Evidence Challenges Bias: Insights from the MERIT Trial and More

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Cedars Sinai

cedars-sinai.org

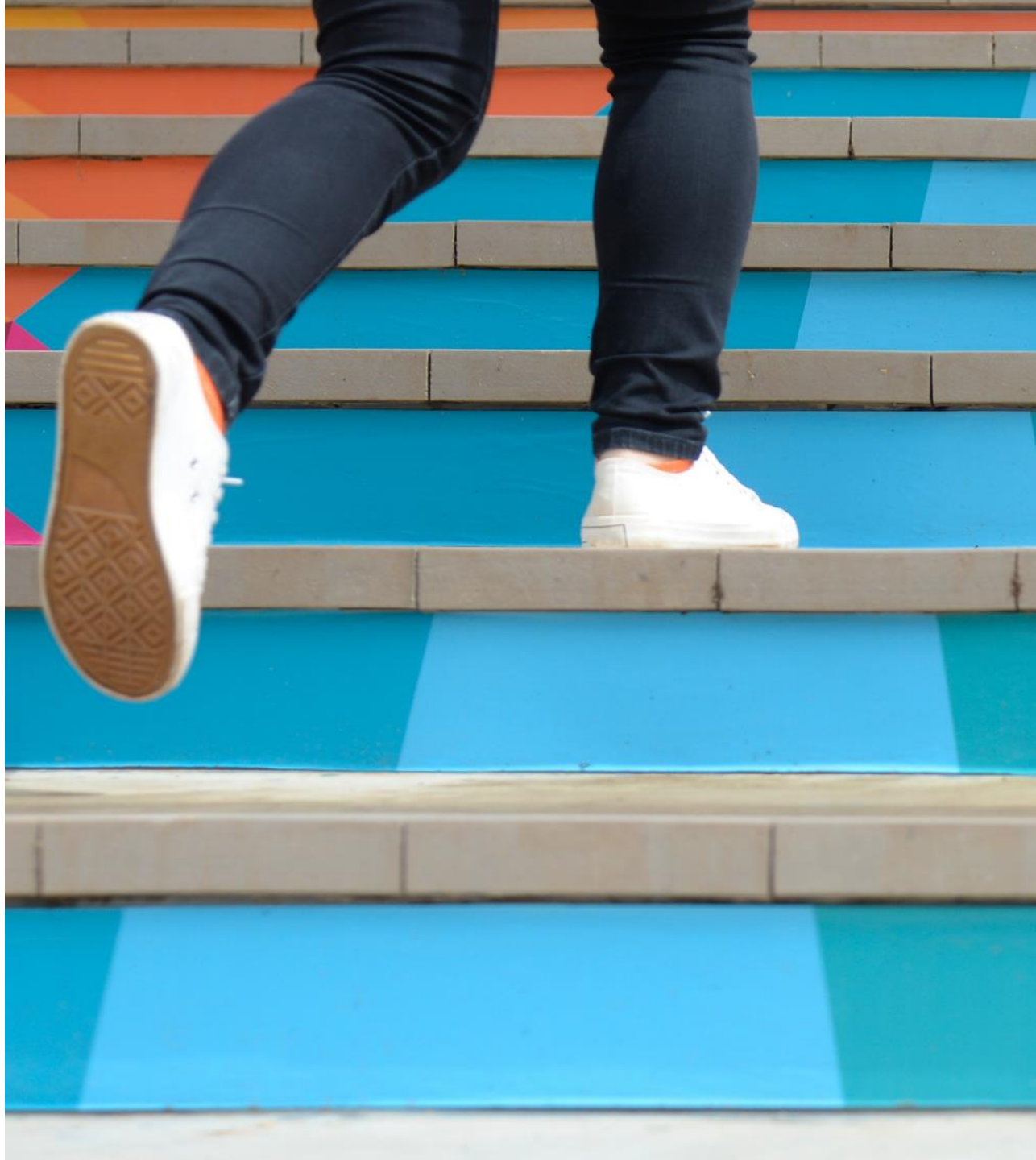
Disclosures

Consultant: Boston Scientific, Olympus, Intuitive

Co-inventor (Licensed Mayo Technology): Endogenex

Research Support: MERIT Medical

THE UNMET NEED



Scalable

Durable

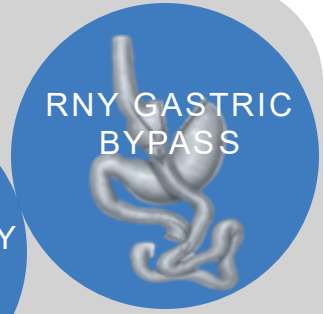
Value

EFFICACY & DURABILITY

ESG +

Medications

ESG

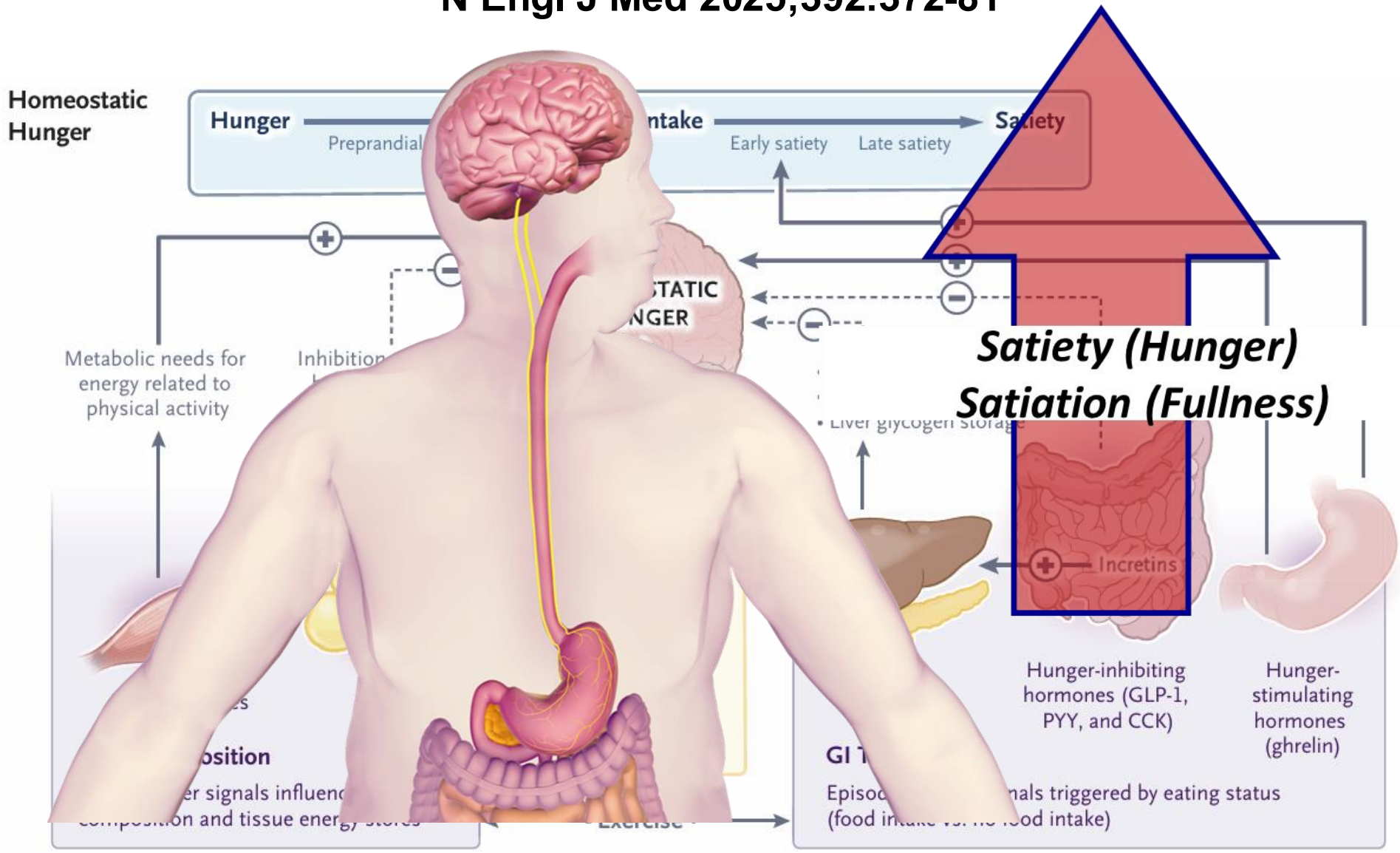


SURGICAL OPTIONS

INVASIVENESS

GUT: DISEASE MODIFICATION VS. MANAGEMENT

N Engl J Med 2025;392:372-81



Animal Experimentation Mayo IACUC#: 12-003195 2010-11 (multiple protocols and multiple failures 2004 – 2010)

High-Impact Pilot and Feasibility Award (HIPFA) Checklist

Scientific Review Panel of CTSA

2011-2012

☒ Budget funding proposal # FP00073684

Complete the budget template below and email it to [redacted]. A budget will be created and sent back to you for review. When finalized, attach it to your application. A budget must be created before you submit your application.

