

Endoscopic sleeve gastroplasty 5 years data: What happened to our patients after 5 years



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SRI AUROBINDO UNIVERSITY
VISION WITH ACTION



← **INDORE, INDIA**

MOHAK BARIATRIC AND ROBOTIC SURGERY CENTER INDORE, INDIA (MBRSC)





Dr Manoel Galvao Neto

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Mohak Bariatric and Robotic Surgery Center

Indore- Mumbai- Hyderabad- Bangaluru



ircad

India



DISCLOSURE

Mohit Bhandari MD

Consultant to:

- Johnson and Johnson
- Medtronic
- Bariatric Solution
- Intuitive Surgical
- Karl Storz
- Stryker
- Apollo Endo-surgery
- Pentax
- Olympus

Mathias Fobi MD FACS, FICS, FACN

- Founding President, Bariatec Corporation

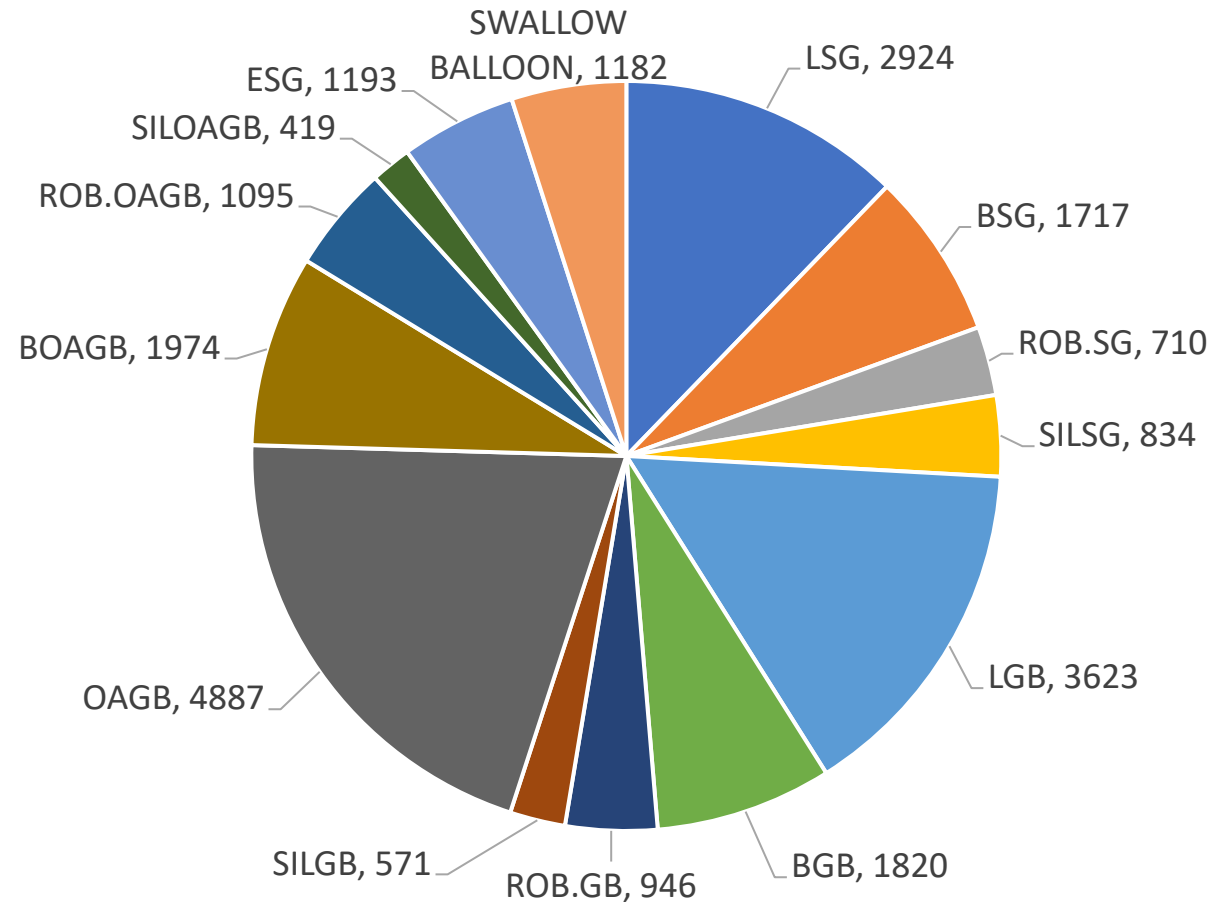
Manoel Galvao Neto

- Director Bariatric Endoscopy



BARIATRIC PROCEDURES MIX DISCLOSURES MBRSC January 2010 – July 2024

TOTAL	25400
LSG	6185
LGB	6960
OAGB	8375
ESG	1193
SWALLOW BALLOON	1182
Other	1505



Bariatric surgery is the most successful treatment for obesity

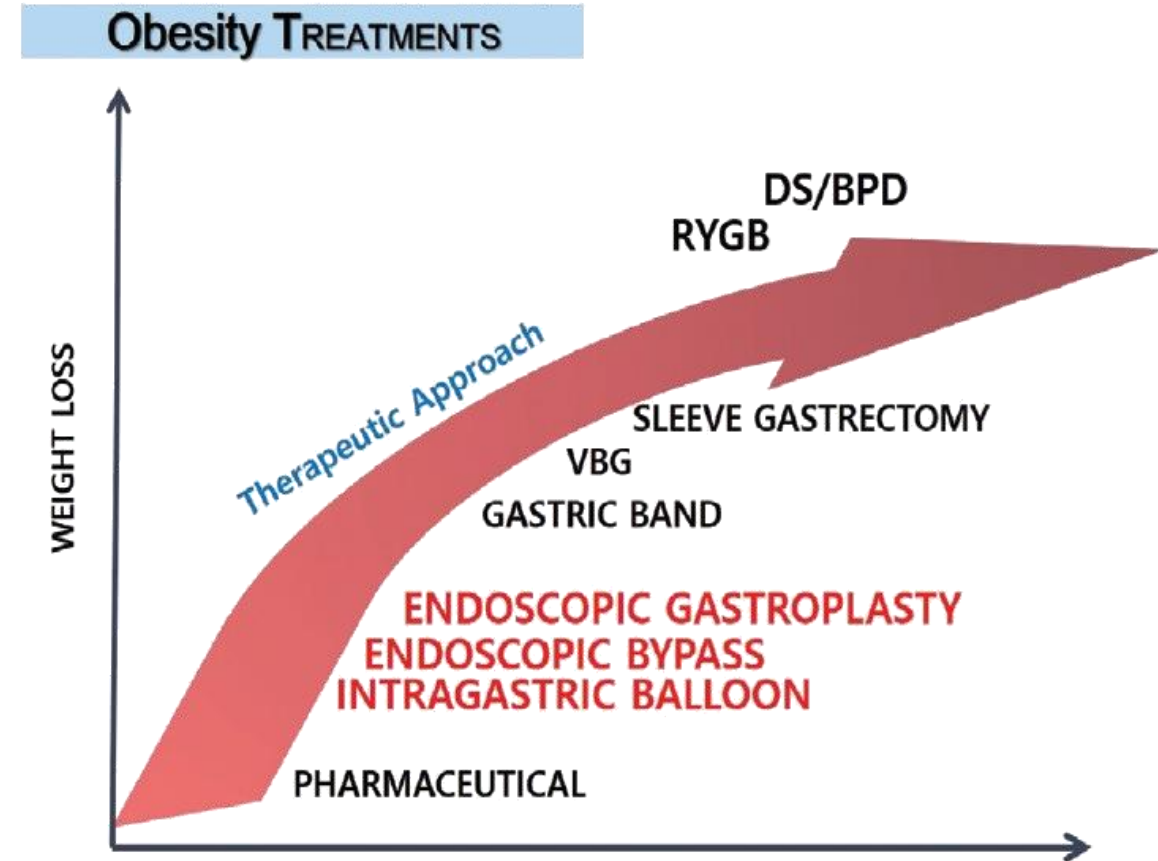
Many patients avoid surgery due to its perceived invasive nature and fear of complications

Endoscopic Sleeve Gastroplasty (ESG)

- **Endoscopic Sleeve Gastroplasty (ESG)** represents a transformative, minimally invasive alternative to traditional bariatric surgery, specifically designed for patients seeking effective weight loss without the risks and invasiveness of surgery. Particularly well-suited for individuals with lower BMI or those apprehensive about surgical procedures

Therapeutic approach to obesity treatment

- The effect of **Endoscopic Bariatric Treatment** for weight loss is greater than that of drugs but lower than that of bariatric surgery, but endoscopic bariatric treatment features fewer complications than bariatric surgery.

