



## Brazilian Consensus on Endoscopic Sleeve Gastroplasty

Manoel Galvão Neto<sup>1,2</sup> · Lyz Bezerra Silva<sup>3</sup> · Luiz Gustavo de Quadros<sup>2,4</sup> · Eduardo Grecco<sup>1,2</sup> · Admar Concon Filho<sup>2,5</sup> · Artagnan Menezes Barbosa de Amorim<sup>6</sup> · Marcelo Falcao de Santana<sup>7</sup> · Newton Teixeira dos Santos<sup>8</sup> · Joao Henrique Felicio de Lima<sup>9</sup> · Thiago Ferreira de Souza<sup>1,2</sup> · Helmut Wagner Poti de Moraes<sup>10</sup> · Felipe Matz Vieira<sup>11</sup> · Rena Moon<sup>12</sup> · André F. Teixeira<sup>12</sup>  · for the Brazilian Endoscopic Sleeve Gastroplasty Collaborative

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### Abstract

**Purpose** Bariatric endoscopy is a less invasive approach for obesity management, with better efficacy than pharmacological treatment and low morbidity. Endoscopic sleeve gastroplasty (ESG) is the remodeling of the stomach using a suturing device showing technical feasibility, safety, and sustained weight loss. With growing numbers of procedures worldwide, there is a need to standardize the procedure.

**Materials and Methods** A consensus meeting was held in São Caetano do Sul-SP, Brazil, in June 2019, bringing together 47 Brazilian endoscopists with experience in ESG from all regions of the country. Topics on indications and contraindications of the procedure, pre-procedure evaluation and multidisciplinary follow-up, technique and post-procedure follow-up, and training requirements were discussed. An electronic voting was carried, and a consensus was defined as  $\geq 70\%$  agreement.

**Results** The panel's experience consisted of 1828 procedures, with a mean percentage total body weight loss (TBWL) of 18.2% in 1 year. Adverse events happened in 0.8% of the cases, the most common being hematemesis. The selected experts discussed and reached a consensus on several questions concerning patient selection, contraindications for the procedure, technical details such as patient preparation, procedure technique, and patient follow-up.

**Conclusions** This consensus establishes practical guidelines for performance of ESG. The experience of 1828 procedures shows the expertise of the selected specialists participating in this consensus statement. The group's experience has a satisfactory weight loss with low adverse events rate. The main points discussed in this paper may serve as a guide for endoscopists performing ESG. Practical recommendations and technique standardization are described.

**Keywords** Consensus statement · Endoscopic sleeve gastroplasty · Obesity · Endoscopy · Bariatric endoscopy

✉ André F. Teixeira  
andre.teixeira@orlandohealth.com

- <sup>1</sup> Endovitta Institute, Santo Andre, Brazil
- <sup>2</sup> Medicine of ABC, Santo Andre, Brazil
- <sup>3</sup> Federal University of Pernambuco, Recife, Brazil
- <sup>4</sup> Kaiser Clinic, Sao Jose do Rio Preto, Brazil
- <sup>5</sup> Galileo Hospital, Valinhos, Brazil
- <sup>6</sup> 9 de Julho Hospital, Sao Paulo, Brazil
- <sup>7</sup> Instituto Falcao de Endoscopia e Cirurgia, Salvador, Brazil
- <sup>8</sup> Hospital Rios Dor, Rio de Janeiro, Brazil
- <sup>9</sup> Endobatel Endoscopia Digestiva, Curitiba, Brazil
- <sup>10</sup> Digestive Center, Fortaleza, Brazil
- <sup>11</sup> Endodiagnostic Clinic, Rio de Janeiro, Brazil
- <sup>12</sup> Department of Bariatric Surgery, Orlando Regional Medical Center, Orlando Health, 89 W Copeland Dr, 1st Floor, Orlando, FL, USA

### Introduction

Bariatric surgery is a well-known and highly effective long-lasting treatment for obesity. [1] However, less than 2% of patients with obesity that meet the criteria for bariatric surgery actually undergo the procedure. [2] As a result, there is a need to develop less invasive therapies to treat obesity, especially for the population with a lower BMI. Bariatric endoscopy appears as a less invasive option, more effective than pharmacological treatment, and lifestyle changes, with lower morbidity when compared with bariatric surgery. [3, 4]

