

Systematic Review

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Effect and safety of endoscopic sleeve gastroplasty for treating obesity – a systematic review

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ABSTRACT

**INTRODUCTION:** Endoscopic sleeve gastroplasty (ESG) represents a novel endoscopic bariatric procedure. It is performed with an endoscope equipped with a suturing device; sutures are placed so that they create a tube-shaped stomach, thereby facilitating weight loss. The aim of this study was to conduct a systematic review evaluating the effectiveness and safety of ESG for treatment of obesity.

**METHODS:** This review was conducted in accordance with the PRISMA guidelines; a protocol was registered with PROSPERO before the start of the study. MEDLINE, Embase and Clinicaltrials.gov were searched through 20 February 2020.

**RESULTS:** A total of 1,088 articles were assessed. In all, 23 studies met the inclusion criteria. 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 ± 6.6 versus 13.9 ± 9.0% total weight loss (TWL) at 12 months, p < 0.05) and “high-intensity diet and lifestyle therapy” (20.6 ± 8.3 versus 14.3 ± 10.2% TWL at 12 months, p < 0.05). In contrast, ESG was associated with a significantly lower weight loss than laparoscopic sleeve gastrectomy (17.1 ± 6.5 versus 23.6 ± 7.6% TWL at six 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).

**CONCLUSIONS:** ESG is a safe method for treatment of obesity and facilitates a significant weight loss.

KEY POINTS

- Endoscopic sleeve gastroplasty (ESG) represents a novel endoscopic bariatric procedure where sutures are placed so that they create a tube-shaped stomach, thereby facilitating weight loss.
- The included data show that ESG is a safe method for treatment of obesity. It facilitates a significantly greater weight loss than both intragastric balloon insertion and “high-intensity diet and lifestyle therapy”.
- There are no randomised controlled studies evaluating ESG and therefore no high-quality evidence on the merits of ESG.
- Future research should investigate the potential of ESG to bridge the gap between non-invasive and surgical interventions.

Obesity is a growing health concern and the WHO estimates that the number of obese persons has nearly tripled worldwide since 1975 [1]. It is well known that overweight and obesity are associated with increased risk of death from cardiovascular disease, cancer and Type 2 diabetes (T2D) [2-4]. Bariatric surgery facilitates a major weight loss and is currently the most effective treatment of obesity and T2D. Laparoscopic Roux-en-Y gastric bypass (RYGB) has been established as the gold standard bariatric procedure owing to a sustained long-term effect on weight loss and obesity-related co-morbidities [5, 6]. Twenty years ago, laparoscopic sleeve gastrectomy (LSG) was introduced as a less extensive alternative to RYGB [7]. LSG is associated with less morbidity than RYGB and has therefore gained popularity [8]. The procedure involves a longitudinal excision of most of the stomach, leaving only a narrow passage for nutrients. At present, LSG is the most common bariatric procedure worldwide [9]. Laparoscopic procedures require access to the abdominal cavity, which might lead to adverse events such as post-operative adhesions, small bowel obstruction and incisional hernias [10, 11]. In contrast hereto, an endoscopic approach might not be associated with the same adverse events and may therefore be safer.

Endoscopic sleeve gastroplasty (ESG) represents a novel endoscopic bariatric procedure that mimics LSG by creating a tube-shaped stomach to facilitate weight loss [12]. ESG is performed with an endoscope that has a suture device mounted on the tip. During the procedure, triangular full-thickness sutures are placed along the greater curvature of the stomach. These sutures create a mucosal opposing fold leaving a tube-shaped lumen of the stomach along the lesser curvature. The aim of this paper was to perform a protocol-based systematic review to investigate the effect and safety of ESG.

## METHODS

Before the study was initiated, a protocol was established in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) [13]. The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 30 April 2019 (registration number: 133754). The manuscript was drafted in accordance with the PRISMA statement [14].

