

Review Articles

Gastroscopic Bariatric Procedures

Dr. Rupesh Mehta

Head of Dept. of Surgical Gastroenterology, Sheth Vadilal Sarabhai General Hospital, Ahmedabad.

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ABSTRACT:

Gastroscopic Bariatric Procedure is a combination of surgical and endoscopic skills. Surgical skill and surgical set up are critical elements of this procedure.

The key difference is that there is no requirement of incision or scars, facilitating fast recovery and healing. Gastroscopic procedure reduces the size of the stomach similar to a Laparoscopic Sleeve Gastrectomy, but does not involve removal of any portion of the stomach.

The procedure takes approximately 70 minutes. The patient is able to walk 3-4 hours later and mostly gets discharged same day to resume their regular routine. The best part is that no bed rest is required.

Overweight/Obese individuals with a BMI (Body Mass Index) between 25 and 35 kg/m.2 are ideal but those with BMI upto 40 kg/m.2 and inability to control weight through diet and exercise or those who are afraid of surgery and young ladies who are averse to scars can undergo the procedure. Patients with co-morbidity/metabolic complications and lesser BMI are good candidates.

A large number of patients suffering from diabetes, hypertension, sleep apnea, fatty liver and dyslipidemia etc. are leading a disease free life or are managing with much reduced medications and support for the same problem, once they have achieved the desired weight loss.

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) & Primary Obesity Surgery Endoluminal (POSE-2).

INTRODUCTION

Obesity epidemic in India is associated with nearly 5.8 million deaths per year [1]. This can be attribute to a large extent to 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 [1]. Noncommunicable diseases are estimated to be responsible for 40% of all hospital admissions and 35% of all outpatient visits in 2004 in India [1,2]. Among these, half of diabetes and one fourth of cardiovascular disease patients are overweight or obese [1,2].

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 <1% of population who qualifies for bariatric surgery will undergo the surgical procedures [3,4]. This unmet need could be fulfilled by minimally invasive endoscopic therapies, which are safe, effective and reversible.

Endoscopic metabolic and bariatric interventions are usually divided into gastric interventions and small bowel interventions [5]. Gastric interventions include intragastric balloons, aspiration therapy, and endoscopic gastroplasty. Small bowel interventions include gastrointestinal bypass sleeves such as endobarrier (GI Dynamics, Lexington, MA, USA), duodenal mucosal resurfacing, and magnetic anastomosis systems [5].

Three gastric remodeling procedures are currently applied in the clinical practice worldwide. These include endoscopic sleeve gastroplasty (ESG), primary obesity

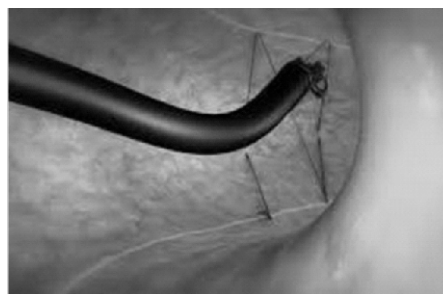
Correspondence Address : **Dr. Rupesh Mehta**
Mehta Hospital, First Floor, Dalia Building, Near V.S. Hospital, Ellisbridge,
Ahmedabad-380006 Email: drrupeshmehta@gmail.com

surgery endoluminal (POSE-2), and transoral anterior to posterior greater curvature plication with the Endomina® suturing device. Currently, only ESG is available in India & POSE-2 will be available soon.

Preferred indications for Gastroscopic Bariatric Procedures: Young female patient, Not responding to medicines and exercise and diet control. Not willing for operation, Revision surgery after Bariatric operation and weight gain. Morbid obesity requiring a step down procedure, Multiple scars over the abdomen, Incisional Hernia and Miliary Tuberculosis.

Endoscopic Sleeve Gastroplasty (ESG)

