeve gastroplasty in obese patients. Endosc Int Open.08(10):E1349-E1358	Retrospective review of prospective data. N=88 patients who had ESG (with 3 different suture patterns - transverse bilinear, longitudinal and transverse monolinear and number of sutures (4 to 7) and stitches (less than 25, 25 to 30 and more than 30) were compared.	ESG is an effective procedure at 12-month follow-up for weight loss and comorbidity resolution. All 3 analysed patterns are safe and effective without differences in %TBWL, but there was a slight increase in %EWL in longitudinal pattern, regardless of the number of sutures or stitches applied.	Higher level evidence included in evidence summary.
Espinete Coll E, Vila Lolo C, Díaz Galán P, et al. Bariatric and metabolic endoscopy in the handling of fatty liver disease. A new emerging approach? Rev Esp Enferm Dig NLM. 2019;111:283–93.	Observational prospective study. N=15 patients with mean BMI 38.82 kg/m <sup>2</sup> and non-alcoholic fatty liver disease had ESG.	Bariatric endoscopy could be proposed during short-term follow-up as an effective and safe alternative in patients with obesity and NAFLD.	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	Follow-up 12 months.		
Espinete-Coll, E. et al. Persistence of Sutures and Gastric Reduction After Endoscopic Sleeve Gastroplasty: Radiological and Endoscopic Assessment. <i>Obes Surg</i> 1–11 (2022)	Prospective study. N=38 patients with obesity (BMI 37.6 kg/m <sup>2</sup> ) had ESG. Follow-up 1 year.	Median %TWL of 17% with TWL more than 10% in 95% of patients was obtained at 1 year. No major AEs were observed. ESG is an effective and safe weight loss strategy at 12-month follow-up with persistence of most sutures and maintenance of notable gastric reduction and remodelling.	High strength evidence included in the evidence summary.
Farha J, McGowan C, Hedjoudje A, et al. (2020) Endoscopic sleeve gastroplasty: suturing the gastric fundus does not confer benefit. <i>Endoscopy</i> . 53(07):727-731.	Retrospective analysis. N=247 patients ESG with fundal suturing versus no fundal suturing (ESG-NFS) Follow-up 12 months.	%EWL at 3 months ESG-NFS: 38%; ESG-FS: 1%. %EWL was significantly greater in the ESG-NFS group at both at 6 months and 12 months compared with the ESG-FS group (p<0.001). SAEs (perigastric abscess, gastric perforation and bleeding) occurred in 2% of patients. Sparing the fundus results in superior mean %EWL at 3, 6,	Higher level evidence included in the evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		and 12 months. Both cohorts achieved a %EWL that exceeded the recommended level of 25%.	
Fiorillo C, Quero G, Vix M, et al. 6-Month Gastrointestinal Quality of Life (QoL) Results after Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: A Propensity Score Analysis. <i>Obes Surg.</i> 2020;30(5):1944-1951.	Retrospective analysis. Propensity scored matched analysis. N=183 ESG versus LSG 23 matched pairs	LSG may significantly affect QoL and results in worsening of gastrointestinal symptoms including GERD. ESG is a promising less invasive bariatric endoscopic procedure that demonstrated a positive impact on both QoL and comorbidities, which could lead to greater patient acceptance earlier in their disease or at a younger age.	Study included in systematic review and meta-analyses added to evidence summary.
Fayad L, Adam A, Schweitzer M, et al. (2019) Endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy: a case-matched study. <i>Gastrointest Endosc.</i> 89(4):782-788.	Retrospective review of prospective data -case-matched study. N=138 patients who underwent ESG (n=54) or LSG (n=83)	At the 6-month follow-up, %TBWL (compared with baseline) was significantly lower in the ESG group compared with the LSG group (17% versus 24%, p<0.01). ESG patients had significantly lower rates of adverse events compared with LSG patients	Study included in systematic review and meta-analyses added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		(5% versus 17%, p<0.05). New-onset GERD was also significantly lower in the ESG group compared with the LSG group (2% versus 15%, p<0.05).	
Glaysner M, Moekotte A, Kelly J. (2019) Endoscopic sleeve gastropasty: a modified technique with greater curvature compression sutures. <i>Endosc Int Open.</i> 07(10):E1303-E1309.	Retrospective review. N=32 patients (BMI 36.5 kg/m <sup>2</sup> ) who had ESG (sutures with longitudinal compression pattern and no pattern).	The technique of ESG is evolving and outcomes continue to improve. Preliminary evidence of superior weight loss achieved through a modified gastropasty suture pattern.	Higher level evidence included in evidence summary.
Goyal H, Kopel J, Perisetti A et al. (2021) Endobariatric procedures for obesity: clinical indications and available options. <i>Ther Adv Gastrointest Endosc</i> , Vol. 14: 1–17.	Review	Review elaborates on the clinical indications and efficacy of the Endo bariatric procedures, together with various types of available endoscopic bariatric therapy procedures.	General review
Gudur AR, Geng C, Hallowell P et al. (2022) Impact of Proceduralist Specialty on Outcomes Following Endoscopic Sleeve Gastropasty.	Retrospective analysis of 6,000 patients who underwent ESG.	No difference in adverse events in ESG performed by gastroenterologists and bariatric surgeons. ESG performed by	Studies with clinical outcomes included in evidence summary.

