

## Original Article

## Endoscopic Sleeve Gastroplasty for Obesity – First Indian Experience: Case Series and Review of Literature

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## ABSTRACT

**Introduction:** In India, obesity affects >135 million and leads to nearly 5.8 million deaths per year. Some of the unmet need in the management of obesity can be fulfilled by endoscopic therapies such as endoscopic sleeve gastroplasty (ESG).

**Methods:** In this case series, we report our preliminary experience of ESG in three obese patients. We recorded baseline demographic data, total procedural time, adverse events, and percentage total body weight loss (%TBWL) up to 20 weeks.

**Results:** All three patients were male with a median age of 29 years (range 26–39) with a median body mass index of 34.28 kg/m<sup>2</sup> (range 32.60–37.13). A total of four full-thickness and additional three submucosal sutures were applied in each patient. There were no adverse events. The median total procedural time was 105 min (range 90–150). All patients were discharged within 48 h. The median percentage total body weight loss (%TBWL) at 12 weeks was 12.02 (range 10.85–13.33) and at 16 weeks was 14.23 (range 13.84–14.62). The maximum follow-up so far is 20 weeks (one patient) with %TBWL of 16.38. **Conclusion:** In our preliminary experience, we conclude that ESG is safe, effective and requires shorter hospital stay. In short-term follow-up, there is adequate weight loss without major adverse events.

**KEYWORDS:** Endoscopic sleeve gastroplasty, endoscopic therapy, metabolic syndrome, obesity, weight loss

## INTRODUCTION

Obesity epidemic in India is associated with nearly 5.8 million deaths per year.<sup>[1]</sup> This is majorly contributed by the change in the dietary habits and lifestyle accompanied by increased abdominal, liver, and pancreatic fat, along with higher body fat and lower lean mass in ethnic Indians compared to the Western population.<sup>[1]</sup> Noncommunicable diseases are estimated to be responsible for 40% of all hospital admissions and 35% of all outpatient visits in 2004 in India.<sup>[1,2]</sup> Among these, half of diabetes and one-fourth of cardiovascular disease patients are overweight or obese.<sup>[1,2]</sup>

The currently accepted intervention to reduce obesity includes dietary and lifestyle changes or laparoscopic bariatric surgery. The former is effective in small subset of patients that too in the short term, while bariatric surgery though effective is associated with its inherent problems such as patient's reluctance, cost, adverse

events, nutritional issues, and difficult reversibility. It is estimated that only <1% of population who qualifies for bariatric surgery will undergo the surgical procedures.<sup>[3,4]</sup> This unmet need could be fulfilled by minimally invasive endoscopic therapies, which are safe, effective, and easily reversible.

Endoscopic metabolic and bariatric interventions are usually divided into gastric interventions and small bowel interventions.<sup>[5]</sup> Gastric interventions include intragastric balloons, aspiration therapy, and endoscopic gastroplasty. Small bowel interventions include gastrointestinal bypass

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sleeves such as endobarrier (GI Dynamics, Lexington, MA, USA), duodenal mucosal resurfacing, and magnetic anastomosis systems.<sup>[5]</sup>

Three gastric remodeling procedures are currently applied in the clinical practice worldwide. These include endoscopic sleeve gastroplasty (ESG), primary obesity surgery endoluminal (POSE), and transoral anterior-to-posterior greater curvature plication with the Endomina® suturing device. Currently, only ESG is available in India. POSE and Endomina are expected to be available within 1 year.

ESG is an effective and safe procedure. We present our preliminary experience of three cases who underwent ESG and their subsequent follow-up. This is the first case series from India to be published.

## METHODS

After the institutional review board approval, we prospectively included three patients with class II obesity for ESG. Baseline demographics, weight, height, body mass index (BMI), waist circumference, and presence of comorbidities such as diabetes, hypertension, and dyslipidemia were noted. Patients with active gastric ulcer, with large hiatal hernia ( $\geq 5$  cm), on anticoagulation therapy, or with previous upper intestinal surgery were excluded. The total procedure time, along with intraprocedural and early postprocedural adverse events, was noted. A multidisciplinary team of nutritionist, behavioral therapist, physiotherapist, gastroenterologist, endocrinologist, and bariatric surgeon were involved in management. Patients were instructed to follow specific dietary and physical activity, both pre- and post-ESG, which was monitored by the nutritionist and the physiotherapist. We calculated percentage of total body weight loss (%TBWL) at 12, 16, and 20 weeks of follow-up.

### Endoscopic sleeve gastroplasty

ESG mimics surgical gastrectomy and is performed using an endoscopic suturing device (Overstitch, Apollo Endosurgery, Austin, TX, USA). The ESG procedure decreases the size of gastric lumen by creating a sleeve along the greater curve of the stomach. ESG is performed with CO<sub>2</sub> insufflation under general anesthesia with double-lumen endoscope over which special device is at the tip of the endoscope with suture control handle attached to scope at working channel. Full-thickness sutures are applied in a triangular fashion along anterior wall, greater curvature, and posterior wall which is tightened so that sleeve is created along lesser curvature [Figure A]. Postprocedure, the patients were observed in hospital for 24 h and discharged once they start tolerating clear liquids. The patients were advised to

take protein shakes for 3–4 weeks followed by semisolid diet for 2–3 weeks with slow transition to regular diet.

