

The Evidence for Endoscopic Sleeve Gastroplasty

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Professor of Surgery

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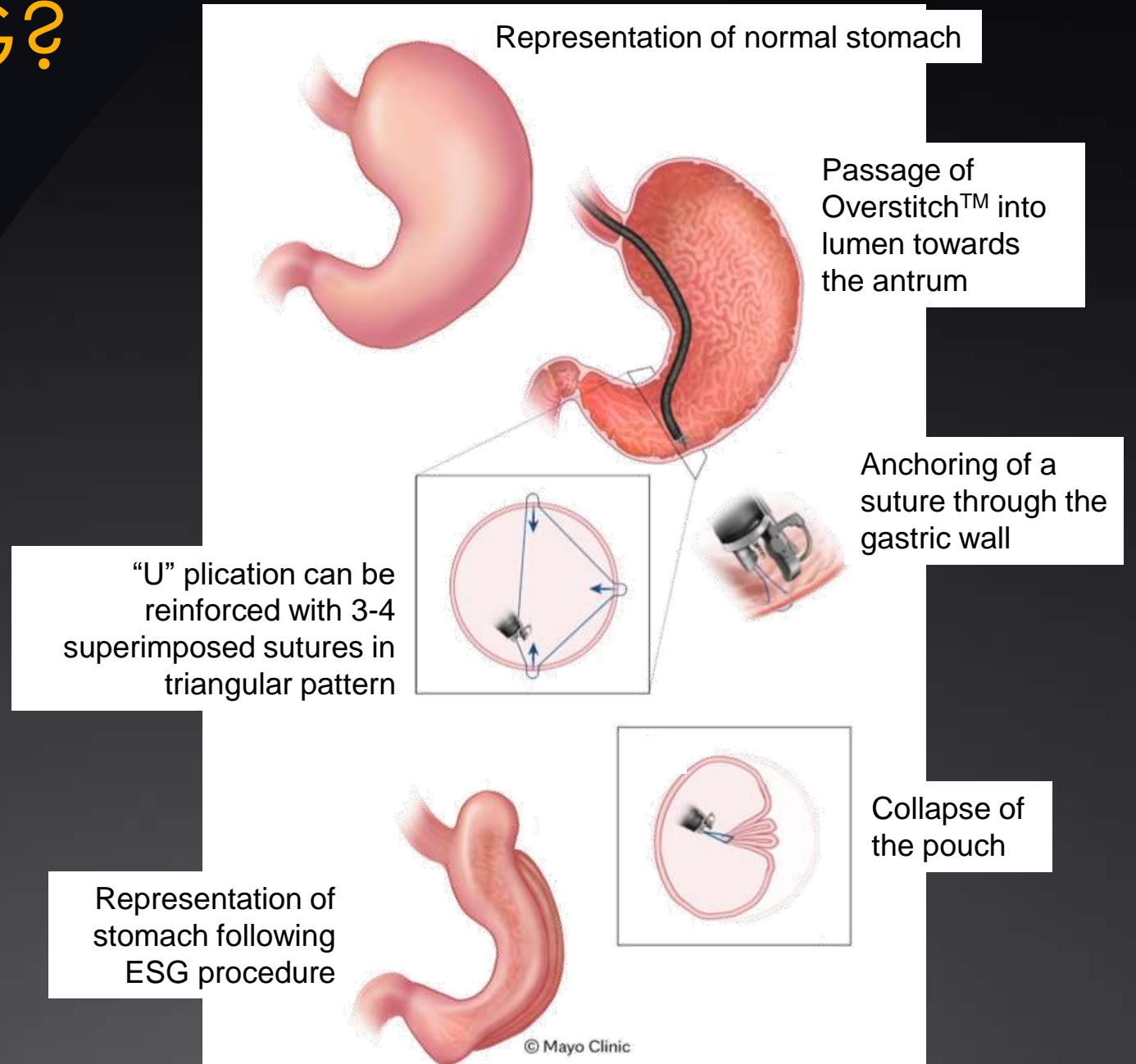
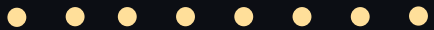
Division Chief, Minimally Invasive and Elective
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What is ESG?

- Restrictive gastric only procedure
- Targeted stomach reduction 70-80%
- Similar shape but different physiologic impact compared to LSG
- Outpatient, general anesthesia
- Procedure time 45 - 90 minutes
- Preserves all future surgical options; can be revised later or converted to LSG or RYG



History of ESG

2004

Concept work – Mayo Developmental Endoscopy Unit

- Early suturing devices used: EndoCinch; Olympus Eagle Claw
- Progression: porcine; canine; baboon