Total direct costs: $ 30,000
Total indirect costs: $ 9,000
Total cost: $ 39,000

Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity

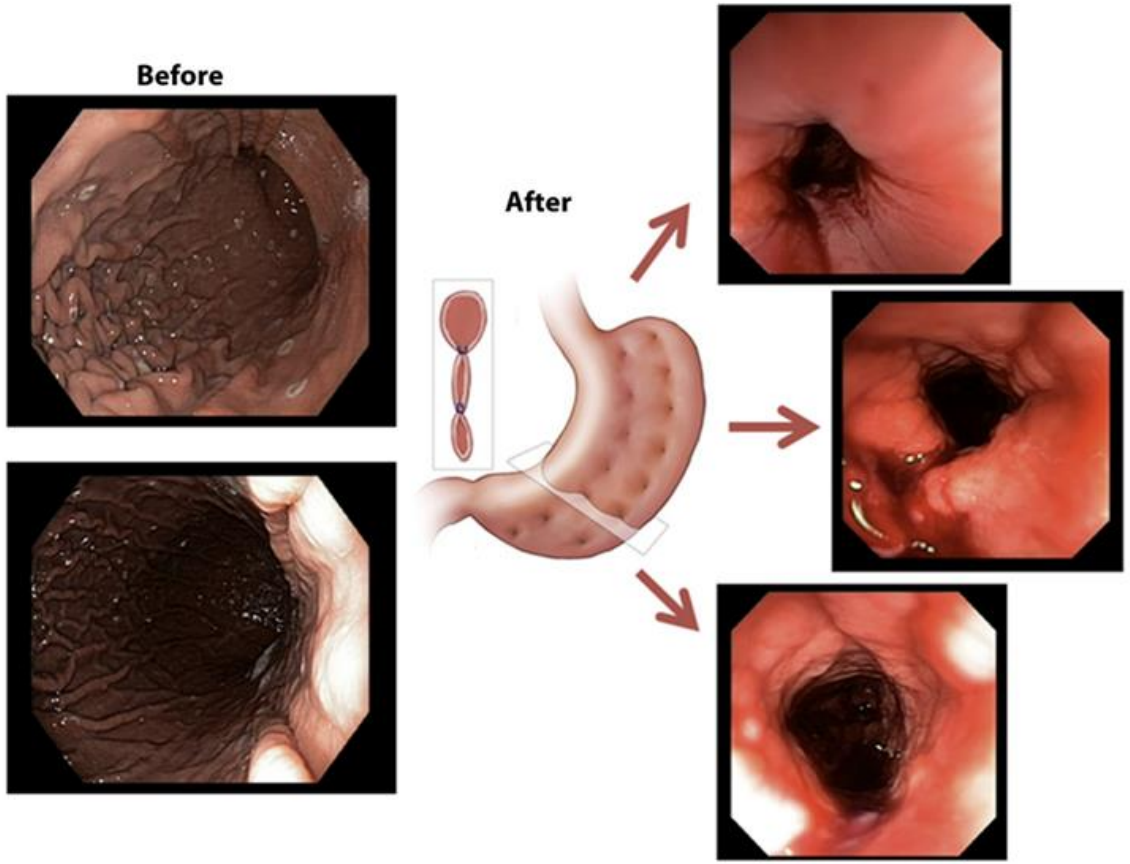
Barham K. Abu Dayyeh, MD, MPH, Elizabeth Rajan, MD, Christopher J. Gostout, MD

