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## RECOMMENDATIONS

# Position statement and guidelines about Endoscopic Sleeve Gastroplasty (ESG) also known as “Endo-sleeve”<sup>☆</sup>

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## Summary

*Is ESG effective in the treatment of obesity and associated comorbidities?* – Endoscopic Sleeve Gastroplasty (ESG) is more effective than lifestyle modifications alone for weight loss and improving obesity-related comorbidities. While it has less effect on weight loss compared to Laparoscopic Sleeve Gastrectomy (LSG) in the short to medium term, it offers similar comorbidities resolution to LSG.

*Is ESG a safe procedure, and what are its risks?* – The safety profile of ESG is consistently supported in the literature. Surgical complications after ESG, ranging from 1.5 to 2.3%, such as bleeding, perforation, fistula, or upper bowel obstruction, are rare and typically managed endoscopically. The incidence of new-onset gastro-esophageal reflux disease (GERD) is deemed negligible and occurs less frequently after ESG compared to SG.

*What are the indications and management methods?* – Multidisciplinary care for patients undergoing ESG should be provided in an accredited center authorized to perform bariatric and metabolic surgery, with validation through a multidisciplinary consultation meeting (RCP). Perioperative management should be personalized and ideally modeled after the protocols already in place for bariatric and metabolic surgery to ensure satisfactory and lasting weight and metabolic outcomes. Adherence to follow-up visits is a significant predictor of successful weight loss outcomes after ESG. Additionally, all endoscopic surgical procedures should be documented in a registry affiliated with a recognized scientific society, as is standard for other bariatric surgical procedures.

*Which healthcare professionals can perform ESG?* – ESG must be performed by a practitioner trained in endoscopy and obesity management, capable of ensuring thorough preoperative care and comprehensive postoperative follow-up, supported by an experienced multidisciplinary team. In France, Notice No. 2021.0040/AC/SEAP of June 10, 2021, issued by the Haute Autorité de santé (HAS) college, specifies that "the technology of ESG via the trans-oral approach, involving wide plication of the greater gastric curvature [...] with an endoscopic suture placement device, enables a gastroenterologist or a visceral and digestive surgeon to perform gastric plication through digestive endoscopy by placing sutures in the stomach". Ideally, this should take place in an accredited center authorized to perform bariatric and metabolic surgery, such as those approved by the Agence régionale de santé (ARS), in accordance with Article R6123-212 of December 2022 of the French Public Health Code.

*What are the recommendations and views of other international scientific societies?* – ESG is an integral part of the therapeutic arsenal available to bariatric and metabolic surgeons, offering an effective and valuable treatment option for obesity in specific patient populations. The International Federation for the Surgery of Obesity (IFSO) Bariatric Endoscopy Committee, following a comprehensive systematic review and meta-analysis, endorsed ESG as an effective and valuable treatment for obesity. ESG is particularly beneficial for patients with class I and II obesity, as well as for those with class III obesity who are not suitable candidates for metabolic bariatric surgery. Additionally, it can be proposed as an addition to lifestyle interventions in adolescent patients with class II obesity. The SOFFCOMM endorses endoscopic sleeve gastroplasty (ESG) as an effective and valuable treatment for obesity and highlights the importance of appropriate patient selection, coupled with rigorous evaluation of long-term outcomes, to refine its indications further.

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## Introduction

Bariatric and metabolic surgery is experiencing significant growth, with an increasing number of surgical techniques and new medications being introduced. Alongside classical surgical techniques, endoscopic techniques are emerging offering a less invasive alternative that preserves organ function and reduces risks. These include endoscopic sleeve gastroplasty (ESG or E-SG), which is currently being evaluated. Endoscopic Sleeve Gastroplasty is a minimally invasive technique that utilizes an endoscopic suturing device to apply full-thickness sutures in the stomach, to reduce gastric capacity induce gastric shortening and ultimately alter gastric motility.

The advantage of the technique lies in its endoscopic nature, which is less invasive than the laparoscopic approach and does not involve resection of the stomach. The technique is potentially reversible and can be repeated in cases of failure or insufficient weight loss and be converted to bariatric surgery.