### Eligibility criteria

The eligibility of articles was assessed using the criteria specified below. All original peer-reviewed studies aiming to evaluate ESG for treatment of obesity were included. Studies with at least one exclusion criterion were excluded from the review. Only English, full-text, peer-reviewed publications were included, but no limitations regarding publication date were applied. If subjects were included in multiple studies, the study with the most subjects was included and the other studies were excluded, unless they were part of a study with a different control group.

#### *Study design*

randomised clinical trials, prospective non-randomised trials, cohort studies, case-control studies, case series and case reports. All guidelines, comments on papers, letters, brief reports, protocol studies and review articles were excluded.

#### *Participants*

Adult patients (18 years or older) treated with ESG were included. All animal studies were excluded. Studies that included patients with previous abdominal surgery were excluded.

#### *Duration*

Both long-term and short-term outcomes were of interest. Thus, all studies reporting weight-loss-related outcomes with a follow-up period of at least three months were included. Due to a general lack of adverse-event data, all follow-up periods were accepted for this parameter.

## *Intervention*

Studies investigating the effectiveness or safety of ESG were included. Any type of treatment comparison was accepted such as other surgical or endoscopic treatment, sham endoscopy, diet or medical treatment.

## **Primary outcome**

Our primary outcome of interest was weight loss. The outcome measures of interest were absolute weight loss, % total weight loss (TWL), % excess weight loss and % excess BMI loss. Studies reporting one or more of these outcomes were included.

## **Secondary outcomes**

### *Adverse events*

We were primarily interested in the frequency and severity of adverse events, but additionally searched for risk factors of adverse events. The Clavien-Dindo classification (CD) was used to rate the adverse events reported in the included studies [15].

### *Decreased morbidity*

Parameters of morbidity were reduced hypertension, reduced sleep apnoea, reduced need for anti-diabetic treatment and increased health-related quality of life measures such as the Short Form (SF)-36, the Obesity-related problem scale, or others [16, 17].

### *Technical success rate*

We analysed the rate of completed procedures and the rate of spontaneous reversal. We also looked at the rate of intentional reversal or conversion to another type of bariatric surgery and the reasons for this.

## **Information sources**

Electronic databases were used to identify studies. We searched MEDLINE, EMBASE and Clinicaltrials.gov for relevant studies. The final search was performed on 20 February 2020.

## **Search strategy**

The search strategy for MEDLINE was developed collectively by all team members. This strategy was adapted to the other sources. The full search strategy for MEDLINE was published on PROSPERO before the search was performed [18].

## **Selection process**

Abstracts and titles resulting from our search strategy were independently screened by two authors using the Covidence software [19]. The full report of articles that appeared to meet the inclusion criteria was assessed before final inclusion. In case of any uncertainty regarding the inclusion of a study, the full text was screened. Disagreement regarding eligibility was solved by consensus between all authors.

## **Statistical analysis**

Combined data were calculated as a weighted mean of the results measured in each study. The weight was derived from the number of subjects included in each study out of the total number of subjects in all studies. Medians, interquartile ranges and confidence intervals were converted to mean and standard deviation according to the Cochrane handbook [20].

## **Risk of bias**

All of the included studies are non-randomised. The Newcastle-Ottawa Scale (NOS) was developed for quality assessment of non-randomised studies and was therefore chosen. This method uses a star system to judge three broad areas of the studies: the selection of the study groups, the comparability of the groups, and the ascertainment of the exposure and outcome of interests [21]. We defined a sufficient time of follow-up as six months, and we considered less than 10% an acceptable rate of loss to follow-up.

## RESULTS

Our search yielded 474, 552 and 62 studies from MEDLINE, EMBASE and ClinicalTrials.gov, respectively. After screening, a total of 23 studies met our inclusion criteria and were included [22-44]. A flow chart showing the inclusion process is presented in **Figure 1**. The intervention in all studies was an ESG procedure and a follow-up programme. These follow-up programmes included doctor visits and, in some instances, follow-up by a multidisciplinary team with dietitians, psychologists, etc. The follow-up programmes were not systematically described across studies. All studies except two used the OverStitch device for suturing. The two studies that did not use the OverStitch device either used the GERDX device or the Endomina device [23, 25].