Rochester, Minnesota, USA

ELSEVIER

Gastrointestinal Endoscopy

Volume 78, Issue 3, September 2013, Pages 530-535



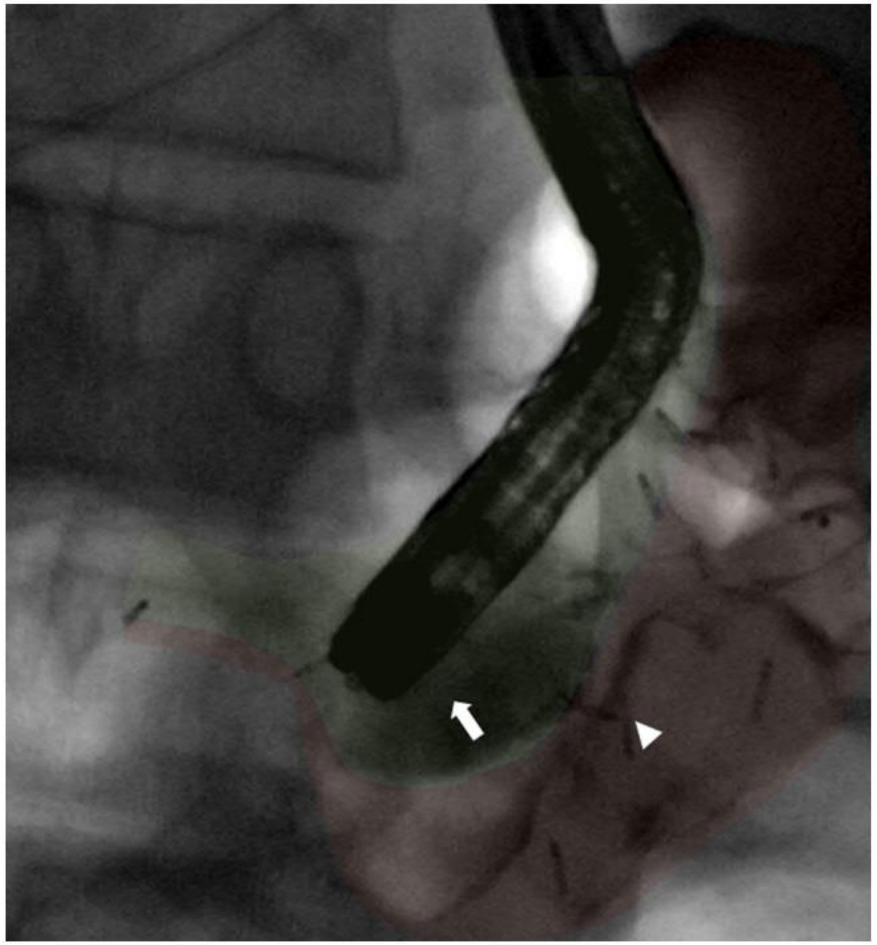
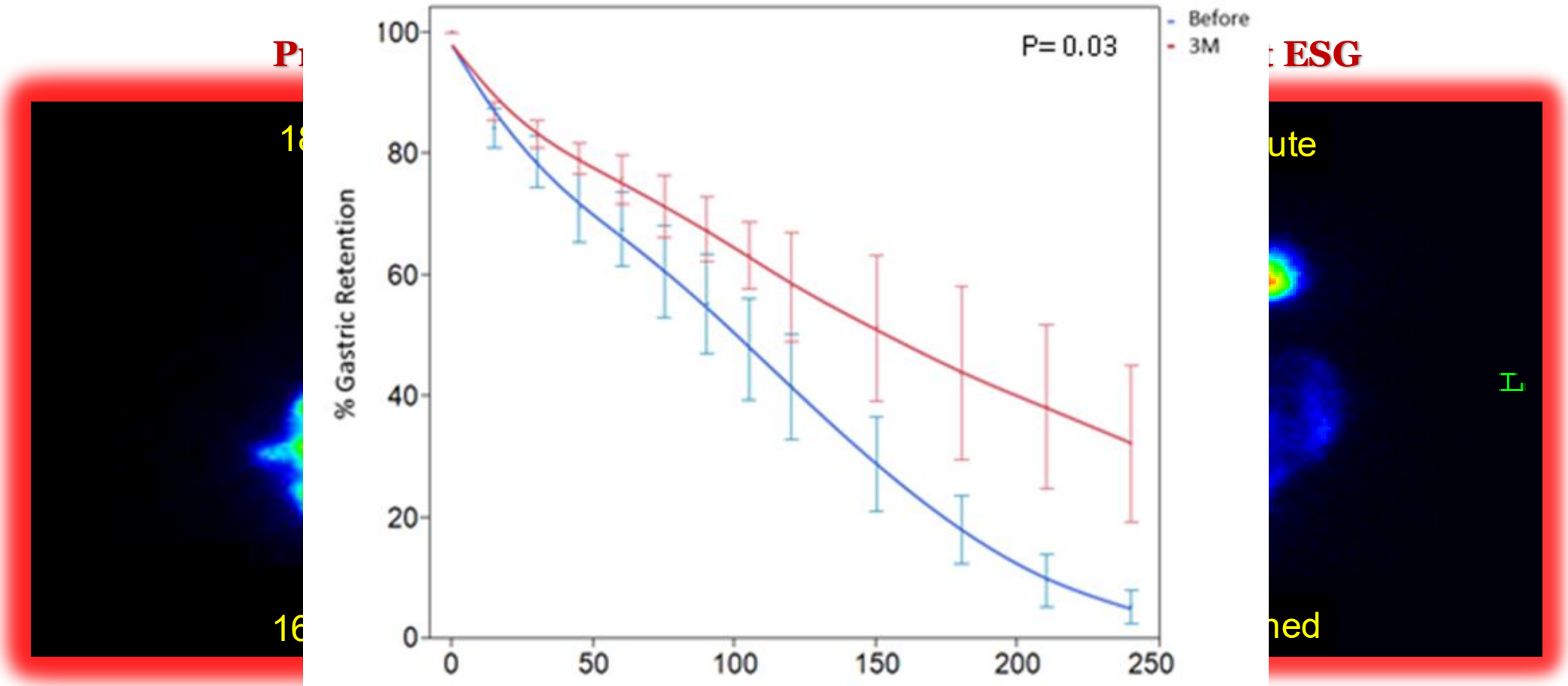