The OverStitch is a device that attaches directly to a dual-channel gastroscope and allows placement of full-thickness sutures in running pattern. This device can deploy non absorbable sutures with the ability to reload additional suture material while maintaining direct endoscopic visualization, a major advancement over previous endoscopic suturing devices [6]. The OverStitch device mounts over the scope tip in a cap-like fashion. This cap includes the suture arm, which moves in an arc-like manner, and the anchor exchange channel. The suture arm is connected to and controlled by a hand lever that attaches near the hand controls of the endoscope. The suture cartridge is passed through an operating channel and contains suture material attached to a pointed tissue anchor. The tissue anchor attaches to the suture arm and serves to drive suture material through the tissue of interest when suturing. If full thickness sutures are desired, a helix device is also included in the kit. This accessory can be passed through the alternate operating channel and used to 'corkscrew' into the tissue of interest for tissue retraction and placement of full-thickness sutures. Finally, a Cinching device is utilized to secure & cut the sutures. Full thickness sutures are applied in a triangular fashion along anterior wall, greater curvature, and posterior wall and again posterior wall, greater curvature and anterior wall. On tightening these sutures, a sleeve is created along lesser curvature [Figure 1]. Post procedure, the patients are observed in hospital for 2-4 hours and discharged once they start tolerating clear liquids. The patients are advised to take protein shakes for 3-4 weeks followed by semisolid diet for 2-3 weeks with slow transition to regular diet.



The advantage of ESG is minimally invasive nature, cost effective with short hospital stay along with lesser adverse events [4,7].

Several studies of ESG using the Overstitch device have shown feasible and significant results [8,9].

Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients [10]. 24 patients were readmitted: 8 for severe abdominal pain, 7 for postprocedure bleeding, 4 for perigastric collection and 5 for postprocedure fever with no sequelae and no mortality.

Primary Obesity Surgery Endoluminal (POSE-2)

To perform the POSE-2 use a special set of endoscopic surgery tools known as the Incisionless Operating Platform (IOP). Patients are put under anesthesia for the procedure. A long flexible tube known as a transport with six channels that is created specifically for procedure is inserted through the mouth and into the stomach [Figure 2]. Then 5.5 mm external diameter Gastroscope passed through the transport. This Gastroscope is held by the assistant which shows the inside view of stomach during the procedure. With the help of g-Prox which is a special instrument with the jaw size 3.3 cm is passed through the above mentioned transport. There is another instrument called g-Lix which has a corkscrew tip. G-Lix will hold the stomach full thickness tissue and g-Prox will create a fold. g-Cath will go through g-Prox and deploy specially designed suture anchors that fasten the folds together. This will shorten the stomach by 7cm vertically. Such 14-18 folds are created in the starting from proximal to antrum up to area below fundus. It reduces the size of stomach vertically.

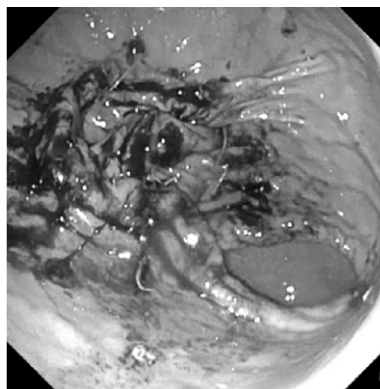


Table ^[14]

No	Study / Country	Study Type	Number of Subjects	Procedure time (minutes)	Follow up duration	Intra-procedure complication	Post-procedure complications
1	Sharaiha et al. (2017) [10] USA	Single center prospective study	Total: 91 Male: 29 Female: 62 Mean BMI: 38.6±7.0 kg/m ²	For all patients: 98.3±39.3	Number of patients with follow up at 6 months: 73/91 12 months: 53/91 24 months: 12/91	None	1. Major a) Perigastric leak: 1/91 (Day 8 post procedure, managed with percutaneous drain and antibiotics) 2. Minor a) Nausea: 35/91 (improved with medications alone) b) Abdominal pain: 25/91 (improved with medications alone)
2	Lopez-Nava et al. (2015) [13] Spain	Single center prospective study	Total: 91 Total: 50 Male: 13 Female: 37 Mean BMI: 37.7±4.6 kg/m ²	Composite: 66	12 months	None	1. Major: none 2. Minor a) Epigastric pain: 25/50 b) Nausea: 10/50
3	Lopez López-Nava Breviere et al. (2016) [15] Spain	Single center prospective study	Total: 55 Male: 13 Female: 42 Mean BMI: 37.7±4.5 kg/m ²	DNA	6 months	None	1. Major: none 2. Minor a) Abdominal pain: 50% (improved with painkillers, one patient required 24 hr hospitalization) b) Nausea: 20% (improved with anti-emetics)

Both POSE-2 and Apollo have FDA approval for tissue approximation. Neither have approval for obesity claim. POSE-2 has CE Mark OBESITY approval in Europe, Australia and New Zealand.