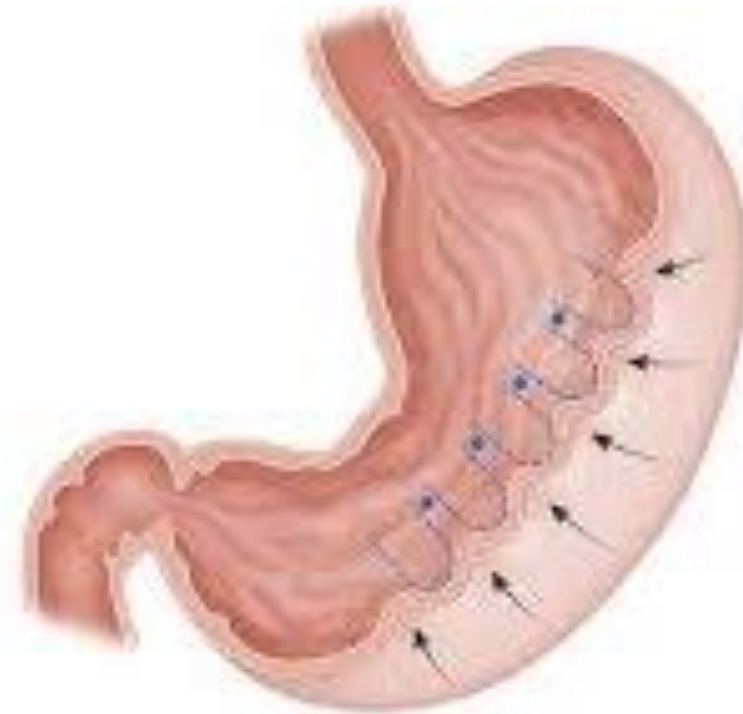


Less invasive

Reversible

Low cost

Repeated



Endoscopic Sleeve Gastroplasty (ESG)

Bridge the Gap between Medical therapy & Surgical management

It may be used as

- Primary Therapy
- Bridging Procedure
- Revisional Procedure

Endoscopic treatment of obesity : New technologies

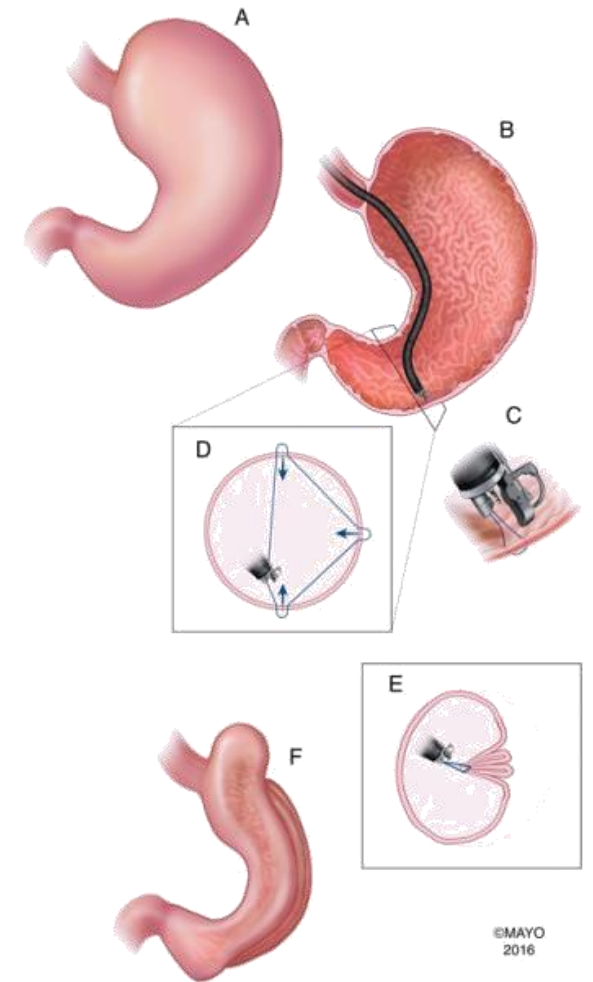
SECONDARY THERAPY

- Endoscopic Oral Outlet Reduction
- Endoscopic pouch reduction
- Argon Plasma Coagulation

PRIMARY THERAPY

Endoscopic sleeve gastropasty (ESG)

- Endoscopic sleeve gastropasty is a newer type of weight-loss procedure.
- Endoscopic sleeve gastropasty reduces the size of your stomach using an endoscopic suturing device without the need for surgery.
- Endoscopic sleeve gastropasty leads to significant weight loss.
- It helps you lose weight by limiting how much you can eat.
- The procedure is minimally invasive, reducing the risk of operative complications.

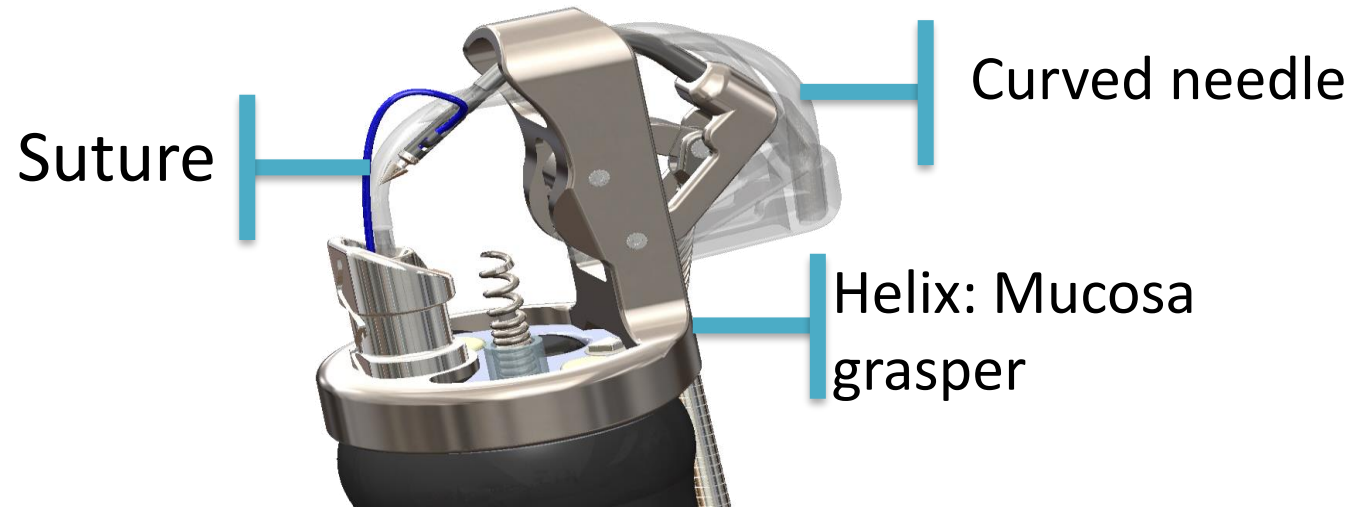


Myths:

- It's an invasive procedure
- Involves cutting of the stomach

Apollo Overstitch

- Apollo Overstitch is capable of full-thickness suturing in a variety of patterns, using a curved needle driver.
- Device is fitted to a dual channel endoscope.
- Device is FDA-approved to place endoscopic sutures.