2012

Mayo launched pilot clinical study, named procedure for manuscript

2012

Cases performed in Panama & India

2012

BWH initiated PROMISE Trial

2017

First 248 patients
24-month follow-up series published

2017

MERIT initiated

2022

MERIT study presented at DDW

2022

FDA Market Authorization ESG™ for Apollo

2022

MERIT study published in the Lancet

2011

ASMBS/ ASGE Bariatric White Paper

2013

Fogel EVG data presented

2014

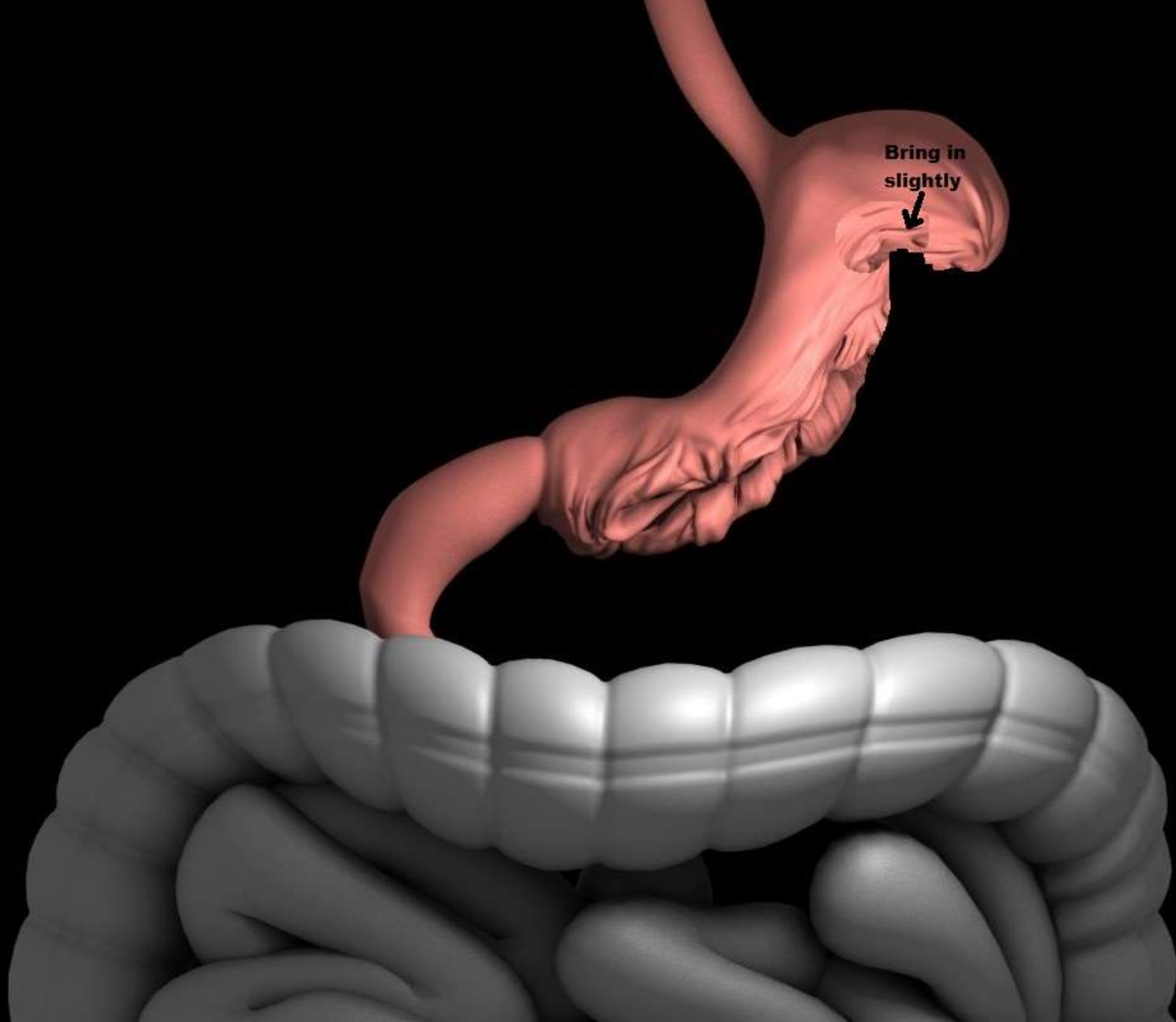
Clinical experience grows globally

2020

Cornell publishes 5-year data

2021

MERIT completion



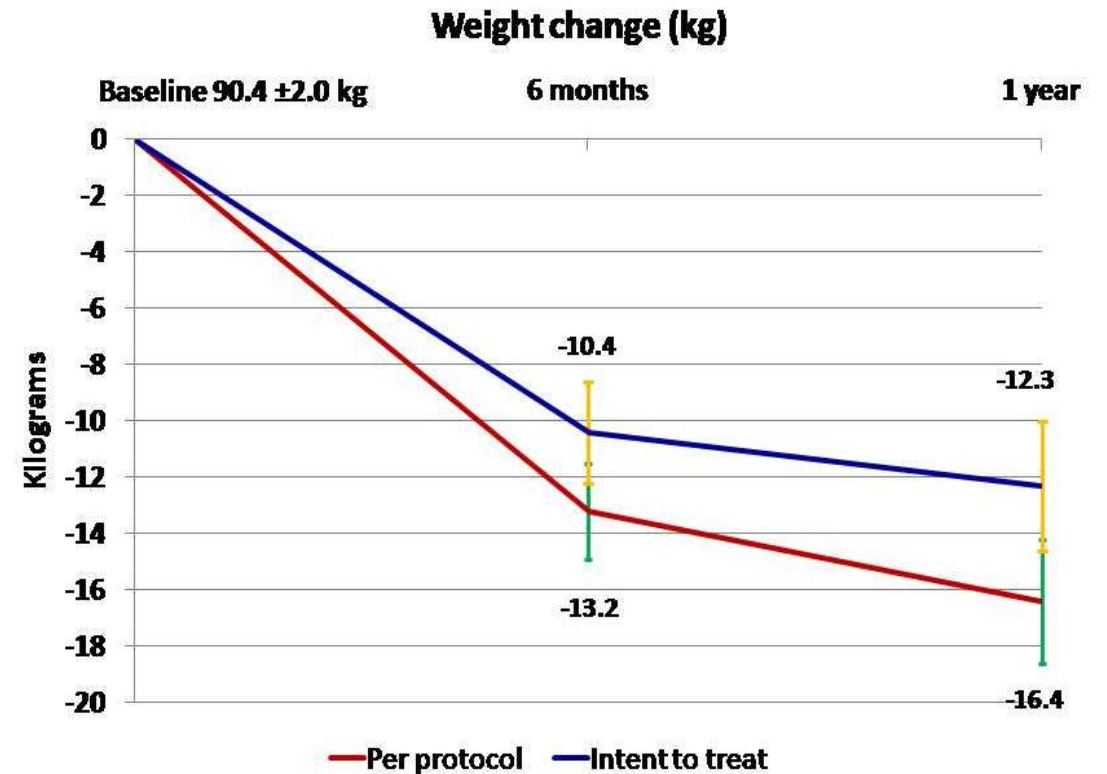
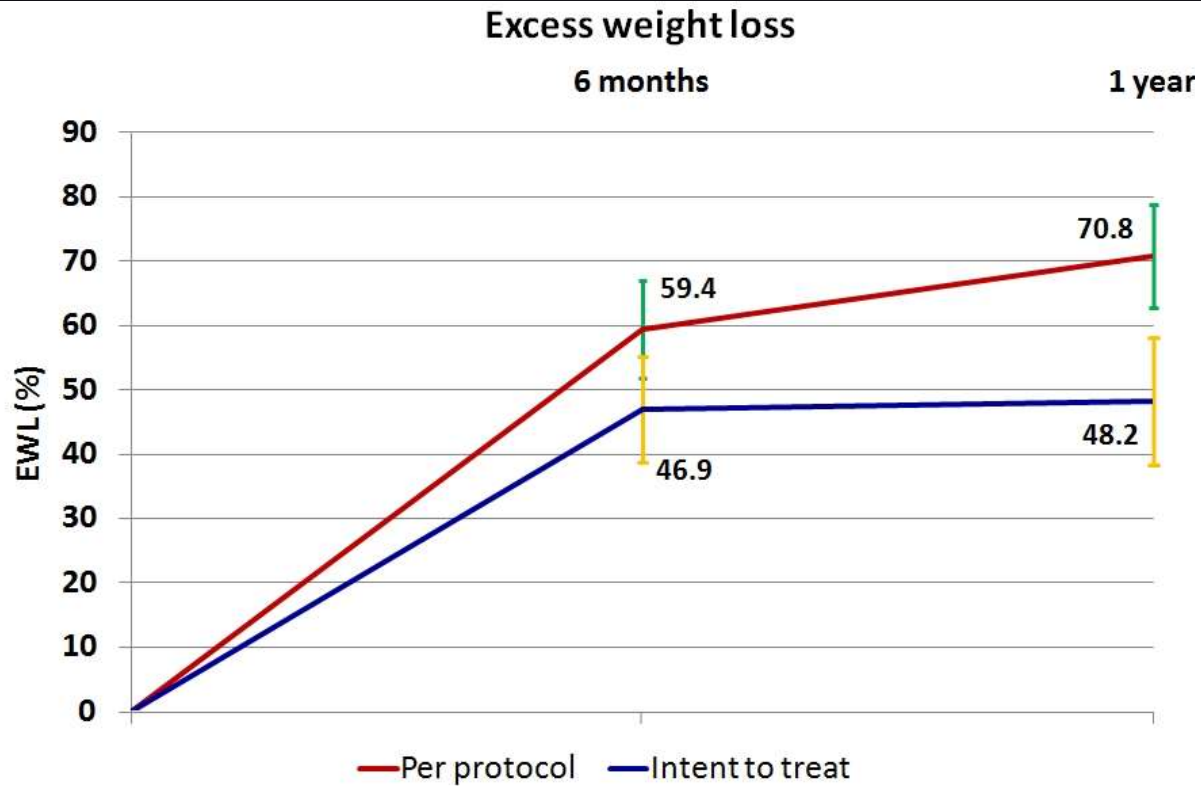
PROMISE Trial 2013

- * **PR**imary **O**besity **M**ulticenter **I**ncisionless **S**uturing **E**valuation
- * Multi-Center
 - * Brigham and Women's Boston
 - * St. Joseph's New Jersey
 - * University of Texas Houston
 - * Jackson South Florida
- * 20 patients total (5 each) BMI 30-35
- * Primary endpoint
 - * Safety and feasibility of the procedure
- * Secondary endpoint
 - * Efficacy and durability