Endoscopic sleeve gastroplasty (ESG) is a minimally invasive procedure that involves remodeling of the greater gastric curvature, using an endoscopic full-thickness suture device (Overstitch, Apollo Endosurgery, Austin, TX, USA), with the objective of reducing gastric lumen in order to shape it into a tube. [5, 6] Publications demonstrate not only technical

feasibility and safety, but also sustained weight loss and improved comorbidities after ESG. [7–10] In a multicenter study, Galvao et al. showed a 19.7% percentage of total body weight loss (TBWL) after 12 months of follow-up, in a group of 233 patients. [11] Although different suture patterns have been used by centers worldwide, a multicenter study evaluated results with a standard U-shape suture pattern. Data from 193 consecutive patients from seven centers showed a TBWL of 15.1% in 12 months, with the percentage of excess weight loss (EWL) higher than 50% for all body mass index (BMI) groups at 1-year follow-up. [12]

A recent systematic review analyzed 11 studies, with a total of 2170 patients. Pooled TBWL was 16.8% and EWL was 73% after 18 months, and no procedure-related mortality was reported. [13] In addition, ESG has shown improvement in type 2 diabetes mellitus, hypertension, and other comorbidities. [14]

With growing acceptance and publications of the ESG procedure, there is an increasing need to standardize the procedure. To fill this gap, a consensus meeting was organized gathering experts from the Brazilian gastroenterologist and surgeon society certified to perform ESG in Brazil. The goal of the meeting was to discuss and evaluate clinical and technical aspects of ESG, with the aim of reaching a consensus on the best practice based on scientific literature and practice of experts. Also, the Brazilian experience was compiled among these experts through a questionnaire, representing over 1800 procedures and reflecting part of the country's experience with this device.

These consensus guidelines are, to our knowledge, the first of their kind regarding ESGs, integrating the consensus of the participants' clinical expertise with current scientific evidence. Therefore, this consensus report was based on the opinions of a selected group of endoscopists and surgeons with extensive experiences in ESG. This report represents a summary of the statements to be used as a guide to ESG best practices.

## Methods

An expert meeting was held on September 19, 2019, in São Caetano do Sul-São Paulo, Brazil. Forty-seven endoscopists were selected to participate in this meeting, all trained and certified to perform ESG. The panel of endoscopists was selected by the organizing committee, according to individual levels of experience with ESG. To avoid bias regarding conflict of interest, the participants paid for their own travel and accommodation expenses.

Prior to the meeting, a questionnaire was sent to all participants to compile the data of ESG procedures performed by the group. These data comprised a total of 1828 cases. In addition to providing a source of information for the meeting,

these reflect the panel's extensive experience in this procedure.

Predetermined questions were formulated to be posed for consensus in themes selected by the chairpersons, consisting of indications and contraindications of the procedure, pre-procedure evaluation and multidisciplinary follow-up, and technique and post-procedure follow-up and training requirements.

The agenda for the meeting was as follows: program presentation; working strategy; literature review of most important evidence regarding ESGs; short overview of categories of predetermined questions, discussion of changes, and new questions to be added; and viewing of predetermined questions and voting.

The Delphi methodology was used for this meeting. The voting process was as follows: for each category, literature data reviews and discussions were conducted. Next, questions were presented, and participants were invited to vote using an audited electronic voting system. The group's responses were calculated as defined by the group to constitute either a consensus ( $\geq 70\%$  agreement) or not ( $< 70\%$ ). The distribution of the group's responses was immediately reviewed by the entire panel after each individual question.

