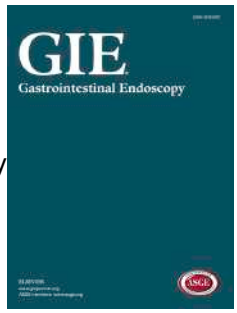

Perspectives toward minimizing the adverse events of endoscopic sleeve gastroplasty

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Perspectives toward minimizing the adverse events of endoscopic sleeve gastroplasty

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INTRODUCTION

The endoscopic sleeve gastroplasty (ESG) transforms the saccular stomach into a tubular structure along the lesser curvature, thereby reducing the gastric functional volume[1-4]. Current medical literature demonstrates that ESG achieves greater than 25% excess weight loss (EWL) at 12 months with a less than 5% rate of severe adverse events (AEs), which is considered satisfactory according to the Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) document created by a task force assembled by the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric Surgery (ASMBS)[5]. Despite widespread adoption of the procedure[6-8], no peer-reviewed resource exists to guide the physician on how to optimally perform the procedure. The aim of this manuscript is to help physicians currently performing or those contemplating performing ESG by providing technical insights to facilitate durable tubularization of the stomach while simultaneously minimizing the rate of AEs.

THE ESG PROCEDURE

ESG using the current generation full thickness endoscopic suturing device (OverStitch; Apollo Endosurgery, Austin, Texas, USA) (**Figure 1**) was first perfomed during a live endoscopy course in 2012 by Thompson and Hawes[9]. Abu Dayyeh et al[10] published the first series in 4 patients the following year. Since then, ESG has been evolving, with variations in the number and orientation of sutures, spacing and frequency of bites, tightness of sutures, fundal suturing, and use of reinforcement sutures[11].

Various descriptions of the ESG technique has been described, although several common tennants exist[1,2,12-16]. The endoscopic suturing device attached to a double-channel endoscope is used to create a restrictive sleeve through the placement of full-thickness sutures from the incisura angularis distally to proximally along the anterior wall, greater curvature, and

posterior wall. The tissue helix is used to bring the gastric tissue into the optimal position to facilitate a full thickness bite.

Contraindications to performing ESG include presence of neoplastic lesions, large hiatal hernia, potential bleeding gastric lesions (ulcers or erosive gastritis), psychiatric and eating disorders, pregnancy, and coagulopathy or antiplatelet/anticoagulant therapy that cannot be corrected[17,18].

Suture Patterns

There are several suture patterns (Z, W and U) with the most common pattern around the world being the U stitch pattern **(Figure 2)**. Serial U stitches are performed starting on the anterior wall, greater curvature and posterior wall, traversing back to the greater curvature to end on the anterior wall immediately proximal to the first bite.

Some physicians prefer to perform individual reinforced sutures ("reinforcing layer") after completion of the first row of sutures plicating the greater curvature is complete as demonstrated in **Figure 3**. This can be challenging as the gastric wall becomes tense and less pliable after the first row, making retraction with the helix and a full-thickness bite difficult. In addition, the lumen is narrowed, restricting movement of the endoscope and impeding, especially when bleeding is encountered. Finally, ooze after each bite is more pronounced, likely due to the vascular congestion precipitated by the first layer of suturing.

TECHNIQUE AND TROUBLESHOOTING

Suturing device and scope passage

The end cap must be secured firmly onto the endoscope because it can dislodge during the procedure, and retrieving it from the stomach can be problematic. To facilitate intubation, placement of an overtube using the double-channel therapeutic endoscope itself before loading with the suturing device will protect the oropharynx, upper esophageal sphincter (UES), and esophagus, however, will also increase the cost of material for the procedure. Thus, many experienced endoscopists have opted to bypass this step. If using the overtube, care must be taken to use extra lubrication on the inside of the tube to avoid friction and lagging of the cable running outside the endoscope. The needle driver must always be closed before advancing or removing the endoscope. If one chooses to omit the overtube, use the tower to gently open the UES while turning the endoscope slightly to ease it into the esophagus and apply slight neck flexion and jaw thrust to open the UES.