The literature on ESG was non-existent before 2013, and there are no specific French guidelines on the subject. In 2020, the HAS published a summary of new bariatric surgery techniques currently under study, presenting ESG as a technique that would complete the surgical arsenal for the management of obesity [1]. ESG could be of particular interest for patients with moderate obesity (class I or II without comorbidity), but also patients with class III obesity at very high risk of surgery or those who are difficult to operate on. Recently the IFSO Bariatric Endoscopy Committee, following a comprehensive systematic review and meta-analysis, endorsed ESG as an effective and valuable treatment for obesity. ESG is particularly beneficial for patients with class I and II obesity, as well as for those with class III obesity who are not suitable candidates for metabolic bariatric surgery. Additionally, it can be proposed as an alternative to lifestyle interventions in adolescent patients with class II obesity [2]. Joint European and American guidelines were published in 2024, covering bariatric and metabolic endoscopic therapeutics [3].

It is therefore necessary to establish recommendations concerning its indications. Through this work, SOFFCOMM proposes a position statement on ESG.

Five questions will be addressed:

- is ESG effective in the treating obesity and associated comorbidities?
- is ESG a safe intervention, and what are its risks?
- what are the indications and management protocols?
- which healthcare professionals can perform ESG?
- what are the recommendations and views of other international scientific societies?

## Question 1: is ESG effective in the treatment of obesity?

### Effectiveness on weight loss

#### Effectiveness in relation to lifestyle modifications

Several studies have shown that ESG is more effective in weight loss than simple lifestyle modifications [4,5].

A recent French series, published in 2024, included 143 patients retrospectively and monocentrically, with a follow-up period of 3 years. The % of Total Weight Loss

(% TWL) reached 14.37% at 12 months [6]. Patients had a Body Mass Index (BMI) > to 30 kg/m<sup>2</sup> or > to 25 kg/m<sup>2</sup> with comorbidities associated with obesity. Optimal clinical response, defined as %TWL ≥ 10%, was achieved in only 41.2% of patients at 3 years. These results are consistent with pre-existing studies. Interestingly, the study shows the existence of a learning curve, with the optimum being reached after 26 procedures.

The American multicenter randomized MERIT trial, published in 2022, reported results for ESG combined with lifestyle modifications, compared with lifestyle modifications alone, at 1 and 2 years postoperatively in 209 patients aged 21 to 65 with class I or II obesity (85 ESG vs. 124 controls) [7]. At 52 weeks, the primary endpoint, mean % of Excess Weight Loss (%EWL), was 49.2% for the ESG group and 3.2% for the control group ( $P < 0.0001$ ). The mean %TWL was 13.6% for the ESG group and 0.8% for the control group ( $P < 0.0001$ ). Fifty-nine (77%) of 77 participants in the ESG group achieved 25% or more excess weight loss at 52 weeks, compared with 13 (12%) of 110 in the control group ( $P < 0.0001$ ). At 104 weeks, 41 (68%) of 60 participants in the ESG group maintained 25% or more excess weight loss [7].

→ ESG is therefore more effective at weight loss than lifestyle modifications alone.

### Effectiveness of ESG on weight loss compared with sleeve gastrectomy (SG)

ESG has been compared primarily with Sleeve Gastrectomy (SG) [8,9], with relatively few comparisons to other procedures currently available in bariatric and metabolic surgery. The similarities between ESG and SG, particularly in terms of the architectural modification of the digestive tract, make direct comparisons with other techniques, such as Roux-en-Y or procedures involving a digestive bypass, more challenging. To date, there have been approximately ten meta-analyses and 80 smaller studies evaluating ESG.

A meta-analysis published in 2020 comparing ESG with SG including patients with a BMI between 30 and 40 kg/m<sup>2</sup> and a minimum follow-up time of 12 months examined 16 studies, adding up to 2188 patients, of whom 1429 had SG and 759 ESG. In the results, the %EWL was 80% for the SG group and 62% for the ESG group. With a difference of around 18%, SG showed moderate superiority over ESG. ESG is less invasive and preferred for patients with class I or II obesity [10]. However, these are short-term results observed in patients without severe forms of obesity.

A US single-center case-control analysis published in 2019 compared 54 ESGs with 84 SGs. Median BMI was 44 kg/m<sup>2</sup> (min = 30 kg/m<sup>2</sup>; max = 65 kg/m<sup>2</sup>). The %TWL was assessed at 6 months post-procedure [11]. At six-month follow-up, %TWL was significantly lower in the ESG group, at 17.1 vs. 23.6% in the SG group [11].

