AIG HOSPITALS | Center for Obesity & Metabolic Therapy

ESG outcomes across the world : What the data really shows?

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AIG Hospitals

Hyderabad, India.

AIG Hospitals IEF Member in India

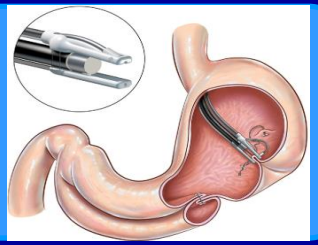
MAYO CLINIC CARE NETWORK Member

Endoscopic Gastric Remodeling

Apollo Over stich
Endoscopic Sleeve Gastroplasty

Primary Obesity Surgery
Endolumenal (POSE)

Endomina



THE LANCET

ARTICLES | ONLINE FIRST

Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial

Prof Barham K Abu Dayyeh, MD • Fateh Bazerbachi, MD • Eric J Vargas, MD • Reem Z Sharaiha, MD • Prof Christopher C Thompson, MD • Bradley C Thaemert, MD • Andre F Teixeira, MD • Christopher G Chapman, MD • Prof Vivek Kumbhari, MD • Michael B Ujiki, MD • Jeanette Ahrens, PhD • Courtney Day, MS • the MERIT Study Group • Prof Manoel Galvao Neto, MD • Prof Natan Zundel, MD • Prof Erik B Wilson, MD • Show less

Published: July 28, 2022 • DOI: https://doi.org/10.1016/S0140-6736(22)01280-6 •

MERIT Study: Excess Body Weight Loss

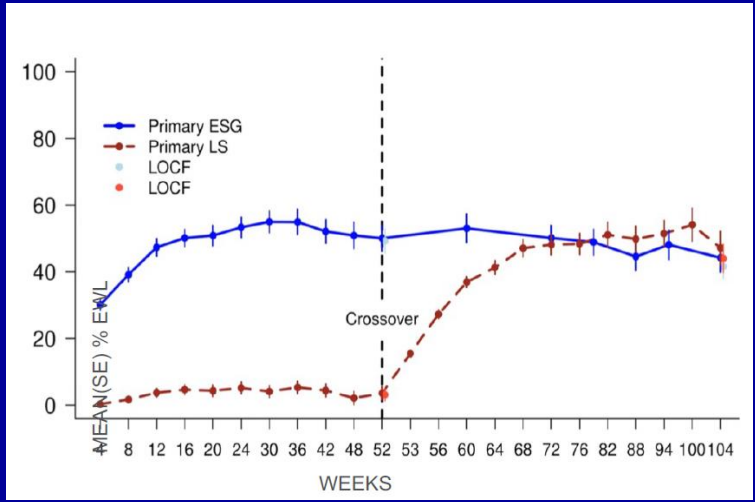
✓ Met primary efficacy endpoint

49% EBWL (+32%) demonstrated by ESG patients at 12 months; target 25%

45% Difference % EWL compared to LS patients; target minimum of 15% EWL

77% of subjects undergoing ESG achieved at least 25% EBWL

16% TBWL for responder group (+7%)



MERIT Study: Co-Morbidities

Compared to standard of care, ESG patients demonstrated clinically and statistically significant **reductions in co-morbidities & improved quality of life**

Metabolic syndrome

- **ESG:**82.8% improvement
- **SoC:**35.4% improvement P<0.001

Diabetes type II

- **ESG:**35% improvement, 35% partial or complete remission
- **SoC:**40% worsening, 20% improvement, 6.6% partial / complete remission P=0.002

Hypertension

- **ESG:**45% improvement, 17% partial remission
- **SoC:**34% worsening, 1.7% partial remission P=0.007

Quality of life

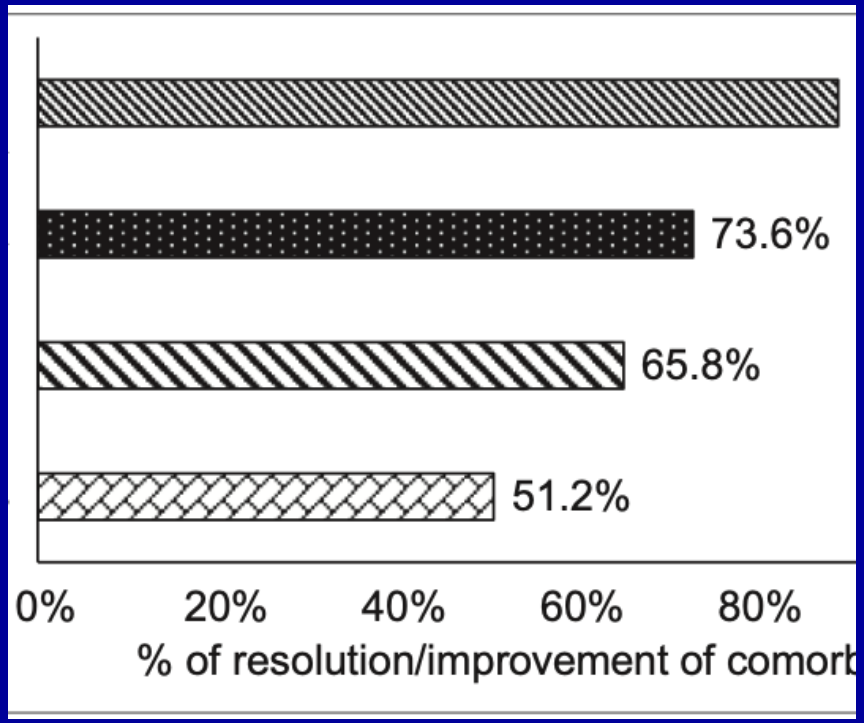
- Significantly improved compared to SoC IWQoL+SF36 p<0.001

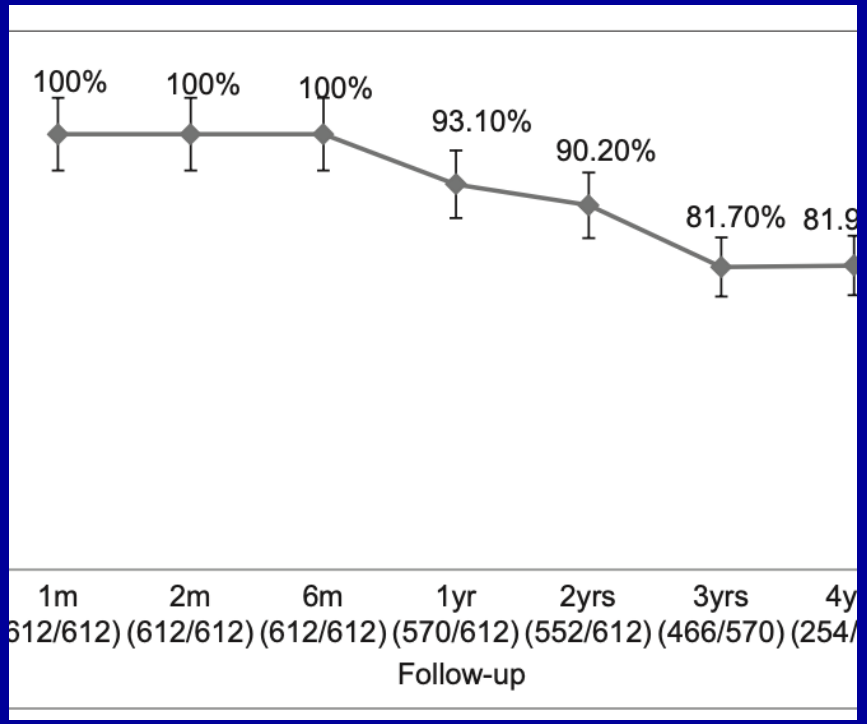
Endoscopic sleeve gastroplasty — minimally invasive treatment for non-alcoholic fatty liver disease and obesity