Suturing

The durability of the ESG is largely dependent on the ability to take full-thickness bites and cinch without causing early cheese wiring (suture cutting through the tissue due to undue tension). Thus, it is critical that the target tissue is grasped with the tissue helix and gently pulled toward the endoscope while adjusting the orientation of the device. A tactile and at times an audible "crunch" should be felt with each bite because porcine explant studies have correlated this with the needle driver traversing through the muscularis propria. On average, 8 to 12 bites are taken per suture. The degree of restriction is regulated by the capability of creating a narrow-diameter sleeve. It is important to periodically clean the stomach by suctioning blood (best to remove the helix to enhance suction) and secretions and inspect the shape and orientation of the sleeve. If the sleeve is irregular it is easier to rectify and remodel early on. If there are crevices inbetween sutures resulting in a flaccid sleeve with pockets this should be corrected with reinforcing sutures. **Table 1** lists techniques to facilitate a robust sleeve.

Techniques to facilitate cinching

After the suture pattern is completed, the anchor should be dropped at least 1 cm from the tip of the endoscope and close to the site of the last bite. Releasing the anchor in the working channel of the endoscope can result in damage to the endoscope. Slow pulls pretighten of the suture before loading the cinch can help tighten the suture and will stop bleeding or oozing quickly while the cinch is being loaded. Care must be taken to avoid cinching the suture such that it is too tight, as this will result in the suture cheese wiring early, and the accordioned stomach opening prematurely. The suture must be taut but should not stretch before firing the cinch.

The cinch should be held perpendicular to the first bite to avoid breaking the cinch. The cinch should be deployed by closing the handle with both hands until a click is noted. Excessive zeal in closing the handle when deploying the cinch, can result in the cinch becoming jammed on the deployment catheter. If this occurs, the suture needs to be cut or the inner wire of the cinch needs to be grasped with pliers and pulled to release the cinch from the catheter.

ESG in those who have undergone prior bariatric surgery

Previous bariatric surgery is not considered an absolute contraindication for ESG and emerging data suggest that it may be as effective as in surgical-naïve patients. A multicenter study including 34 patients who underwent ESG after sleeve gastrectomy showed 18.3% total weight loss (TWL) without any severe AEs[19]. A recent multicenter including 82 patients confirmed these favorable results, revealing a TWL of 15.7% with only one moderate AE[20]. Additionally, anecdotal reports exist of performing ESG in patients who have had a prior laparoscopic adjustable gastric band or have the band still remaining in situ. Care should be taken to avoid plicating near the region of the band (gastric cardia). The advantages of performing ESG after sleeve gastrectomy includes a smaller stomach without the fundus, which may make the procedure more efficient. The remnant sleeve is less vascular as there was likely takedown of vessels along the greater curvature during surgery, which will reduce the risk of major bleeding. However, the smaller stomach also translates to less space, which can make manuevers with the Overstitch device technically more difficult.

ADVERSE EVENTS

As a relatively new procedure, there is still a paucity of data concerning long-term safety. A meta-analysis including 1772 patients reported a pooled post-ESG rate of severe AEs of 2.2%[7], in accordance with the <5% threshold set by the PIVI document created by ASGE/ASMBS[5], suggesting that ESG may safely be introduced into clinical practice. Other recent systematic review and meta-analysis[8] including 11 studies and 2,170 patients evaluated AEs in detail based on the ASGE Quality Task Force recommendations[21] and confirmed the safety profile of ESG. Overall, a 2.3% (95% CI, 1.2–4.1; I2 24.08%; 7 studies) rate of AEs has been observed. A rate of 1.5% (95% CI, 0.5–4.3; I2.0%, 2 studies) for mild, 1.7% (95% CI, 0.9–3.1; I2.8.16%; 6 studies) for moderate, and 0.8% (95% CI, 0.3–2.0; I2.0%; 3 studies) for severe AEs were reported. AEs reported in the literature[2,12,13,15,22-33] are shown in **Table 2**.

Intraprocedural adverse events

Until now, there has been no report of major intraprocedural AEs. In a small single-center study of 20 patients, Lopez-Nava et al[34] reported minor intraprocedural bleeding in 2 patients that was controlled with injection therapy. In another study of 148 patients by Morales et al[29], there was one case of similar intraprocedural bleeding at an insertion point of the helix, that was successfully treated with sclerotherapy.

Due to the full-thickness suturing, a small amount of pneumoperitoneum is expected from CO_2 leakage during the procedure, often without clinical significance[12,24]. Other possible

adverse events include subcutaneous emphysema, high end-tidal CO_2, and high peak inspiratory pressure[35]. The occurrence of tension pneumothorax, is a rare, but serious AE requiring chest tube placement and has been described in 2 ESG procedures[12,32].