An American meta-analysis published in 2020, involving 15 studies and almost 4000 patients, evaluated the safety and efficacy of ESG with follow-up points at 1, 6 and 12 months in patients with moderate to severe obesity [12]. The mean BMI range was 33.3 to 38.9 kg/m<sup>2</sup> in the ESG cohort and 37.4 to 48 kg/m<sup>2</sup> in the LSG cohort. Other characteristics were comparable between the two groups. At 12 months, %TWL, %EWL and BMI in the ESG group were 17.1%, 63% and 32 kg/m<sup>2</sup> respectively, versus 30.5%, 69.3% and 29.3 kg/m<sup>2</sup> in the LSG group, with a significant difference for %TWL in favor of LSG ( $P = 0.001$ ). Consequently, the superior efficacy of SG over ESG was strongly suggested [12].

In a Korean literature review published in 2021, ESG had a mean %EWL of 60% and a mean %TWL of 16% over a 12-month follow-up period [9]. BMIs ranged from 30 to 45 kg/m<sup>2</sup>. These results were inferior to those obtained with SG. Regular observant follow-up was identified as a key factor in effectively maintaining weight loss.

In a 2022 Australian prospective cohort study including 16 ESG and 45 SG (> 80% women in both groups, the majority with at least one obesity-related comorbidity), results were reported at baseline, six-month and 12-month follow-up [13]. BMIs ranged from 35 to 50 kg/m<sup>2</sup>. The median BMI was 35.5 kg/m<sup>2</sup> for ESG and 40.7 for LSG. The mean %EWL at 12 months post-procedure was 57% for ESG and 79% for LSG. Improvements in quality of life reached 19.8% in the ESG group and 48.1% in the LSG group, implying a better tolerance of LSG than ESG [13]. Studies comparing quality of life between ESG and SG are still rare.

An American study published in 2023 reports the results of a propensity score-matched analysis of 6054 ESG patients and 30,270 SG patients. The mean age was 44 years and the mean BMI after matching was 42.8 kg/m<sup>2</sup>. The mean %TWL at 30 postoperative days was higher in the SG group than in the ESG group (5.4 vs. 4.0%,  $P < 0.001$ ). Mean BMI also decreased more significantly in the first 30 days post-procedure in the SG group than in the ESG group (-2.36 vs. -1.77 kg/m<sup>2</sup>,  $P < 0.001$ ) [14].

An Australian systematic review with meta-analysis examining 5 studies comparing 1451 ESG with 203 SG was published in 2020. BMIs ranged from 33 to 45 kg/m<sup>2</sup>; groups were relatively comparable in terms of comorbidities. This study reports modest weight loss, with a mean 6-months %TWL of around 14.5% for ESG [15]. The mean %TWL for the SG group was 23.5% at 6-months follow-up. One article reported a %TWL of 29.3% at 12 months' follow-up. In the ESG group, two articles reported a %TWL of 14.8% and 18.6% at 18- and 24-months follow-up. Overall, ESG showed inferior results on short-term weight loss compared with SG [15].

Finally, a meta-analysis published in 2022, involving 6775 individuals, compared the safety and efficacy of ESG and SG [16]. Seven studies were reviewed, adding up to 3143 ESG and 3362 SG. At 6- and 12-month follow-up, mean %TWL in the ESG group were 7.5 and 7.6%. Mean %TWL in the SG group was significantly better; at 10.4% and 11.3% at 6 and 12 months. ESG had fewer adverse effects, so the study recommended that ESG should be offered to patients with moderate obesity [16].

→ ESG is clearly less effective than SG for weight loss, with results published only in the short-mid-term.

## Effectiveness on obesity-related comorbidities

### ESG alone

In a single-center prospective cohort study of 612 patients who underwent ESG for the treatment of obesity, resolution or improvement of comorbidities was reported in 51% of patients with diabetes, 66% of patients with hypertension, 74% of patients with dyslipidemia, and 90% of patients with obstructive sleep apnea after 4 years of follow-up [17].

### ESG + lifestyle modification versus lifestyle modification alone or drug treatment

In the randomized multicenter MERIT trial described above, 80% of patients (41/51) in the ESG group showed improvement in one or more metabolic comorbidities, while 12% (6/51) worsened. Forty-five percent of patients (28/62) in

the control group (lifestyle modifications alone) showed improvement, while 50% (31/62) worsened [7].

A U.S. cost-effectiveness study published in 2024, suggests superiority of ESG in improving obesity-related comorbidities compared with treatment with a GLP-1 analogue (semaglutide) alone over 5 years [18]. This should be viewed within the context of each country's healthcare system, as variations in funding, accessibility, and the availability of advanced bariatric procedures can significantly influence cost-effectiveness and patient outcomes.