Standardization of Procedures

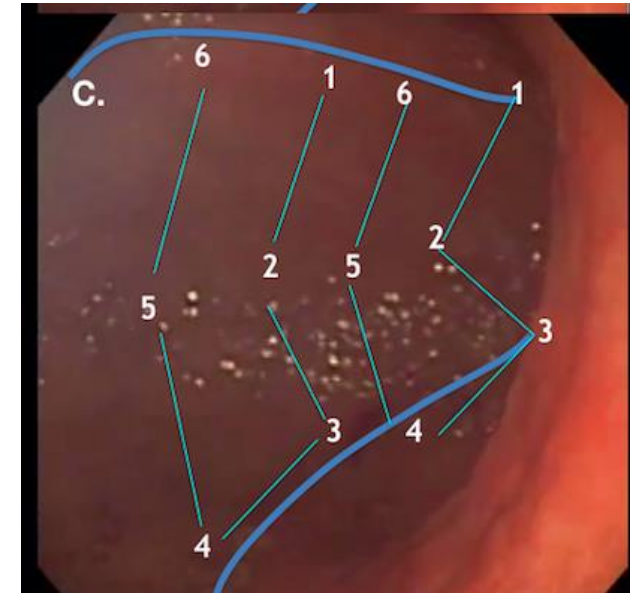
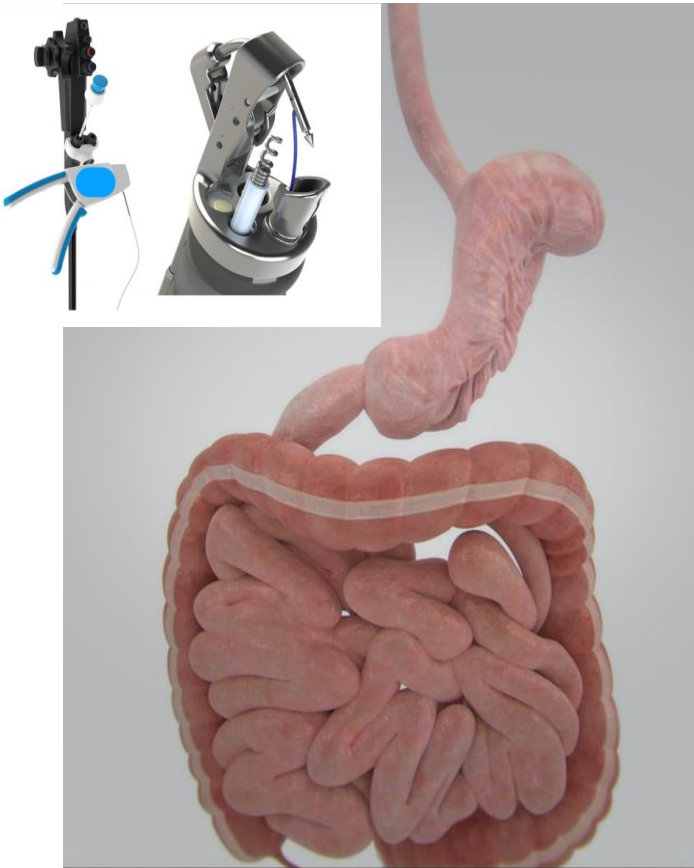
Standard Endoscopic Sleeve Gastroplasty

Double-channel endoscope and Endosuturing equipment.

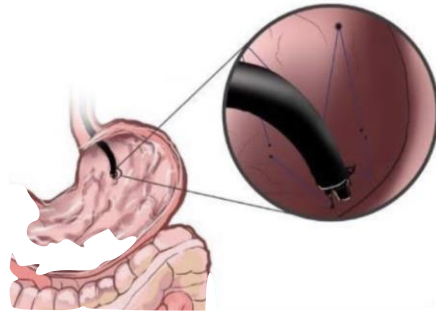
- Use of general anesthesia,
- Use of an overtube
- CO2 insufflation,
- Prophylactic antibiotics

Start suturing from the Proximal body in direction to the fundus involving the greater curvature of the stomach.

Place the sutures by sequentially catching the anterior wall, the greater curvature and the posterior wall returning to the anterior wall on a U-Shape or crossing directly from the posterior wall to the anterior wall to end on the posterior wall (always involving the greater curvature).