Postprocedure adverse events

Abdominal pain, nausea, vomiting, fever and symptomatic gastroesophageal reflux disease (GERD) are minor postprocedural AEs that are expected and typically self limited. Postprocedural abdominal pain and nausea have been described in 22.6% to 92.4% of cases[22,33]. A recent case-matched study by Fayad et al[23] comparing ESG with laparoscopic sleeve gastrectomy (LSG) demonstrated significantly less-severe adverse effects in the ESG group (5.2% vs 16.9%), including new onset GERD (1.9% vs 14.5%). Compared with intragastric balloons, ESG is associated with fewer adverse events such as nausea, vomiting, esophagitis, and ulcers. However, ESG is associated with more severe abdominal pain that usually resolves in the first 5 to 7 days[36]. Rarely, abdominal pain is intense and requires protracted treatment with narcotic pain medications. It is unusual for patients to require hospitalization for pain after ESG.[12,24,25] . Alqahtani et al[33], in their cohort of 1000 patients, had 8 readmissions for the same reason, and ultimately 3 patients requested ESG reversal.

Obesity is associated with abnormalities of metabolic homeostasis due to chronic inflammation and impaired fibrinolysis, leading to increased thrombotic risk[37]. Studies by Abu Dayyeh et al[12] and Lopez-Nava et al[32] reported the occurrence of pulmonary embolism. Barrichello et al[31] presented 1 case of deep vein thrombosis in their cohort of 193 patients. All cases were managed with medication.

Despite this thrombotic risk, bleeding is actually the most-common serious adverse event during ESG. Lopez-Nava et al[32] reported a single case of extragastric haemorrhage, requiring blood transfusion. Cases of upper gastrointestinal bleeding (UGIB) have also been described in several other cohorts[3,15,23,31,33]. Patients may present with either hematemesis and/or melena. Patients typically present in the first week after the procedure; however, in some cases, there is a delayed presentation, with symptoms reported 10 days to one month postprocedure.

Another relevant AE associated with ESG is the development of gastric leaks and perigastric fluid collections, reported in <1% of cases[7]. Diagnosis should be suspected in all patients who present with severe abdominal pain or fever after the procedure. In some cases, perigastric fluid collections may be accompanied by a pleural effusion[33]. A possible explanation is the bacterial translocation along a suture tract or a small leak caused by

intractable vomiting after full-thickness sutures that transect the gastric wall. Treatment includes the use of antibiotics, either alone[38] or in association with percutaneous drainage[39], EUS-guided transgastric drainage,[40] or surgery[31].

Gastric perforation is a rare but dreaded adverse event that was recently reported by Surve et al[41]. The patient presented with severe abdominal pain, and CT showed a large amount of free air and fluid. Exploratory laparoscopy followed, revealing the presence of a gastric perforation. de Siqueira Neto J et al[42] and Lopez-Nava et al[43] reported 2 cases where patients were readmitted due to abdominal pain, tenderness, and fluid in the abdominal cavity on subsequent CT. Surgical exploration revealed a gallbladder attached to the gastric wall within a full-thickness suture, causing a bile leak and peritonitis.

PREVENTION AND MANAGEMENT OF ADVERSE EVENTS

Abdominal pain, nausea, and emesis

Postprocedural abdominal pain, nausea and emesis usually subside in the first 48 to 72 hours. In order to prevent early readmission, all ESG protocols should include administration of analgesics and antiemetics to treat the expected abdominal pain, cramping and nausea post procedure. Recommended protocols include the use of Emend 125 mg preprocedure, and 80 mg on the second and third day, Zofran 8 mg sublingual as needed, Phenergan or steroids. Additionally, 2 to 3 liters of intravenous fluids should be administered during the perioperative period to prevent dehydration in the ensuing 48 hours. Most protocols include a liquid opiate for pain, but extra-strength Tylenol or a fentanyl patch can also be used.

Deep venous thrombosis prophylaxis

To decrease the risk of thromboembolic events, patients should receive prophylaxis with low-molecular weight heparin 5000 IU intraprocedurally and in selected cases, intermittent pneumatic compression devices should be placed on lower extremities during the procedure. This is particularly important during the early learning curve[3,28] when the procedure may take 2 hours or more for completion[44-46].