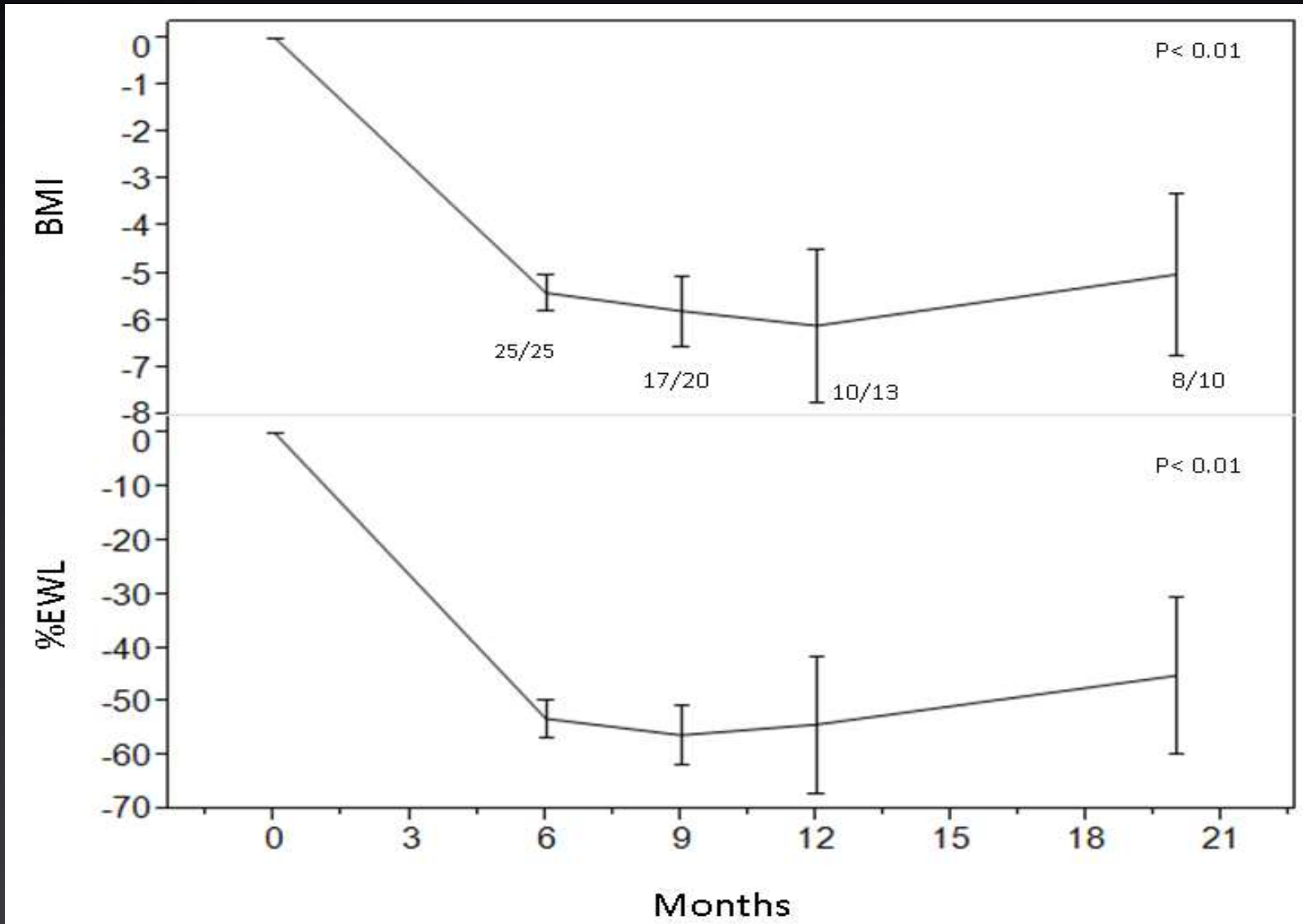
PROMISE Trial Data

- * 20 Females
- * Average Age 36.7 \pm 2.3 years
- * Starting weight 90.4 \pm 2.0 kg (199 \pm 4.4 lbs)
- * Initial BMI 33.4 \pm 0.3 kg/m²
- * Initial Adverse Events
 - * Nausea and vomiting in 3 patients
 - * Postoperative pain in 2 patients
- * Severe Adverse Events—None
 - * No clinical postoperative bleeding
 - * No clinical postoperative infection
- * 15 patients followed for a year (2 pregnant)

PROMISE Trial Data



Outcomes: Mayo Experience



Endoscopic Sleeve Gastroplasty for Obesity: A Multicenter Study of 248 Patients with 24 Months Follow-up

Gontrand Lopez-Nava^{2}, Reem Z. Sharaiha^{1*}, Manoel Galvao Neto⁴, Nikhil A. Kumta¹, Mark Topazian³, Alpana Shukla¹, Michel Kahaleh¹, Karen Grothe³, Manpreet Mundi³, Andrea Benvenuto¹, Andres Acosta³, Louis J. Aronne¹, Christopher Gostout³, Barham K. Abu Dayyeh³*

GOAL:

Evaluate weight outcomes, serious adverse events, and predictors of response in a large cohort

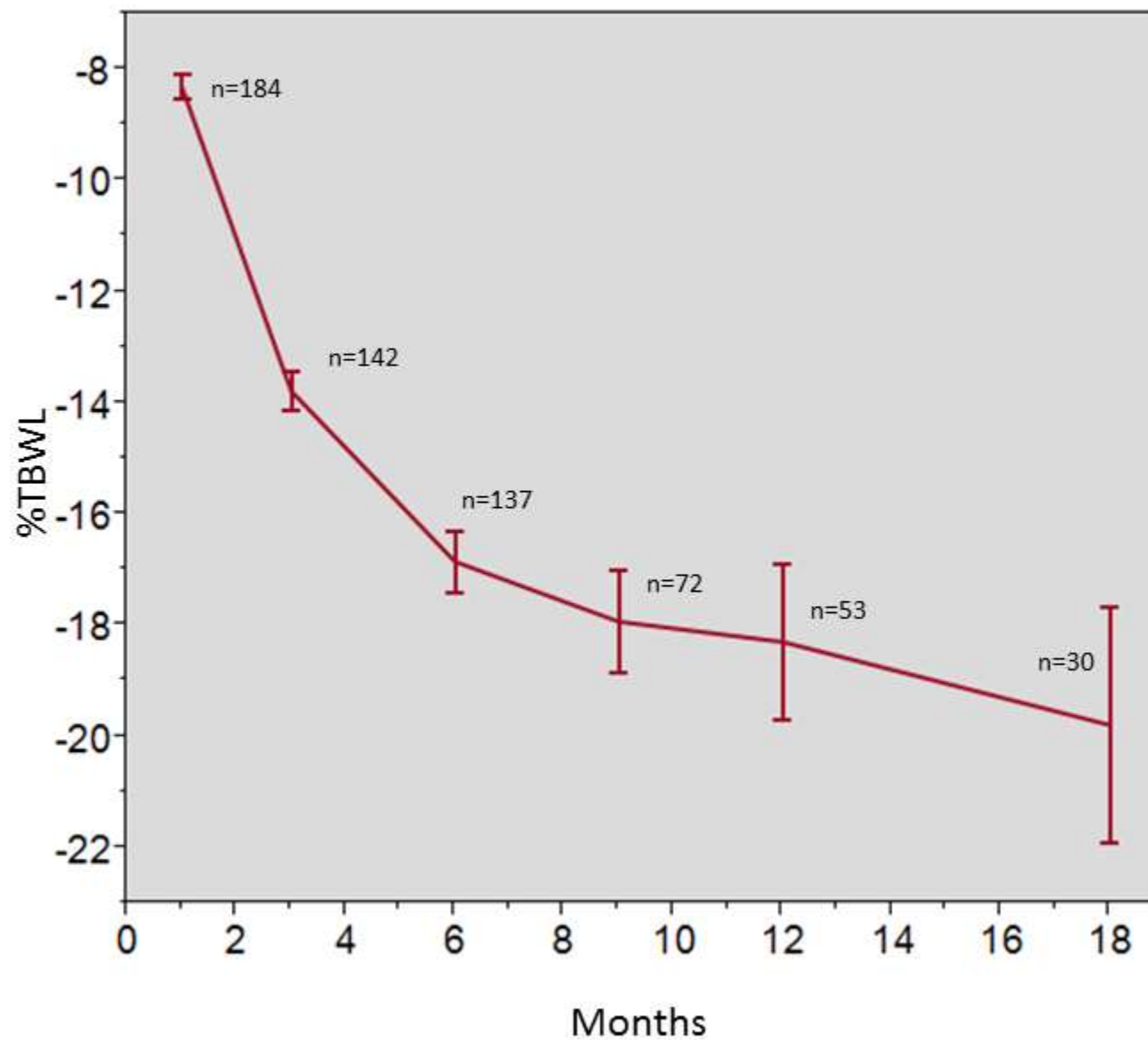
Methods and Results

- * Retrospective multicenter study
- * 3 tertiary care centers
 - * Weill Cornell Medical Center, NYC NY
 - * Mayo Clinic, Rochester Mn
 - * Hospital Universitario Madrid, Spain
- * Data evaluated
 - * Patient characteristics Initial Average BMI 38
 - * Clinical follow-up and sustained weight loss
 - * 15.2 % TBWL at 6 months (248 patients)
 - * 18.6 % TBWL at 24 months (92 patients)

%TBWL

%TBWL

- 1M – 8.3 ± 4.2
- 3M – 13.8 ± 4.3
- 6M – 16.84 ± 6.4
- 9M – 17.9 ± 7.8
- 12M – 18.2 ± 10
- 18M – 19.78 ± 11.6



MERIT-Randomized Trial Centers



Barham Abu Dayyeh,
M.D., M.P.H., FASGE



Erik Wilson, M.D.,
FACS



Christopher Thompson, M.D.



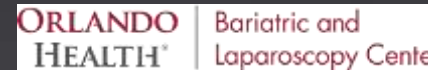
Christopher Chapman, M.D.



Bradley Thaemert, M.D.



Vivek Kumbhari, M.D.
Dilhana Badurdeen, M.D.



Andre Teixeira, M.D.



MERIT Study

Multicenter Endoscopic Sleeve Gastrectomy (ESG) Randomized Interventional Trial

design

- Multi-center, prospective, randomized clinical trial
- Evaluated safety & effectiveness of ESG procedure vs medically monitored regimen of diet & healthy lifestyle
- Direct response to collaborative surgical and GI society position statement

primary endpoints

- **EFFICACY:** At least 25% excess body weight loss (%EBWL) at 12 months and at least 15% EBWL vs. control at 12 months
- **SAFETY:** SAE rate of less than 5%

principal investigators

Co-principal investigators:

Dr. Barham Abu Dayyeh, Mayo Clinic

And Dr. Erik Wilson, University of Texas at Houston

secondary endpoints

Patients also evaluated for improvement in hypertension and type 2 diabetes at 24 months