### Patient characteristics

A total of 2,142 patients undergoing ESG were identified, of whom 68% were women. The average age of the included patients was 37.2 years, and the average BMI was 34.9 kg/m<sup>2</sup>. The studies followed the patients for up to two years. The median time of follow-up was six months, with an interquartile range of eight months. An overview of the included studies is presented in **Table 1**.

### Clinical success rate

A TWL ranging 13.2-19.5% and from 15.0 to 20.6% at six and 12 months, respectively, was seen in the included studies (**Table 2**). The average TWL loss at six and 12 months was 14.6% and 16.3%, respectively. Five studies compared ESG with other weight loss interventions [22, 27, 28, 32, 35].

In a study by Alqahtani et al. with 1,000 consecutive patients, 28 of the included patients had hypertension and 17 patients had T2D [24]. The patients were followed for up to 18 months. All 28 patients with hypertension undergoing ESG became normotensive. The 17 patients with T2D all improved their glycaemic control with reduced medication dose and 13 of these patients (76%) showed complete remission.

One study recorded quality of life data using the Gastrointestinal Quality of Life Index questionnaire. It found an increased score after ESG, but no difference between ESG and LSG [32, 45].

### Technical success rate

No study recorded how many of the procedures had to be aborted due to intraoperative difficulties. In addition, no study systematically evaluated the integrity of sutures. The conversion rate of ESG to LSG was recorded in two studies; a rate of 0.8% and 3.8% was observed [24, 30]. All the conversions were due to unsatisfactory weight loss, and all patients had broken sutures. The rate of redo-ESGs was recorded in one case series (0.5%) [24]. It was performed because of weight regain, and none of the patients had intact sutures. One study reported that two out of 148 included patients had broken sutures, but it was not reported how these patients were identified [42].

### Adverse events

Adverse events of CD grade II or higher were seen in 1.5% of cases when case reports were excluded. An overview of the reported adverse events can be seen in **Table 3**. Mild adverse events such as light pain and nausea were not systematically recorded across studies. No fatal cases were registered. Our search identified a