Nitin Jagtap[1] · Rakesh Kalapala[1] · Abhishek Katakwar[2] · Mithun Sharma[1] · Mohsin Aslam[1] · Rajesh Gupta[1] · P Nagaraja Rao[1] · Rajesh Goud[1] · Manu Tandan[1] · Haranath Kanakagiri[3] · Santosh Darishetty[3] · D. Nageshwar Reddy[1]

Parameter	Pre ESG	6 months Post ESG	12 months Post ESG	p value
ALT	59.54 (17.02)	49.50 (11.71)	48.42 (13.22)	0.001
HSI	44.64 (5.19)	40.22 (4.41)	39.21 (4.89)	0.001
NFS	0.228 (1.00)	-0.202 (1.16)	-0.552 (1.08)	0.001
FIB-4	2.646 (1.26)	2.275 (0.79)	1.970 (0.79)	0.001
APRI	1.191 (0.37)	0.952 (0.26)	0.785 (0.25)	0.001

Rakesh et al Indian J Gastroenterol 2021





Mohit et al, J Min Access Surg 2023;19:101-6

Primary surgery obesity endoluminal (POSE)

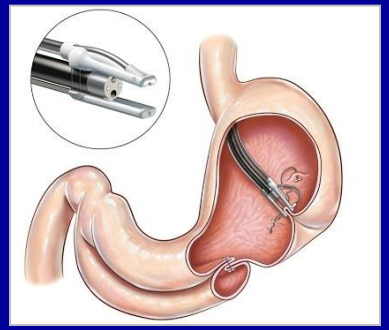
- POSE – (Incisionless Operating Platform – USGI medical)

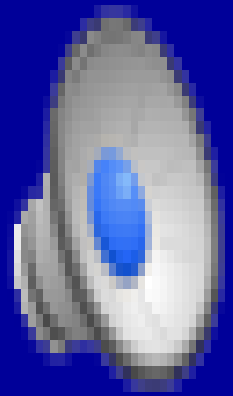
POSE2.0 CLINICAL STUDY SUMMARY

USGI Studies	Location	Type	N	SAE* Rate	Mean Wt. Loss 1 Year (%TBWL)
Spain Cohort	Barcelona & Madrid, Spain	Prospective Multi-Center	36	0%	16.8% (n=35)
US Pilot 5 Patient Cohort	US	Prospective Single-Center	5	0%	11.3% (n=5)
US Pilot Lead-in Cohort	US	Prospective Multi-Center	4	0%	14.5% (n=4)
US Expansion Pilot Randomized Cohort	US	Prospective Multi-Center	25	0%	12.8% (n=25)

Courtesy : Roman Tourro

ENDOMINA





51patients
Mean BMI – 35

EWL & TBWL –
29 & 7.4 % at 1 yr

Vincent H et al GIE April 2017, 85, Issue 4, Pages 833–837

Endoscopy

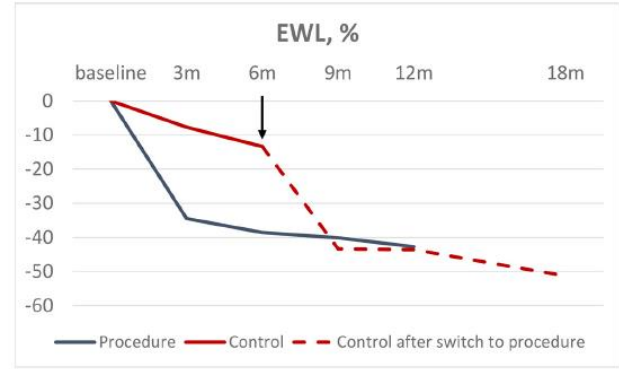
ORIGINAL RESEARCH

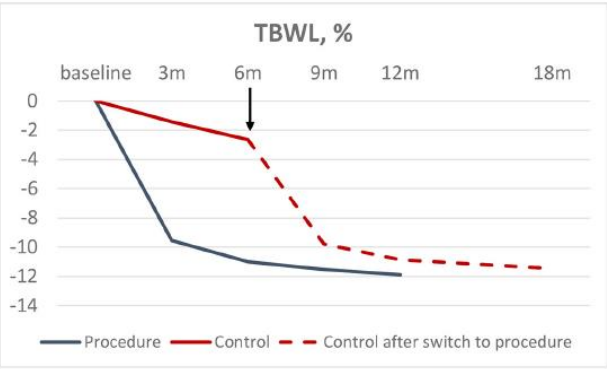
Endoscopic sutured gastroplasty in addition to lifestyle modification: short-term efficacy in a controlled randomised trial

GUT 2020

Vincent Huberty ,[1] Ivo Boskoski ,[2] Vincenzo Bove,[2] Pauline Van Ouytsel,[1] Guido Costamagna,[2] Marc A Barthet ,[3] Jacques Devière[1]

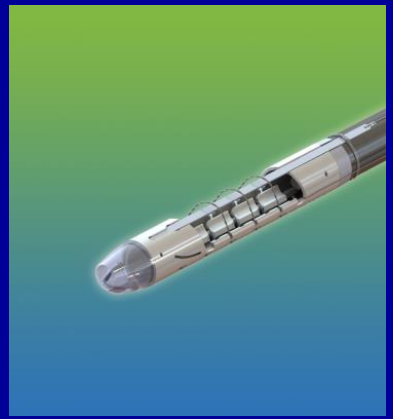
- - E-ESG is safe and effective;
- 25% better EWL at 6 months than lifestyle modification alone
- Weight loss maintained with improvement in QoL up to 18 months after treatment.