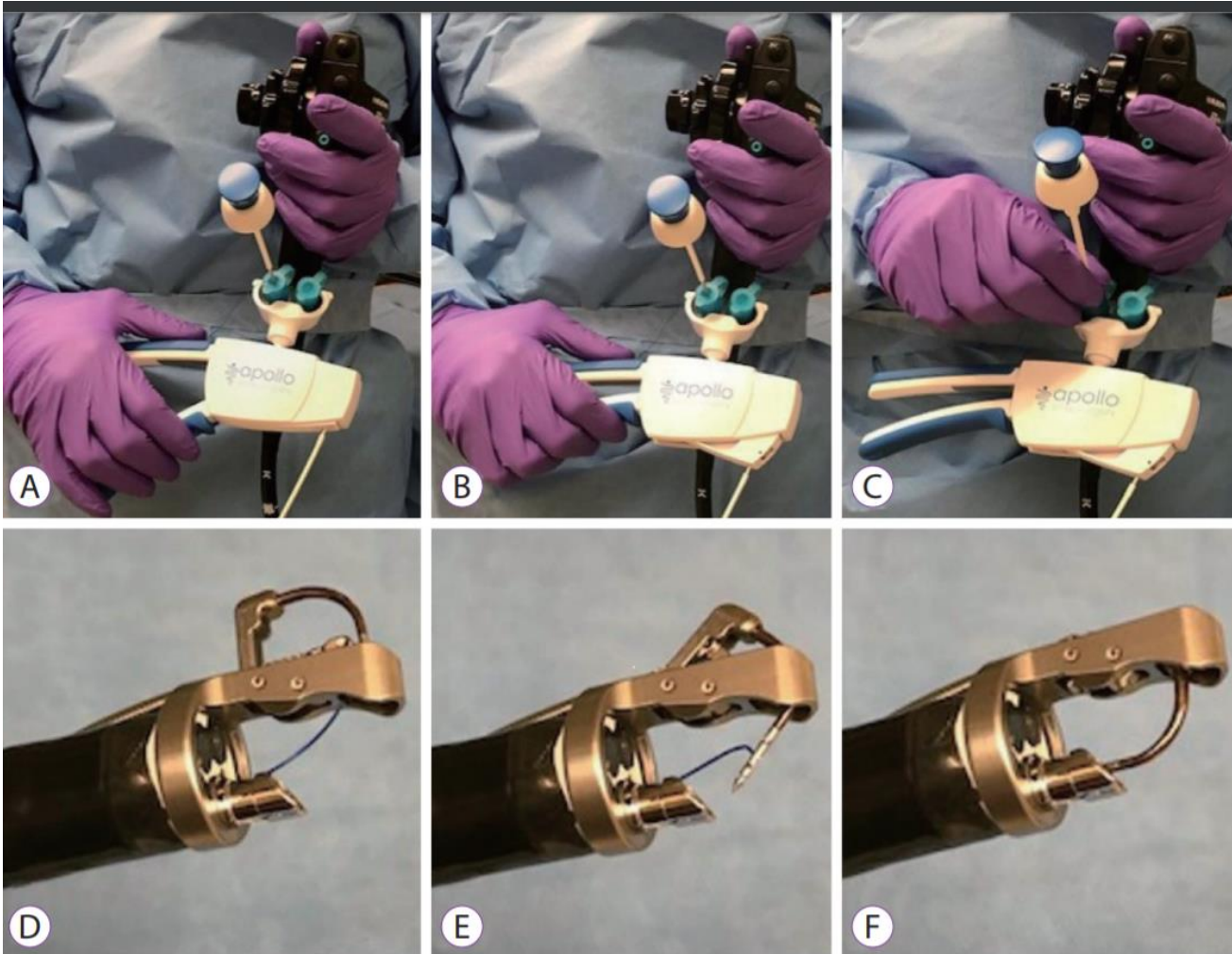


Endoscopic Gastroplasty

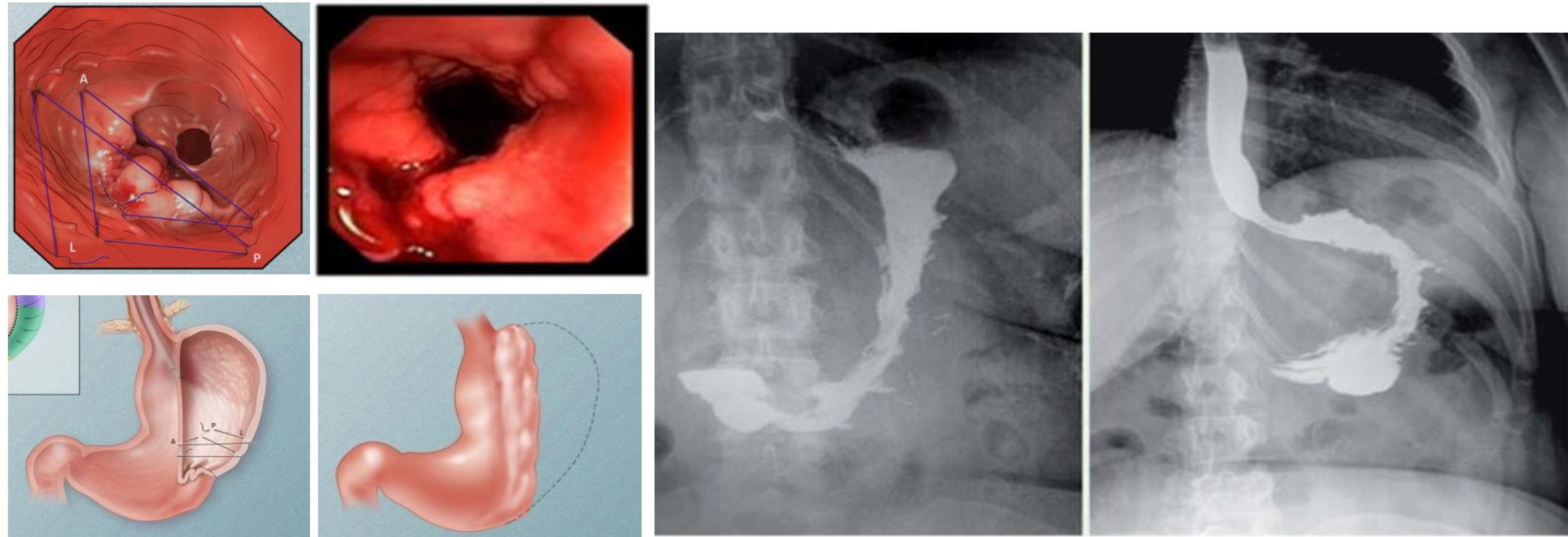


Apollo Overstitch

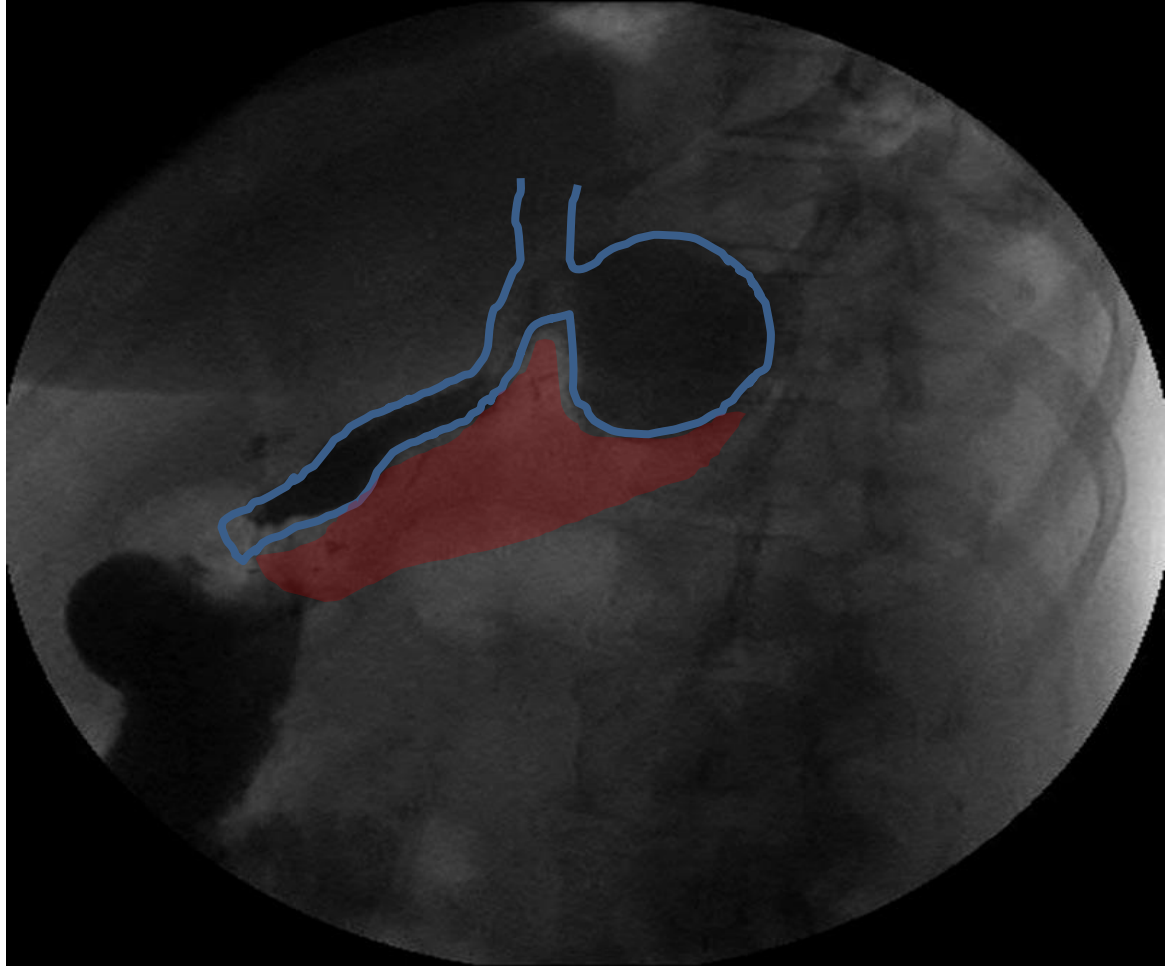
- (A) The handle open corresponds to (D).
- (B) The handle being closed corresponds to (E).
- (C) Fully closed handle with anchor exchange catheter (pick-up) being advanced to remove the needle from the curved suture arm. This corresponds to (F).
- (D) The needle and suture loaded on the curved suture arm in a fully open configuration.
- (E) The needle and suture on the curved suture arm as it would appear being advanced through tissue.
- (F) The curved suture arm in a closed configuration.



Endoscopic Sleeve Gastroplasty

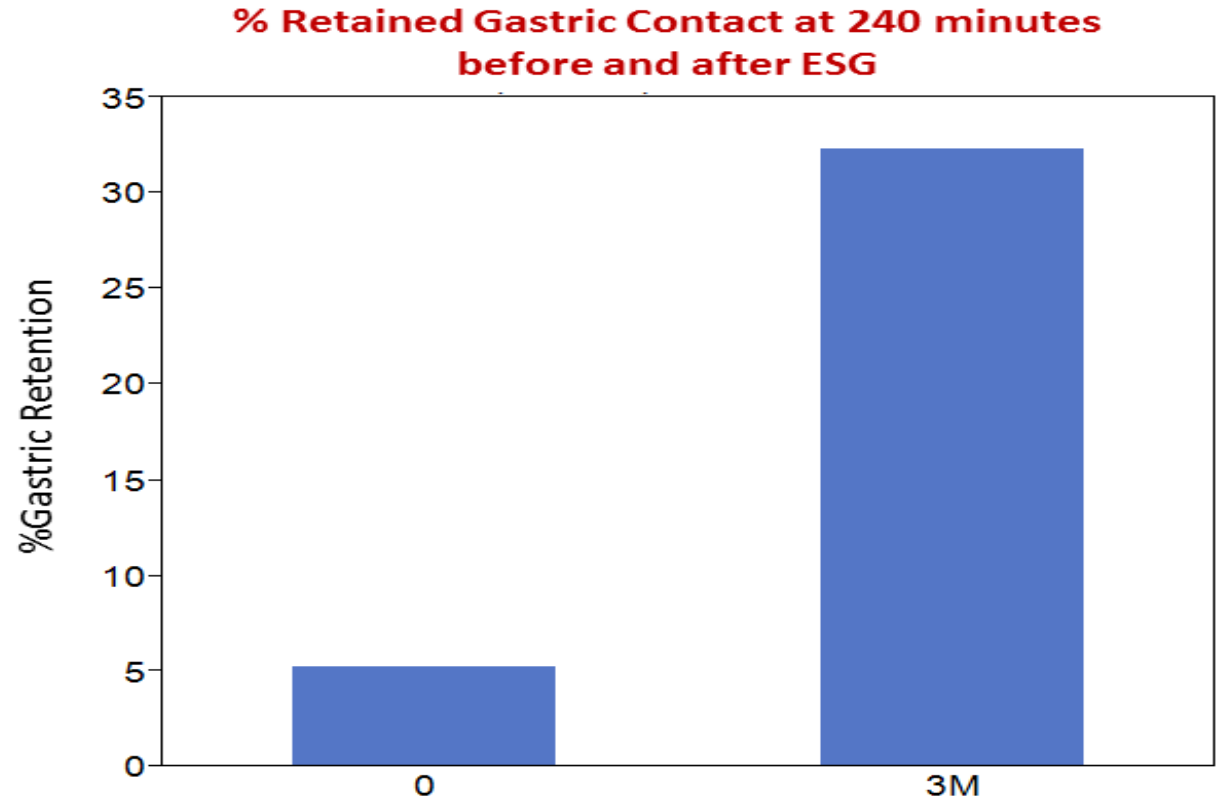
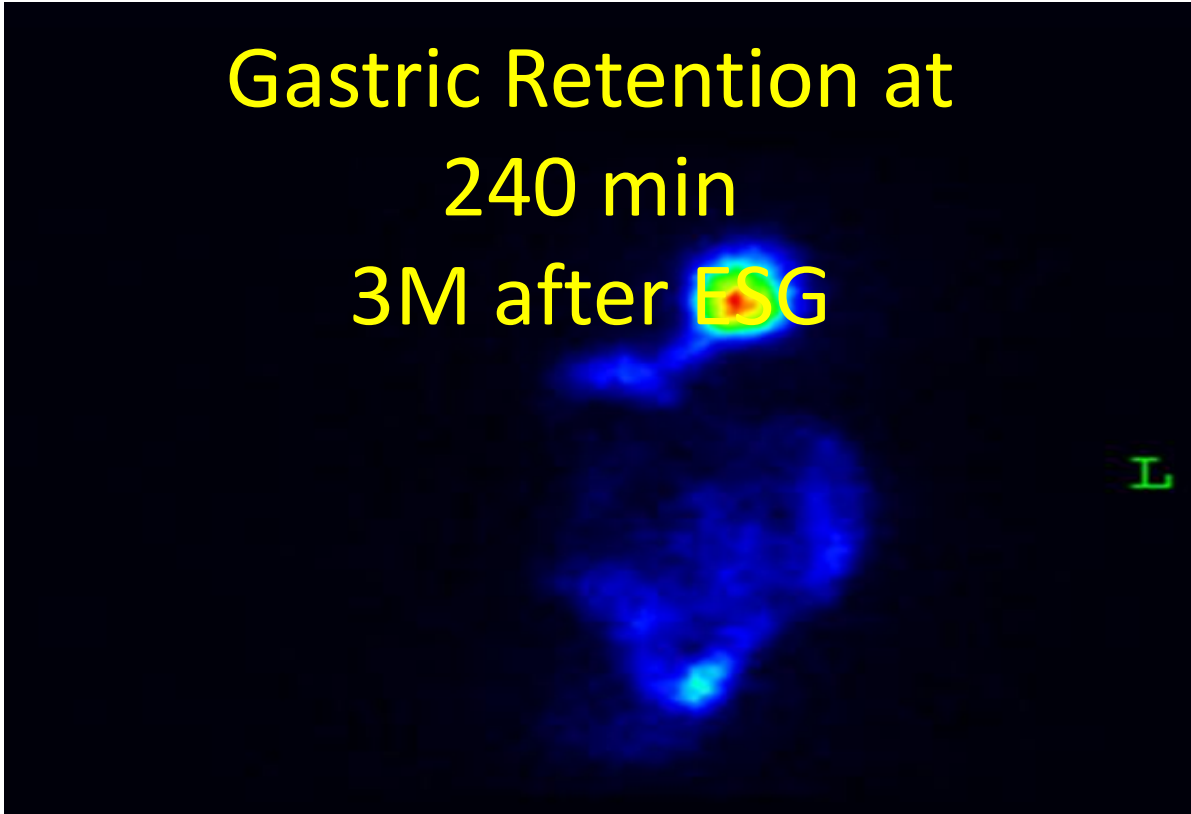