## ESG versus LSG

A meta-analysis of 7 studies (involving 6775 patients) comparing 3413 ESG with 3362 SG reported that improvement or remission of type 2 diabetes at 12 and 24 months was significantly higher with SG than with ESG (82 versus 64% respectively; RR 0.78,  $P = 0.001$ ). Improvement or remission of hypertension was equivalent between the ESG and LSG groups (51% versus 46%  $P = 0.39$ ) [16].

→ ESG is more effective than lifestyle modifications alone in improving obesity-associated comorbidities, but less effective than LSG, with short-term data.

## Question 2: is ESG a safe intervention? What are the associated risks and complications?

Several meta-analyses reported fewer overall adverse events in ESG compared to LSG [16,19,20].

A 2020 Danish literature review and meta-analysis on the complications of ESG analyzed 23 studies, involving 2142 patients. ESG had a significantly lower rate of adverse events than SG (5.2 versus 16.9%,  $P < 0.05$ ) [21].

An American study published in 2022 compared the mortality and morbidity of ESG and SG during the first 30 days postoperatively. Patients had a BMI between 35 and 40 kg/m<sup>2</sup>. The ESG group comprised 211 patients, the SG group 9,059 (ratio 1:50). Analyses reported a lower rate of adverse events in the ESG group compared with the SG group, with an OR of 0.39 (95% CI: 0.19, 0.79), in line with previous studies [22].

In a systematic review and meta-analysis of 16 studies comparing ESG with LSG, the overall mean rate of perioperative complications in the ESG group was 0.15%. The overall mean rate of perioperative complications in the LSG group was 0.30%. The difference in the mean rate of adverse events was 0.19% ( $P = 0.20$ ) [10].

## Surgical complications

In a 2020 meta-analysis, gastric bleeding and the occurrence of perigastric collection due to minimal transfixing perforation were the most frequently reported major complications, occurring in 0.1 to 2.5% of cases, depending on the series [7,23]. Treatment was usually managed conservatively by endoscopy.

The prospective study of 216 people reported a serious adverse event rate of 1% ( $n = 3$ ). These events included suture pain after 18 months (managed by releasing the suture lines to increase gastric volume); 2 cases of fistulae (treated with antibiotics and radiological drainage in 1 case) [4].

High gastric occlusion caused by a technical error creating a mechanical obstruction can occur but is rare.



## Other complications

A US single-center case-control analysis published in 2019 compared 54 ESGs with 84 SGs. Postoperative GERD was assessed at 6 months postoperatively [11]. The proportion of patients with preoperative GERD was 25.3% in the SG group and 16.7% in the ESG group. The occurrence of postoperative GERD was significantly higher in the SG group (14.5%) than in the ESG group (1.9%) [11].

A meta-analysis of 6775 individuals was published in 2022 to compare the safety and efficacy of ESG and SG [16]. Seven studies were reviewed, adding up to 3143 ESG and 3362 SG. The risk of developing GERD was 1.3% for the ESG group and 17.9% for the SG group at 12 months. Thus, ESG had fewer adverse events than LSG [24].

In a Korean literature review published in 2021, the rate of adverse events in the ESG group ranged from 1.5 to 2.3%, while the incidence of postoperative GERD was considered negligible. Thus, the safety profile of ESG remained superior to SG [9]. This result was consistent with a French propensity score analysis published in 2020 assessing the quality of life (QoL) at 6 months after ESG, showing better QoL and fewer GERD than LSG [25].

A prospective single-center Indian study published in 2023 included more than 600 patients aged 28 to 62 with a mean initial BMI of 34.3 kg/m<sup>2</sup> (ranging from 29 to 39 kg/m<sup>2</sup>) followed up over 4 years. At least half of them initially had one or more obesity-related comorbidities. This study shows that revision or redo surgery (ESG redo/redux) was required in 3.6% of cases at 2 years post-op. Conversion to SG was necessary in 0.4% of patients at 12 months after ESG due to weight regain [17].