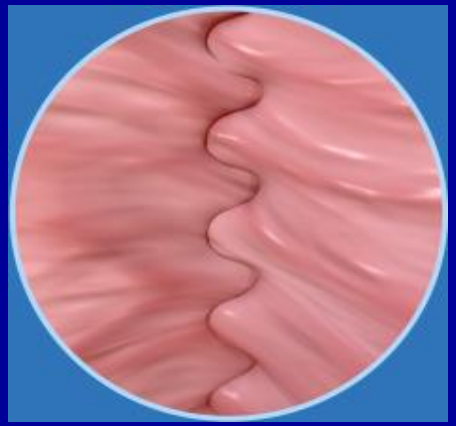


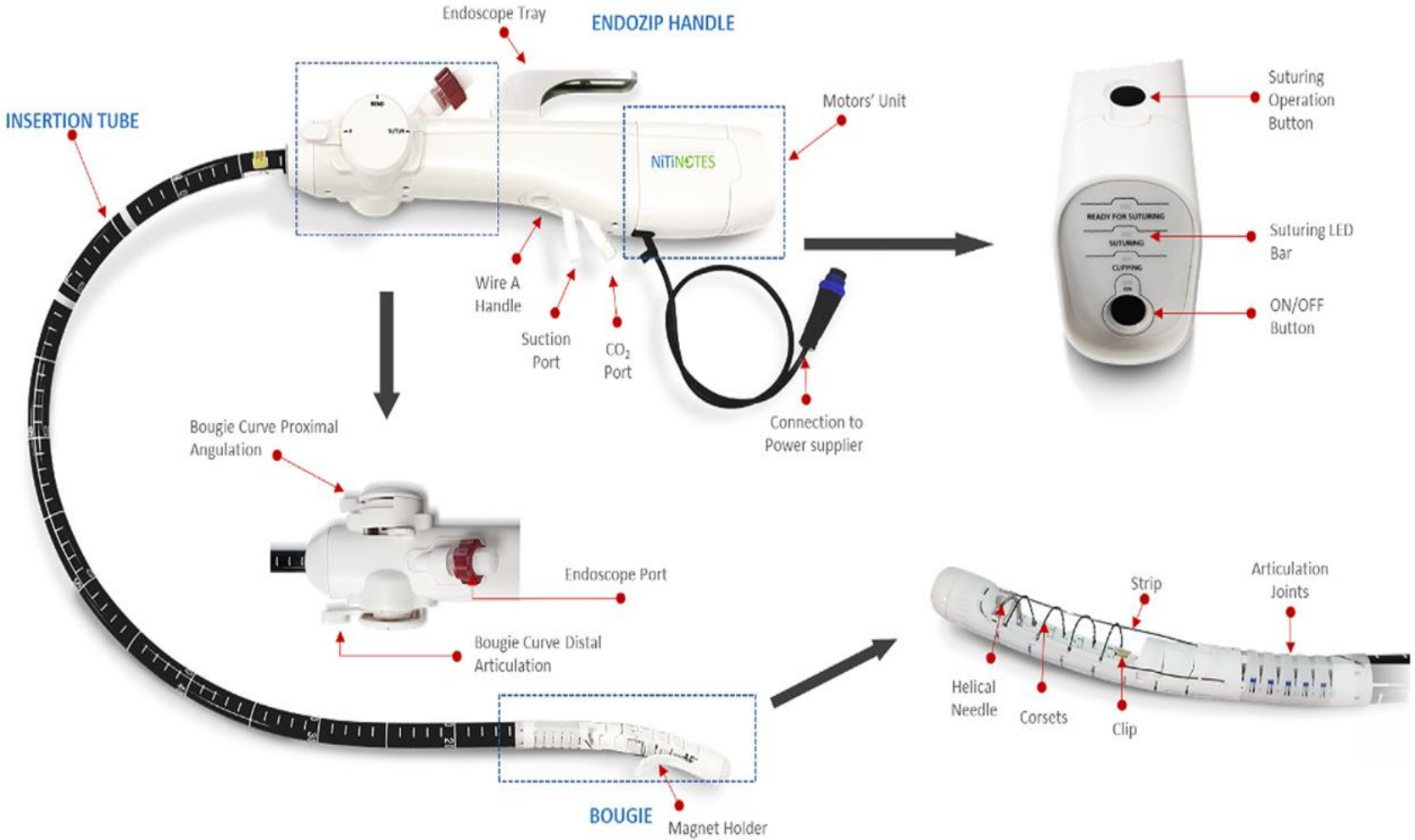


Vincent et al Gut 2020

Endo Zip





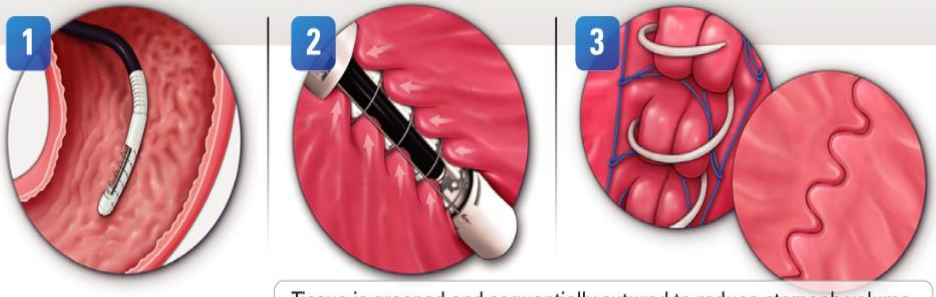

Endoscope Tray
ENDOZIP HANDLE
INSERTION TUBE
Motors' Unit
NiTiNOTES
Wire A Handle
Suction Port
CO_2 Port
Connection to Power supplier
Suturing Operation Button
READY FOR SUTURING
SUTURING
CLIPPING
ON
Suturing LED Bar
ON/OFF Button
Bougie Curve Proximal Angulation
Endoscope Port
Bougie Curve Distal Articulation
BOUGIE
Magnet Holder
Strip
Articulation Joints
Helical Needle
Corsets
Clip

Automatic endoscopic gastroplasty for the treatment of obesity: results from a prospective multicenter study (with video)

Ivo Boskoski, MD, PhD, FESGE,[1,2] Gontrand Lopez-Nava, MD, PhD,[3] Asokkumar Ravishankar, MD,[3,4] Vincenzo Bove, MD, PhD,[1,2] Maria Valeria Matteo, MD,[1,2] Martina De Siena, MD,[1,2] Valerio Pontecorvi, MD, PhD,[1,2] Giulia Giannetti, PhD,[1,2] Amerigo Iaconelli, MD, PhD,[5] Cristiano Spada, MD, PhD,[1,2] Steven E. Shamah, MD[6]

GRAPHICAL ABSTRACT

Automatic Endoscopic Gastroplasty For The Treatment of Obesity: Results from A Prospective Multicenter Study



Outcomes	2-month	6-month	12-month	p-value
Mean ±SE TBWL, Kg	9.9±0.6	13.7±1.3	12.5±1.5	<.0001*
Mean ±SE %TBWL	10.35±0.60	14.32±1.33	13.21±1.58	<.0001*
Mean ±SE %EWL	40.1±2.7	55.0±5.4	4.6±0.5	<.0001*
Mean ±SD DBMI, Kg/m^2	3.6±0.2	5.0±0.5	4.6±0.5	<.0001*
>5% TBWL, n (%)	41 (95.7 %)	37 (86.4 %)	33 (76.6 %)	0.449**
>10% TBWL, n (%)	24 (55.8 %)	33 (76.6 %)	26 (60.5 %)	0.105**

* The P-values refers to the adjusted %mean difference – i.e., from baseline

** The P-values refers to difference between the % responders in the 3 mentioned points in time.

Automatic Endoscopic Gastroplasty with the Endozip™ device is safe and effective for obesity treatment

ESG - follow up

2 yr follow up

Mean age 44yr, 73% female
Baseline BMI - 37.8

Results: (%TBWL)

6 mths 15.2% (95% CI 14.2-16.3)
24 mths 18.6% (95% CI 15.7-21.5)