Physiology of ESG

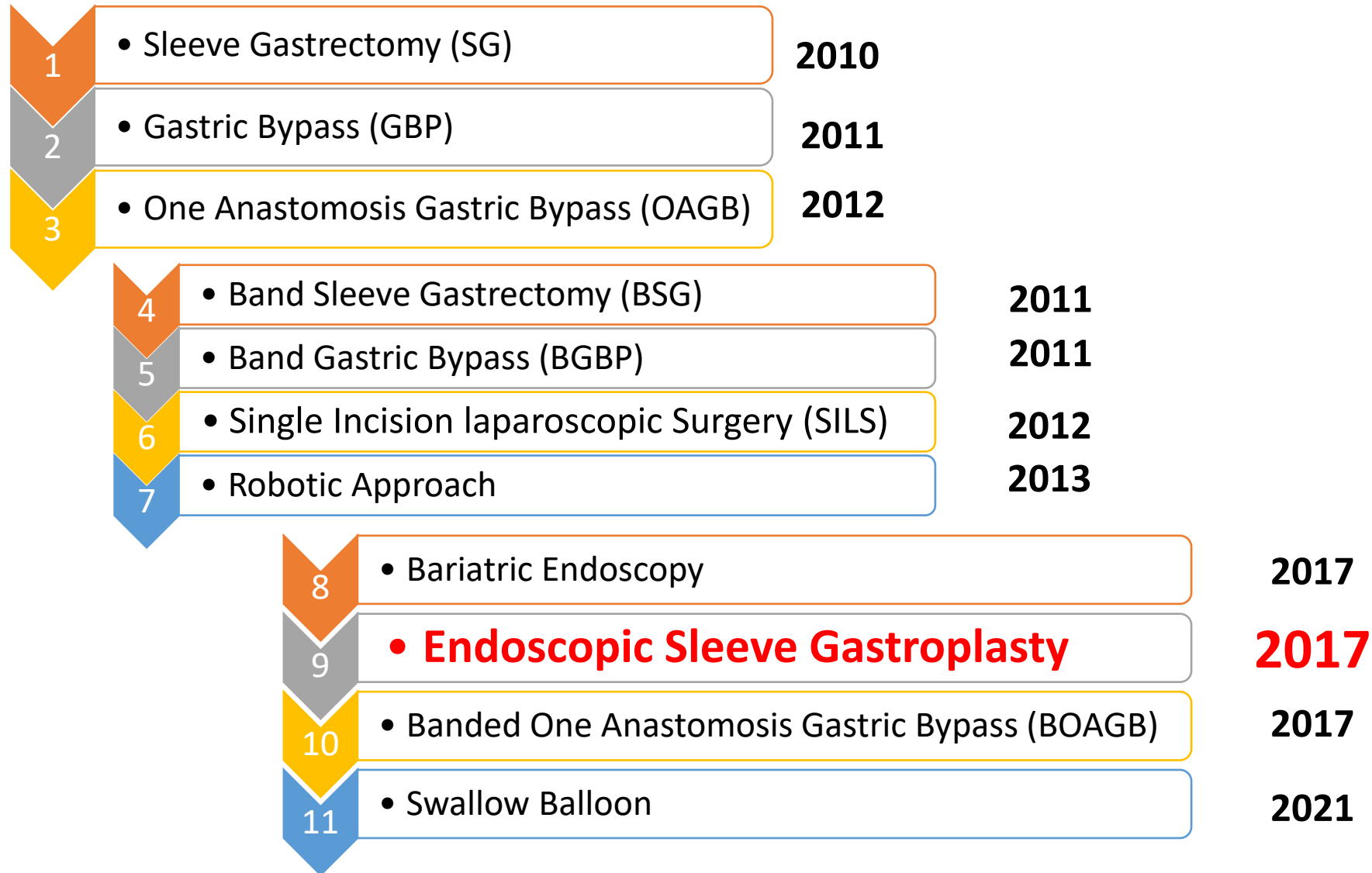


Physiology of ESG

Changes in gastric emptying by scintigraphy



Planned and Metered growth of the MOHAK program



Endoscopic Sleeve *Data: Mohak*

TOTAL = 993 (ESG)