IP overview: Endoscopic sleeve gastropasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Obesity Surgery. 32:3714–3721.		bariatric surgeons demonstrated a trend towards higher rate of re-operations within 30 days. ESG performed by gastroenterologists had more ED visits but did not lead to higher rate of re-intervention. Length of stay was shorter in ESG performed by gastroenterologists, but procedure time was longer.	
Gys B, Paleke P, Lamme B et al. (2019) Endoscopic Gastric Plication for Morbid Obesity: a Systematic Review and Meta-analysis of Published Data over Time. Obesity Surgery, 29:3021–3029.	22 cohort studies on 7 different devices, with 2,475 patients were included. BMI 37.8 ± 4.1 kg/m <sup>2</sup> . Either a transoral endoluminal stapling or (suction based) (full thickness) stitching and/or anchor device was used to obtain gastric volume reduction and/or alter gastric outlet.	Endoscopic sleeve gastropasty (ESG) and the primary obesity surgery endolumenal (POSE). Average pooled %EWL at 6 months (p=0.02) and 12 months (p=0.04) in favour of ESG was 57.9% (50.5 to 65.5, I <sup>2</sup> =0%), 44.4% (40.2 to 48.5, I <sup>2</sup> =0%), and 68.3% (60.9 to 75.7, I <sup>2</sup> =5.8%), 44.9% (40.9 to 49.0) for ESG and POSE respectively.	Devices included in this review vary in technique and have their own specific features. Evidence on ESG already covered in other studies added to table 2.

IP overview: Endoscopic sleeve gastropasty for obesity



Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	Mean follow-up was 13 months (median 12; range 6–24)	Major adverse events without mortality were described in 25 patients (9 studies, p=0.63).	
Hajifathalian K, Mehta A, Ang B, et al. (2021) Improvement in insulin resistance and estimated hepatic steatosis and fibrosis after endoscopic sleeve gastroplasty. <i>Gastrointest Endosc.</i> 93(5):1110-1118.	Prospective study. N=118 patients with obesity (mean BMI 40.7 kg/m <sup>2</sup> ) and non-alcoholic fatty liver disease (NAFLD) underwent ESG. Follow-up 2 years	Results suggest a significant and sustained improvement in estimated hepatic steatosis and fibrosis after ESG in patients with NAFLD. Importantly, showed an early and weight-independent improvement in insulin resistance, which lasted for 2 years after the procedure.	Studies reporting weight loss as primary outcome were included in the evidence summary.
Hedjoudje A, Abu Dayyeh BK, Cheskin JL et al. (2020) Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis. <a href="#">Clinical Gastroenterology and Hepatology</a> 18, 5, 1043-1053.	Systematic review and meta-analysis. N=1,772 patients from 8 studies	Study reported 6-month mean %TBWL of 15.1%, mean percentage of excess body weight loss (%EBWL) of 58%, and mean reduction in body mass index (BMI) of 5.7 kg/m <sup>2</sup> . Weight loss was sustained at 12 and 18 to 24 months with a TBWL of 17%. Rate of severe adverse events	More recent and comprehensive study included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		was 2% including pain or nausea requiring hospitalisation (n=18, 1%), upper gastrointestinal bleeding (n=9, 0.6%), and peri-gastric leak or fluid collection (n=8, 0.5%).	
Jain D, Bhandari BS, Arora A, Singhal S. Endoscopic sleeve gastropasty—a new tool to manage obesity. Clin Endosc 2017;50:552–6	Review of 9 studies (n=172 patients) on ESG. Only 51 patients had 6 months follow-up.	Technical success rate for intact gastric sleeve was 50% to 100%. A statistically significant weight loss was reported in 7/8 studies. No mortality but 2% (4/172) of patients experienced major post-procedure complications.	More comprehensive systematic reviews included in evidence summary.
James TW, Reddy S, Vulpis T et al. (2020). Endoscopic Sleeve Gastropasty Is Feasible, Safe, and Effective in a Non-academic Setting: Short-Term Outcomes from a Community Gastroenterology Practice. Obes Surg. 30(4):1404-1409.	Retrospective review. N=100 patients who had ESG.	Mean 12-month TBWL was 29.8 kg (23%), with excess weight loss of 66%. Over this time period, mean change in BMI was 9.43 kg/m <sup>2</sup> .	Higher strength studies included in evidence summary.
Jagtap N, Kalapala R, Katakwar A, et al. Endoscopic sleeve gastropasty — minimally invasive treatment for non-alcoholic fatty liver disease and obesity. Indian J	Prospective study. N=26 patients with obesity (mean weight 99 kg/m <sup>2</sup> ) and	ESG is a safe and effective treatment option for patients with NAFLD and obesity causing significant total body weight loss (18%) at	High strength studies included in evidence summary.