TABLE 1. Baseline demographics and procedural characteristics

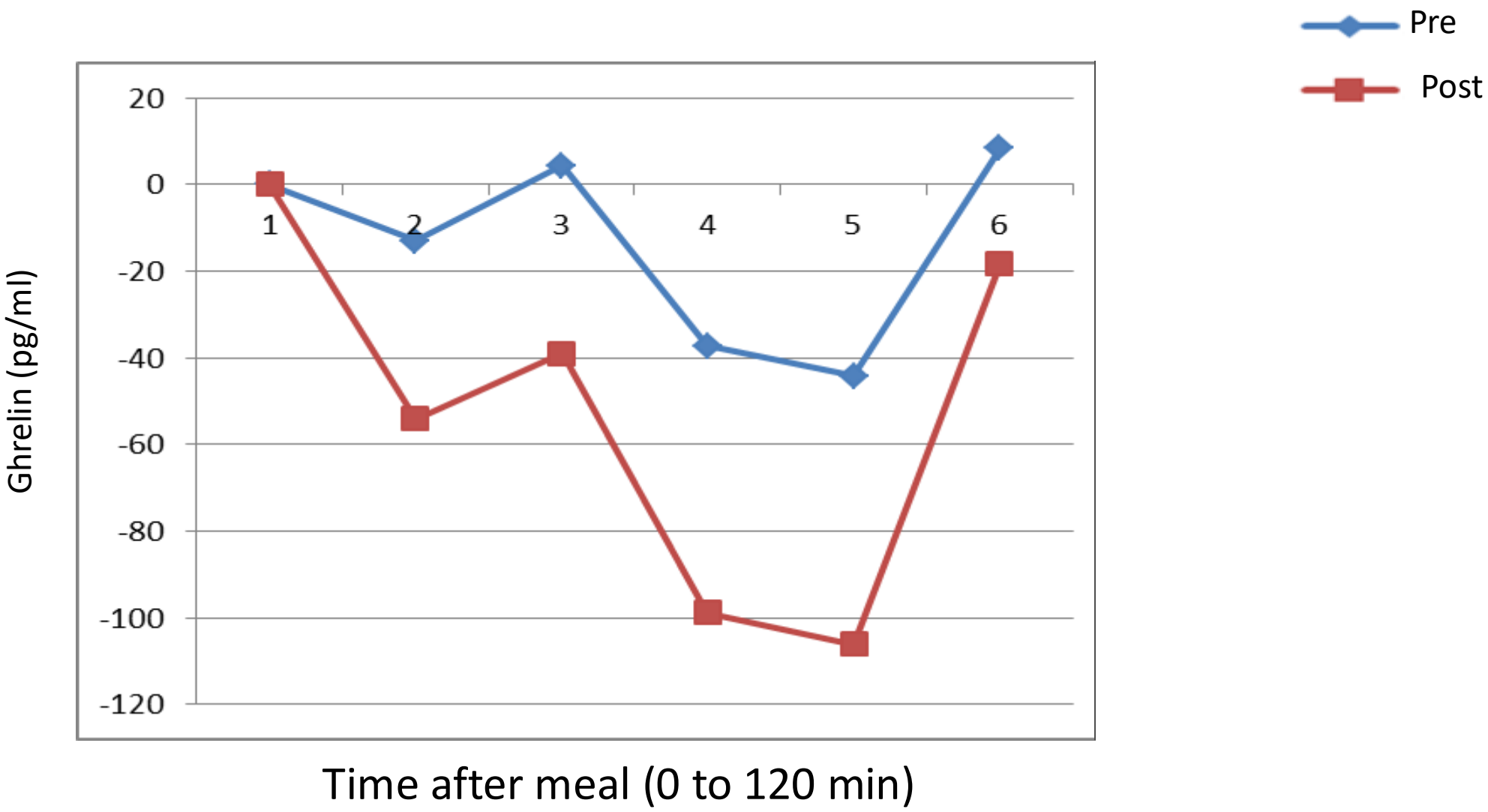
Subject	Age, y	Sex	BMI, kg/m^2	Procedure length, min	No. of sutures placed	Disposition
1	31	Female	38.3	245	23	Inpatient observation
2	48	Male	37.3	211	28	Outpatient
3	43	Female	34.6	222	25	Outpatient
4	25	Female	33.2	172	26	Outpatient

BMI, body mass index.