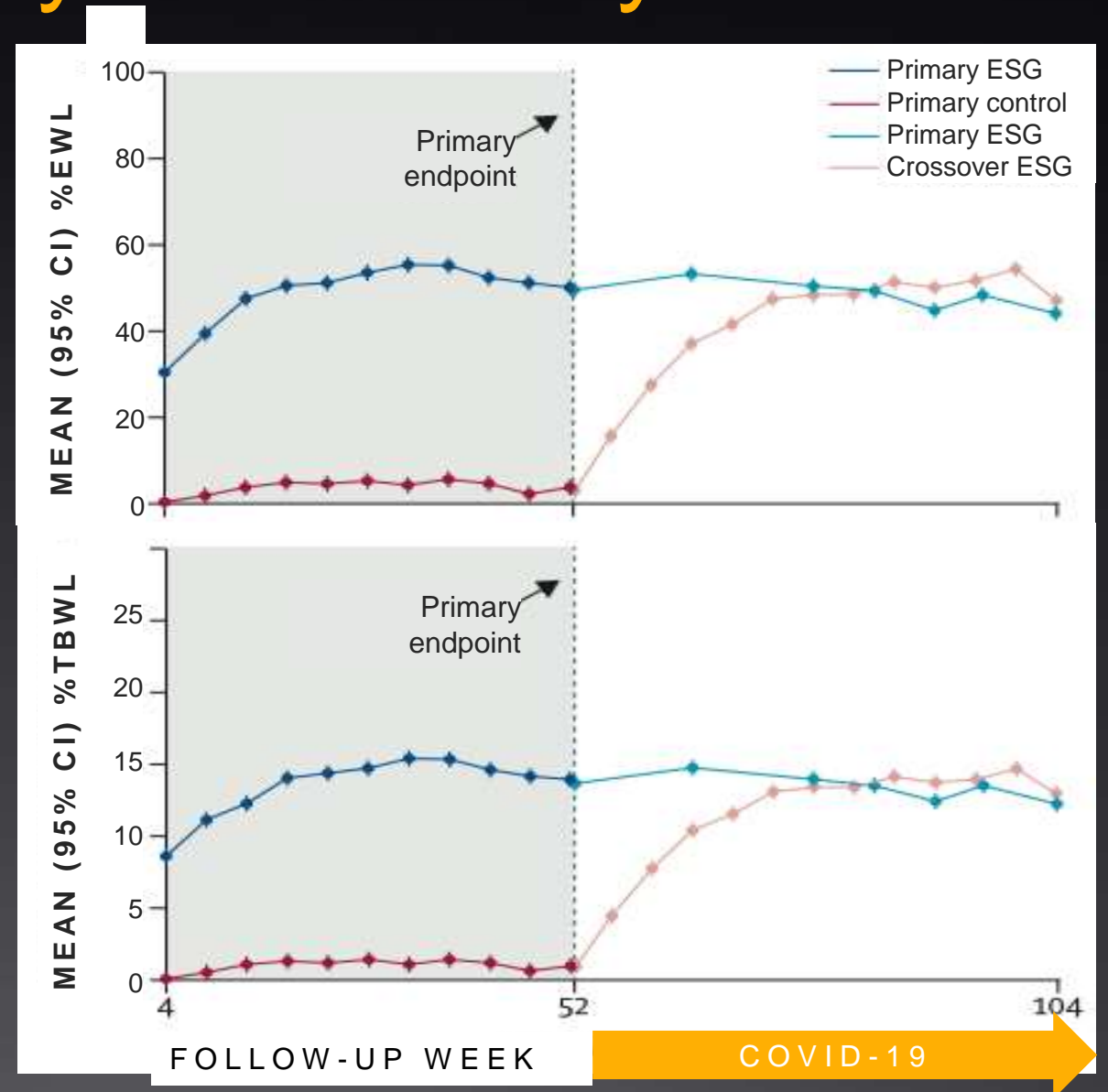
MERIT Results: Efficacy & Durability

49% \pm 32%, target 25%

45% delta vs lifestyle [95% CI 39 – 51]; target 15%

77% responder rate \geq 25% EWL

16% \pm 7% TBWL among responders; 15% > control



MERIT Results: Safety

✓ Met primary safety endpoint

2%

SAE rate among all ESG completers n=150
All recovered

SAE Grade III Clavien-Dindo, ZERO grade IV or V

Peri-Gastric Abscess

Endoscopy
Antibiotics

Upper GI Bleed

Endoscopy
No transfusion

Malnutrition

Endoscopic Reversal

6 patients (4%) hospitalized for conservative management of accommodative symptoms

MERIT Results: Significant Impact on Comorbidities

ESG compared to standard of care

	ESG		SoC		p
	Improve	Worsen	Improve	Worsen	
Diabetes Mellitus Type II (DMII)	92%	0%	15%	44%	<0.001
Metabolic Syndrome + NAFLD + Inflammation	83%	0%	35%	38%	<0.001
Hypertension (HTN)	67%	6%	40%	23%	=0.01

diabetes mellitus type II (DMII)

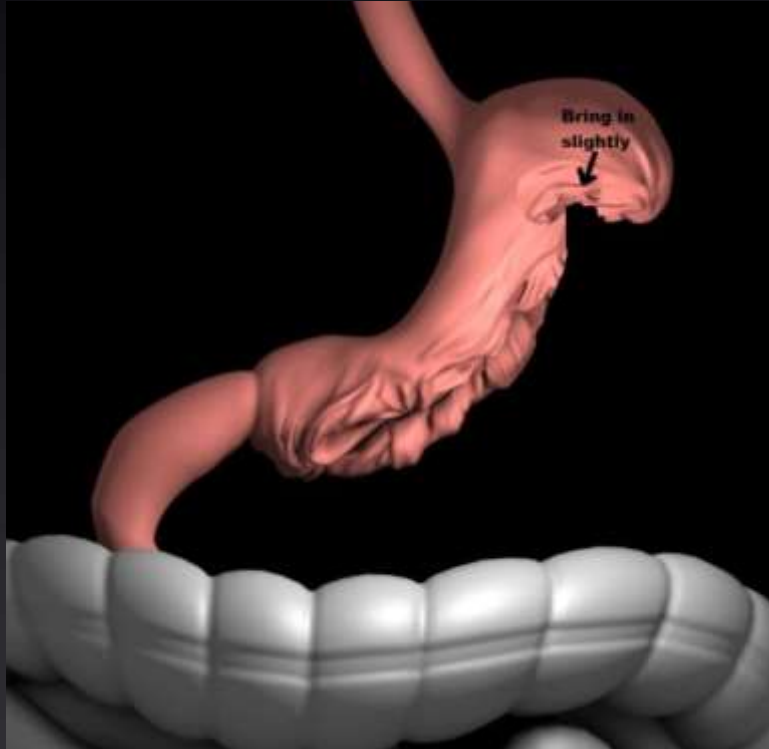
	Improve ESG	Worsen (SoC)	p
HOMA-IR	-3 (SD 6.354)	+1.35 (SD 3.2)	P=0.01
HgA1c (Diabetics)	-0.87 (SD 1.1)	+0.39 (SD 0.7)	P<0.001
HgA1c (baseline>7)	-1.77 (SD 0.755)	+0.16 (SD 0.635)	p<0.001

metabolic syndrome + NAFLD + inflammation

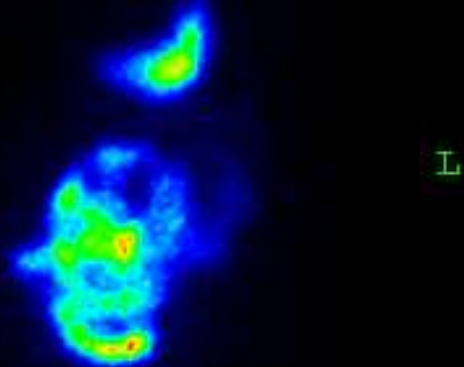
	Improve ESG	Worsen (SoC)	p
Hepatic Steatosis Index (HSII)	-2.24 (SD 3.075)	-0.61 (SD 3.409)	P=0.01
CRP	-1.78 (SD 4.04)	+0.51 (SD 3.525)	P<0.01
Waist/ Hip Ratio (% Change)	-2.91 (SD 8.5188)	-0.36 (SD 7.2852)	P=0.02