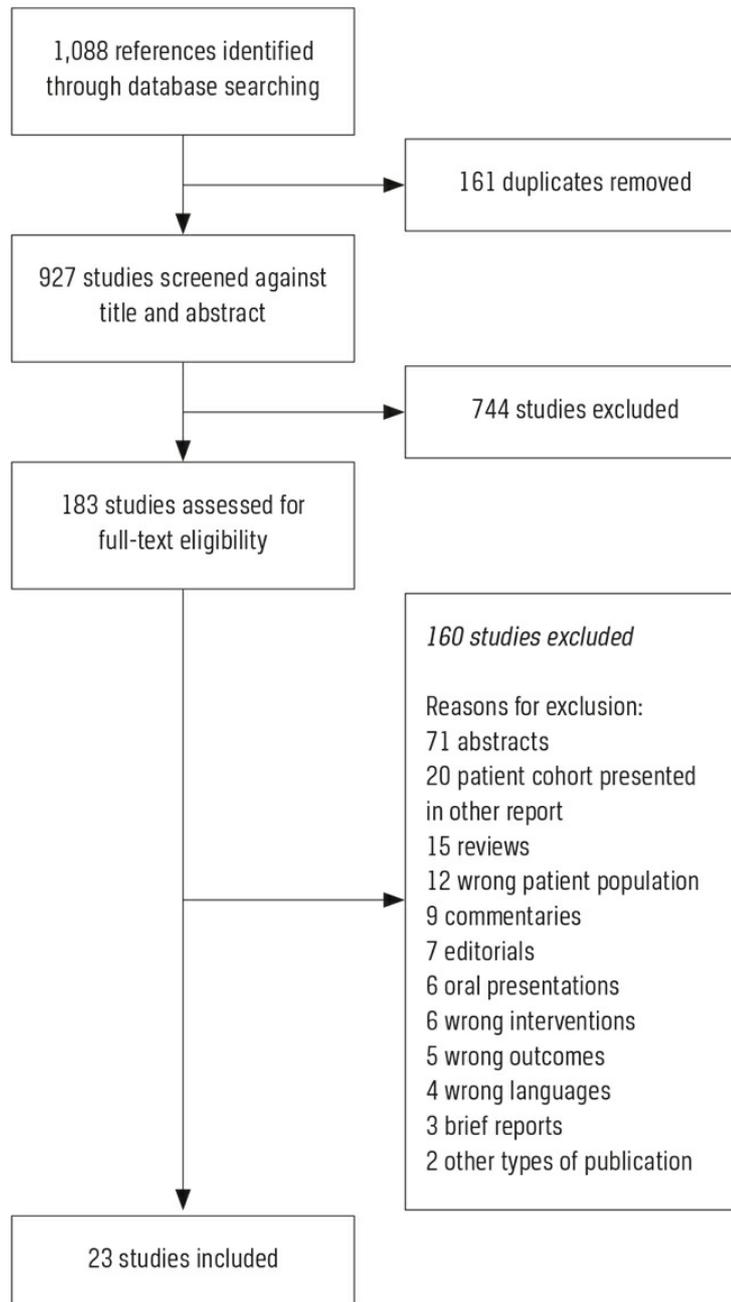
total of five cases requiring surgical intervention under general anaesthesia (CD grade IIIb); two gastric perforations, one gallbladder perforation, one perigastric fluid collection and one perigastric abscess. Whereas the perigastric abscess was treated endoscopically, the other patients underwent either open or laparoscopic surgery [29, 34, 36, 39]. Two of these patients were not reported as case reports, leading to a severe adverse event rate of 0.1% (CD grade IIIb) when case reports were excluded [29]. ESG had a significantly lower rate of adverse events than both LSG (5.2 versus 16.9%,  $p < 0.05$ ) and IGB (5.2 versus 17%,  $p < 0.05$ ) [22, 27].

## Quality of evidence and conflicts of interests

The risk of bias for individual studies was estimated using NOS [21]. All the included case series and cohort studies received a perfect score in the selection category, meaning that the cohort was representative, secure records were used and the comparison groups were representative [22, 24, 27-33, 35, 37, 40, 42, 43]. In three out of five cohort studies, the groups were controlled for BMI and at least one additional factor [22, 28, 32]; the two remaining studies did not control for any factors [27, 35]. All the cohort studies were followed for a sufficient period to be considered of high quality (six months), but none of them had less than 10% loss to follow-up. Six out of nine case series had less than 10% loss to follow-up [24, 29-31, 33, 42]. An overview of the NOS score of the individual studies is provided in [Supplementary Table 1](#).

All included studies presented information regarding conflicts of interest. A total of 18 out of 23 studies (78%) had at least one author with an economic interest in or a relationship to a company producing ESG equipment. There were five studies without any conflicts of interest [23-25, 32, 41].