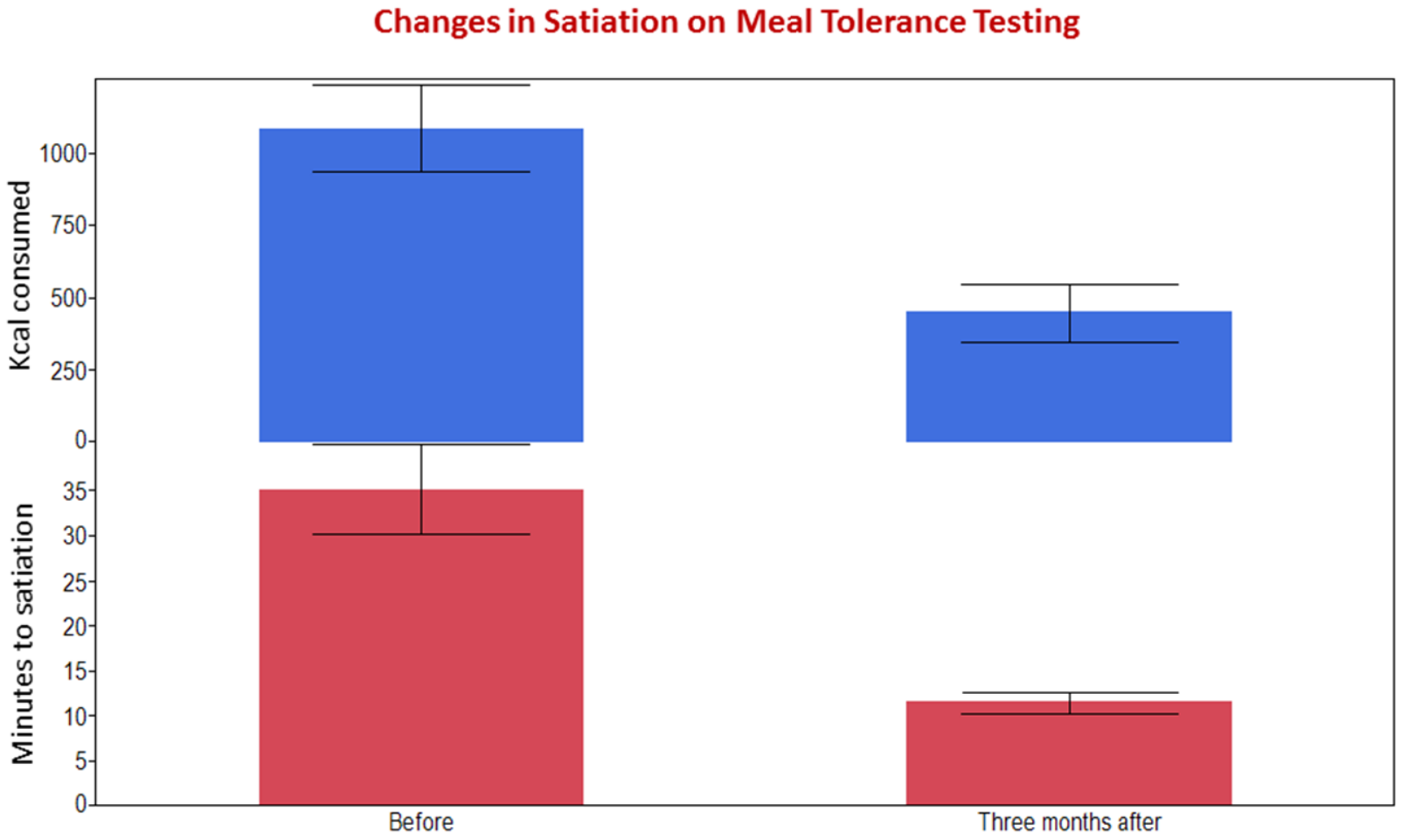
Gastric Emptying Studies (2013-2016)