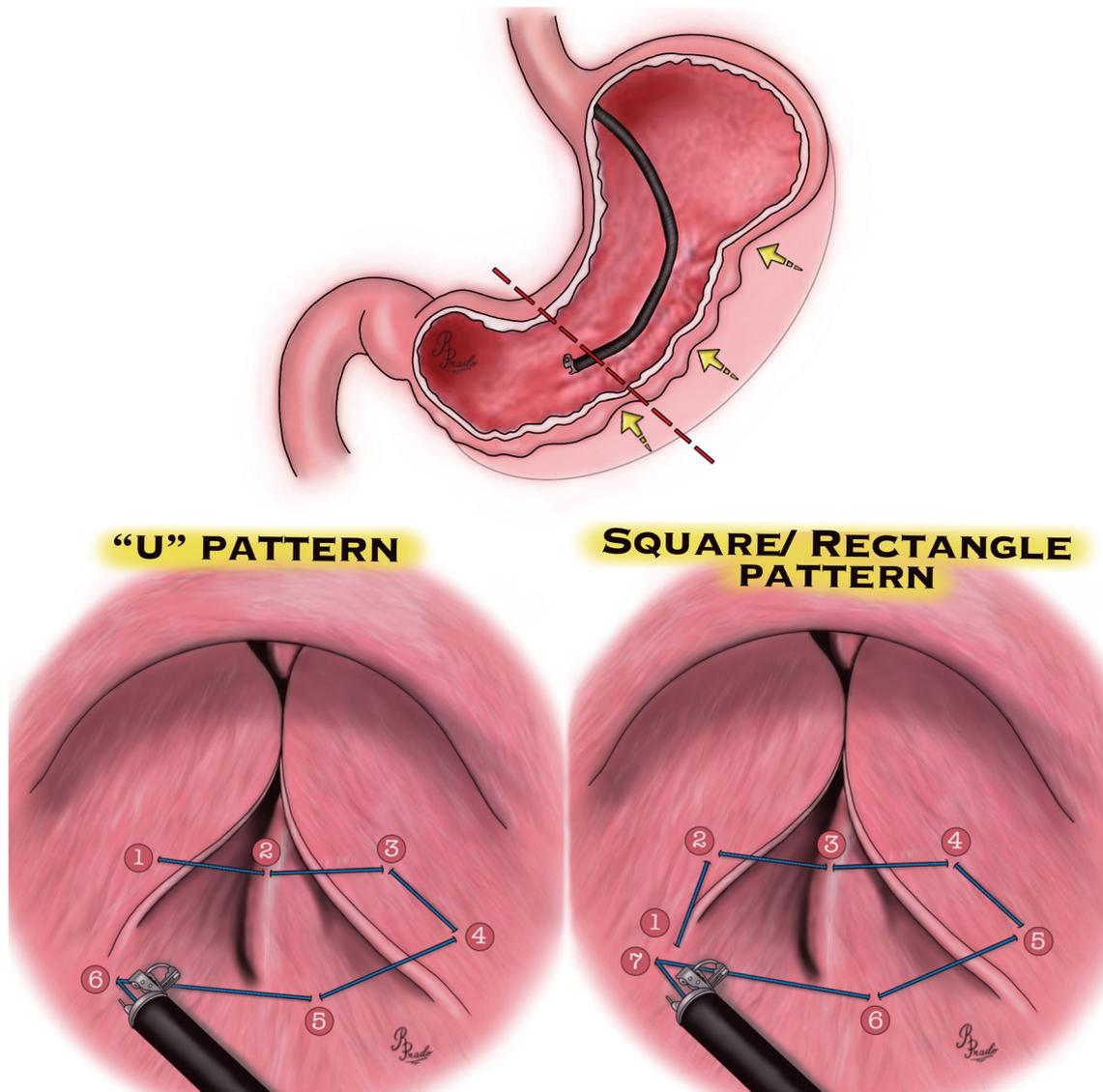
## Statistical Method

For data analysis, a data spreadsheet was built using a Microsoft Excel which was then exported to Minitab 18® (version 18, Minitab, LLC, State College, Pennsylvania, USA) and to OriginPro® 9 (DPR Group, Inc., Northampton, Massachusetts, USA). Anderson-Darling normality assumption test was performed for continuous variables and descriptive statistical analyses were performed.

For patient-related variables such as age, BMI, TBWL, and weight loss failure rate, weighted arithmetic means were calculated. Two- and three-dimensional graphs were created for the frequency distribution.