**FIGURE 1 /** Flow chart of the study selection process.



**TABLE 1 /** Study characteristics.

Reference <sup>d</sup>	Study type	Comparator	Participants, n (comparator group)	Mean age ± SD, yrs (comparator group)	Mean BMI ± SD, kg/m <sup>2</sup> (comparator group)	Proportion men/ women, n/N	Loss to follow-up 12 mo.s, % (comparator group)	Duration of follow-up, mo.s
Alqahtani et al, 2018	Case series	None	1,000	34.4 ± 9.5	33.3 ± 4.5	103/897	6.9	18
Fayad et al, 2019	Cohort	LSG	54 (83)	48, 24-72 (47, 30-67) <sup>a</sup>	43.0, 30.2-65.6 (44.1, 29.7-64.5) <sup>a</sup>	23/31 (24/59)	35.1 (15.7)	6
Fayad et al, 2019	Cohort	IGB	58 (47)	48.2 ± 11.8 (47.7 ± 12.4)	41.5 ± 8.2 (34.5 ± 6.7)	24/34 (1/46)	63.8 (57.4)	12
Galvão-Neto et al, 2016	Case report	None	1	56	35	1/0	-	0
Graus Morales et al, 2018	Case series	None	148	41.5 ± 10	35.1 ± 5.5	127/21	0	18
James et al, 2019	Case report	None	1	44	-	0/1	-	1
Loo et al, 2017	Case report	None	1	45	32.6	1/0	0	5
Lopez-Nava et al, 2017	Case series	None	248	44.5 ± 10	37.8 ± 5.6	67/181	38 <sup>c</sup>	24
Peng et al, 2019	Case report	None	1	-	36.2	-	-	3
Wallstabe et al, 2018	Case report	None	2	-	39.1	-	-	3
Wannhoff et al, 2019	Case report	None	1	41	42.9	0/1	-	1
Glaysher et al, 2019	Case series	None	32	43.5 ± 10.6	36.3, 29.8-43.8 <sup>a</sup>	9/23	-	6
Cheskin et al, 2019	Cohort	HIDLT	105 (281)	47.6 ± 12.0	40.5 ± 7.9 (39.9 ± 7.6)	30/75 (92/189)	59.4 (64.4)	12
Galvão-Neto et al, 2019	Case series	None	233	41.1 ± 10.5	34.7 ± 2.6	53/170	47	12
Surve et al, 2019	Case report	None	1	44	38	0/1	-	0
Lopez-Nava et al, 2019	Case report	None	1	72	48	1/0	-	6
Barrichello et al, 2019	Case series	None	193	42.3 ± 9.6	34.1 ± 3.0	45/148	11.1	12
Bhandari et al, 2019	Case series	None	53	40.5 ± 13.8	34.8 ± 5.2	10/43	9.0	12
de Souza et al, 2020	Case series	none	7	38.1 ± 4.1	33.4 ± 0.8	2/5	-	6
Fiorillo et al, 2020	Cohort	LSG	84 (99)	41 ± 5.9 (37 ± 13.3)	39.5 ± 5.9 (41 ± 3.8)	4/9	-	6
Huberty et al, 2018	Case series	None	51	40.9 ± 10.3	35.1 ± 3	1/7	11.8	12
Lopez-Nava et al, 2019	Cohort	POSE <sup>b</sup>	247 (234)	45.9 ± 9.6 (47.0 ± 10.1)	38.3 ± 5.7 (37.6 ± 4.8)	73/174 (63/171)	39.3 (51.7)	12
Villa et al, 2019	Case report	None	1	46	42.8	1/0	-	6

HIDLT = high-intensity diet and lifestyle therapy; IGB = intra-gastric balloon; LSG = laparoscopic gastric sleeve; POSE = primary obesity surgery, endoluminal; SD = standard deviation.

a) Median, range.

b) Cohort was also compared to intra-gastric balloon.

c) At 24 mo.s.

d) Please contact authors for further information.