Bleeding

Bleeding is common during ESG, as the suturing device may inadvertently pierce a gastric wall vessel. Most bleeding episodes are minor and self-limited. Generally, if bleeding is encountered, simply deflate the lumen using endoscope and withdraw the endoscope slightly

while pulling the anchor exchange into the working channel. This will provide tension on the suture and will cause the tissue to approximate which will tamponade the bleeding. Hold this for 1 to 2 minutes and gently release and continue with the suture pattern as initially planned. If bleeding restarts, then consider cinching prematurely.

Occasionally, a large hematoma will be visible, and it is crucial to differentiate this from a gastric fold as piercing through it with the tissue helix will exacerbate bleeding. If the patient presents with postoperative bleeding and a drop in hematocrit it is important to repeat the EGD and inspect the gastric sleeve. If bleeding is identified it can be treated by using conventional techniques. Having said this, the majority of patients can be managed conservatively with high-dose proton pump inhibitors and supportive care. To decrease bleeding risk we recommend that one adheres to guidelines for antithrombotic therapy in patients undergoing gastrointestinal endoscopy[47] and avoid nonsteroidal anti-inflammatory drugs both before and after the procedure.

Infection related adverse events

Due to the full-thickness sutures applied during ESG bacterial translocation may occur resulting in contamination of the peritoneal cavity by gastric contents. Delayed gastric wall perforations and small leaks may also occur. Given the possibility for ESG-related infections we recommend antibiotic prophylaxis with Cefazolin 1 to 2g intravenous ≤60 minutes before procedure. Infections occur due to the fact that full-thickness bites are performed, which can occasionally result in a microperforation with translocation of bacteria into the peritoneal cavity. Severe retching can also result in tearing of tissue around the suture with resultant larger perforations and perigastric fluid collection or abscess formation. If a fluid collection is identified on CT, conservative treatment with antibiotics, and occasional radiological or endoscopic intervention is required. Surgical intervention is very rarely indicated.

Injury to adjacent organs

One of the most feared ESG-related AEs is the possibility of damaging organs surrounding the stomach when taking a full-thickness bite. It is important to ensure that the tissue helix is carefully deployed and retracted to avoid trapping tissue and causing trauma. It is imperative to communicate clearly with the technician and keep track of each turn of the helix during deployment. To avoid deeper tissue injury and injury to adjacent organs, it is important to avoid using excessive pressure or an excessive number of turns when deploying the helix.

Excessive pulling on the helix should be avoided and if the tissue does not retract easily, this likely represents (1) the bite being too close to a previous bite or already plicated tissue or (2) an extra gastric stucture such as the anterior abdominal wall being caught by the helix. Simply rotating counterclockwise while providing tension will release the extragastric structure, represented by the tissue now easily being able to be retracted. Care should be taken to not overinsufflate the stomach so as to minimize contact of the serosal surface of the stomach to extragastric structures. Additionally, we recommend placing the patient in a semisupine to the left position instead of the traditional left lateral decubitus position because it facilitates a safety margin between the stomach and surrounding structures (**Figure 4**). Another procedural change is the sparing of gastric fundus because it presents a thin tissue layer and is located close to the spleen and diaphragm, therefore minimizing the possibility of adverse events[1,3].

CONCLUSION

ESG has been well received as a minimally invasive endoscopic bariatric procedure throughout the world and is currently being performed in every continent. The procedure is alluring to patients due to it being performed as an outpatient procedure with minimal recovery time and low risk of severe AEs. As adoption increases, it is imperative for bariatric endoscopists to understand the technical nuances to improve procedural success and decrease the rate of adverse events.

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Table 1: Techniques to facilitate a robust plication

1. To ensure full-thickness bites, the scope should be maneuvered toward the left as the tissue helix is being pulled toward the scope.
2. Move the tower away from the wall so that the tower itself does not prevent a large bite being taken.
3. Take bites 2 cm apart and not more to reduce tensions on the suture.
4. Always be aware of the location of the trailing and leading sutures to prevent crossing and knots. This will decrease the strength of the suture and hinder completion of the desired pattern.
5. Keep the endoscope in the midline of the stomach, and avoid moving the scope back and forth repeatedly to prevent the suture from getting trapped behind the tower.
6. To prevent damage to extragastric tissue avoid pushing the helix against the gastric wall with force.
7. To prevent perforation and damage to extra gastric organs start pulling back gently after 3 turns of the helix.
8. Use 3 or 4 rotations of the helix in the distal body and 2 to 3 rotations in the proximal body.
9. If the helix cannot be withdrawn with ease, unwind a few turns until the extragastric structure (abdominal wall, omentum, liver etc) adhered to the stomach is released.