Reflux Not Worsened in ESG

Pre Gastroplasty



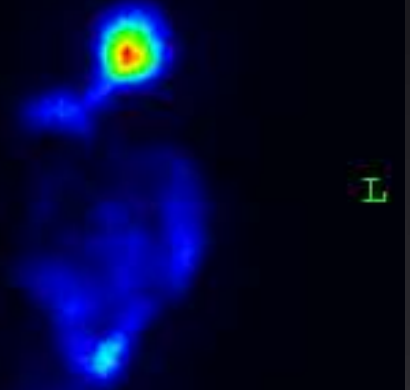
180 minute



16% retained

3 Months Post Gastroplasty

180 minute



45% retained

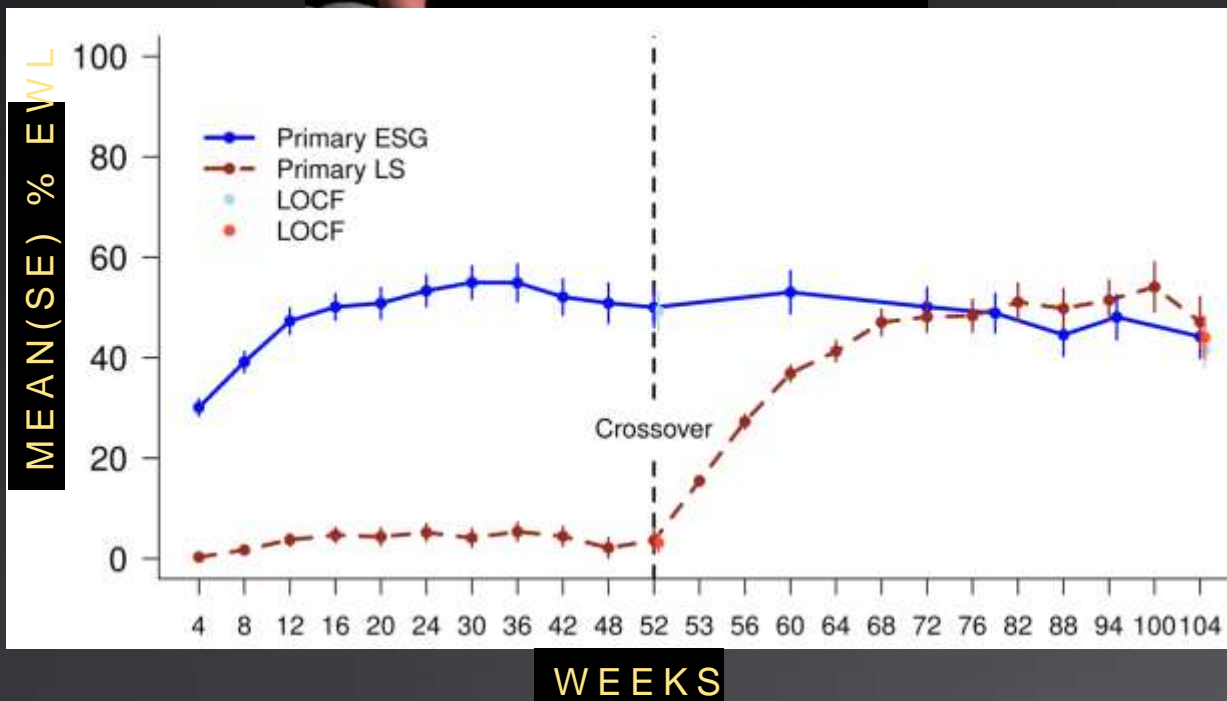
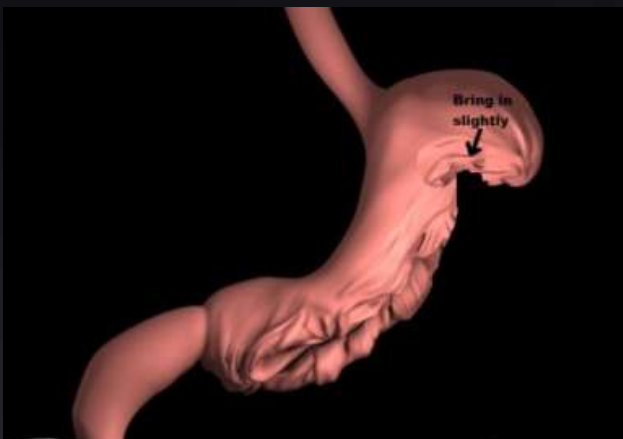
Maximum Tolerated Volume Test

Losing weight
Less long term DGE

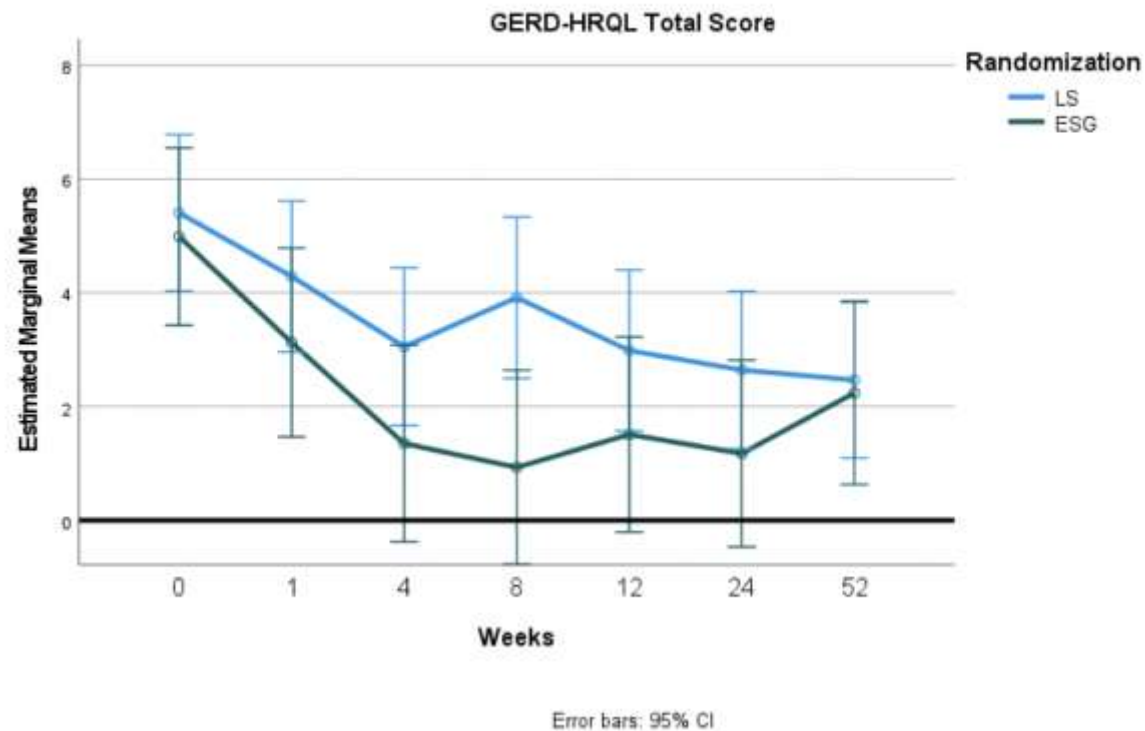
32 minutes at 30mL/min= 960kcal
with fullness of 72 /100mm VAS

10 minutes at 30mL/min=300kcal
with fullness of 78/ 100mm VAS

Reflux and Endoscopic Plication



eFigure 5. GERD-HRQL Total Scores after Adjusted Means



MERIT Publication and FDA Approval

MARKET AUTHORIZATION

The FDA authorized for marketing the Apollo ESG & Revise Systems, the **first FDA-authorized systems for endoscopic sleeve gastroplasty**, a minimally invasive procedure **to facilitate weight loss**. It is intended for adults with obesity (BMI 30-50 kg/m²) who have not been able to lose weight or maintain weight loss through more conservative measures such as diet and exercise.