618



Done at Mohak

375



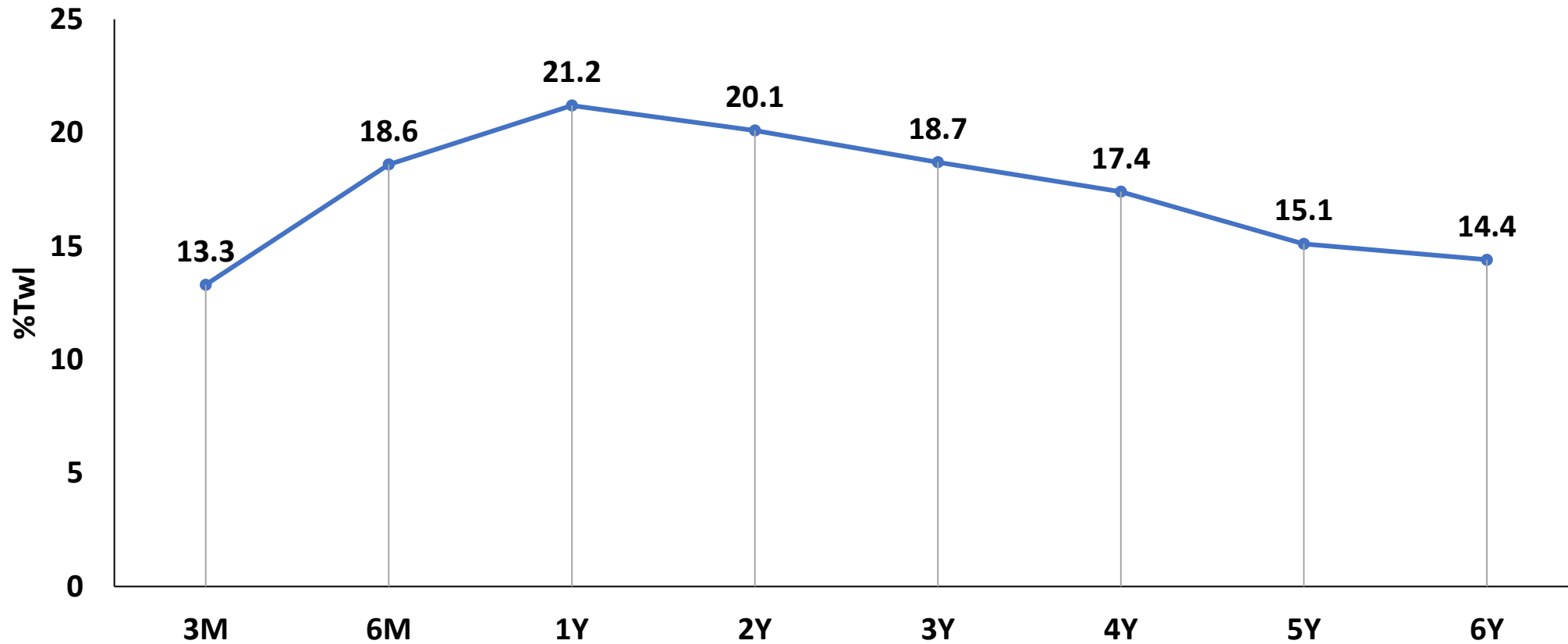
Done Outside

Endoscopic Sleeve *Data: Mohak*

ESG (n= 993)	
Mean age, y (SD)	42.02(10.1)
Mean HT, (SD)	1.61(8.11)
Male/female, n/N (%)	344/649 (34.6 %/65.4%)
Mean WT, Kgs (SD)	93.43(13.1)
Mean BMI, kg/m ² (SD)	35.12(3.16)

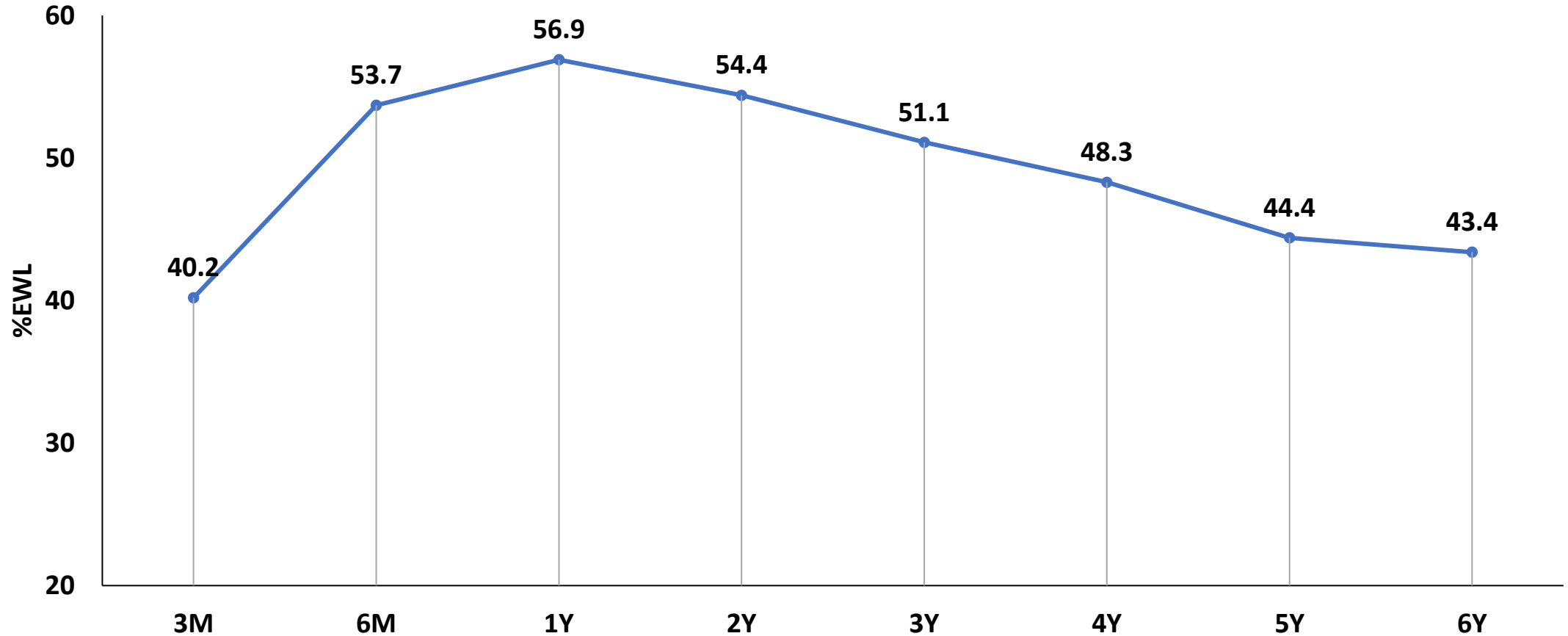
Endoscopic Sleeve *Data: Mohak*

%TWL (Primary = 996)



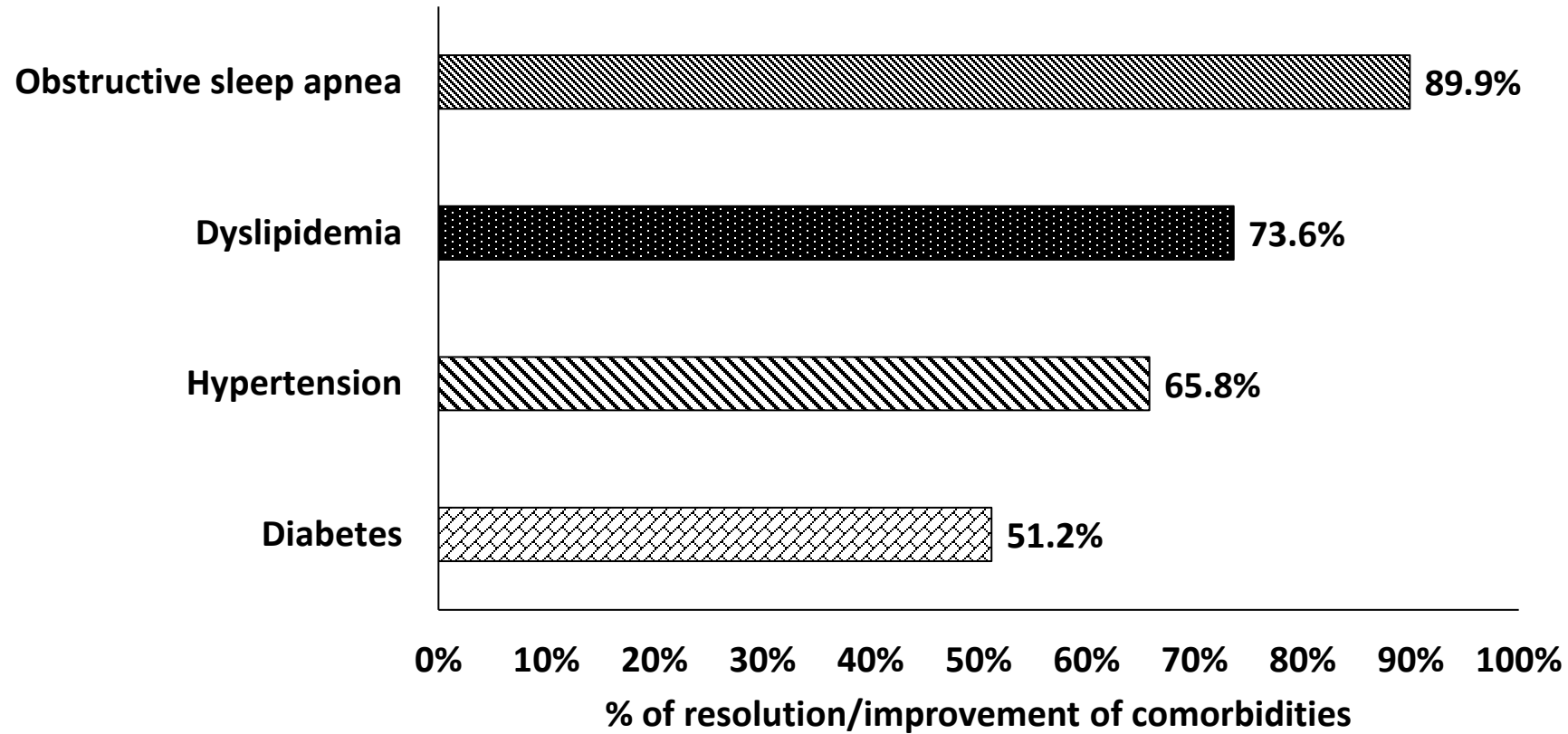
Endoscopic Sleeve *Data: Mohak*

%EWL (Primary = 996)



Endoscopic Sleeve *Data: Mohak*

% of Comorbidities Remission





MBRSC DATA

Dig_Endosc. 2019 Aug 8. doi: 10.1111/den.13508. [Epub ahead of print]

Endoscopic Sleeve Gastroplasty is an effective and safe minimally invasive approach for treatment of obesity: First Indian experience.