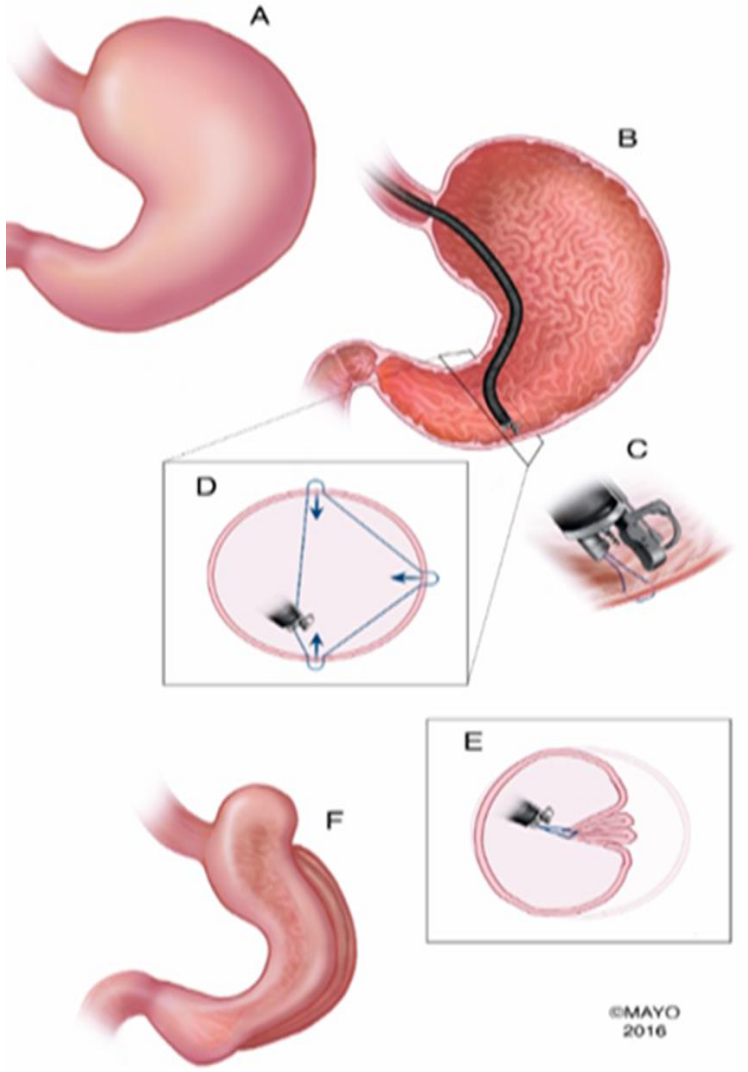
Ghrelin post ESG



PHYSIOLOGY OF ESG
CHANGES IN SATIATION ON MEAL TOLERANCE TEST

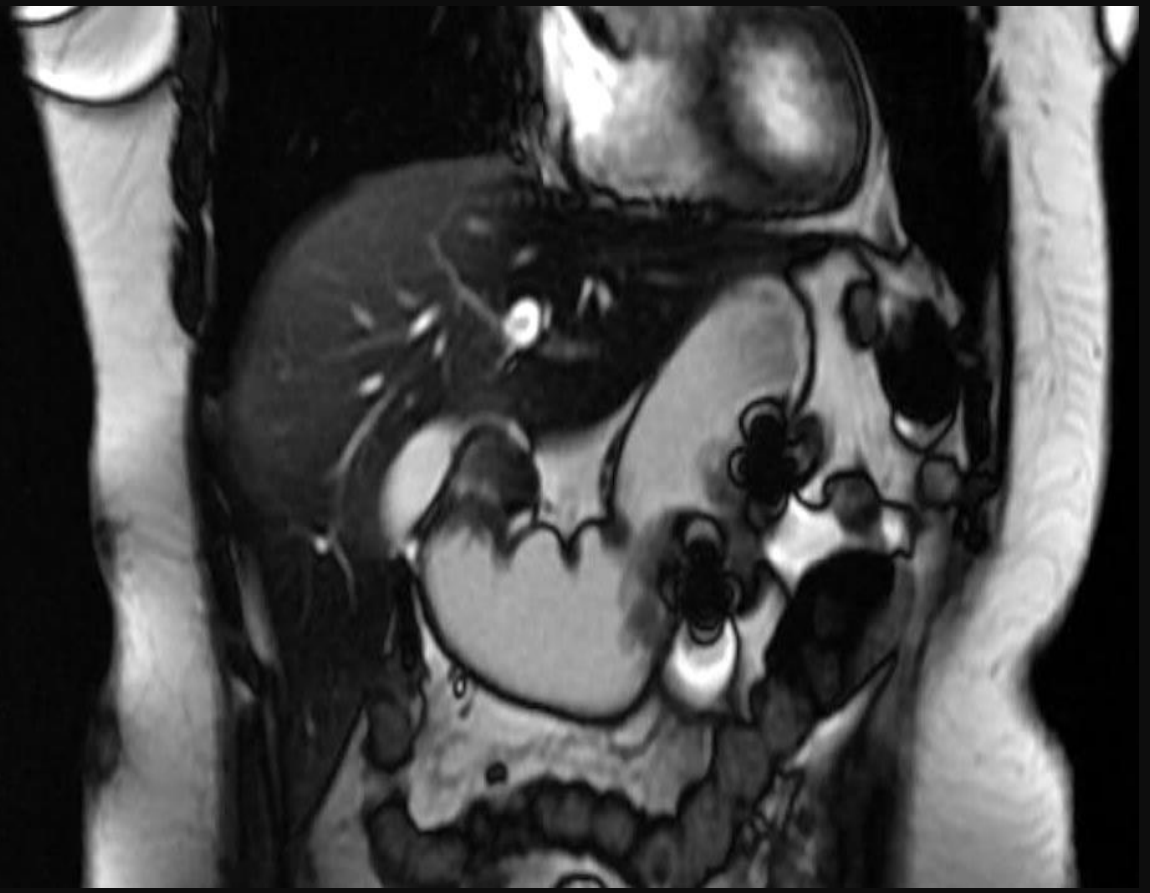


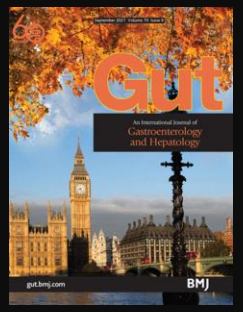