10. Drop the anchor adjacent to the tissue so it does not get caught in the scope channel or suture material.
11. Only drop the anchor when you are sure you have not crossed. If the suture material coming from the tissue to the scope is very close together, it has likely crossed. There should be a nice separation between the home suture and the active suture. The cinch cannot be optimally tightened if the sutures cross.
12. Prematurely dropping or breaking the suture could mean the loss of the entire suture. If the suture is prematurely dropped, the suture should be cinched immediately.

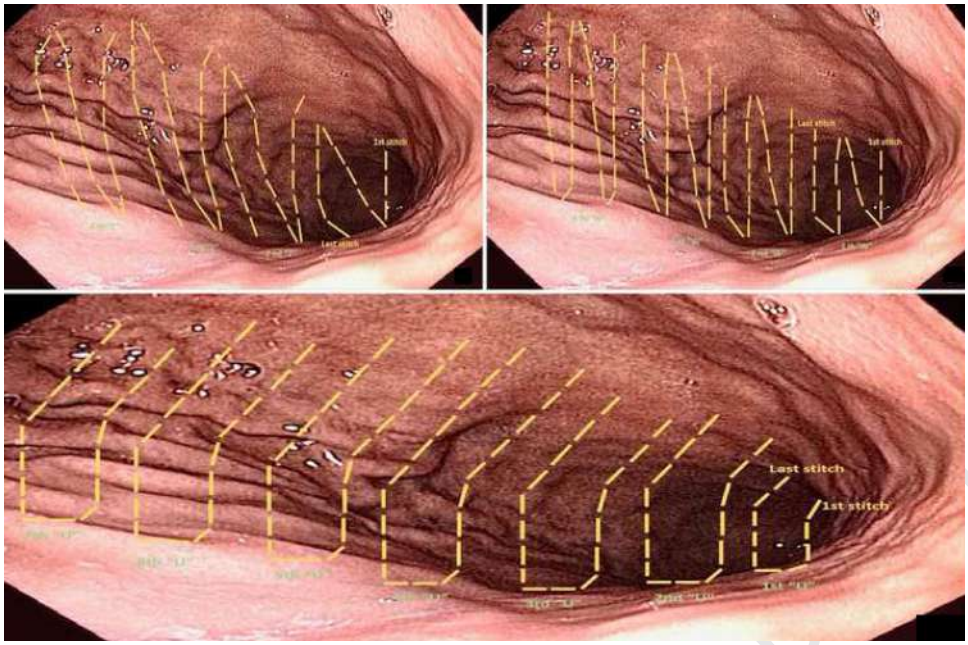
Table 2. Incidence of AEs in selected ESG studies