Lopez Nava et al Obese Surg Apr 2017

5 yr follow up

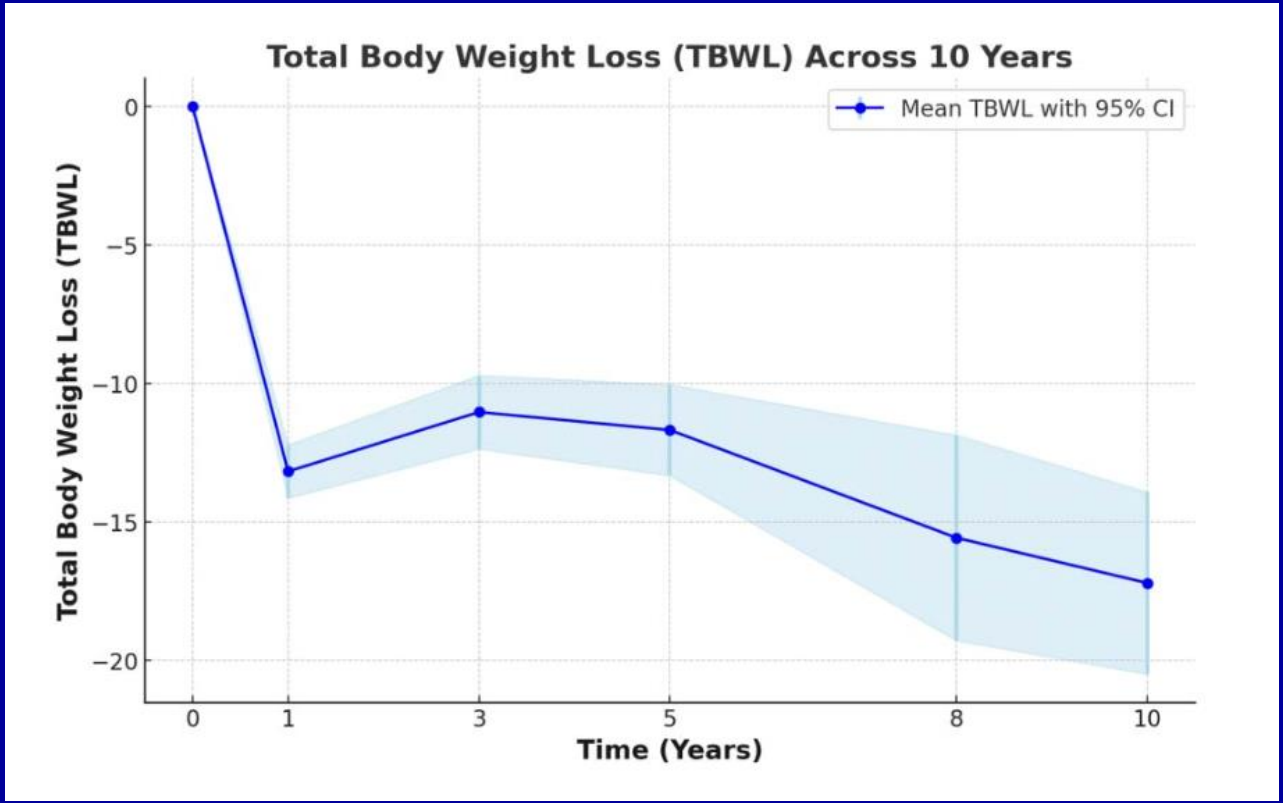
Baseline BMI – 39

Results: (%TBWL)