THE LANCET

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

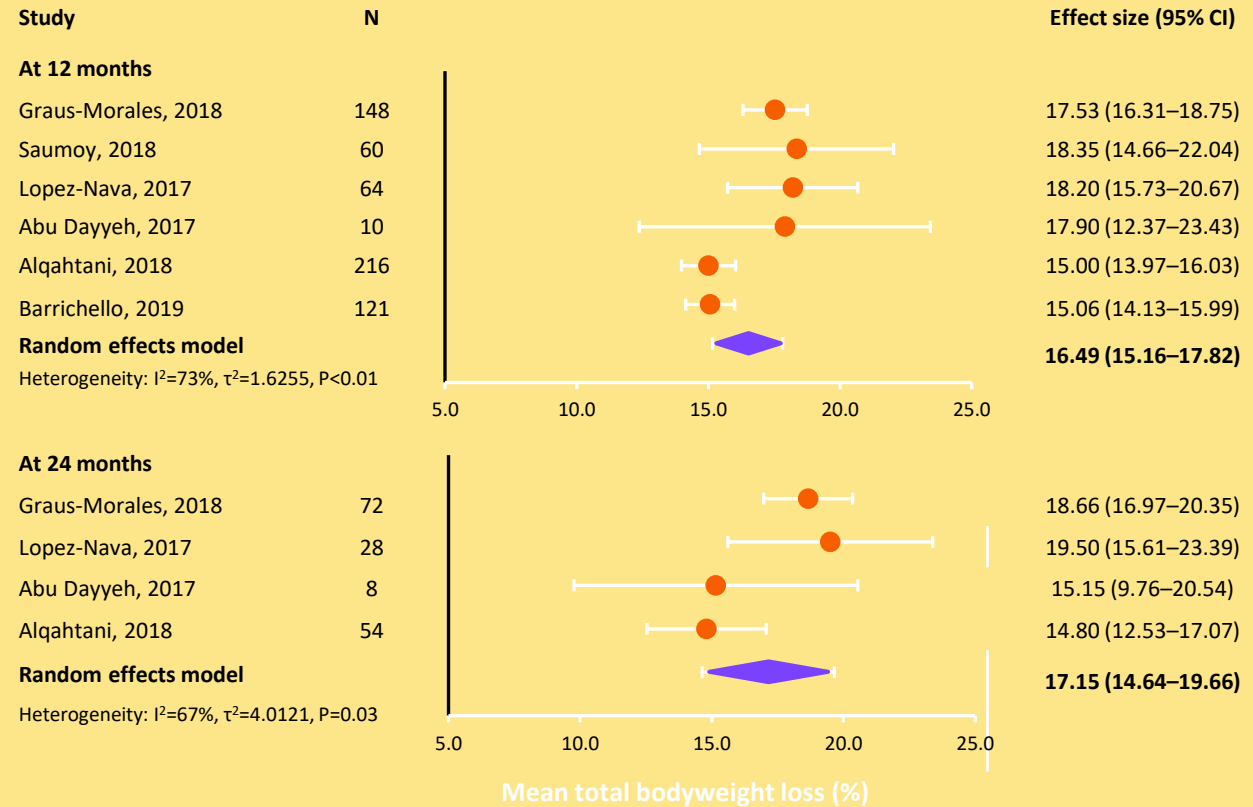


Barham K Abu Dayyeh, Fateh Bazerbachi, Eric J Vargas, Reem Z Sharaiha, Christopher C Thompson, Bradley C Thaeemert, Andre F Teixeira, Christopher G Chapman, Vivek Kumbhari, Michael B Ujiki, Jeanette Ahrens, Courtney Day, the MERIT Study Group, Manoel Galvao Neto, Natan Zundel, Erik B Wilson

ESG effectiveness and safety for treating patients with obesity

ESG demonstrates consistent weight loss across multiple studies

Meta-analysis: weight loss across multiple studies*



ESG confers significant, sustained weight loss with an acceptable safety profile

CI, confidence interval.

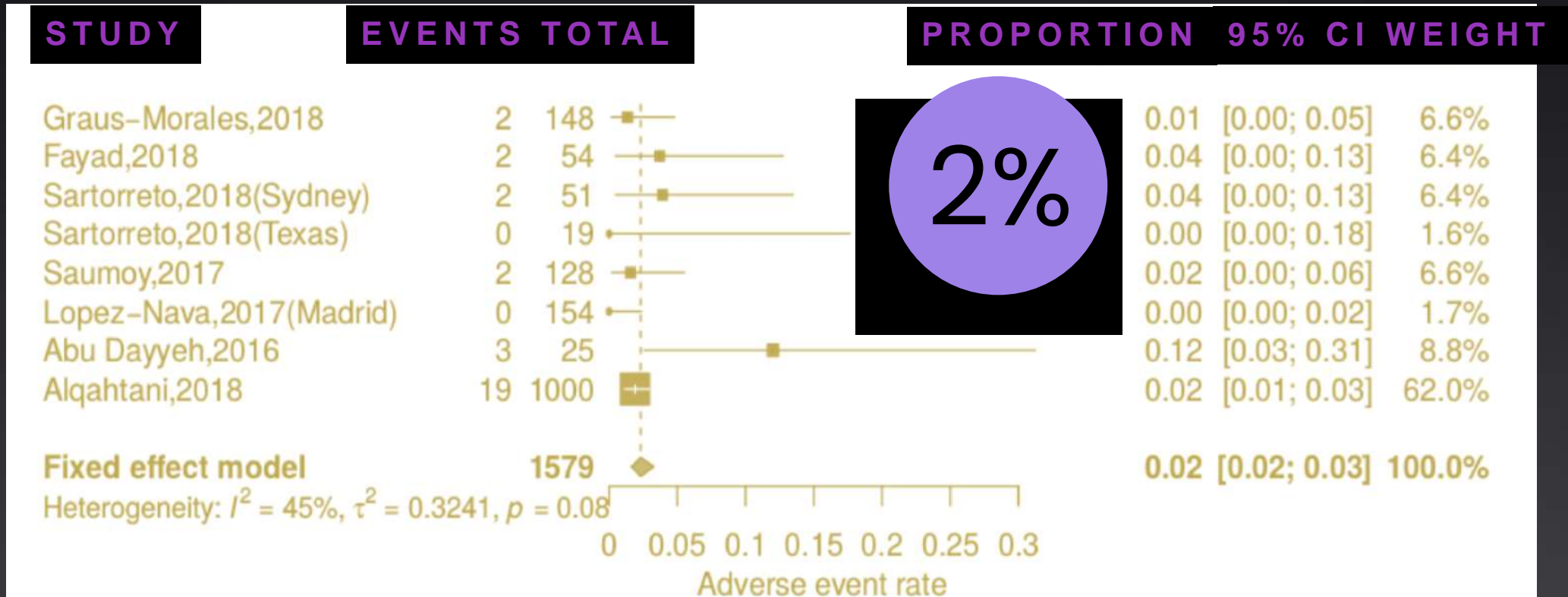
*Data from 8 original studies (retrospective, prospective, case-control, or cohort studies, or clinical trials), published from 2016 to 2019 (N=1772).

Hedjoudje A, et al. Clin Gastroenterol Hepatol 2020;18:1043–53.e4.

ESG Safety Profile

Low Rate of Serious Adverse Events

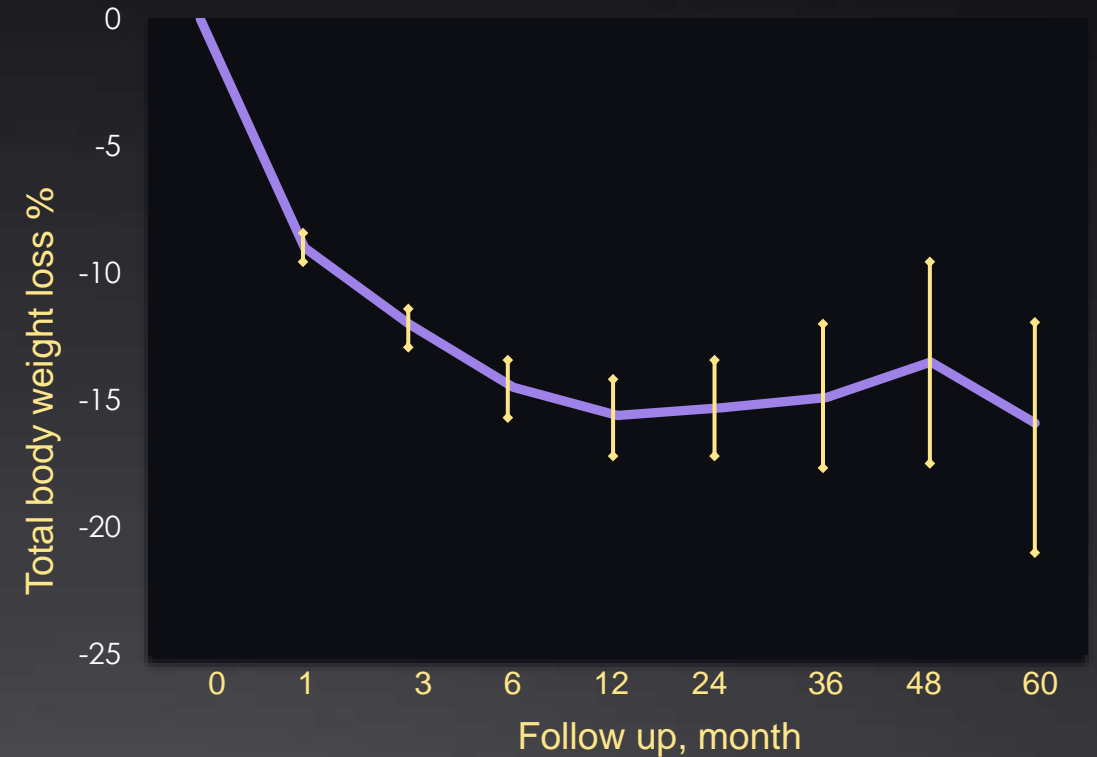
adverse events



ESG Durability

Outcomes to Five Years

Follow up, month	TBWL% (95% CI)	pvalue	TBWL ≥ 10%, n(%)
12	15.6 (14.1-17.1)	<0.0001	(77)
24	15.3 (13.4-17.2)	<0.0001	(72)
36	14.9 (12.1-17.7)	<0.0001	(63)
48	13.5 (9.6-17.4)	<0.0001	(67)
60	15.9 (11.7-20.5)	<0.0001	(61)
Weight loss % at nadir weight	16.7 (15.6-17.7)	<0.0001	(80)



ESG In Patients With Class III Obesity



results

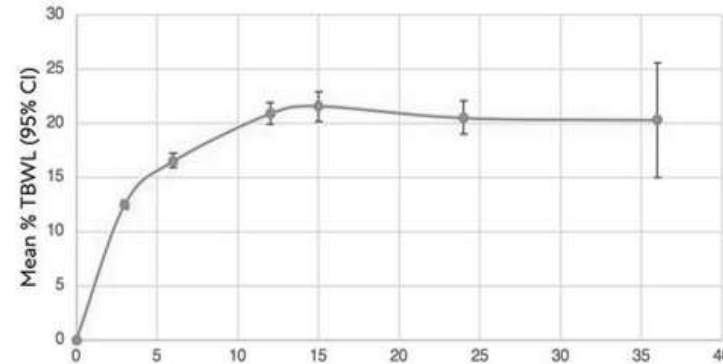
Study Design

- Multi-center trial conducted in U.S. and Brazil
- 404 consecutive ESG patients with BMI > 40kg/m²
- Mean BMI: 44.8 kg/m² (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