The propensity score analysis by Gudur et al. of 6054 ESGs and 30,270 SGs reported few adverse events at 30 days postoperatively. There was no significant difference in the occurrence of major adverse events between groups at 30-day follow-up (1.4 vs. 1.1%,  $P=0.058$ ). Patients in the ESG group had more readmissions (3.8 vs. 2.6%), re-operations (1.4 vs. 0.8%) and reinterventions (2.8 vs. 0.7%) within 30 days postoperatively compared with the SG group ( $P < 0.001$ ). In the ESG group, readmissions were mainly due to nausea, vomiting, fluid and electrolyte disorders (26%), abdominal pain (17%), fistula (6%) or gastric bleeding (5%). Reintervention or re-operation was defined as any procedure requiring either sedation or anesthesia (endoscopy or surgery). The most common re-operation performed after ESG and SG was exploratory laparoscopy. The most common reason for re-operation after ESG was suspected gastric occlusion or perforation, while gastrointestinal bleeding and fistula were the most common reasons for re-operation after SG. Therapeutic endoscopy was the most frequently performed reintervention after ESG (48%) and SG (32%) [14]. Endoscopic dilatation, with or without prosthesis, was the most frequently used reintervention.

Main results regarding safety outcomes after ESG are reported in Table 1.

→ Complications after ESG are fewer and less severe compared to those following SG. Treatment is mainly endoscopic. The onset of GERD is less frequent after ESG than after SG in the short-term. Abdominal pain is relatively frequent after ESG, and treatment is symptomatic in most cases.

## Question 3: what are the indications and modalities for perioperative management of ESG?

### Indications

The IFSO has endorsed ESG as an effective treatment of obesity and provided recommendations [2] stating that ESG is suited for patients with:

- class I obesity;
- class II obesity;
- class III obesity who are not suitable candidates for metabolic and bariatric surgery.

Various elements in the literature reflect that ESG is potentially indicated for certain sub-groups of patients. These subgroups include those who:

- are considered high risk for bariatric surgery due to age or comorbidities;
- refuse bariatric surgery due to fear of associated risks and complications;
- have already undergone complex abdominal surgery(ies), making bariatric surgery technically difficult and increasing the risk of intra- and postoperative complications;
- have a BMI in class I or II without comorbidities, for whom ESG could be useful as an early intervention to prevent disease progression but also the onset of associated comorbidities (type 2 diabetes, MASH, cardiovascular disease);
- have a high BMI, as the first step in bariatric and metabolic management, as a complement or replacement for drug therapy to which access is still difficult (non-reimbursed, logistical shortages).

SOFFCOMM's position is as follows: the indications for ESG must be discussed on a case-by-case basis, following a multidisciplinary care path identical to that for patients undergoing bariatric surgery, and then validated in a pluridisciplinary team concertation involving surgeons and/or physicians practicing bariatric endoscopy, nutritionists, dieticians and psychologists. These concertation meetings must take place in an accredited center, authorized to perform bariatric and metabolic surgery, with experience in the management of obesity and able to offer all types of bariatric management.

### Preoperative evaluation workup

There is insufficient evidence to suggest that the preoperative workup for ESG should differ from that for OS. The HAS recommendations updated in February 2024 set out the content of the preoperative assessment and postoperative follow-up recommended for bariatric surgery [26]. The assessment should be carried out as soon as BMI  $\geq 30$  kg/m<sup>2</sup> to comply with HAS guidelines.

SOFFCOMM recommends a preoperative assessment workup ideally similar to that carried out for all bariatric and metabolic surgery. Patients must be prepared for the procedure via accredited centers authorized to perform bariatric and metabolic surgery, according to the same procedures as for any metabolic and bariatric surgery procedure. In particular, the preoperative nutritional, dietary, psychological and psychiatric assessment must be carried out with