1 yr 15.2% (95% CI, 13.5-16.8)
3 yr 15.7 %
5 yr 14.5%

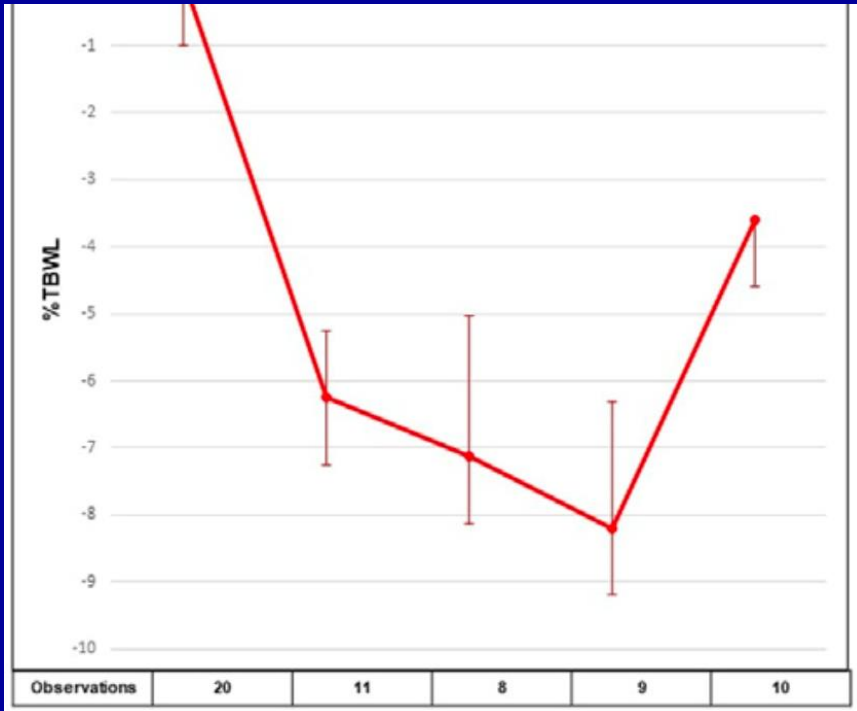
Reem et al CGH 2021

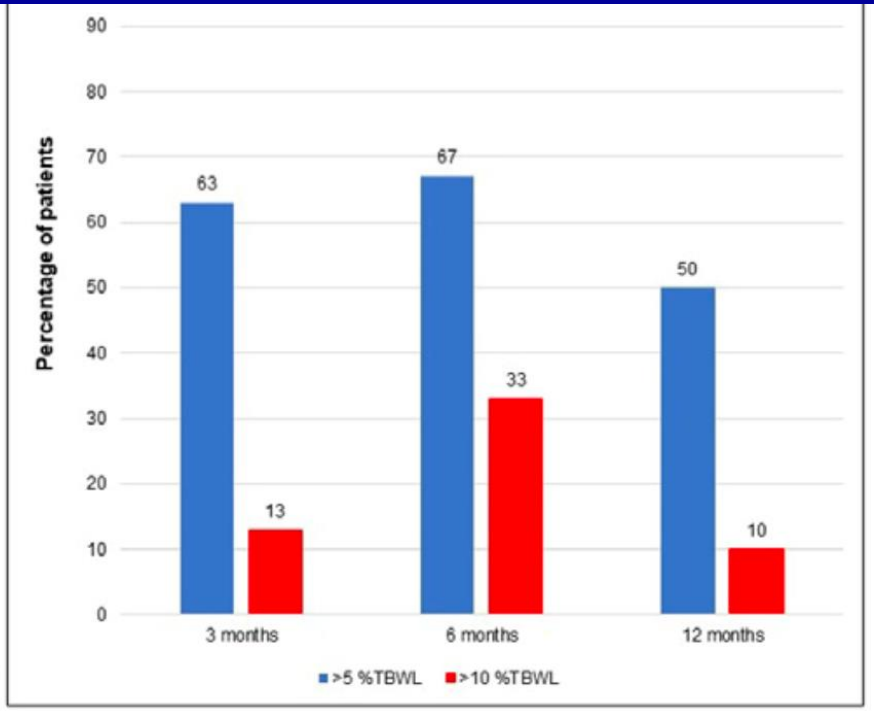
10 yr follow up post ESG



Obesity Surgery (2025) 35:2092–2100

Redo ESG





Barham et al

Meta Analysis

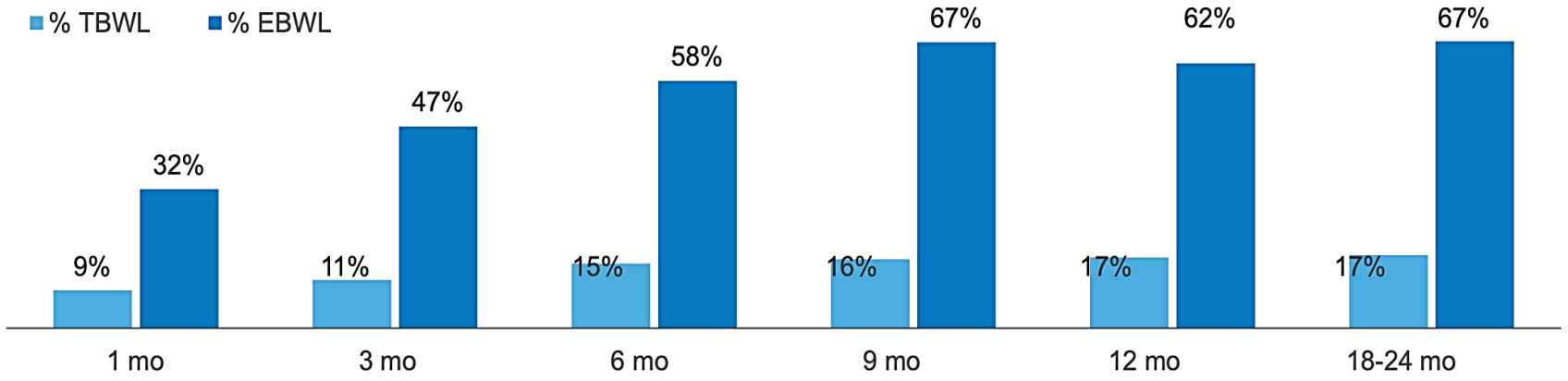
ESG Efficacy

Systematic Review & Pooled Meta-Analysis

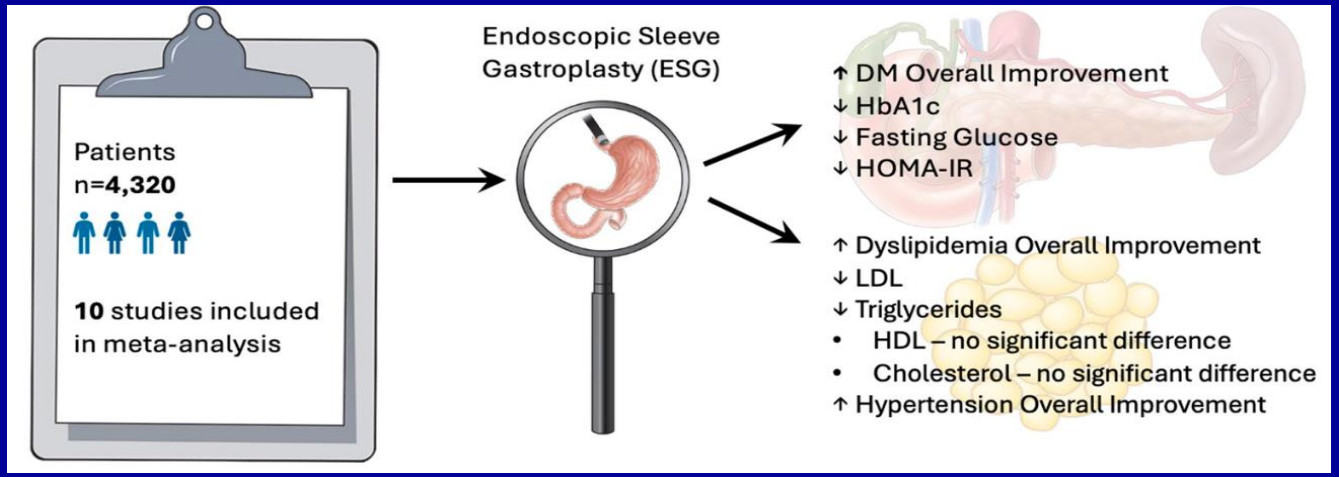
Studies **8**

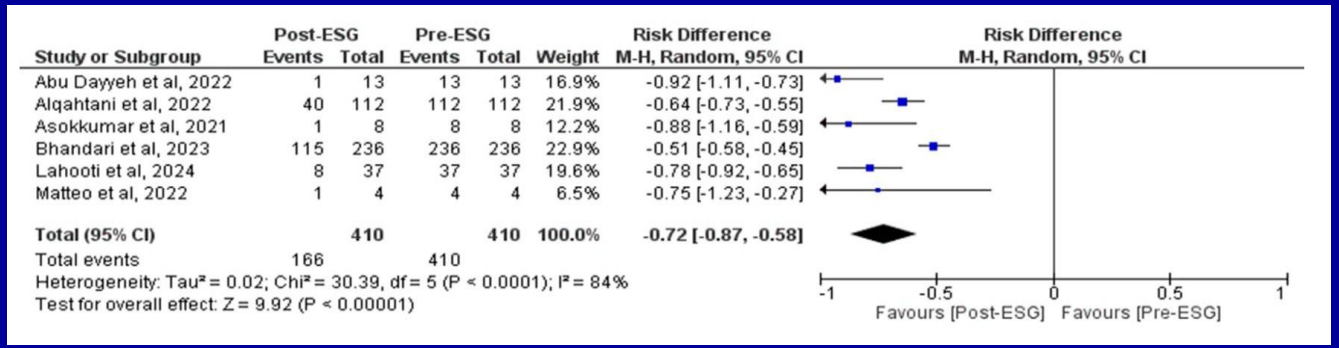
1,772 Subjects

50%+ Clinically significant excess body weight loss



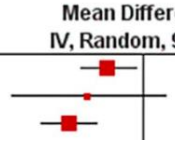
Hedjoudje, A., et al. Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis. Clinical and Gastroenterology and Hepatology 2020





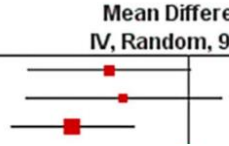
Reem et al Obesity Surgery (2025) 35:2092–2100

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Abu Dayyeh 2022	-1.4	0.5714	43.9%	-1.40 [-2.52, -0.28]
Espinet-Coll 2019	-2.2	1.6004	12.2%	-2.20 [-5.34, 0.94]
Lahooti 2024	-3	0.5712	43.9%	-3.00 [-4.12, -1.88]



Total (95% CI)
Heterogeneity
Test for overa

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Abu Dayyeh 2022	-6.11	3.2245	25.7%	-6.11 [-12.43, 0.21]
Alexandre 2023	-5	3.9029	17.7%	-5.00 [-12.65, 2.65]
Carr 2022	-9	2.415	44.9%	-9.00 [-13.73, -4.27]
Espinet-C				



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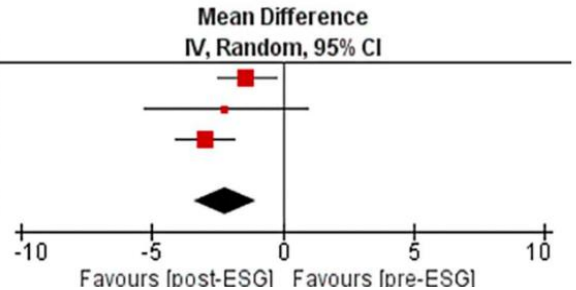
Total (95% CI)			**100.0%**	**-2.20 [-3.40, -1.00]**

Heterogeneity: Tau² = 0.53; Chi² = 3.92, df = 2 (P = 0.14); I² = 49%
Test for overall effect: Z = 3.58 (P = 0.0003)



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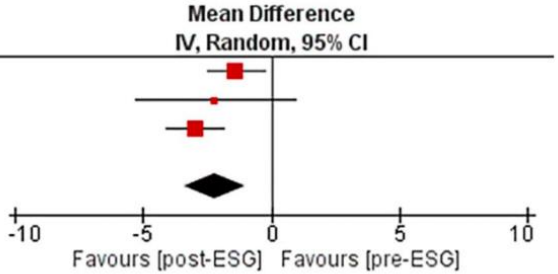


Efficacy and Safety of Endoscopic Gastroplasty versus Lifestyle Modification for Obesity: A Meta-Analysis of Randomized Controlled Trials with Technique-Specific Subgroup Analysis