## Participants

A total of 1828 cases were performed by 47 endoscopists. Most experts were male, with 15.0 years of experience performing digestive endoscopy. The mean number of cases for each participant was 87 ESG procedures. All participants were trained in the same fashion, except from one, who was a developer of the device and acted as a proctor for the others. The training methodology consisted of attending a course at Faculdade de Medicina do ABC, São Caetano do Sul, São Paulo, Brazil, with theoretical classes, hands-on laboratory, and observing at least one live case. In sequence, a certified proctor would perform three procedures on-site with the training endoscopist. U-shaped pattern sutures were used to create a tube-like of the gastric body (Fig. 1). The selected



**Fig. 1** Comparison of “U” pattern and square/rectangle pattern sutures

participants were also required to have the title of specialists in endoscopy or surgery of the digestive system and at least 10 cases performed without preceptorship.

### Complications

Of 1828 patients, 15 complications were reported, corresponding to 0.82% of the cases. Adverse events that are common in the first post-procedure day were not counted as complications.

Hematemesis was the most common complication, corresponding to 7 of the 15 reported cases. All were resolved either endoscopically or by conservative treatment (1 argon plasma coagulation, 1 clip, 2 sclerotherapy, 3 conservative). Two cases of prolonged pain due to residual pneumoperitoneum were reported: in one case, a Veress needle was used to

evacuate gas, with pain resolution in 3 days and the other case where ambient air was used had spontaneous pain resolution after 2 days. One case of persistent vomiting in the immediate postoperative period was reported, needing 1 day of hospital admission for medication control. Respiratory insufficiency in the immediate postoperative period happened in a chronic obstructive pulmonary disease (COPD) patient, needing hospital admission for noninvasive ventilatory support. Three cases of complications needed laparoscopic intervention: two retrogastric abscesses drainages (one case related with a leak), and one peritonitis after perforation of gallbladder by the device. All advent events were resolved with favorable outcomes.

One death was reported in a 66-year-old male patient who was bed-restrained with previous stroke, hypertension, and BMI of 31 kg/m<sup>2</sup>. ESG was performed without event, and

on the 5th day, the patient developed dyspnea, hypotension, and cardiorespiratory arrest due to a pulmonary embolism.

### Consensus Statements

The most important consensus statements discussed in the event are listed in Table 1.

### Indications and Contraindications

#### Patient Selection

According to the panel, there was no maximum age for the procedure and each patient should be evaluated individually

(97.4%). No consensus was reached on minimum age—43.9% voted for 12 years and older after psychologist, endocrinologist, and pediatrician evaluation; 39.0% voted for older than 16 years—which is in accordance with the government guidelines for Bariatric Surgery in Brazil.

The ideal BMI range for ESG was 30–40 kg/m<sup>2</sup> (100%)—according to the participants, better results were achieved in these patients. The minimum BMI is 27 kg/m<sup>2</sup> (73.2%) with no maximum BMI and each patient should be evaluated individually according to clinical conditions (100%).

#### Absolute Contraindications

Gastric ulcers located in the body or fundus were considered as an absolute contraindication, even with no signs of

**Table 1** Summary of the main points of consensus

Indications/contraindications
<p>There is no maximum age for endoscopic sleeve gastropasty (if adequate clinical status)</p> <p>The ideal BMI range to perform ESG is 30–35 kg/m<sup>2</sup>.</p> <p>The minimum BMI to perform ESG is 27 kg/m<sup>2</sup></p> <p>There is no upper limit for BMI when performing ESG</p> <p>Absolute contraindications for ESG include: active gastric ulcers in the body or fundus (even with no signs of bleeding), congestive gastropathy, gastric polyposis, gastric or esophageal varices, uncontrolled/untreated psychiatric disorder.</p>
Preparation
<p>Preoperative endoscopy should be carried out before the ESG procedure, done by any endoscopist or by the endoscopist who will perform the procedure</p> <p>Complete laboratory work-up should always be done before ESG</p> <p>Pre-operative anticoagulation (prophylaxis for DVT) should be done in accordance with clinical criteria</p> <p>A surgeon should always be part of the team (if the professional performing ESG is a gastroenterologist)</p> <p>In the multidisciplinary team, the presence of a dietitian and psychologist is mandatory in order to carry out patient follow-up throughout the treatment.</p>
Technique
<p>The procedure should only be performed under general anesthesia carried out by an anesthesiologist</p> <p>Insufflation should always be done using CO<sub>2</sub></p> <p>There is no obligation to perform stomach marking for orientation before starting the procedure</p> <p>Most used suture pattern is the square/rectangle (Barham/Galvao)</p> <p>On average, 4–6 sutures are used on each case</p> <p>The antrum should never be sutured</p> <p>The main goal is to reduce the greater gastric curvature</p> <p>When it comes to the fundus, most endoscopists try only to reduce the most distal part of the fundus</p> <p>Antibiotics should be infused before or right after the procedure</p> <p>Hospital discharge can be done on the same day (outpatient procedure)</p>
Post-implant recommendations
<p>Recommended medications to reduce symptoms in the adaptation period are: PPI, ondansetron, hyoscine/scopolamine, steroid (dexamethasone), analgesics.</p> <p>PPIs should be maintained for 1–3 months after the procedure</p>