## RESULTS

ESG was done in three patients; all were male with BMI  $>32.5$  kg/m<sup>2</sup>. Total four full-thickness sutures were applied in all patients, along with additional three submucosal sutures were applied along sleeve for augmentation and relieve tension on full-thickness sutures. The median total procedural time was 105 min (range 90–150 min). ESG was technically successful in all patients. There were no intraprocedural or early adverse events. All patients were discharged by 24–48 h. Mean %TBWL at 12 weeks was 12.07%. The results of weight loss are summarized in Table 1.

## DISCUSSION

Endoscopic-sutured gastroplasty is evolved in three phases. It was started from phase I in which procedure was developed in India followed by phase II in which technical refinement was achieved and finally

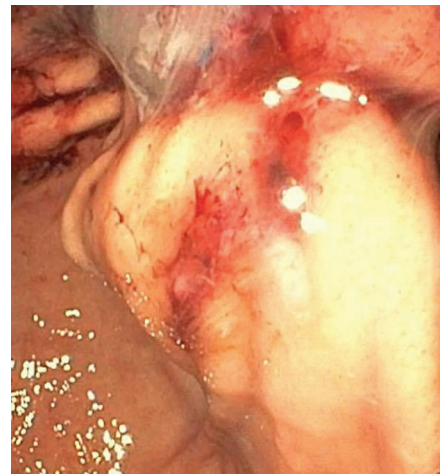


Figure A: Endoscopic view of sleeve

Table 1: Summary of cases

Parameters	Patient 1	Patient 2	Patient 3
Age (years)	39	26	29
Weight (kg)	105	123	98
Height (m)	1.75	1.82	1.73
BMI (kg/m <sup>2</sup> )	34.28	37.133	32.6
Comorbidities	HTN	DM, HTN	DM
Procedure time	105	150	90
Follow-up			
Percentage TBWL (weeks)			
12	13.33	12.02	10.85
16	14.62	13.84	
20	16.38		

TBWL=Total body weight loss, BMI=Body mass index, HTN=Hypertension, DM=Diabetes mellitus

phase III which established the technique and weight loss outcomes.<sup>[6]</sup> ESG induces mean %TBWL of  $18.7\% \pm 10.7$  at 1 year with significant improvement in metabolic parameters.<sup>[4]</sup> In the current study, the mean %TBWL at 12 weeks was 12.07%. Adverse events occur in <2% of patients which include bleeding, nausea, pain, perigastric fluid collection, and pulmonary embolism; majority are nonfatal.<sup>[7]</sup> There were no adverse events in our study. The uniqueness of ESG is that like laparoscopic sleeve gastrectomy (LSG), it produces significant and sustained weight loss. The advantage of ESG is minimally invasive nature, cost-effective with short hospital stay along with lesser adverse events.<sup>[4,7]</sup>

In one prospective case study aiming at learning curve for ESG, it showed median total procedural time of 105 min (range 63–220), which decreases significantly to reach plateau at 101.5 min and a learning rate of seven cases.<sup>[8]</sup> The learning curve of ESG, both in terms of procedure time and number needed to acquire technical skills, is not steep. Saumoy *et al.* defined “efficiency of ESG” as refining performance to decrease procedure time was attained after 38 procedures, while “mastery” defined as the absence of outlier was achieved after 55 procedures.<sup>[9]</sup> In our preliminary case series, the median procedure time was 105 min (range 90–150 min) and expected to improve eventually with more cases in the future.

Previously published study on ESG demonstrated safety and efficacy of ESG at par with bariatric surgery.<sup>[4,7]</sup> A recent study demonstrated at 1-year follow-up that ESG had significantly lower morbidity and shorter hospital stay compared to LSG. However, LSG achieved more %TBWL compared to ESG (29.28 vs. 17.57,  $P < 0.01$ ).<sup>[10]</sup> This study highlights that ESG is a safe and feasible endobariatric therapy as compared to LSG. The Overstitch (Apollo Endosurgery) is an FDA-approved therapeutic flexible endoscopic suturing device. Several studies of ESG using the Overstitch device have shown feasible and significant results.<sup>[11,12]</sup>

The technology of bariatric and metabolic endoscopy has developed rapidly in recent years, and many new endoscopic devices have been introduced. Several technologies are now available and FDA approved in the U.S.A such as intragastric balloons and full-thickness endoscopic suturing. There is no clinical study which compared different types of endoscopic interventions. However, ESG appears to have more weight loss and safer than intragastric balloon. Recent advances in endoluminal technology for the treatment of obesity and metabolic diseases have been promising. Endoscopic bariatric treatment must be an attractive option to both patients and physicians.

## CONCLUSION

The overall treatment of obesity requires a multidisciplinary team approach involving nutritionist, psychologist, endocrinologist, and bariatric surgeon along with gastroenterologist for better standard of care in patients with obesity and metabolic syndrome. The development of new endoscopic techniques allows the endoscopist to play an increasingly important role in the management of obesity.

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## Conflicts of interest

There are no conflicts of interest.

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