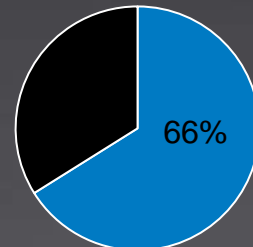
% TBWL by Time from Procedure



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

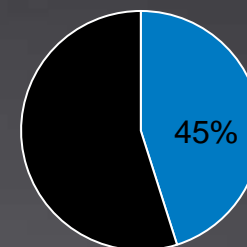
Comorbidity improvement at 6+ months for patients with baseline condition

Hypertension



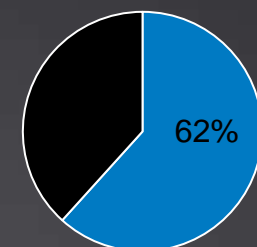
n=115

Hyperlipidemia



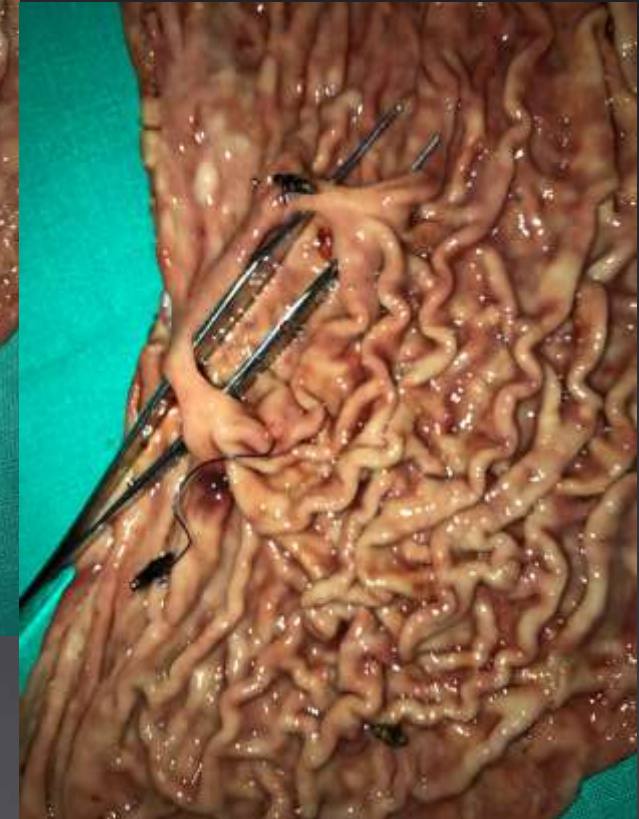
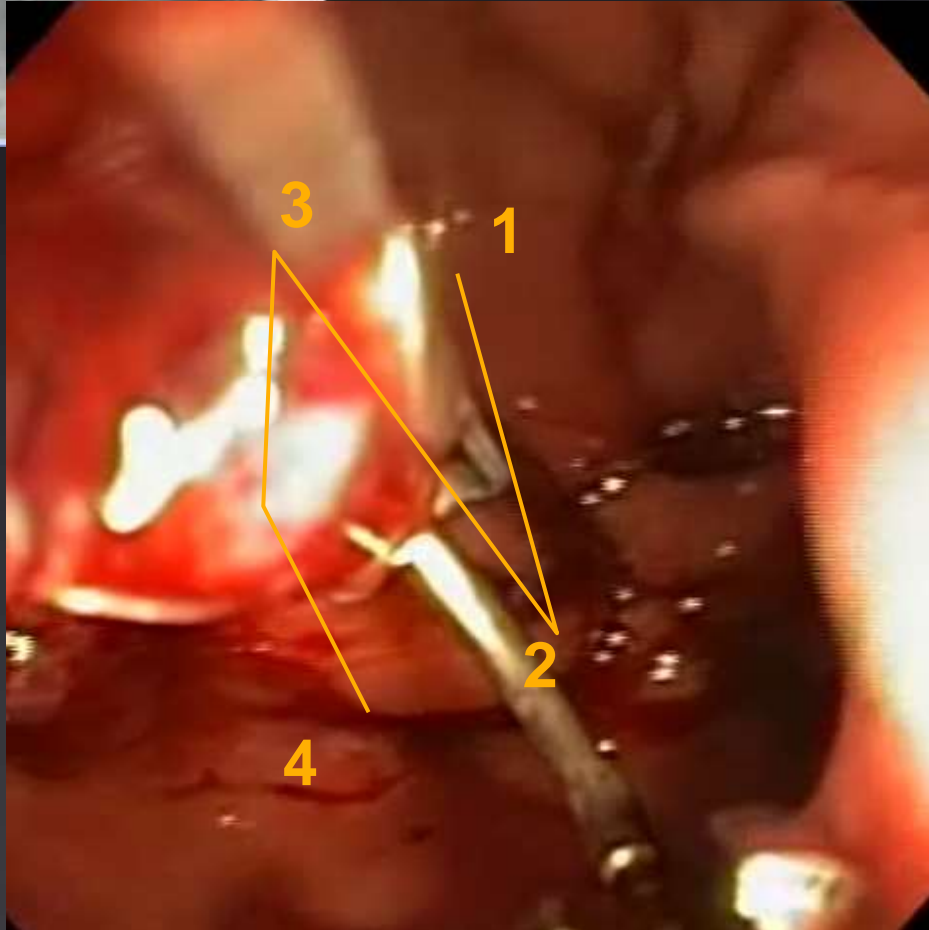
n=51

Diabetes, type 2



n=60

Recidivism: Re-Suturing and Conversion to Sleeve or Bypass



Preserves Treatment Options, Including LSG and RYGB



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

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^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-Darwish¹; Ahmed Elsayed Mahmoud¹, MD; Yara A. Alqahtani¹, MD; MD; Mohamed Elahmedi¹, 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



ORIGINAL ARTICLE

Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: How Do They Compare?

Aleksey A. Novikov¹ · Cheguevara Afaneh² · Monica Saumoy¹ · Viviana Parra³ · Alpana Shukla⁴ · Gregory F. Dakin² · Alfons Pomp² · Enad Dawod¹ · Shawn Shah¹ · Louis J. Aronne⁴ · Reem Z. Sharaiha¹

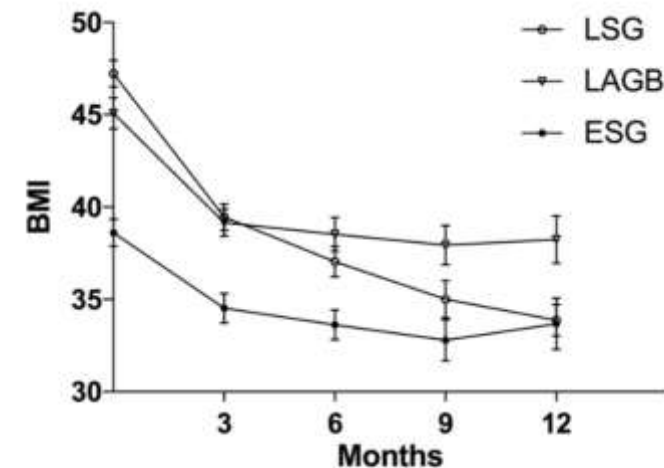


Fig. 1 Weight loss at 12 months—BMI. This is a XY plot depicting average BMI ± standard error of measurement at the time of surgery, 3, 6, 9, and 12 months after LSG, ESG, or LAGB

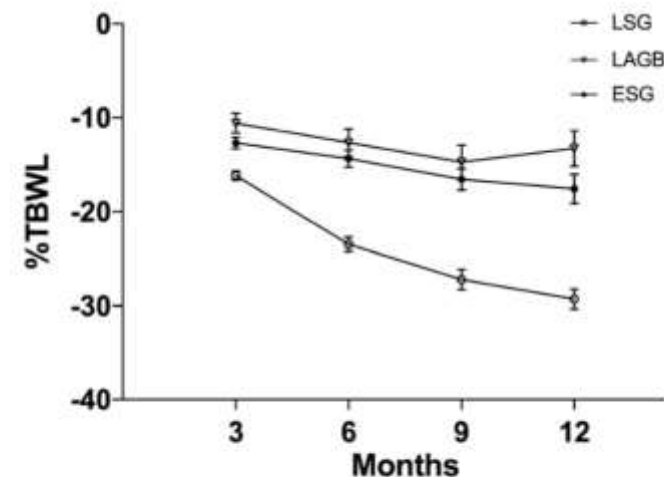


Fig. 2 Weight loss at 12 months—TBWL. This is a XY plot depicting average %TBWL ± standard error of measurement at 3, 6, 9, and 12 months after LSG, ESG, or LAGB