BMI body mass index, ESG endoscopic sleeve gastropasty, DVT deep venous thrombosis, PPI proton-pump inhibitor

bleeding. Also, congestive gastropathy (high risk of bleeding), gastric polyposis, gastric or esophageal varices, and uncontrolled/untreated psychological diseases were absolute contraindications. In the case of esophageal ulcers, care should be taken because of the caliber of the equipment, which may harm the esophagus.

### Not Considered Contraindications

Mild or moderate gastritis, previous gastric surgery (non-bariatric), hyperplastic or benign polyps, and positive *H. pylori* test were not considered as contraindications by the experts.

### No Consensus

There was no consensus regarding nonbleeding active ulcers in the antrum—47.5% voted as an absolute contraindication and 47.5% as a relative contraindication, considering that the antrum were not usually sutured. For nonbleeding ulcer in any other location, 56.4% considered it to be a relative contraindication. While 48.7% considered nonbleeding angioectasia not to be a contraindication, 46.2% considered it to be a relative contraindication. The use of antiplatelet agent was considered a relative contraindication by 59.0%—each case should be evaluated individually, according to type of medication, half-life, and possibility of stopping before the procedure. For untreated eosinophilic esophagitis, 48.7% considered it to be an absolute contraindication (Table 2).

## Pre-procedure Evaluation

### Prior Endoscopy and Imaging Exams

Regarding pre-procedure evaluation, a diagnostic endoscopy before ESG was considered essential (83.3%), done by an experienced endoscopist or the one who will perform the procedure. For the positive *H. pylori* status, no consensus was reached—31.0% considered that all cases should be treated (including asymptomatic cases and cases with no gastric lesions), while 42.9% considered that each case should be evaluated individually, due to the high probability of recurrence. There was no consensus regarding other imaging exams—47.5% of the participants considered them to be necessary for all candidates.

### Blood Work

The majority (88.1%) agreed that laboratory works should always be requested, since the procedure involves general anesthesia and has greater potential for complications when compared with other endoscopic approaches such as intragastric balloons. Preoperative cardiological evaluation should be requested depending on the patient's medical history (63.4%) (Table 1).

## Multidisciplinary Team

In the multidisciplinary team, dietitian (97.4%) and psychologist (95.1%) were considered essential. Endocrinologist and psychiatrist were recommended but not considered essential. If the endoscopist is not a surgeon, a digestive or bariatric surgeon should be part of the team to provide support in the case of complications (79.5%).

Concerning the nutritional follow-up, 97.6% believe that the dietitian should follow up with the patient during the entire treatment. The psychologist should decide for how long the patient must be followed after individualized evaluation (66.7%) (Table 3).

## Technique

The minimum structure for performing the procedure should be an outpatient clinic with advanced life support—46.2%—or a day-hospital (38.5%). The choice of sedation should be general anesthesia according to 100% of the participants.

There was no consensus regarding use of the overtube (58.5% considered its use mandatory)—some experienced endoscopists can perform the procedure without an overtube, which was not advised for those still in their learning curve. For stomach insufflation, CO<sub>2</sub> should always be used (100%) since some degree of pneumoperitoneum could be expected. Hospital discharge could happen on the same day—outpatient procedure (95%).