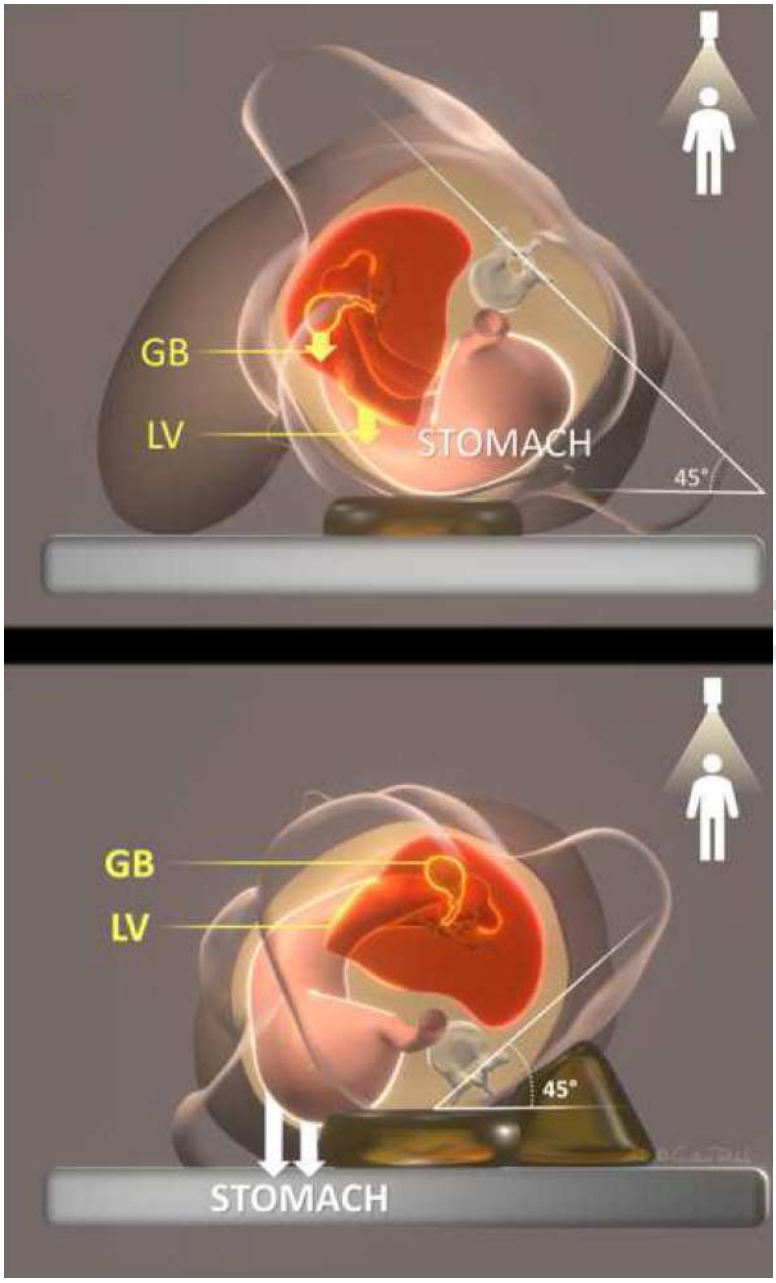
Author (year)	**Number of patients**	**Relevant adverse events**
Sartoretto et al (2018)[2]	112	3 (2.7%)
Abu Dayyeh (2017)[12]	25	3 (12%)
Lopez-Nava et al (2015)[13]	50	0
Neto et al (2019)[15]	233	1 (0.4%)
Bandhari et al (2019)[22]	53	0
Fayad et al (2019)[23]	54	3 (5.6%)
Lopez-Nava et al (2016)[24]	55	1 (1.8%)
Kumar et al (2018)[25]	77	0
Novikov et al (2018)[26]	91	2 (2.2%)
Sharaiha et al (2017)[27]	91	1 (1.1%)
Saumoy et al (2018)[28]	128	2 (1.6%)
Morales et al (2018)[29]	148	1
Lopez-Nava et al (2017)[30]	154	0
Barrichello et al (2019)[31]	193	4 (2.1%)
Lopez-Nava et al (2017)[32]	248	5 (2.1%)
Alqahtani et al (2019)[33]	1000	24 (2.4%)

Figures and Tables Legends:

Figure 1.	Endoscopic suturing device

Figure 2.	Different stitch patterns performed around the world. A, Z stitch pattern. B, W stitch pattern. C, U stitch pattern.
Figure 3.	Reinforcement sutures.
Figure 4.	Patient´s position. A, In the left lateral position the surrounding organs are close to the stomach wall. B, Semi-supine left position facilitates a safety margin between the stomach and surrounding structures. LV: liver; GB: gallblader.
Table 1.	Techniques to facilitate a robust plication.
Table 2.	Incidence of relevant adverse events in selected endoscopic sleeve gastroplasty studies.





Perspectives Towards Minimizing the Adverse Events of Endoscopic Sleeve Gastroplasty (ESG)

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Abbreviations:

Adverse events (AEs)
American Society of Gastrointestinal Endoscopy (ASGE)
American Society for Metabolic and Bariatric Surgery (ASMBS)
Computed Tomography (CT)
Deep Venous Thrombosis (DVT)
Diabetes mellitus (DM)
Endoscopic Bariatric and metabolic Therapies (EBMT)
Endoscopic Sleeve Gastroplasty (ESG)
Esophagogastroduodenoscopy (EGD)
Excess Weight Loss (EWL)
Gastroesophageal Reflux Disease (GERD)
Laparoscopic Sleeve Gastrectomy (LSG)
Preservation and Incorporation of Valuable endoscopic Innovations (PIVI)
Upper Esophageal Sphincter (UES)
Upper Gastrointestinal Bleeding (UGIB)