**Table 1** Main results regarding safety outcomes after ESG (endoscopic sleeve gastroplasty).

Study	Studied population	Safety outcomes	Comparison with SG
Due-Petersson et al. (2020) [21]	Meta-analysis 23 studies, 2142 patients	Significantly lower adverse event rate for ESG (5.2%) compared to SG (16.9%; $P < 0.05$ )	ESG is safer than SG in terms of complications
Fayad et al. (2022) [22]	Propensity score matching 211 ESG vs. 9059 SG (BMI 35–40 kg/m <sup>2</sup> )	Lower adverse event rate at 30 days with ESG (OR 0.39; CI: 0.19–0.79)	ESG demonstrated fewer short-term risks compared to SG
Marincola et al. (2021) [10]	Meta-analysis 3143 ESG vs. 3362 SG	Mean perioperative complication rate: ESG: 0.15%; SG: 0.30%. No significant difference ( $P = 0.20$ )	ESG slightly safer, but differences were not statistically significant
Gudur et al. (2023) [27]	Propensity score analysis 6054 ESG vs. 30,270 SG	ESG: higher readmissions (3.8 vs. 2.6%) and reinterventions (2.8 vs. 0.7%) within 30 days postoperatively	ESG linked to more frequent reinterventions, but these were less invasive (therapeutic endoscopy most common after ESG)
Fiorillo et al. (2020) [25]	Propensity score assessing Quality of Life (QoL) at 6 months	Better QoL and less GERD with ESG compared to SG	ESG associated with better gastric tolerance compared to SG
Yoon et al. (2021) [9]	Literature review on ESG patients	Postoperative GERD incidence was negligible with ESG (adverse event rate: 1.5 to 2.3%)	ESG is safer, with less GERD compared to SG
Bhandari et al. (2023) [17]	Prospective, monocentric > 600 patients (mean BMI 34.3 kg/m <sup>2</sup> ), 4-year follow-up	Revision (redo/redux) required in 3.6% of ESG cases at 2 years. Conversion to SG necessary in 0.4% at 12 months	Rare SG conversion, complications primarily addressed with endoscopic revisions

SG: sleeve gastrectomy; BMI: body mass index; GERD: gastro-esophageal reflux disease; QoL: quality of life.

the same rigor and according to the same procedures as for bariatric and metabolic surgery procedures currently recommended by the HAS. This approach is necessary to guarantee maximum and lasting weight and metabolic efficacy in patients who have benefited from therapeutic education, and who are ready to make long-term lifestyle modifications, as is the case for patients undergoing bariatric surgery.

### Perioperative management and the role of outpatient care

There is no evidence in the literature to suggest that perioperative management should differ from other bariatric and metabolic procedures. Overall glycemic, clinical and hemodynamic control should be modeled on that of SG. Adherence to follow-up visits is a significant predictor of successful weight loss outcomes after ESG [24].

Available evidence suggests that ESG could be performed on an ambulatory basis, as is the case for other bariatric procedures in experienced, accredited centers. An additional precaution should be observed, given the high number of rapid readmissions after ESG for abdominal pain [27]. SOFF-COMM recommends that each practitioner assesses the place of ambulatory surgery in ESG on a case-by-case basis.

Any procedure performed should be entered in the SOFF-COMM register, like all other bariatric surgery procedures.

→ The care pathway and perioperative management of a patient undergoing ESG must be identical to that of patients undergoing bariatric and metabolic surgery, to optimize management and maximize the weight loss and metabolic efficacy of the procedure. Adherence to follow-up visits is essential for successful weight loss after ESG.

### Question 4: which healthcare professionals can perform ESG?

#### Technical platform required

ESG should be performed in a specialized, authorized obesity center with a high-performance surgical endoscopy technical platform, staffed by professionals trained in endoscopy and in the operative and perioperative management of patients with obesity associated with comorbidities and higher anesthetic risks. The presence of digestive surgeons trained in bariatric and metabolic surgery is also essential in the event of intraoperative or immediate postoperative complications.

#### The operator

There is currently no data in the literature specifying which healthcare professional is best suited to perform ESG, nor is there any legal text restricting endoscopic activity to a specific medical specialty. Any practitioner – whether a surgeon or gastroenterologist – trained both in endoscopy and in the management of patients with obesity is considered competent to safely perform ESG, provided they have received appropriate training and practice within an accredited center authorized to conduct bariatric and metabolic surgery. Notice No. 2021.0040/AC/SEAP of June 10, 2021, issued by the Haute Autorité de santé (HAS) college, specifies that “the technique of ESG via the trans-oral approach, involving wide plication of the greater gastric curvature [...] with an endoscopic suture placement device, enables a gastroenterologist or a visceral and digestive surgeon to perform gastric

plication through digestive endoscopy by placing sutures in the stomach” [28].

SOFFCOMM’s position is as follows: first and foremost, ESG must be performed by a practitioner who is part of a multidisciplinary team specializing in obesity management and actively involved in both preoperative preparation and postoperative follow-up. Both the procedure and the practitioner performing it must comply with the specific protocols of each authorized center and the regulatory care pathway established for all bariatric and metabolic surgeries. The practitioner is also responsible for conducting postoperative follow-up to ensure compliance with associated treatments.