No consensus was reached regarding the preoperative use of proton-pump inhibitors (PPIs). The pre-procedure use of anticoagulants (as prophylaxis for thrombotic events) should be done in accordance with the clinical criteria (92.5%). Antibiotics should be administered by the anesthesiologist as prophylaxis (97.4%).

The equipment supplied by the manufacturer was considered to be sufficient to perform the procedure by 62.5% of the participants. Other equipment considered essential to have during the procedure in case of adverse events were endoscopic scissors (33.3%), injection needle (18.0%), and endoscopic clips (38.5%).

Most of the endoscopists did not use argon plasma coagulation markings to guide the procedure (95.1%) and most (77.5%) used the square/rectangle (Barham/Galvão) suture pattern (Fig. 1). Reinforcement was done on a case-by-case basis by 66.7% of the participants, while 23.8% always reinforced the sutures. The gastric antrum should not be sutured (95.1%) because of its muscular strength and suture rupture. On average, most endoscopists use 4–6 sutures per case (92.7%), with a varying number of bites per suture (more than 8–10 bites, at least, according to most participants). The aim of ESG should be to reduce (in a tube-like manner) the greater curvature rather than reducing the lumen as much as possible.

**Table 2** Indications and contraindications for ESG

Consensus statement	Consensus (%)
Indications and patient selection	
There is no maximum age limit for ESG, each patient should be evaluated individually	97.4%
The minimum BMI to authorize ESG is > 27 kg/m <sup>2</sup> .	73.2%
The ideal BMI range for ESG is 30–40 kg/m <sup>2</sup> (considering this group will achieve the best results)	100%
Absolute contraindications for ESG	
Active gastric ulcers in the body or fundus, without signs of bleeding	78.1%
Congestive gastropathy	90.5%
Gastric polyposis	72.5%
Gastric varices	74.4%
Esophageal varices	76.9%
Uncontrolled/untreated psychological illness	90.2%
NOT considered as contraindications	
Mild or moderate gastritis	80.0%
Previous non-bariatric gastric surgery	77.5%
Hyperplastic or benign polyps	90.0%
<i>H. pylori</i> positive	81.0%
No Consensus	
Eosinophilic esophagitis	
Antiplatelet agent use	
Nonbleeding angioectasias	
Non-bleeding ulcers in other locations (including antrum)	

*BMI* body mass index, *ESG* endoscopic sleeve gastropasty

Most endoscopists only sutured the most distal part of the fundus (78.1%) (Table 4).

**Medications, Complications, and Post-procedure Follow-Up**

The main medications to be administered during or after ESG procedure were antibiotics, antiemetic, hyoscine/scopolamine,

corticosteroids (dexamethasone), PPIs, and analgesics. Metoclopramide should not be used routinely (74.3%). PPIs should be prescribed for 1–3 months post-procedure (70.0%). Non-steroidal anti-inflammatory drugs (NSAIDs) should not be used (84.6%).

There was no need to maintain antibiotic therapy after the procedure (75.0%). Post-procedure deep vein thrombosis prophylaxis should be prescribed if clinical evaluation indicated

**Table 3** Recommendations regarding patient preparation

Consensus statement	Consensus (%)
Pre-procedure evaluation and multidisciplinary team	
It is mandatory to perform endoscopy prior to ESG. This can be carried out by the physician who will perform the procedure or by any other certified endoscopist.	83.3%
Laboratory exams should always be carried out before the procedure.	88.1%
In relation to the multidisciplinary team, the presence of a dietitian is mandatory.	97.4%
In relation to the multidisciplinary team, the presence of a psychologist is not mandatory.	95.1%
In relation to the multidisciplinary team, the presence of an endocrinologist is not mandatory.	87.8%
In relation to the multidisciplinary team, the presence of a nutrologist (physician specialized in clinical nutrition) is not mandatory.	97.4%
In relation to the multidisciplinary team, the presence of a psychiatrist is not mandatory.	97.6%
A gastrointestinal or bariatric surgeon should always be part of the team (if a surgeon is not the one performing ESG), to assist in the occurrence of adverse events.	79.5%
In relation to the multidisciplinary team the dietitian should carry out patient follow-up throughout the treatment period.	97.6%