IP overview: Endoscopic sleeve gastropasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastroenterology. 2021;40(6):572-579.	NAFLD who had ESG. Follow-up 12 months.	12 months, with significant improvement in HbA1c. No serious major events reported. Rigorous randomized trials are required to incorporate ESG in NAFLD treatment algorithm.	
Jalal MA, Cheng Q, Edey MB et al. (2020) Systematic Review and Meta-Analysis of Endoscopic Sleeve Gastroplasty with Comparison to Laparoscopic Sleeve Gastrectomy. Obesity Surgery, 30:2754–2762.	Systematic review and meta-analysis. 5 studies (3 ESG cohort studies and 2 case-matched cohort studies comparing ESG with LSG). ESG and LSG patients were 1,451 and 203.	Short-term total body weight loss (TBWL%) at 6 months ranging from 14 to 15% for ESG reported. 2 LSG papers demonstrated a superior TBWL% of 24% at 6 months, with 1 paper reporting a 12-month TBWL% of 29%. 2 ESG papers reported medium-term results at 18 months and 24 months of 15% and 19%, respectively. ESG had a complication rate between 2 and 3%, while LSG had a complication rate between 9 and 17%. In both	More recent meta-analysis included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		procedures, there were no grade 4 or 5 complications.	
Khan Z, Khan MA, Hajifathalian K, et al. Efficacy of Endoscopic Interventions for the Management of Obesity: a Meta-analysis to Compare Endoscopic Sleeve Gastroplasty, AspireAssist, and Primary Obesity Surgery Endolumenal. <i>Obes Surg.</i> 2019;29:2287–98.	Systematic review and meta-analysis included ESG, AspireAssist, and primary obesity surgery endolumenal (POSE). 12 studies with 1,149 patients were included.	During a follow-up of 6 to 12 months, both AspireAssist and ESG had excellent efficacy in achieving significant and sustained weight loss; however, ESG was found to be superior in terms of weight loss when compared with POSE.	3 different endoscopy procedures assessed here and Aspire Assist is different to the other 2 plication procedures used. So recent comprehensive reviews on ESG included in evidence summary.
Kozłowska-Petriczko K, Pawlak KM, Wojciechowska K et al. (2023) The efficacy Comparison of Endoscopic Bariatric Therapies: 6-Month Versus 12-Month Intra-gastric Balloon Versus Endoscopic Sleeve Gastroplasty. <i>Obesity Surgery</i> , 33:498–505.	Retrospective analysis. IGB (Orbera) removal after 6 months (124 patients), at IGB (Orbera365) removal after 12 months (61 patients) and at 6 months and 12 months after ESG (42 and 34 patients, respectively).	All 3 studied methods were effective for achieving weight loss. However, there was no significant difference between 6-month and 12-month IGB therapies outcomes. ESG appeared to be a more effective obesity treatment modality than IGB.	Similar comparative studies included in a systematic review added to evidence summary.
Kumar N, Abu Dayyeh BK, Lopez-Nava Breviere G, et al. (2018) Endoscopic sutured gastroplasty: procedure evolution from	Observational prospective study. N=99 patients	Phase 2- 1-year total weight loss was 17% (n=22) Phase 3- mean weight loss was	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
first in-man cases through current technique. Surg Endosc. 32: 2159–64	Phase 2- mean BMI 34.3 kg/m <sup>2</sup> (n=22) Phase 3-mean BMI 36.1 kg/m <sup>2</sup> (n=77) Follow-up 6-12 months.	16% at 6 months and 17% at 12 months (n=44). No significant adverse events reported.	
Lopez-Nava G, Negi A, Bautista-Castaño I, et al. (2020) Gut and Metabolic Hormones Changes After Endoscopic Sleeve Gastroplasty (ESG) Vs. Laparoscopic Sleeve Gastrectomy (LSG). Obes Surg. 30(7):2642-2651.	Prospective study. N=24 patients 12 ESG compared with 12 LSG Follow-up 6 months	ESG induced gut hormone changes differently as compared to LSG. ESG prevented a compensatory rise in ghrelin and promoted beneficial changes in the insulin secretory pattern with weight loss.	Primary outcome not weight loss.
Lopeznava G, Asokkumar R, Bautista I, et al. (2020) Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic greater curve plication: do they differ at 2 years? Endoscopy. 53(03):235-243	Retrospective review. N=296 patients who had (ESG 135, LSG 43, LGCP 32). Follow-up 2 years.	ESG had a significantly lower TBWL, %TBWL, and BMI decline compared with LSG and LGCP at all time points (p=0.001). The adjusted mean %TBWL at 2 years for ESG, LSG, and LGCP were 19%, 28%, and 27%, respectively.	Included in systematic reviews added to evidence summary.
Lopeznava G, Asokkumar R, Negi A et al. (2021) Resuturing After Primary Endoscopic Sleeve Gastroplasty For Obesity.	Retrospective analysis. N=of 482 patients with primary ESG	The need for redo-ESG after primary ESG is low. redo-ESG is safe and induced	Not primary ESG. Revisions of ESG. Higher level evidence