Table 3 Procedure-related outcomes

Mean ± SD (range)	LSG (n = 120)	ESG (n = 91)	LAGB (n = 67)	p value
Hospital length of stay (days)	3.09 ± 1.47 (2–11)	0.34 ± 0.73 (0–3)	1.66 ± 3.07 (0–19)	< 0.001
Re-admissions at 90 days (%)	5 (4.17%)	2 (2.20%)	2 (2.99%)	0.72
Total post procedure morbidity (%)	11 (9.17%)	2 (2.20%)	6 (8.97%)	< 0.05
Events required no procedure (%)	6 (5.00%)	1 (1.10%)	4 (5.97%)	
Events required surgery or endoscopy (%)	5 (4.17%)	0 (0.00%)	2 (3.00%)	
Events required interventional radiology (%)	0 (0.00%)	1 (1.10%)	0 (0.00%)	

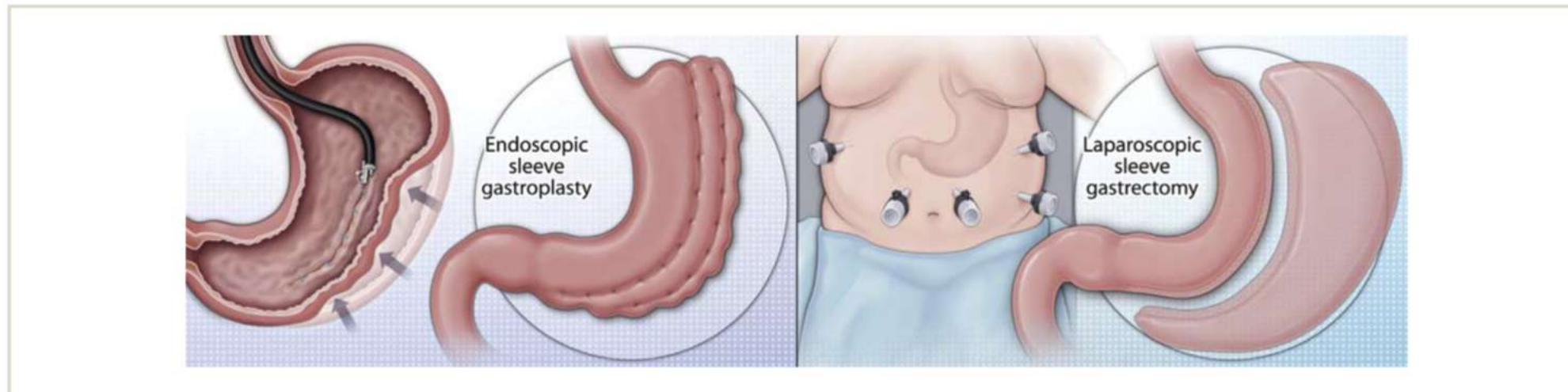
Endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy: a case-matched study



Lea Fayad, MD,¹ Atif Adam, MD, MPH, PhD,² Michael Schweitzer, MD,³
Lawrence J. Cheskin, MD, FACP, FTOS,⁴ Tokunbo Ajayi, MD,⁵ Margo Dunlap, BSN,¹
Dilhana S. Badurdeen, MD,¹ Christine Hill, BA, BS,⁴ Neethi Paranjhi, MD,¹ Sepehr Lalezari, MD,³
Anthony N. Kalloo, MD,¹ Mouen A. Khashab, MD,¹ Vivek Kumbhari, MD¹

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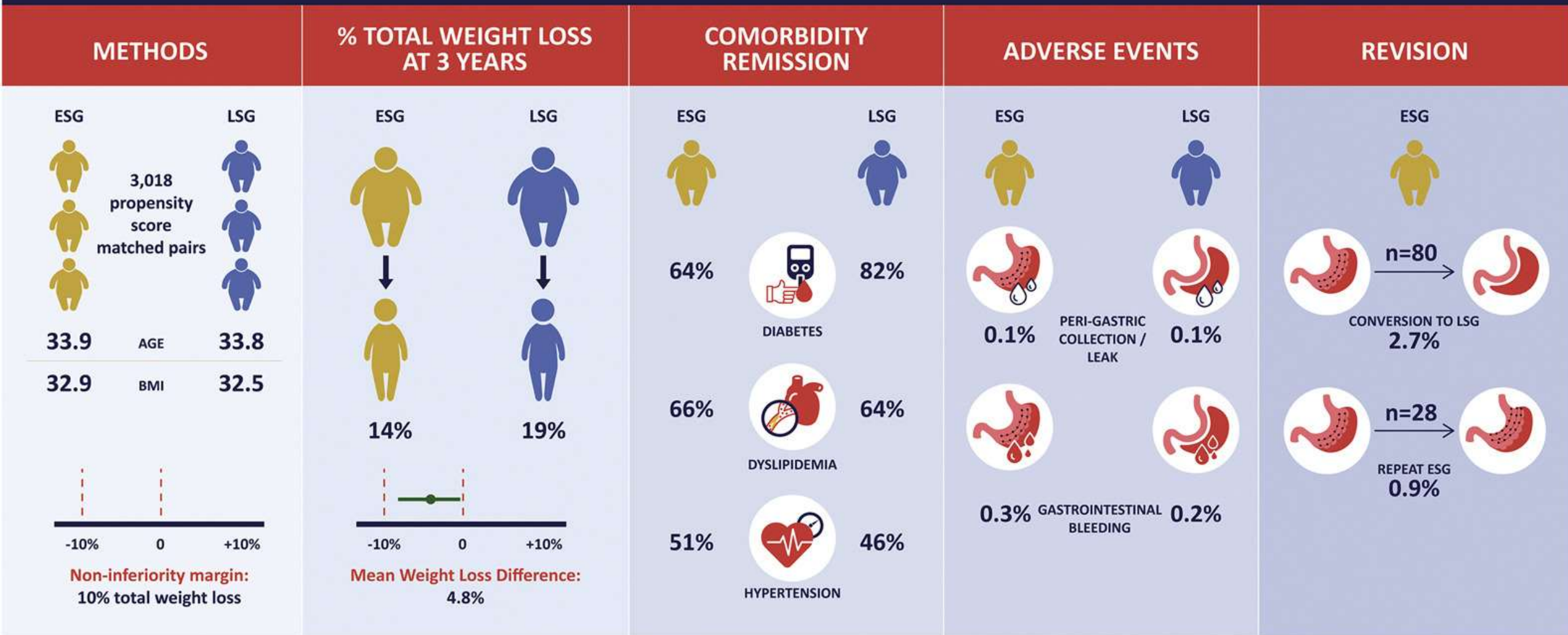
GRAPHICAL ABSTRACT



Results: A total of 54 ESG patients were matched with 83 LSG patients by age, sex, and body mass index. The proportion of patients with GERD at baseline was similar in the 2 groups (16.7% in ESG group vs 25.3% in LSG group, $P = .27$). At the 6-month follow-up, %TBWL (compared with baseline) was significantly lower in the ESG group compared with the LSG group ($17.1\% \pm 6.5\%$ vs $23.6\% \pm 7.6\%$, $P < .01$). ESG patients had significantly lower rates of adverse events compared with LSG patients (5.2% vs 16.9%, $P < .05$). New-onset GERD was also significantly lower in the ESG group compared with the LSG group (1.9% vs 14.5%, $P < .05$).

Conclusions: ESG, a minimally invasive same-day procedure, achieved less weight loss at 6 months than LSG, with the caveat that LSG caused more adverse events and new-onset GERD than ESG. (Gastrointest Endosc 2019;89:782-8.)

Endoscopic Gastroplasty vs Laparoscopic Sleeve Gastrectomy: A Non-Inferiority Propensity Score Matched Comparative Study



Who is Performing ESG Procedures? • • • • •

>25,000

ESGs performed globally (2018-2021)

>300

GIs globally perform ESG procedures

>100

Surgeons globally perform ESG procedures

>70%

of top US GI programs perform ESG procedures¹

30+

US Endobariatric Programs in academic medical centers, including:

- Mayo
- Brigham & Women's
- UT Health Houston
- University of Michigan
- Robert Wood Johnson
- UCLA (*new program*)
- Cleveland Clinic (*new program*)
- Cedars Sinai (*new program*)

1. U.S. News and World Report ranking of top 25 hospitals for gastroenterology and GI surgery

Conclusion

ESG has a growing body of evidence as an appropriate primary bariatric procedure

- * ESG is approved for BMI 30-50 but more studies have been performed in BMI 30-40
- * ESG has fewer AEs and SAEs compared to bariatric surgery but less average weight loss
- * Patients who get ESG and then consider surgery can receive surgery safely but need to be committed to ESG for approximately 1-2 years to allow for dilation of the sutures.

Thank You

Erik B. Wilson, MD, FACS

Professor and Vice Chair of Surgery

Division Chief, Minimally Invasive Surgeons of Texas

University of Texas Health Science Center at Houston