**Table 4** Recommendations regarding patient preparation and technique for ESG performance

Consensus statement	Consensus (%)
Patient preparation and facilities required	
Use of anticoagulants before the procedure (DVT prophylaxis) should be done in accordance with clinical criteria.	92.5%
Placement of the balloon can be performed in clinics with advanced life support or day-hospital structure. <sup>10</sup>	84.6%
Sedation should always be done by means of general anesthesia carried out by an anesthesiologist.	100%
Hospital discharge can be done on the same day (outpatient procedure).	95.0%
PPIs should be prescribed for at least 1–3 months.	70.0%
Technique	
Antibiotic prophylaxis should be done right before or during the procedure.	97.4%
CO <sub>2</sub> should be used for stomach insufflation.	100%
Marking of the stomach with Argon plasma coagulation to guide the stitches is not necessary.	95.1%
Most used suture pattern is the square/rectangle (Barham/Galvao).	77.5%
On average, 4–6 sutures are used in each case.	92.7%
Sutures should never be placed on the gastric antrum.	95.1%
The main objective is to reduce the gastric greater curvature.	74.4%
The gastric fundus should only be sutured in its most distal part.	78.1%

ESG endoscopic sleeve gastropasty, DVT deep venous thrombosis

the use (92.7%). Follow-up should be done for at least 6 months (92.5%, Table 5).

The most reported complication in the consensus was hematemesis. Because the sutures are performed from the inside of the stomach in ESG procedures, occasional bleeding, even in small amounts, could cause gastric irritation and vomiting. However, post-procedure intraluminal bleeding did not commonly occur. In the series studied, participants reported seven cases of hematemesis, but only four required an endoscopy approach, and no case required a transfusion. These four cases corresponded to 0.21% of the sample.

**Table 5** Recommended medications and guidance for the adjustment period

Consensus statement	Consensus (%)
Ondansetron	95.0%
Hyoscine/scopolamine	79.5%
Steroid (dexamethasone)	78.1%
Analgesic	92.5%
Proton pump inhibitor (PPI)	95.0%
The use of metoclopramide is not recommended.	74.3%
Anti-inflammatory drugs are not recommended.	84.6%
Post-operative DVT prophylaxis with anticoagulants should be done on a case-by-case basis.	92.7%

DVT deep venous thrombosis

## Training Requirements for ESG Performance

The minimum requirement was to be a physician with a specialization that enabled to perform endoscopic exams (77.5%). Initial experience should be through theoretical and laboratory training, followed by proctoring by a certified proctor physician (77.5%).

## Conclusions

This consensus report reflects the experience of Brazilian bariatric endoscopy experts, with the most available experience in ESG in the country.

This is the first consensus establishing practical guidelines for the performance of ESG. Brazil is a pioneer when it comes to Bariatric Endoscopy, and the experience of over 1800 procedures shows the expertise of the selected specialists participating in this consensus statement. The main points discussed in this paper may serve as a guide for endoscopists aiming to perform ESG. However, no consensus was reached for many technical points showing that it is still an evolving procedure, although safety and efficacy have been proven.

The first ESG procedure was described in 2012 and since then, many countries have started performing and improving it. In Brazil, the first cases were performed in the late 2016 at Faculty of Medicine of ABC (FMABC) under the Institutional Review Board (IRB) protocol. In the presented data, we showed a good safety profile with a low rate of complications.

Still, it should be noted that many of the cases described were done in the beginning of a learning curve. After passing this learning curve, results and safety profile tend to improve. Regarding weight loss, in the group's experience, 18.2% of TBWL was achieved. This agrees with the weight loss already described in other series and reviews. [15]

The weakness of this consensus is the retrospective nature and lack of homogeneity on data. In the future, we hope to present technical standardization with a larger and more uniform data. We also do not have long-term results because the ESG procedure is relatively new, and longer follow-up would be needed to confirm our findings. We would like to acknowledge that one of the participants was the developer of the device and trained others, presenting possibility of bias. This consensus only includes experience from one device, Apollo Overstitch platform, which may not be extended to endoscopic devices manufactured by other companies.

The consensus statements presented here can be used as best practice guidelines for beginning endoscopists using Apollo Overstitch worldwide.