Additionally, the ESG must be performed by a practitioner trained in bariatric endoscopy, in a center capable of managing intraoperative complications (which may require surgical intervention) and addressing postoperative complications that could necessitate further treatment.

→ The ESG must be performed by a practitioner trained in bariatric endoscopy, capable of ensuring rigorous preoperative management and postoperative follow-up, in an accredited center authorized to perform bariatric and metabolic surgery, with an experienced multidisciplinary team.

## Question 5: what are the recommendations and viewpoints of other international scientific societies?

### United Kingdom

The most thorough investigation to date has been carried out by the UK’s National Institute for Health and Care Excellence (NICE). NICE published recommendations on ESG in February 2024. The main recommendations and comments are as follows [29]:

- ESG can be used as an alternative to SG, to be discussed on a case-by-case basis;
- patients should be selected, prepared and monitored by experienced, accredited multidisciplinary teams;
- the procedure must be carried out by an experienced metabolic and bariatric professional;
- each patient’s clinical and biological parameters must be recorded in the national database;
- ESG may be particularly beneficial for certain patient subgroups (class III obesity with excessively high operative risk, interesting foreseeable benefits in terms of prevention of certain obesity-related comorbidities);
- GERD is not, as itself, a contraindication to ESG;
- there are many cases of readmission rapidly after the procedure when it is performed on an ambulatory basis.

### United States of America

- The American Society for Metabolic and Bariatric Surgery (ASMBS) has issued no clear recommendations concerning ESG, but took a position in 2022 on devices accredited for performing ESG (Apollo ESG™, Apollo ESG Sx™ Endoscopic Suturing System) [30]. The procedure is performed by professionals accredited and insured to perform bariatric surgery.

### Internationally

- The European Association for Endoscopic Surgery (EAES), took a position in 2020, without however issuing recom-

mendations: endoluminal endoscopic procedures could have a role in the treatment of patients with class I and II obesity, with a BMI between 30 and 39.9 kg/m<sup>2</sup> [31].

- The European Society of Gastrointestinal Endoscopy (ESGE) and the American Society for Gastrointestinal Endoscopy (ASGE) published a joint guideline in April 2024 concerning the majority of available bariatric and metabolic endoscopic therapies (EBMTs) [3]. This guideline advocates the use of bariatric and metabolic endoscopic therapies in combination with lifestyle modifications as a first procedure for patients with a BMI ≥ 30 kg/m<sup>2</sup> with or without obesity-related comorbidities, or for patients with a BMI between 27 and 29.9 kg/m<sup>2</sup> with at least one obesity-related comorbidity. The guideline recommends that ESG combined with lifestyle modifications would be preferable to lifestyle modifications alone. It also recommends the use of antiemetics, analgesics, PPIs and antibiotics perioperatively. The level of certainty of the evidence used to provide these recommendations is still limited.
- The International Federation for the Surgery of Obesity (IFSO) – International Chapter issued a position statement to establish a consensus on ESG through a systematic review with meta-analysis [2]. This comprehensive systematic review included 44 articles encompassing approximately 15,700 patients receiving ESG. The IFSO endorsed ESG as an effective treatment of obesity. This treatment is suited for patients with class I and II obesity, and for those with class III obesity who are not suitable candidates for metabolic and bariatric surgery. Additionally, it can be proposed as an alternative to lifestyle interventions in adolescent patients with class II obesity (MILESTONE Project).

## Conclusion

ESG is an integral part of the therapeutic arsenal available to bariatric and metabolic surgeons, offering an effective and valuable treatment option for obesity in specific patient populations. The SOFFCOMM endorses endoscopic sleeve gastroplasty (ESG) as an effective and valuable treatment for obesity and highlights the importance of appropriate patient selection, coupled with rigorous evaluation of long-term outcomes, to refine its indications further.

## Objective

Establish scientific recommendations on the indications and follow-up of patients suffering from obesity and candidates for the endoscopic sleeve gastroplasty (ESG), integrating a multidisciplinary care pathway.

## Professionals concerned

All practitioners involved in the multidisciplinary management of obesity, in particular: digestive and bariatric surgeons, gastroenterologists, nutritionists, endocrinologists, dieticians and anesthetists.

## Disclosure of interest

Pr M. Robert (Lyon) and Pr F. Pattou (Lille): investigators of the ESTIME protocol ('Endoscopic sutured gastroplasty with Endomina® device versus standard of care in patients with type 2 diabetes and class I obesity: a multi-center, randomized controlled trial').

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