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Surgical Endoscopy. 35:2523–2530	7% (32) had red o ESG – 12 for weight loss failure, 12 for weight regain, and 11 for weight plateau.	weight loss in all patients. The maximum benefit was observed in patients who lost 10% or more TBWL but could not lose further over 3 months. No serious complications occurred.	included in evidence summary.
Lopeznava G, Lster J, Negi A et al. (2022) Endoscopic sleeve gastroplasty (ESG) for morbid obesity: how effective is it? Surgical Endoscopy. 36:352–360.	Retrospective review. N=435 patients (class 1 33 kg/m <sup>2</sup> : 105, class 2 37.5 kg/m <sup>2</sup> : 169, class 3 44.5 kg/m <sup>2</sup> : 161) who had ESG. Follow-up 12 months.	ESG had a significantly higher TBWL, %TBWL, and BMI decline in class 3 compared to classes 1 and 2 obesity at all time points (p<0.001). The adjusted mean %TBWL at 1 year with classes 1, 2, and 3 obesity was 17%, 18%, and 21%, respectively. The overall complication rate and the hospital stay was identical in the 3 groups.	Higher level evidence included in evidence summary.
Lopez-Nava G, Sharaiha RZ, Vargas EJ, et al. (2017) Endoscopic Sleeve Gastroplasty for Obesity: a Multicenter Study of 248 Patients with 24 Months Follow-Up. OBES SURG. 27(10):2649-2655.	Retrospective review. N=248 patients who had ESG. BMI 37.8 kg/m <sup>2</sup> Follow-up 24 months.	At 6 and 24 months, %TBWL was 15 and 19 respectively. At 24 months, the proportion of patients achieving 10% or more	Study included in systematic reviews added in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		TBWL was 84 and 53%, respectively.	
Lopez-Nava G, Galvão MP, Bautista-Castaño I, et al. (2017) Endoscopic sleeve gastroplasty for obesity treatment: two years of experience. Arq Bras Cir Dig. 30:18–20.	Observational prospective study. N=154 patients with BMI 38.3 kg/m <sup>2</sup> had ESG. Follow-up 24 months.	Baseline mean BMI change from 38.3 to 30.8 kg/m <sup>2</sup> at 24 months. TBWL, %TBWL and %EWL were of 21.3 kg, 19.5% and 60.4% respectively. 86% of patients achieved the goal of more than 25% %EWL. There were no major adverse events.	Included in systematic reviews added to evidence summary.
Lopez-Nava G, Asokkumar R, Rull A et al. (2019) Bariatric endoscopy procedure type or follow-up: What predicted success at 1 year in 962 obese patients? Endosc Int Open. 07(12):E1691-E1698.	Retrospective review of prospective data. N=962 patients had either endoscopic gastroplasty (n=481) and intragastric balloons (n=481)	Only 480 patients (IGB 45%; ESG-55%) completed 1 year follow-up. Among them, Apollo ESG achieved significantly higher TBWL (19.5%, p=0.035), %TBWL (17.4%, p=0.025), and 20% or more TBWL (36.7%, p=0.032).	Higher strength evidence included in evidence summary.
Lopez-Nava G, Galvão MP, Bautista-Castaño I, Jimenez-Baños A, Fernandez-Corbelle JP. Endoscopic Sleeve Gastroplasty: How I Do It? OBES SURG. 2015;25(8):1534-1538.	Prospective study. N=50 patients (average BMI 37.7 kg/m <sup>2</sup> ) who had ESG Follow up 12 months.	There were no major intra-procedural, early, or delayed adverse events. Weight loss parameters were satisfactory, mean BMI changes from 37.7 to 30.9 kg/m <sup>2</sup>	Larger studies included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		at 1 year and mean %TBWL was 19.0.	
Lopez-Nava G, Galvo M, Bautista-Castaño I et al. Factors predictive of success with endoscopic sleeve gastroplasty... Endoscopy International Open 2016; 04: E222–E227	Prospective study. N=25 patients with mean BMI 38.5 kg/m <sup>2</sup> had ESG. Follow-up 1 year	Endoscopic sleeve gastroplasty is a feasible, reproducible, and effective procedure to treat obesity. Nutritional and psychological interaction are predictive of success.	Larger studies included in evidence summary.
Li P, Ma B, Gong S, et al. (2019) Efficacy and safety of endoscopic sleeve gastroplasty for obesity patients: a meta-analysis. Surg Endosc; 34:1253–1260.	Systematic review and meta-analysis. ESG in 1,542 patients from 9 studies.	The pooled results of %TBWL at 1, 3, 6, and 12 months were 8.8% (p=0.000), 11.9% (p=0.000), 14.5% (p=0.024), and 16.1% (p=0.063), respectively. The pooled results of %EWL at 1, 3, 6, and 12 months were 31.2% (p=0.000), 43.6% (p=0.000), 53.1% (p=0.000), and 59.1% (p=0.015), respectively. The pooled rate of mild adverse events was 72% (p<0.01) and severe adverse events was 1% (p=0.08).	More recent comprehensive studies included in the evidence summary.



Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Li R, Veltzke-Schlieker W, Adler A, et al. (2021) Endoscopic Sleeve Gastroplasty (ESG) for High-Risk Patients, High Body Mass Index (> 50 kg/m <sup>2</sup> ) Patients, and Contraindication to Abdominal Surgery. <i>Obes Surg.</i> 31:3400–3409.	Prospective study. N=24 patients with high-risk, high BMI (49.9 kg/m <sup>2</sup> ) and those contraindicated to abdominal surgeries. Follow-up 12 months.	Weight loss, BMI reduction, %TWL, and %EWL were 17.5 kg, 5.6 kg/m <sup>2</sup> , 12.2%, and 29.1% at post-ESG 12-month, respectively. One (4%) moderate post-procedure adverse event (gastric mucosal bleeding) was observed.	Larger studies included in table 2.
Morales JG, Crespo LC, Marques A, et al. (2018) Modified endoscopic gastroplasty for the treatment of obesity. <i>Surg Endo sc.</i> 32:3936–42.	Observational study, retrospective. N=148 patients with average BMI 35 kg/m <sup>2</sup> has ESG with a Z suture pattern. Follow-up 18 months.	TWL was 17.5 kg in 12 months and 18.5 kg in 18 months. Patients with a BMI less than 35 kg/m <sup>2</sup> benefited most. One case of mild bleeding reported.	Included in systematic reviews added to evidence summary.
Mohan BP, Asokkumar R, Khan SR et al. (2020) Outcomes of endoscopic sleeve gastroplasty; how does it compare to laparoscopic sleeve gastrectomy? A systematic review and meta-analysis. <i>Endoscopy International Open</i> ; 08: E558–E565.	Systematic review and meta-analysis. 3,994 patients from 15 studies. 8 ESG studies (1,815 patients) and 7 LSG studies (2,179 patients).	In ESG the pooled rates of %TWL at 1 month, 6 months, and 12 months were 8.7, 15.3 and 17.1, respectively. The pooled rates of %EWL at 1 month, 6 months, and 12 months were 31.7, 59.4 and 63 respectively. The pooled rates of BMI at 1 month,	Similar analysis included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		6 month, and 12 months were 32.6, 30.4 and 30 respectively. At 12 months, the pooled %TWL, %EWL and BMI with LSG (7 studies, 2,179 patients) were 30.5 69.3 and 29.3 respectively. %TWL with LSG was superior to ESG (p=0.001). %EWL and BMI were comparable. All adverse events, were significantly lower with ESG when compared to LSG.	
Manos T, Noel P, Bastid C et al. Endoscopic Gastroplasty. Initial Experience. Chirurgia (2019) 114 (6): 747-752.	Prospective study. N=17 patients had ESG. Group A (with BMI less than 35 and primary obesity – 10 patients) and Group B (with BMI more than 35, or previous gastric balloon or bariatric surgery – 7 cases).	Endoscopic gastroplasty represent a safe minimal invasive approach that can be considered as an effective and well tolerated procedure especially for primary obesity treatment. For patients with previous bariatric surgical procedures or with severe obesity the results are less favourable.	Larger studies included in table 2.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Manos T, Costil V, Karsenty L et al. Safety of Endoscopic Sleeve Gastroplasty with a Single-Channel Endoscope. Obesity Surgery (2022) 32:3074–3078.	Retrospective study N=191 had ESG using the new suturing device OverStitch Sx™	Endoscopic gastroplasty represents a safe minimal invasive approach with the new device OverStitch Sx™. 2 postprocedural complications (1%), a transparietal suturing of falciform ligament which needed laparoscopic exploration for severe abdominal pain and a perigastric collection with antibiotic treatment, both with favourable outcome. 12 patients underwent revisional bariatric procedure.	Safety outcomes already reported in studies included in the evidence summary.
Matteo MV, Bove V, Pontecorvi V et al. Outcomes of Endoscopic Sleeve Gastroplasty in the Elder Population. Obesity Surgery (2022) 32:3390–3397.	Retrospective analysis. N=18 patients (BMI was 41.2 kg/m <sup>2</sup> ) aged 65 years and older had ESG.	The median TBWL% was 15%, 16%, and 16% at 6, 12, and 24 months, while the median %EWL was 39%, 37%, and 41% at 6, 12, and 24 months. ESG is a promising therapeutic option for elder individuals with	Larger studies included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		obesity who fail non-invasive methods, and who refuse or are deemed not suitable for bariatric surgery because of age and comorbidities.	
Maydeo A, Patil G, Dalal A et al. (2020) An Indian Experience of Endoscopic Treatment of Obesity by Using a Novel Technique of Endoscopic Sleeve Gastroplasty (Accordion Procedure). Journal of The Association of Physicians of India. 68,	Prospective study. n=58 patients who had ESG.	The mean weight reduced significantly from baseline of 98.3 to 81.8 kg at 6 months (p<0.001). mean BMI reduced from 37.8 to 31.3 kg/m <sup>2</sup> at 6 months (p<0.001). The mean % of TWL was 8.8, 12.6 and 17.1 at 1, 3 and 6 months respectively. The % of EWL was 21.3, 30.5 and 42.8 at 1, 3 and 6 months respectively. No major complications reported.	Larger studies included in evidence summary.
Moura D de, Jr SB, Moura E de, et al. Endoscopic sleeve gastroplasty in the management of weight regain after sleeve gastrectomy. Endoscopy. 2020;52(03):202-210	Retrospective study. N=34 patients with weight regain following sleeve gastrectomy	ESG appears to be safe and effective in the management of weight regain following sleeve gastrectomy.	Not primary ESG.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	who underwent ESG.		
Novikov AA, Afaneh C, Saumoy M, et al. (2018) Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: How Do They Compare? J Gastrointest Surg. 22(2):267-273.	Retrospective study. N=278 obese (BMI more than 30) patients (n=278) who underwent ESG (n=91, overStitch), LSG (n=120), or LAGB (n=67, lap-band system). 12 months follow-up.	At 12-month follow-up, LSG achieved the greatest %TBWL compared to LAGB and ESG (29.3 vs 13.3 vs 17.6%, respectively; p<0.001). However, ESG had a significantly lower rate of morbidity when compared to LSG or LAGB (p=0.01). The LOS was significantly less for ESG compared to LSG or LAGB (0.34 vs 3.09 vs 1.66 days, respectively; p<0.01). Readmission rates were not significantly different between the groups (p=0.72).	Study included in systematic review and meta-analyses included in the summary of evidence.
Neto MG, Moon RC, de Quadros LG, et al. (2020) Safety and short-term effectiveness of endoscopic sleeve gastroplasty using overstitch: preliminary report from a multicenter study. Surg Endosc. 34:4388–4394.	Observational prospective study. N=233 patients with mean 34.7 kg/m <sup>2</sup> had ESG. Follow-up 12 months.	Mean %TWL was 17.1% at 6 months and 19.7% at 12 months. Percentage of excess BMI loss was 47.3% at 6 months and 54.8% at	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		12 months. The mean EBML was significantly greater among patients with class 1 obesity than those with class 2 obesity at 6 (51.1% vs. 43.7%) and 12 months (60.2% vs. 49.2%). One patient experienced bleeding and was treated with sclerotherapy.	
Neto MG, Learning Process Effectiveness During the COVID-19 Pandemic: Teleproctoring Advanced Endoscopic Skills by Training Endoscopists in Endoscopic Sleeve Gastroplasty Procedure. Obesity Surgery (2021) 31:5486–5493.	Retrospective study N=10 patients had ESG guided by a proctor expert using an online platform.	The proposed teleproctoring program was effective to deliver advanced endoscopic skills such as endosuturing for ESG, despite the restrictions imposed by the COVID-19 pandemic.	Learning program.
Neto ACM, Bernardo WM, de Moura DTH et al. (2018) The Effectiveness of Endoscopic Gastroplasty for Obesity Treatment According to FDA Thresholds: Systematic Review and Meta-Analysis Based on Randomized Controlled Trials. Obesity Surgery, 28:2932–2940.	Systematic review and meta-analysis of RCTs of endoscopic gastroplasty techniques (POSE, TOGA) versus conservative treatment	3 RCTs were included in the meta-analysis n=459 patients (312 EBTs vs 147 control). Mean total body weight loss in the intervention group was 4.8% higher than the control group at	Review grouped 2 procedures with different devices accessories (for suture and plication) and does not include studies on ESG as there were no RCTs. The rationale of both