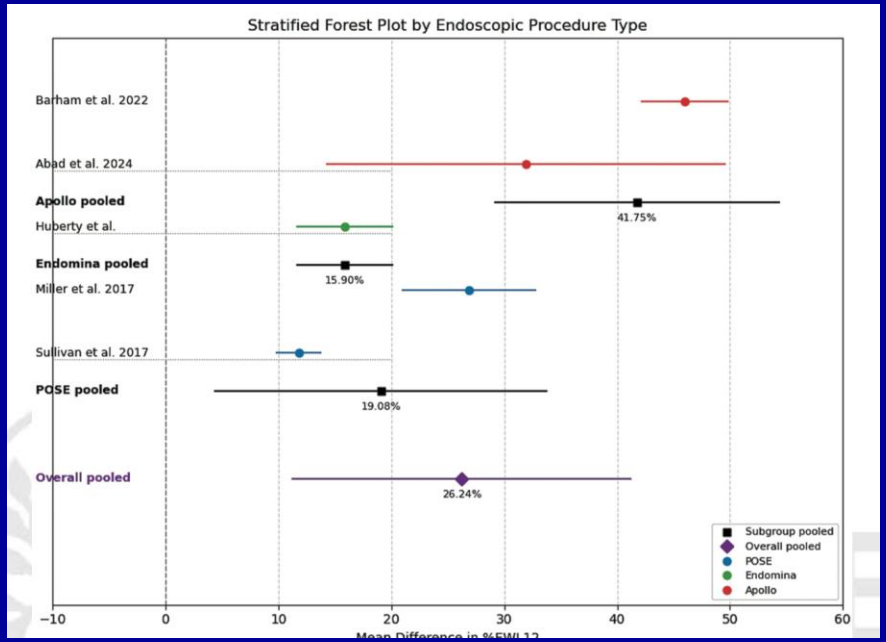
Nitin Jagtap[Q11] Aman Golchha[1] Saransh Jain[2] Ivo Boskoski[3] Vincent Huberty[4]
Rakesh Kalapala[1] D. Nageshwar Reddy[1]

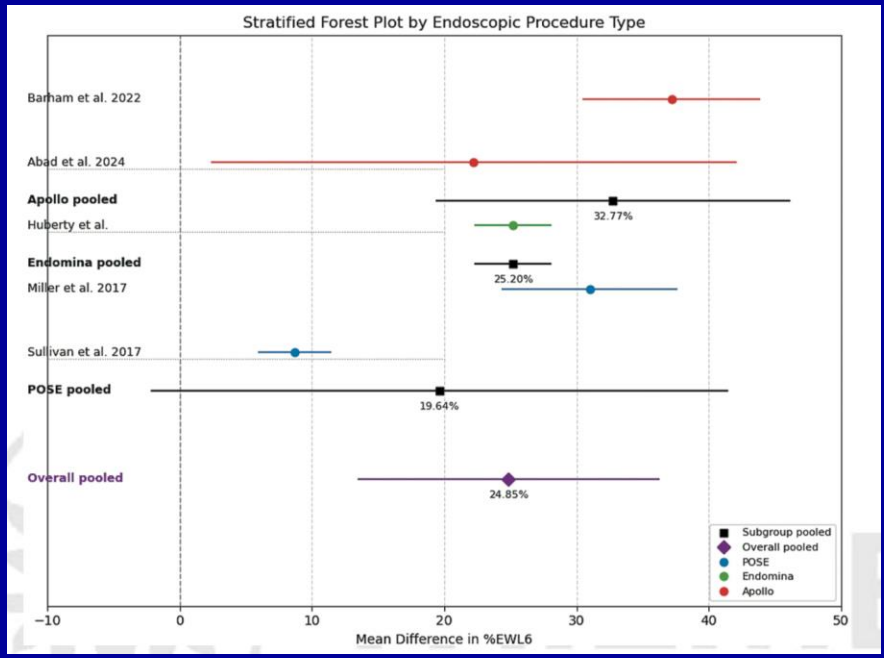
- Primary aim : to evaluate the impact of ESG versus LSM on total body weight loss (TBWL) at 12 months
- Secondary aim : TBWL and excess weight loss (EWL) at 6 months, and EWL at 12 months & Adverse events and publication bias were also assessed.

Journal of Digestive Endoscopy © 2025.

	Miller et al, 2017	Sullivan et al, 2017	Huberty et al, 2020	Abu Dayyeh et al, 2022	Abad et al, 2024
Design	Multicenter RCT	Multicenter RCT	Multicenter RCT	Multicenter RCT	Multicenter RCT
Site	Three centers, Europe	Eleven centers, USA	Two centers, Europe	Nine centers, USA	Four centers, Spain
Inclusion criteria	Age 20–60 years, obesity class I and III, failure of conservative weight loss measures, no significant weight change (± 5.0% TBWL) in the last 6 months, had an American Society of Anesthesiologists score of ≤ 2, not taken any weight-loss medications for ≥ 6 months, agreed not to have additional weight-loss interventions or liposuction for ≥ 30 months after study enrollment, and been willing to cooperate with postoperative dietary recommendations and assessments	Age 22–60 years, obesity class 1 with at least one nonsevere comorbid obesity-related condition, or BMI ≥ 35 and < 40 kg/m^2 without any condition, cannot opt other weight loss measures for the next 24 months	Age 18–65 years, class I or II obesity, must be able to comply with study protocol, must live within 75 km of treatment site, following the bariatric multidisciplinary workup	Age 21–65 years, class I or II obesity, failed nonsurgical weight loss methods interventions, willing to comply with study protocol	Age 18–70 years, histological evidence of MASH, NAS score > 3, BMI > 30 kg/m^2
Exclusion criteria	History of bariatric, gastric, or esophageal surgery, stricture, or other anatomy or condition that could preclude passage of endoluminal instruments, gastroesophageal reflux disease (L.A. classification of grade B, C, or D), known hiatal hernia > 3 cm, pancreatic insufficiency/disease; active peptic ulcer; pregnancy or plans of pregnancy within 12 months; present corticosteroid use; inflammatory gastrointestinal disease; coagulation disorders; hepatic insufficiency or cirrhosis; >2 years type 2 diabetes mellitus (HbA1C > 6.5) or uncontrolled type 2 diabetes (HbA1C > 7%); diabetes treatment with insulin; quit smoking in last 6 months; immunosuppression; portal hypertension or varices; or active gastric ulcer disease, outlet obstruction, or stenosis	History of bariatric, gastric or esophageal surgery, stricture or other esophageal anatomical defect, severe GERD, hiatal hernia > 3 cm, inflammatory gastrointestinal diseases, type II DM > 10 years, HbA1c > 7, known hormonal or gastric cause for obesity	Achalasia or any other motility disorders, severe esophagitis, gastro-duodenal ulcer, heart disease, uncontrolled diabetes mellitus or hypertension, TBWL > 5% over last 6 months, severe comorbidity, GI stenosis or obstruction, previous bariatric therapy, impending gastric surgery 60 days postintervention	History of foregut, GI surgery or bariatric surgery, Inflammatory GI disease, hiatal hernia > 4 cm, achalasia or any other motility disorder, severe coagulopathy, any major illness such as cardiac, pulmonary, etc.	History of prior bariatric surgery, acute cardiac event, heart failure, liver cirrhosis, > 5% TBWL in 6 months, esophagogastric varices, hepatocellular carcinoma, retroviral disease, any unstable disease or medical condition that could reduce life expectancy to less than 2 years

	Miller et al, 2017	Sullivan et al, 2017	Huberty et al, 2020	Abu Dayyeh et al, 2022	Abad et al, 2024
Sample size Active arm Control arm	 34 (POSE) 10 (lifestyle)	 221 (POSE) 111 (sham)	 49 (EndoMina) 22 (Lifestyle)	 85 (ESG) 124 (control)	 20 (ESG) 20 (sham)
Age, y, mean (SD) Active arm Control arm	 38.3 (10.3) 38.5 (12.5)	 44.2 (8.6) 45.3 (9.1)	 37.6 (9.9) 45.3 (11.7)	 47.3 (9.3) 45.7 (10.0)	 55.15 (10.9) 53.05 (11.8)
Male, *n* (%) Active arm Control arm	 9 (26.5) 1 (10.0)	 26 (11.8) 10 (9.0)	 3 (6.0) 2 (9.0)	 9 (12.0) 18 (16.0)	 11 (55.0) 11 (55.0)
Diabetes mellitus, *n* (%) Active arm Control arm	 1 (2.9) 1 (10.0)	 4 (7.0) 2 (7.4%)		 18 (23%) 36 (33%)	 9 (45.0) 11 (55.0)
Weight, kg, mean (SD) Active arm Control arm	 99.9 (11.1) 96.8 (12.1)	 99.7 (12.2) 98.7 (11.6)	 93.3 (8.8) 94.7 (9.5)	 *N* = 77, 110 98.4 (12.3) 99.1 (12.8)	 106.15 (21.85) 106.50 (18.15)
BMI, kg/m^2, mean (SD) Active arm Control arm	 36.2 (3.3) 37.2 (3.7)	 36.0 (2.4) 36.2 (2.2)	 34.8 (2.7) 34.2 (2.5)	 35.5 (2.6) 35.7 (2.6)	 37.54 (4.81) 38.17 (4.76)