**TABLE 2 /** Weight loss.

Reference <sup>c</sup> Study type	%TWL at 6 mo.s, mean ± SD (comparator)	%TWL at 12 mo.s, mean ± SD (comparator)	%TWL at 18 mo.s, mean ± SD	%TWL at 24 mo.s, mean ± SD
Alqahtani et al, 2018	13.7 ± 6.8	15.0 ± 7.7	14.8 ± 8.5	-
Fayad et al, 2019 LGS	17.1 ± 6.5 (23.6 ± 7.6) <sup>a</sup>	-	-	-
Fayad et al, 2019 IGB	19.5 ± 5.7 (15.0 ± 7.6) <sup>b</sup>	21.3 ± 6.6 (13.9 ± 9.0) <sup>b</sup>	-	-
Graus Morales et al, 2018	15.1 ± 4.9	18.2 ± 6.8	18.7 ± 7.3	-
Lopez-Nava et al, 2017	-	15.17 ± 8.2	-	18.6 ± 23.3
Glaysheer et al, 2019	13.2 (19.5)	-	-	-
Cheskin et al, 2019	17.7 ± 6.4 (14.7 ± 8.2) <sup>b</sup>	20.6 ± 8.3 (14.3 ± 10.2) <sup>b</sup>	-	-
Galvão-Neto et al, 2019	17.1 ± 4.9	19.7 ± 5.7	-	-
Barrichello et al, 2019	14.3 ± 5.3	15.1 ± 5.2	-	-
Bhandari et al, 2019	14.25 ± 6.17	19.94 ± 4.89	-	-
de Souza et al, 2020	21.3 ± 2.4	-	-	-
Fiorillo et al, 2020	13.4 ± 9.7 (18.8 ± 3.1) <sup>a</sup>	-	-	-
Huberty et al, 2018	8.0 ± 5.0	-	-	-
Lopez-Nava et al, 2019	16.1 ± 7.4 (14.5 ± 6.8) <sup>b</sup>	17.4 ± 10.2 (15.3 ± 8.7) <sup>b</sup>	-	-

ESG = endoscopic sleeve gastroplasty; IGB = Intra-gastric balloon; LGS = Laparoscopic gastric sleeve; SD = standard deviation; TWL = total body weight loss.

a) ESG significantly lower weight loss than comparator, p < 0.05.

b) ESG significantly greater weight loss than comparator, p < 0.05.

c) Please contact authors for further information.

**TABLE 3 /** Adverse events.

Reference <sup>a</sup> Study type	Patients, n			
	CD I	CD II	CD III-a	CD III-b
Alqahtani et al, 2018	196	16	3	0
Fayad et al, 2019 LSG	0	3	0	0
Fayad et al, 2019 IGB	0	3	0	0
Galvão-Neto et al, 2016	0	0	0	0
Graus Morales et al, 2018	1	1	0	0
James et al, 2019	0	0	1	0
Loo et al, 2017	0	0	0	0
Lopez-Nava et al, 2017	0	2	3	0
Peng et al, 2019	0	0	0	0
Wallstabe et al, 2018	0	0	0	0
Wannhoff et al, 2019	0	0	0	0
Glaysher et al, 2019	0	0	0	0
Cheskin et al, 2019	1	4	0	0
Galvão-Neto et al, 2019	0	0	0	0
Surve et al, 2019	0	0	0	1
Lopez-Nava et al, 2019 CR	0	0	0	1
Barrichello et al, 2019	13	2	0	2
Bhandari et al, 2019	0	0	0	0
de Souza et al, 2020	0	0	0	0
Fiorillo et al, 2020	0	0	0	0
Huberty et al, 2018	0	0	0	0
Lopez-Nava et al, 2019	-	-	-	-
Villa et al, 2019	0	0	0	1

CD = Clavien-Dindo grade; CR = case report; IGB = intra-gastric balloon; LSG = laparoscopic gastric sleeve.

a) Please contact authors for further information.

**DISCUSSION**

All the included studies in our systematic review demonstrated weight loss with an average TWL of 16.3% at 12 months. Our search did not include any randomised studies, and only five studies compared ESG with other interventions [22, 27, 28, 32, 35]. Three of these studies were based on the same patient material [22, 27, 28]. Sufficient evidence to determine the efficacy of ESG compared with any other intervention is therefore lacking. However, in the studies that were included, ESG was shown to facilitate a significantly greater weight loss than

both IGB and “high-intensity diet and lifestyle therapy” ( $p < 0.05$ ). In opposition to this, ESG was associated with a significantly lower weight loss than LSG ( $p < 0.05$ ). No study had a follow-up period of more than 24 months; thus, data on the long-term outcome of ESG is currently lacking.