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
	(sham or diet/exercise).	12 months (p=0.01). The intervention group responder rate was 44.3% at 12 months. Therefore, the endoscopic gastroplasty is more effective than conservative therapies but do not achieve FDA thresholds.	devices is the same: the apposition of the total thickness of tissue to reduce gastric volume.
Due-Petersson, R., Poulsen, I. M., Hedbäck, N., & Karstensen, J. G. (2020). Effect and safety of endoscopic sleeve gastroplasty for treating obesity – a systematic review. Danish Medical Journal, 67(11), 1-13	Systematic review. ESG, 23 studies included.	The average total weight loss at 12 months was 16.3%. ESG was associated with a significantly greater weight loss than both intragastric balloon insertion (21.3 versus 13.9% TWL at 12 months, p<0.05) and “high-intensity diet and lifestyle therapy” (20.6 versus 14.3% TWL at 12 months, p<0.05). In contrast, ESG was associated with a significantly lower weight loss than laparoscopic sleeve gastrectomy (17.1 versus 23.6%	Similar recent assessment included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		TWL at 6 months, p<0.05). ESG had a significantly lower rate of adverse events than both laparoscopic sleeve gastrectomy (5.2 versus 16.9%, p<0.05) and intragastric balloon placement (5.2 versus 17%, p<0.05).	
Pizzicannella M, Fiorillo C, Barberio M, et al. Endoscopic assessment of morphological and histopathological upper gastrointestinal changes after endoscopic sleeve gastroplasty. Surg Obes Relat Dis. Published online 2021	Retrospective analysis (of prospective data). N=86 patients who underwent ESG and upper endoscopy. Follow-up 12 months.	At 12 months, %TWL was 14.1% and %EWL was 35.8%. 16 patients had revisions; esophagitis resolved in all but one. Hyperaemic and erosive gastropathy decreased to 17.4% (n=15) and 1.2% (n=1) (p=0.44) H. pylori resolved in all previous cases. ESG does not promote the new onset of macroscopic and histopathologic abnormalities within 1-year follow-up.	Studies with higher level of evidence included in evidence summary.
Pizzicannella M, Lapergola A, Fiorillo C, et al. Does	Prospective study.	ESG was open in 6, partially intact	High level evidence