Bhandari M¹, Jain S¹, Mathur W¹, Kosta S¹, Neto MG¹, Brunaldi VO¹, Fobi M¹.

Author information

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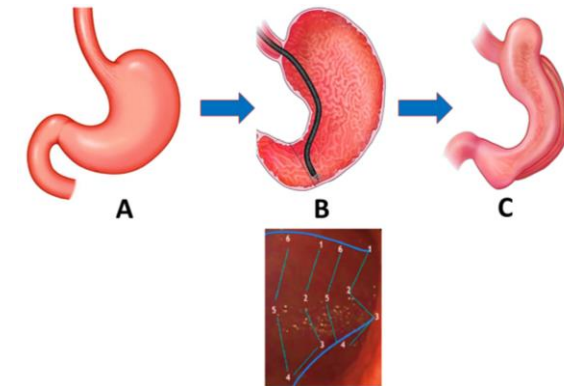
Abstract

OBJECTIVES: Endoscopic Sleeve Gastroplasty (ESG) is gaining acceptance as a non-surgical option for the treatment of obesity. However, its role is still not consolidated for all populations and the ideal indications are yet to be determined. We aimed to study the efficacy and safety of ESG in Indian patients.

METHODS: We conducted a single-center retrospective study of obese patients who underwent consecutive ESG at our tertiary care center. Data on weight loss and adverse events at 1, 3, 6, and 12 months were collected and analyzed.

RESULTS: Fifty-three patients underwent ESG from March 2017 to October 2018. Eighty one percent patients were female (43/53). The mean baseline age and BMI were 40.54 ± 13.79 years and 34.78 ± 5.20 kg/m², respectively. Mean duration of procedure was 68.96 ± 11.19 minutes. Immediate postoperative complications included mainly epigastric pain (45.2%) and nausea (22.6%) but there was no serious adverse event. The average %TWL was 8.26%, 11.96%, 14.25%, and 19.94% at 1, 3, 6, and 12 months, respectively. Eighty-eight percent of patients achieved >15%TWL at 12 months. Younger patients (<30 years old) and female patients had greater %TWL at 12 months (p=0.01 and p=0.021, respectively). Last 18 procedures were significantly faster than the first 35 cases (p=0.01).

CONCLUSIONS: ESG is effective and safe at promoting weight loss in Indian population. Young age and female gender are related to better outcomes. This article is protected by copyright. All rights reserved.





Four-year outcomes for endoscopic sleeve gastropasty from a single centre in India

Bhandari M, Kosta S, Reddy M, Mathur W, Neto MG, Bhandari M. Four-year outcomes for endoscopic sleeve gastropasty from a single centre in India. *J Minim Access Surg.* 2023 Jan-Mar;19(1):101-106. doi: 10.4103/jmas.jmas_3_22. PMID: 36124467; PMCID: PMC10034804.

Bhandari et al. 2022

Recently Published manuscript on:

Four-year outcomes for Endoscopic Sleeve Gastropasty from a single center in India

- This study shows acceptable results with ESG at 4 years in our unit.
- Regular monitoring by a multidisciplinary nurtures weight loss, resolution or improvement of comorbidities and improvement of quality of life with low perioperative complications.

Background: Bariatric endoscopy has emerged for non-surgical treatment of obesity, providing a treatment option for weight loss and associated comorbidities. Outcomes of endoscopic sleeve gastropasty (ESG) of 12 months have been published by our team and there is a need for longer follow-up period understanding the effects of ESG techniques.

Aim: This report emphasises on weight loss pattern in follow-up time points and monitors the post-procedure improvement in comorbidities with minimum 4-year follow-up of patients undergoing ESG at a single academic centre in India.

Subjects and methods: This was a prospective cohort study. All procedures were performed by the same surgeon. Patients with a body mass index of $>30 \text{ kg/m}^2$ (or >27 with comorbidities) underwent ESG for treatment of obesity. Patients were systematically followed yearly after their procedure. Data collected on the primary outcome and secondary outcomes were analysed and presented.

Results: 612 patients (69.3% female) with a mean age of 40.70 ± 12.66 years and mean body mass index of $34.30 \pm 5.05 \text{ kg/m}^2$ underwent ESG. Out of 612 patients, follow-up rates for a 1-2-3 and 4 years were 93.1%, 90.2%, 81.7% and 81.9%, respectively. The mean percentage total body weight loss was 18.19% (95% confidence interval [CI]: 17.72-18.57) and %EWL was 49.30% (95% CI: 48.91-49.68) with 90% of participants-maintaining a percentage of total weight loss of $\geq 5\%$ and 70% of patients maintaining an EWL of $\geq 25\%$ at 4 years, respectively. Resolution/improvement of comorbidities was 51.2% cases of T2DM, 65.8% cases of hypertension, 73.6% cases of dyslipidaemia and 89.9% remission were in obstructive sleep apnoea. No patient required an emergency intervention, and there was no mortality or significant morbidity.

Conclusions: This study shows acceptable results with ESG at 4 years in our unit. Regular monitoring by a multidisciplinary nurtures weight loss, resolution or improvement of comorbidities and improvement of quality of life with low perioperative complications. There is a need for more reports with this approach to determine the amount and duration of weight loss outcome and medical intervention.

The year 2022 marked the 10th anniversary of endoscopic sleeve gastroplasty (ESG), and 2023 will mark the 20th anniversary of the first application of endoscopic suturing to treat obesity and with it the birth of bariatric endoscopy

History of Bariatric Endoscopy

- 1985-2000**
 - Gastro-Edwards Gastric Bubble FDA approval in 1985 and removal from market in 1992
 - Bioresorbable Intragastric Balloon (BIB) CE-mark and commercialisation, 1997
 - Rapid EndoCinch Suture System FDA approval for acute approximation and treatment of symptomatic GERD, 2000
- 2003**
 - First applications of endoscopic suturing for weight loss
 - First-in-human gastrointestinal (Gastric sleeve) - C. Thompson, Boston
 - First-in-human Transoral Outlet Reduction (TORO) - C. Thompson, Boston
 - First-in-human Endoluminal Vertical Gastroplasty (EVG) - R. Fogel, Wisconsin
 - 'Diction of Bariatric Endoscopy' title created at Brigham and Women's Hospital - C. Thompson
- 2006**
 - First Instructional DVD on Bariatric Endoscopy (ASGE) - C. Thompson
- 2012**
 - First-in-human ESG with Apollo OverStitch
 - C. Thompson and R. Sharma, India
 - ASGE Special Interest Group (SIG) in Bariatric Endoscopy
 - C. Thompson and N. Kasari
 - Launch of Bariatric Endoscopy and Energy Endosurgery Fellowship at BMH - C. Thompson
- 2013**
 - First-in-human Diode-laser Resurfacing (Gastric) - M. Galvao Neta, I. Rodriguez-Grauert and P. Becerra, Chile
 - TORO US Multicenter Randomized Sham-controlled Trial (RESTORE Trial) - C. Thompson et al
 - First Annual Medical International Bariatric Endoscopy (MIBE) Course - G. Lopez-Nava
 - First Textbook of Bariatric Endoscopy - C. Thompson, Doherty
- 2014**
 - First US annual Flexible Endoscopy Surgery and Bariatric Endoscopy Course - C. Thompson and L. Sicastrina, Miami Beach
 - First-in-human magnetic suspension (endoluminal) diversion for metabolic disease - E. Machyloka, M. Budga, M. Ryso, P. Zizka, H. Laitz and C. Thompson, Czech Republic
- 2015**
 - Founding of the Association for Bariatric Endoscopy (ABE) - N. Kasari, B. Abu Dayyeh, S. Soliman, S. Jovanovski, M. Lamas, C. Thompson (Co-Chair), P. Hake (ASGE CEO) and S. Edrassovice (Co-Chair)
 - First-in-human ESG-TORO, combining third space and bariatric endoscopy - C. Thompson
 - First-in-human Endoscopy procedure - V. Dubey, Belgium
- 2017**
 - Orbicon Balloon US Pivotal Trial (SMART Trial) - S. Salinas et al
 - Short-term outcomes of endoscopic sleeve gastroplasty in 100 consecutive patients - A. Alqahtani et al, Saudi Arabia
- 2018**
 - Orbicon Balloon US Pivotal Trial (SMART Trial) - S. Salinas et al
 - Short-term outcomes of endoscopic sleeve gastroplasty in 100 consecutive patients - A. Alqahtani et al, Saudi Arabia
- 2020**
 - Bariatric Endoscopy Live (BEL) - Global - E. de Moura, C. Thompson and D. de Moura
 - Five-year outcomes of TORO for weight regain after RYGB - P. Anagnostis et al, Boston
- 2021**
 - Five-year Outcomes of ESG - R. Shardin et al, New York
 - First-in-human Gastroplasty with Endoscopic Myotomy - combination of third space and jejunal RYGB (JREAM) - C. Thompson, Boston
 - Spain Balloon US Pivotal Trial - B. Abu Dayyeh et al
- 2022**
 - ESG US Multicenter Randomized Controlled Trial (MERT Trial) - B. Abu Dayyeh et al
 - FDA Grants De Novo Marketing Authorization for Apollo ESG™ and Apollo REVISE™
 - Pylorus Sparing Atrial Myotomy for weight loss - third space only procedure without suturing - C. Thompson, Boston