In our material, we identified a total of 2,142 patients undergoing ESG with a rate of 1.5% (CD Grade II or higher) adverse events per procedure. None of the adverse events produced any long-term morbidity and only five patients required surgical intervention. The included studies that compared ESG to LSG and IGB found that ESG was associated with a significantly lower rate of adverse events [22, 27]. However, the rate of adverse events for LSG and IGB in these studies seems to be higher than what has been otherwise reported in the literature (3.5 versus 16.7% for LSG and 2.8 versus 17% for IGB) [8, 46]. A small portion of patients undergoing LSG experience new-onset gastroesophageal reflux disease [47]. Patients undergoing ESG also experience this, but the risk seems significantly lower than for those undergoing LSG (1.9% versus 14.5%,  $p < 0.05$ ) [22]. Overall, the present data implicate that ESG is a safe procedure. No study systematically investigated the rate of spontaneous reversal. All the patients who had either a redo-ESG or conversion to LSG because of unsatisfactory weight loss had incomplete suture lines [24, 30]. It seems that an unsatisfactory effect may be related to broken sutures.

Alqahtani et al. was the only study reporting the effect of ESG on T2D and hypertension [24]. All patients with hypertension had complete remission, and all patients with T2D either had remission or lowered their antidiabetic medication. This suggests that ESG has an effect on obesity-related morbidities.

Obesity is usually treated with lifestyle or pharmaceutical interventions before surgery such as LSG or RYGB is considered. Many guidelines recommend a threshold BMI of 35 kg/m<sup>2</sup> with obesity-related co-morbidities or 40 kg/m<sup>2</sup> without any obesity-related co-morbidities for surgery [48, 49]. However, not all patients with an unsatisfactory response to non-invasive interventions reach these thresholds or are not candidates for surgery for other reasons. Being associated with fewer adverse events than LSG, ESG could potentially bridge this gap. The majority of patients in our systematic review had a BMI below 35 kg/m<sup>2</sup>, demonstrating that ESG may potentially serve as a successful treatment modality for this population. Data on patients with a BMI exceeding 40 kg/m<sup>2</sup> are limited, and further data are needed to draw firm conclusions for this patient group.

As previously mentioned, there are no randomised studies and therefore no high-quality evidence on the merits of ESG. The included studies were either case series or cohort studies; study types with a considerable inherent risk of bias. There was a limited number of studies with a control group; however, the studies that did include a control group had a relatively low risk of bias according to their NOS score. There are some case series with a large sample size. One example is Alqahtani et al., a case series with 1,000 included patients [24]. For its study type, the risk of bias is relatively low. It has a sufficient time of follow-up and a low rate of loss to follow-up. The patients were recruited from a Saudi Arabic centre performing several different types of bariatric surgery, all of which were financed by out-of-pocket payments. Thus, the included patients may represent the typical Saudi Arabian patient who might undergo bariatric surgery. However, since 89.7% of the included patients were female and only 1.7% had T2D, the cohort composition may raise some questions about the general applicability of this study. Most of the included studies are based on a population where the procedures were paid for out of pocket. This makes it hard to apply them to a publicly financed healthcare system, such as the Scandinavian healthcare systems. A limitation to the included studies is that the majority had at least one author with a financial interest in a company producing equipment for ESG. This might lead to an overestimation of the treatment effect [50]. Another limitation is the variation of the follow-up programmes in the included studies. The programmes are not systematically reported across studies, and they differ in intensity. Furthermore, there is a general lack of long-term results, so the long-term effect is relatively unknown. The high loss to follow-up in most studies further complicates the estimation of the treatment effect.

## CONCLUSIONS

The included data indicate that ESG might be a safe method for treatment of obesity. The short-term data also demonstrate that subjects undergoing ESG can achieve a significant weight loss. We did not identify any randomised controlled trials; high-quality evidence on the merits of ESG is therefore lacking. Future research should investigate the potential of ESG to bridge the gap between non-invasive and surgical interventions. The first step may be to prove the superiority of ESG over non-invasive therapies. This should preferably be investigated by randomised controlled trials.

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**CONFLICTS OF INTEREST:** Disclosure forms provided by the authors are available with the full text of this article at [Ugeskriftet.dk/dmj](http://Ugeskriftet.dk/dmj)

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