IP overview: Endoscopic sleeve gastroplasty for obesity



Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
endoscopic sleeve gastroplasty stand the test of time? Objective assessment of endoscopic ESG appearance and its relation to weight loss in a large group of consecutive patients. Surg Endosc. 2020;34(8):3696-3705	N=133 patients underwent ESG. Follow-up 12 months	in 38 and intact in 43 cases at 6 months. The overall %EWL and %TWL was 34.5 and 13.2, respectively; 25.7 and 11.8 for the open group, 30.8 and 12.4 for the partially intact group; 39.1 and 14 for the intact group. At 12 months, 10 (24%) had an intact ESG, 24 (59%) had a partially intact gastroplasty, and in 7 (17%) cases the sutures were lost. Overall %EWL and %TWL at 12 months was 34.3 and 13.1, 19.3 and 8.9 for the open group; 36.0 and 13.1 for the partially intact group; 40.3 and 17.2 for the intact group. Weight loss correlates with ESG endoscopic appearance over time.	included in evidence summary.
Polese L, Prevedello L, Belluzzi A et al. Endoscopic sleeve gastroplasty: results	Prospective study.	%TBWL and %EWL were 11 and 39,	Larger studies included in

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
from a single surgical bariatric centre. Updates in Surgery (2022) 74:1971–1975.	N=27 patients ineligible for bariatric surgery due to comorbidities or low BMI had ESG. Mean BMI 36.9 kg/m <sup>2</sup> . Mean follow-up 18 months.	respectively. The latter was significantly higher in the patients with an initial BMI less than 40. The patients whose gastric sleeve extended for more than a third of the length of the stomach had better results.	evidence summary.
Rapaka B, Maselli DB, Lopez Nava G et al. (2022) Effects on physiologic measures of appetite from intragastric balloon and endoscopic sleeve gastroplasty: results of a prospective study. Chinese Medical Journal;135(10)	Prospective case series. N=41 IGB 18 ESG 23	IGB and ESG both induce weight loss but likely through distinct gastric motor function phenotypes, and gastric emptying may predict future weight loss in patients with IGB.	Similar comparative studies reporting weight loss as primary outcome were included in evidence summary.
Runge TM, Juliana Yang J, Fayad L et al. (2020) Anatomical Configuration of the Stomach Post-Endoscopic Sleeve Gastroplasty (ESG)—What Are the Sutures Doing? Obesity Surgery, 30:2056–2060	Prospective case series. N=5 patients who had ESG.	ESGs were successfully reversed at 3 weeks and 1 month following index ESG without significant fibrosis or scarring. At 8 and 14 months, a few sutures had dehiscence though there were extensive areas of fibrosis. By 2 years, most of the sutures had dehiscence; however, the	Large studies included in evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		gastric volume remained reduced.	
Sarkar A, Tawadros A, Andalib I, et al. (2022) Safety And Efficacy Of Endoscopic Sleeve Gastroplasty For Obesity Management In New Bariatric Endoscopy Programs: A Multicenter International Study. Ther Adv Gastrointest Endosc 15: 1–9	Retrospective analysis. N=91 patients who had ESG.	BMI reduction at 3 months was 7.3 (p<0.000), at 6 months 9.3 (p<0.000), at 12 months 8.6 (p<0.000) from baseline. EBWL was 17.3% at 1 month (p<0.000), 29.2% at 3 months (p<0.000), and 35.6% at 6 months (p<0.000).	Higher level evidence included in evidence summary.
Sartoretto A, Sui Z, Hill C, et al. (2018) Endoscopic sleeve gastroplasty (ESG) is a reproducible and effective endoscopic bariatric therapy suitable for widespread clinical adoption: a large, international multicenter study. Obes Surg. 28:1812–21.	Observational study (retrospective). N=112 patients overweight or obese with BMI ranging from 28.5 to 69.0 kg/m <sup>2</sup> Follow-up 6 months	At 1, 3, and 6 months, absolute weight loss was 9.0 kg (TBWL 8.4%), 12.9 kg (TBWL 11.9%), and 16.4 kg (TBWL 14.9%), respectively. The proportion of patients who attained greater than 10% TBWL and 25% EWL was 62 and 78% at 3 months post-ESG and 81 and 87% at 6 months post-ESG.	Included in systematic reviews added to evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Saumoy M, Schneider Y, Zhou XK, et al. (2018) A single-operator learning curve analysis for the endoscopic sleeve gastroplasty. <i>Gastrointest Endosc.</i> 2018;87:442–7.	Observational study (prospective). N=128 patients with BMI > 30 kg/m <sup>2</sup> with failed non-invasive weight loss measures or BMI > 40 kg/m <sup>2</sup> and nonsurgical candidates or declined surgery. ESG Follow-up 12 months.	Efficiency for ESG was attained after 38 ESGs, with mastery after 55 procedures. At 12 months, the mean percent total body weight loss was 15.8%. A total of 71.7% of patients achieved successful weight loss.	Learning curve; included in systematic reviews added to evidence summary.
Singh S, Hourneaux de Moura DT, Khan A, et al. (2020) Safety and efficacy of endoscopic sleeve gastroplasty worldwide for treatment of obesity: a systematic review and meta-analysis. <i>Surg Obes Relat Dis.</i> 16(2): 340–351.	Systematic review and meta-analysis. n=8 observational studies (n=1,859 patients) ESG	Pooled mean %TWL at 6, 12, and 24 months was 14.9 (95% CI 13.8 to 15.9), 16.4 (95% CI 15.2 to 17.6) and 20.0 (95% CI 16.9 to 23.1), respectively. Pooled mean %EWL at 6, 12, and 24 months was 55.8 (95% CI 50.6 to 60.9), 61.8 (95% CI 54.8 to 68.9), and 60.4 (95% CI 48.9 to 71.9), respectively. The pooled incidence of SAE was 2.3% (95% CI 1.3 to 4.0), and no	More recent comprehensive studies included in the evidence summary.