- Endoscopic gastroplasty (ESG) leads to significantly greater weight loss at 6 and 12 months compared to lifestyle modification (LSM).
- Among techniques, OverStitch ESG showed the highest efficacy, followed by Endomina and POSE.
- Safety profile was favorable, with very low rates of serious adverse events (2.9%).
- Trial Sequential Analysis confirmed that evidence for ESG's superiority over LSM is conclusive.

ESG In Patients With Class III Obesity

DDW2022 Digestive Disease Week® MAY 21-24 | SAN DIEGO, CA IN PERSON & VIRTUAL

Study Design

- Multi-center trial conducted in U.S. and Brazil
- **404 consecutive** ESG patients with BMI > 40kg/m^2
- Mean BMI: 44.8 kg/m^2 (40.0-64.4)
- Female: 79%
- Mean age: 43 years (20-72)

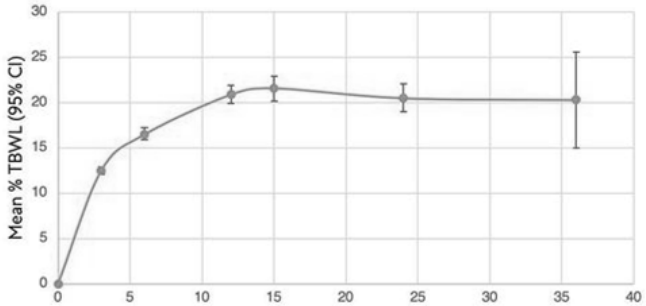
Study Outcomes

- Mean TBWL > 20% at 1, 2, and 3 years
- Improvement in metabolic co-morbidities, including hypertension, hyperlipidemia and type 2 Diabetes
- 0.5% rate of serious adverse events

Source: Gainey et al, Presentation at Digestive Disease Week, 2022

Results

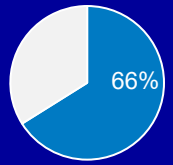
% TBWL by Time from Procedure



6 month: 16.5%
12 month: 20.9%
24 month: 20.5%
36 month: 20.3%

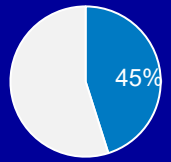
Comorbidity improvement at 6+ months for patients with baseline condition

Hypertension



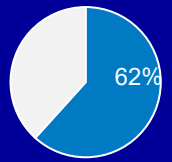
n=115

Hyperlipidemia



n=51

Diabetes, type 2



n=60

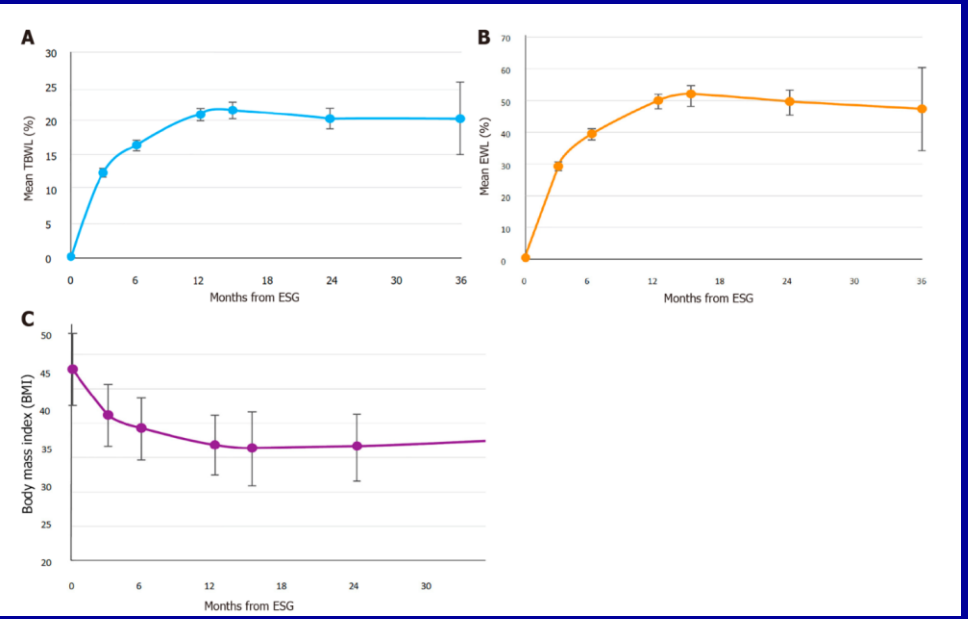
ORIGINAL ARTICLE

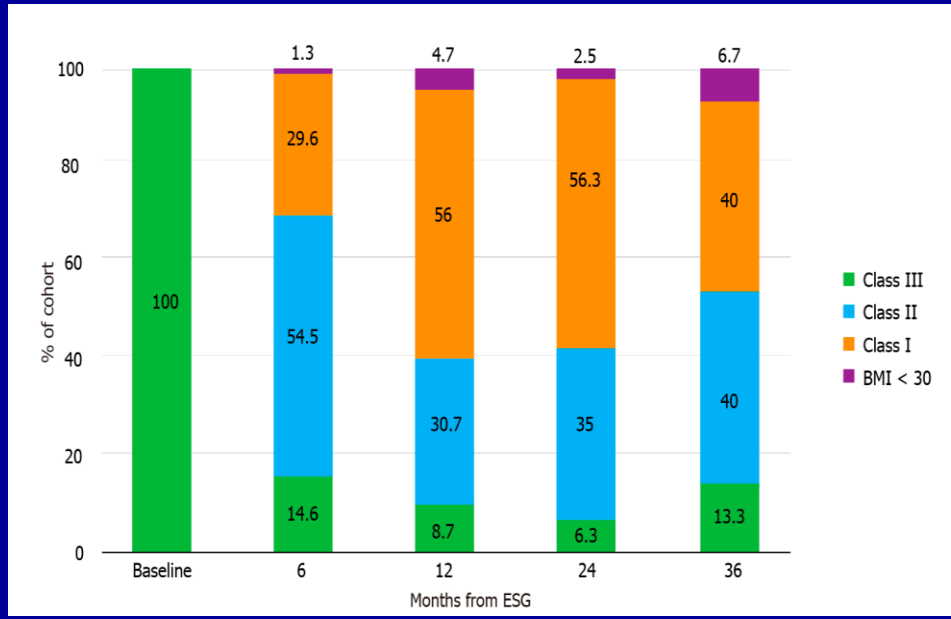
Retrospective Cohort Study

Endoscopic sleeve gastroplasty in class III obesity: Efficacy, safety, and durability outcomes in 404 consecutive patients