Aspiration Therapy

The Aspiration therapy system called as Aspire Assist has also been used to treat obesity which consists of an endoscopically placed gastrostomy tube and siphon assembly [11]. Patients can aspirate gastric contents about 20 min after eating. It is not as much popular.

DATA FROM PAPERS PUBLISHED ON ESG & POSE-2

Short-term outcomes of Endoscopic Sleeve Gastroplasty in 1000 consecutive patients: The 1000 patients in this study had a baseline body mass index of

33.3 ± 4.5 kg/m² and age of 34.4 ± 9.5 years. Eight hundred ninety-seven patients (89.7%) were women. Mean percentage of total weight loss at 6, 12, and 18 months was 13.7% ± 6.8% (n = 369; follow-up rate = 423; 87.2%), 15.0% ± 7.7% (n = 216; follow-up rate = 232; 93.1%), and 14.8% ± 8.5% (n = 54; follow-up rate = 63; 85.7%), respectively. Lost to follow-up at the 12- and 18-month visits were 6.9% and 14.3%, respectively. Thirteen of 17 cases of diabetes, all 28 cases of hypertension, and 18 of 32 cases of dyslipidemia were in complete remission by the third month [10].

Endoscopic Gastric Plication for Morbid Obesity:

Twenty-two cohort studies on 7 different devices met the inclusion criteria, with a total of 2475 patients. The mean baseline BMI was 37.8 ± 4.1 kg/m² (median 37.9; range

28.0-60.2). Either a transoral endoluminal stapling or (suction based) (full-thickness) stitching and/or anchor device was used to obtain gastric volume reduction and/or alter gastric outlet. The mean follow-up was 13 months (median 12; range 6-24) for the specified outcomes of each study. Two active, FDA-approved devices were taken into account for meta-analysis: Endoscopic sleeve gastroplasty (ESG) and the primary obesity surgery endolumenal (POSE™). Average pooled %EWL at 6 months ($p = 0.02$) and 12 months ($p = 0.04$) in favor of ESG was $57.9 \pm 3.8\%$ (50.5-65.5, $I^2 = 0.0$), $44.4 \pm 2.1\%$ (40.2-48.5, $I^2 = 0.0$), and $68.3 \pm 3.8\%$ (60.9-75.7, $I^2 = 5.8$), $44.9 \pm 2.1\%$ (40.9-49.0, $I^2 = N/A$) for ESG and POSE respectively [12].

Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: Aim was to compare ESG to laparoscopic sleeve gastrectomy (LSG) and laparoscopic adjustable gastric banding (LAGB).

278 obese (BMI > 30) patients who underwent ESG ($n = 91$), LSG ($n = 120$), or LAGB ($n = 67$) at our tertiary care academic center. Primary outcome was percent total body weight loss (%TBWL) at 3, 6, 9, and 12 months. Secondary outcome measures included adverse events (AE), length of stay (LOS), and readmission rate. At 12-month follow-up, LSG achieved the greatest %TBWL compared to LAGB and ESG (29.28 vs 13.30 vs 17.57%, respectively; $p < 0.001$). However, ESG had a significantly lower rate of morbidity when compared to LSG or LAGB ($p = 0.01$). The LOS was significantly less for ESG compared to LSG or LAGB (0.34 ± 0.73 vs 3.09 ± 1.47 vs 1.66 ± 3.07 days, respectively; $p < 0.01$). Readmission rates were not significantly different between the groups ($p = 0.72$). Although LSG is the most effective option for weight loss, ESG is a safe and feasible endobariatric option associated with low morbidity and short LOS in select patients [13].

CONCLUSION

The overall treatment of obesity requires a multidisciplinary team approach for better standard of care in patients with obesity and metabolic syndrome. The development of new Gastroscopic techniques allows the endoscopist to play an increasingly important role in the management of obesity.

ESG & Pose-2 are both safe and feasible procedures with good short term weight loss without any mortality, low morbidity, and short length of stay.

ESG and POSE-2 procedures are a promising option for the bariatric patient. However long term studies are required for proper assessment.

Professor Gontrand Lopez-Nava from Madrid, Spain is authority on above mentioned procedures. During his recent presentation in Ahmedabad National Conference on above subject mentioned that both the procedures are effective and will help in management of Obesity.

At present the Cost of Gastroscopic Bariatric Procedures is approximately equal to Laparoscopic Sleeve Gastrectomy and may be less in near future.

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Nil

Conflicts of Interest

There are no conflicts of interest.

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