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		<p>mortality was reported. Gastrointestinal bleeding and peri-gastric fluid collection were the most common reported SAE; however, the pooled incidence of both was less than 1%. Variations in procedural technique were seen, but the full-thickness nature of suturing was reported in all studies. A layer of reinforcement sutures was performed in most studies (n=6).</p>	
<p>Sharaiha RZ, Kumta NA, Saumoy M, et al. Endoscopic Sleeve Gastroplasty Significantly Reduces Body Mass Index and Metabolic Complications in Obese Patients. Clin Gastroenterol Hepatol. 2017;15(4):504-510.</p>	<p>Prospective study. N=91 patients with BMI &gt;30 kg/m<sup>2</sup> and had failed non-invasive weight loss measures or BMI &gt;40 kg/m<sup>2</sup> not suitable or refused surgery. Follow-up 24 months</p>	<p>Mean BMI 40.7 kg/m<sup>2</sup>. ESG is a minimally invasive and effective endoscopic weight loss intervention. In addition to sustained total body weight loss up to 24 months, ESG reduced markers of hypertension, diabetes, and hypertriglyceridemia.</p>	<p>Study included in systematic reviews added to evidence summary.</p>

IP overview: Endoscopic sleeve gastroplasty for obesity

© NICE 2023. All rights reserved. Subject to [Notice of rights](#).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Sharaiha RZ, Kedia P, Kumta N et al. (2015) Initial experience with endoscopic sleeve gastroplasty: technical success and reproducibility in the bariatric population. <i>Endoscopy</i> ; 47: 164–166	Prospective study. N=10 patients with mean BMI 45.2 kg/m <sup>2</sup> had ESG. Follow-up 6 months.	There were no significant adverse events noted. After 1 month, 3 months, and 6 months, excess weight loss of 18%, 26%, and 30%, and mean weight loss of 11.5 kg, 19.4 kg, and 33.0 kg, respectively, were observed.	Large studies included in evidence summary.
Sowier A, Pyda P, Borucka AM et al. (2018) Initial experience with endoscopic sleeve gastroplasty in Poland. <i>POL PRZEGL CHIR</i> , 90 (4), 36-41.	Prospective case series. N=10 patients with obesity had ESG.	No severe peri-operative complications. The only adverse event was a minor haemorrhage in 1 patient, which did not need any surgical intervention. Mean %TBWL was 8.6%, 15.4% and 19.6% at 1, 2 and 3 months, respectively.	Large studies included in evidence summary.
Yoon JY, Arau RT, and the study group for Endoscopic Bariatric and Metabolic Therapies of the Korean Society of Gastrointestinal Endoscopy. (2021) The Efficacy and Safety of Endoscopic Sleeve Gastroplasty as an Alternative to Laparoscopic Sleeve Gastrectomy. <i>Clin Endosc</i> ; 54:17-24.	Review of efficacy and safety.	Weight loss for ESG is significantly greater than that of high-intensity diet and lifestyle therapy and lower than that of LSG. Percentage of total body weight loss and excess body weight loss	Review

IP overview: Endoscopic sleeve gastroplasty for obesity

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		was approximately 16% and 60% at 12 months. The pooled rate of adverse events in several meta-analysis studies ranged from 1.5% to 2.3%. ESG reduced the risk of obesity-related metabolic comorbidities, and even improved quality of life.	