## Compliance with Ethical Standards

**Conflict of Interest** Drs. Manoel Galvão Neto, Luiz Gustavo de Quadros, Thiago Ferreira de Souza, Eduardo Grecco, Admar Concon Filho, and Felipe Matz are consultants for Apollo Endosurgery. Dr. Andre Teixeira is a consultant for Intuitive Surgical.

**Ethical Approval** For this type of study, formal consent is not required.

**Informed Consent** Does not apply.

## Appendix

Brazilian Endoscopic Sleeve Gastroplasty Collaborative:

Adriano Tomas Vasconcelos Alexandre, Digestive Center, Fortaleza, Brazil.

Leonardo Salles de Almeida, Instituto Mineiro de Obesidade, Belo Horizonte, Brazil.

Jose Rubes Armoni, Clinica Imec, Sao Paulo, Brazil.

Fernanda Nascimento Bueno, Endovale Clinica, Sao Jose dos Campos, Brazil.

Keila Regina Matos Cantanhebe, Hospital Sao Domingos, Sao Luis, Brazil.

Rafael Pasqualini de Carvalho, Medicina de Ribeirao Preto-USP, Ribeirao Preto, Brazil.

Alexandre Cenatti, Unimed Hospital, Casias do Sul, Brazil.

Bruna Durelli, Clinica Scoppo, Sao Paulo, Brazil.

Elaine Moreira Ferreira, Endovitta Institute, Santo Andre, Brazil.

Luiz Henrique de Sousa Filho, Clinica Cirurgica Digestiva e Obesidade, Goiania, Brazil.

Idiberto Jose Zotarelli Filho, Kaiser Clinic, Sao Jose do Rio Preto, Brazil.

Anna Carolina Hoff, Angioskope Vale, Sao Jose dos Campos, Brazil.

Mauro Rodrigues Coelho Jacome, Clinica Cronos Endoscopia, Belo Horizonte, Brazil.

Muhammad Jawad, Orlando Regional Medical Center, Orlando, FL, USA.

Igor Marchetti, Servico de Endoscopia Diagnostica e Tereapeutica, Sorocaba, Brazil.

Luiz Augusto Matta, Clinica Lev, Uberlandia, Brazil.

Tulio Medeiros, Clinica Scoppo, Sao Paulo, Brazil.

Luiz Henrique Mazzone Mestieri, Clinica Mestieri, Salto, Brazil.

Marcus Vinicius de Moraes, Instituto Endogastro, Goiania, Brazil.

Joao de Siqueira Neto, Universidade Federal do Espirito Santo, Vitoria, Brazil.

Alvaro Oliveira Neto, Nucleo Integrado de Obesidade e Diabetes, Itabuna, Brazil.

Joffre Rezende Neto, Instituto de Gastroenterologia de Goiania, Goiania, Brazil.

Harley Pandolfi, Gastroclinica de Palmas, Palmas, Brazil.

Andre Pupo, Ipiranga Hospital, Mogi das Cruzes, Brazil.

Flavio Metidieri Ramos, Endodiagnostic Clinic, Rio de Janeiro, Brazil.

Almino Cardoso Ramos, Gastro-Obeso-Center, Sao Paulo, Brazil.

Leonardo Teixeira Rodrigues, Complexo Hospitalar de Niteroi, Niteroi, Brazil.

Guilherme Becker Sander, Ernesto Dornelles Hospital, Porto Alegre, Brazil.

Rodrigo Dallegrave Correa da Silva, Clinobeso, Porto Alegre, Brazil.

Jose Americo Gomides de Sousa, Clinica Lev, Uberlandia, Brazil.

Mauricio Spagnol, Clinica Cirurgica Chapeco, Chapeco, Brazil.

Eduardo Nobuyki Usuy, Clinica Gastrica, Florianopolis, Brazil.

Julio Cesar de Soares Veloso, Instituto do Aparelho Digestivo, Brasilia, Brazil.

Hans Roman Wulf Vieira, Hansgastroclinica, Blumenau, Brazil.

Jorge Luiz de Mattos Zeve, Gastrocentro de Palmas, Palmas, Brazil.

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