<https://doi.org/10.1016/j.igie.2022.10.009>



In July 2022, the United States Food and Drug Administration (FDA) granted De Novo Market Authorization for the creation of the ESG using the Apollo ESG™ (formerly OverStitch device, Apollo Endosurgery, Austin, TX, United States) for treatment of obesity in those with BMI from 30 kg/m² to 50 kg/m².

This authorization makes ESG the first and only FDA-approved endoscopic bariatric procedure for the treatment of obesity in adults with a body mass index (BMI) of 35 or higher

Boston Scientific Announces Agreement to Acquire Apollo Endosurgery, Inc.

Boston Scientific Announces Agreement to Acquire Apollo Endosurgery, Inc.



Acquisition to expand endoluminal surgery portfolio and add differentiated technologies for endobariatric procedures

MARLBOROUGH, Mass., Nov. 29, 2022 /[PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has entered into a definitive agreement to acquire Apollo Endosurgery, Inc. (Nasdaq: APEN) for a cash price of \$10 per share, reflecting an enterprise value of approximately \$615 million.¹

The Apollo Endosurgery product portfolio includes devices used during endoluminal surgery (ELS) procedures to close gastrointestinal defects, manage gastrointestinal complications and aid in weight loss for patients suffering from obesity. ELS provides a less-invasive alternative to open and laparoscopic surgery for patients with diseases in the gastrointestinal tract or morbid obesity, while providing the potential for quicker recovery and minimizing the risks of surgical complications.^{2,3,4}

> Arq Bras Cir Dig. 2017 Jan-Mar;30(1):18-20. doi: 10.1590/0102-6720201700010006.

ENDOSCOPIC SLEEVE GASTROPLASTY FOR OBESITY TREATMENT: TWO YEARS OF EXPERIENCE

[Article in English, Portuguese]

Gontrand Lopez-Nava ¹, M P Galvão ¹, I Bautista-Castaño ¹, J P Fernandez-Corbelle ¹, M Trel ¹, N Lopez ¹

Affiliations + expand

PMID: 28489162 PMCID: PMC5424680 DOI: 10.1590/0102-6720201700010006

- In the study reported results up to 2 years follow-up.
- At 24 mo after the procedure baseline mean body mass index (BMI) changed from 38.3 to 30.8 kg/m²; %TWL and %EWL were 19.5% and 60.4%, respectively.
- In this study, 85.7% of patients achieve greater than 25% EWL.

Abstract in English, Portuguese, Portuguese

Background: Bariatric endoscopic techniques are minimally invasive and induce gastric volume reduction to treat obesity. Aim : To evaluate endoscopic sleeve gastroplasty (Apollo method) using a suturing method directed at the greater curvature, as well as the perioperative care, two year safety and weight loss.

Method: Prospective single-center study over 154 patients (108 females) using the endoscopic sleeve gastroplasty procedure under general anesthesia with overnight inpatient observation. Of the 154 initial patients, 143 were available for 1-month of follow-up, 133 for 6-month, 64 for 12-month and 28 completed the 24 month assessment. Follow-up was carried out by a multidisciplinary team (nutritionist and psychologist). Outcomes evaluated were: change in BMI; change in body weight (TBWL); % of loss of initial body weight (%TBWL); % of excess body weight loss (%EWL) (segregated in > or <25% and adverse effects. Voluntary oral contrasted radiological examinations were scheduled to assess the gastroplasty at different times post-procedure.

Results: Mean age was 44.9 (23-69) years. At 24 months after the procedure baseline mean BMI change from 38.3 to 30.8 kg/m². TBWL, %TBWL and %EWL were of 21.3 kg, 19.5% and 60.4% respectively. 85.7% of patients achieve the goal of >25% %EWL. There were no mayor adverse events intraprocedure or during the 24 months of follow-up .

Conclusion: Endoscopic sleeve gastroplasty with regular monitoring by a multidisciplinary team can be considered an effective, safe and well tolerated procedure for obesity treatment, at least for two years of follow-up.

Alqahtani A, Al-Darwish A, Mahmoud AE, Alqahtani YA, Elahmedi M.

Gastrointest Endosc. 2018

Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients. .

- This study showed satisfactory results of ESG in the management of obesity with a mean %TWL at 6, 12, and 18 mo of $13.7\% \pm 6.8\%$, $15.0\% \pm 7.7\%$, and $14.8\% \pm 8.5\%$, respectively.
- The mean %EWL at 6, 12, and 18 mo were $64.3\% \pm 56.2\%$, $67.5\% \pm 52.3\%$, and $64.7\% \pm 55.4\%$, respectively.

Abstract

Background and aims: Questions related to the safety and long-term efficacy of endoscopic sleeve gastroplasty (ESG) are not yet answered. Here we report weight loss, morbidity, revisions, and comorbidity resolution during the first 18 months after primary ESG.

Methods: This is a consecutive case series from a prospective observational study executed in a specialized center with a standardized pathway for multimodal management of obesity.

Results: The 1000 patients in this study had a baseline body mass index of $33.3 \pm 4.5 \text{ kg/m}^2$ 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 $13.7\% \pm 6.8\%$ ($n = 369$; follow-up rate = 423; 87.2%), $15.0\% \pm 7.7\%$ ($n = 216$; follow-up rate = 232; 93.1%), and $14.8\% \pm 8.5\%$ ($n = 54$; 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. With regard to postoperative complaints, 924 patients (92.4%) complained of nausea or abdominal pain that was controlled with medications during the first week after ESG. Twenty-four patients were readmitted: 8 for severe abdominal pain, of whom 3 had ESG reversal; 7 for postprocedure bleeding, 2 of whom received 2 units of packed red blood cells each; 4 for perigastric collection with pleural effusion, 3 of whom underwent percutaneous drainage; and 5 for postprocedure fever with no sequelae. Eight patients were revised to sleeve gastrectomy, and 5 had redo-ESG. No patient required an emergency intervention, and there were no mortalities.

Conclusions: ESG appears to be well tolerated, safe, and effective. Significant weight loss occurs during the first 18 months without mortality or significant morbidity. Some patients require revision or reversal during the first year.

Conclusion

- In conclusion, **Endoscopic Sleeve Gastroplasty (ESG)** has emerged as a safe, effective, and minimally invasive option for addressing obesity, particularly in light of the increasing demand for less invasive therapies.
- Our findings further confirm ESG's efficacy in the Indian population, with six-year outcomes highlighting significant weight loss, improvement or resolution of comorbidities, and enhanced quality of life.
- The success of ESG, particularly with regular multidisciplinary follow-up, reinforces its value as a viable long-term solution for obesity management with minimal perioperative complications.



MOHAK TEAM

THANK YOU

We offer various treatment modalities for obesity. The operation is determined by the profile of the patient and guided by findings from analysis of the data from our prospectively maintained database