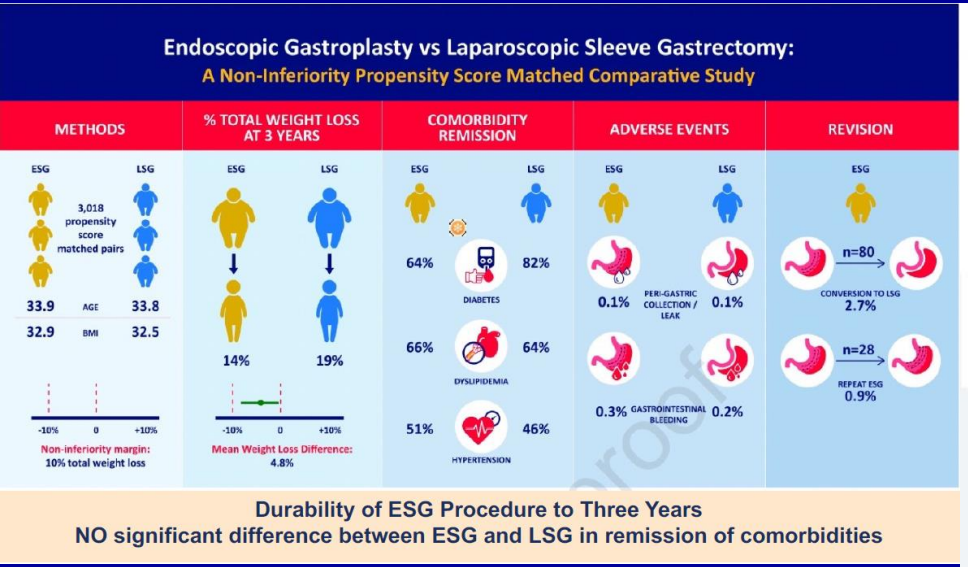
Daniel Barry Maselli, Anna Carolina Hoff, Ashley Kucera, Emily Weaver, Laura Sebring, Lori Gooch, Kathleen Walton, Daniel Lee, Taylor Cratty, Selena Beal, Srikar Nanduri, Kendall Rease, Christina S Gainey, Laura Eaton, Brian Coan, Christopher E McGowan

World J Gastrointest Endosc 2023


A
Mean TBWL (%)
Months from ESG
B
Mean EWL (%)
Months from ESG
C
Body mass index (BMI)
Months from ESG


% of cohort
Baseline
6
12
24
36
Months from ESG
100
1.3
29.6
54.5
14.6
4.7
56
30.7
8.7
2.5
56.3
35
6.3
6.7
40
40
13.3
Class III
Class II
Class I
BMI < 30

LSG vs ESG & post ESG,Surgery conversion



ESG Efficacy and Impact on Comorbidities in 3,018 Subjects (2022)

Alqahtani, et al Endoscopic Gastroplasty Versus Laparoscopic Sleeve Gastrectomy: A Non-Inferioirty Propensity Score Matched Comparative Study, GIE Article in Press Feb 28 2022

Reversal of endoscopic sleeve gastroplasty and conversion to sleeve gastrectomy – Two case reports

Qiuye Cheng[a,b,*], Kevin Tree[a], Michael Edye[a,b], Michael Devadas[a]

[a] Department of Surgery, Blacktown Hospital, Australia
[b] Discipline of Surgery, University of Western Sydney, Australia

Conversion of endoscopic sleeve gastroplasty to laparoscopic Roux-en-Y gastric bypass

Melissa Beitner, M.B.B.S.*, George Hopkins, M.B.B.S., F.R.A.C.S.

Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia

Received 25 September 2019; accepted 21 December 2019

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

Aayed Alqahtani[1*], MD, FRCSC, FACS; Abdullah Al-Darwish[1]; Ahmed Elsayed Mahmoud[1], MD; Yara A. Alqahtani[1], MD;, MD; Mohamed Elahmedi[1], MBBS

Table 4. Revision rates after primary ESG in the first 1000 patients who underwent the procedure at our center

Procedure	n (%)
Endoscopic-Laparoscopic Revision to Sleeve Gastrectomy	8 (0.8)
Redo ESG	5 (0.5)
Reoperation	0 (0.0)

ESG: Endoscopic sleeve gastroplasty

Preserves Treatment Options, Including LSG and RYGB?

Obesity Surgery
https://doi.org/10.1007/s11695-024-07510-z

RESEARCH

IFSO Bariatric Endoscopy Committee Evidence-Based Review and Position Statement on Endoscopic Sleeve Gastroplasty for Obesity Management

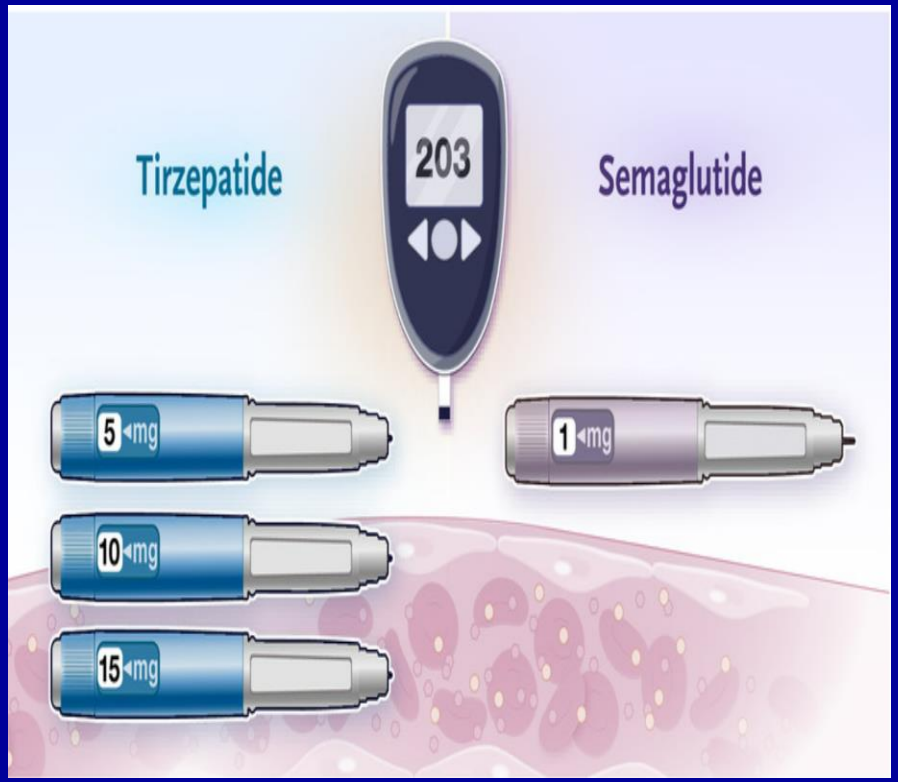
Meta-analysis:

Time point	Mean %EWL	Mean %TBWL
6 months	**48.04**	**15.66**
12 months	**53.09**	**17.56**
18 months	**57.98**	**16.25**
24 months	**46.57**	**15.2**
36 months	**53.18**	**14.07**
60 months	**45.3**	**15.9**

Conclusions The IFSO Bariatric Endoscopy Committee, after conducting a comprehensive systematic review and meta-analysis, endorses endoscopic sleeve gastroplasty (ESG) as an effective and valuable treatment for obesity. ESG is particularly beneficial for patients with class I and II obesity, as well as for those with class III obesity who are not suitable candidates for metabolic bariatric surgery. ESG provides significant weight loss outcomes and demonstrates a favorable safety profile with a low rate of serious adverse events. Despite the limitations of the included observational studies, the randomized controlled trial included in the analysis reinforces the efficacy and safety of ESG and provides an evidence-based foundation for the position statement. Thus, the IFSO position statement supports and provides an evidence base for the role of ESG within the broader spectrum of obesity management.

Combination RCT

+



Endobariatrics – Stomach + Small bowel Futuristic