Endoscopic Sleeve Gastroplasty



Abu Dayyeh and Gostout GIE 2013 Sep;78(3):530-5

Abu Dayyeh BK, et al. Clin Gastroenterol Hepatol. 2017 Jan;15(1):37-43



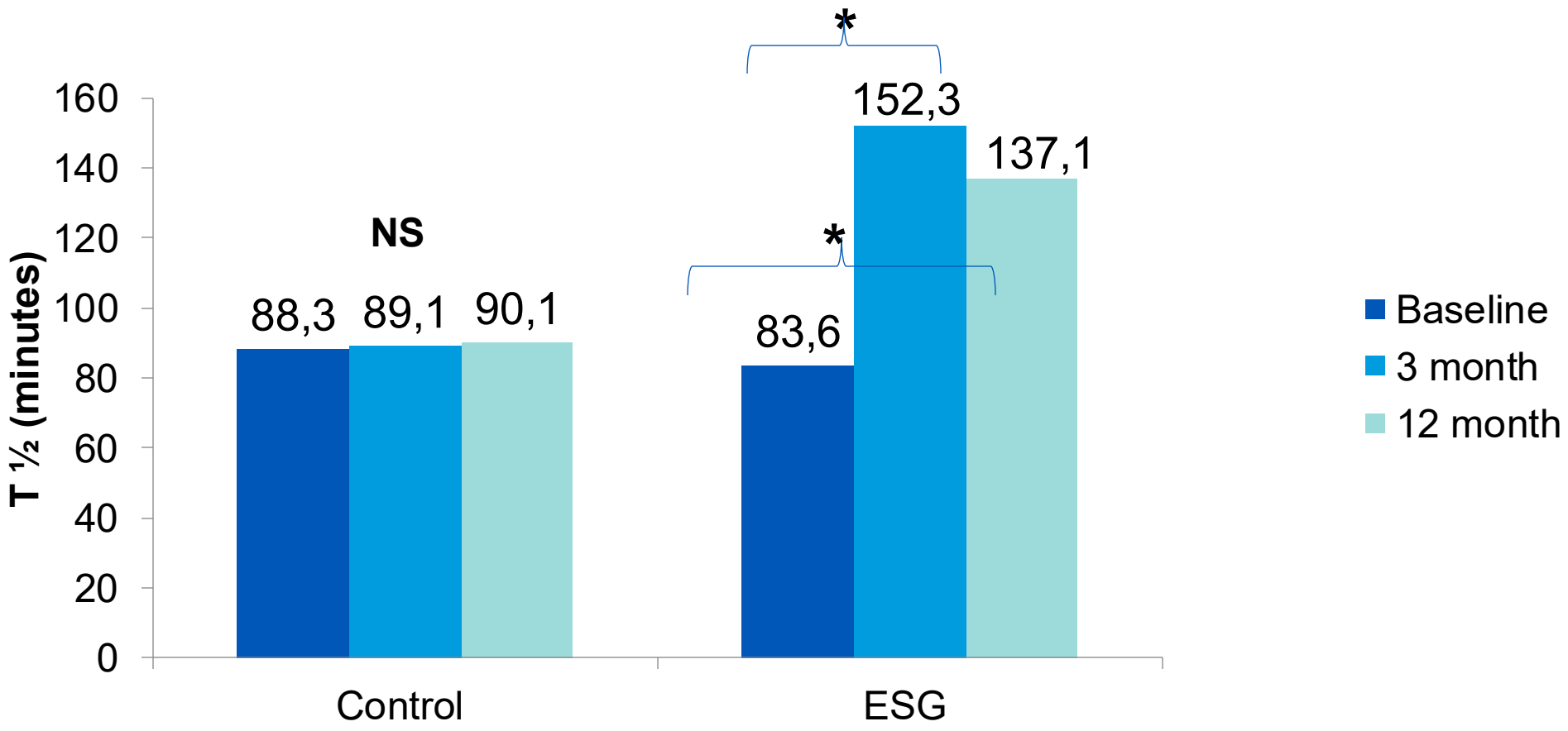


Original research

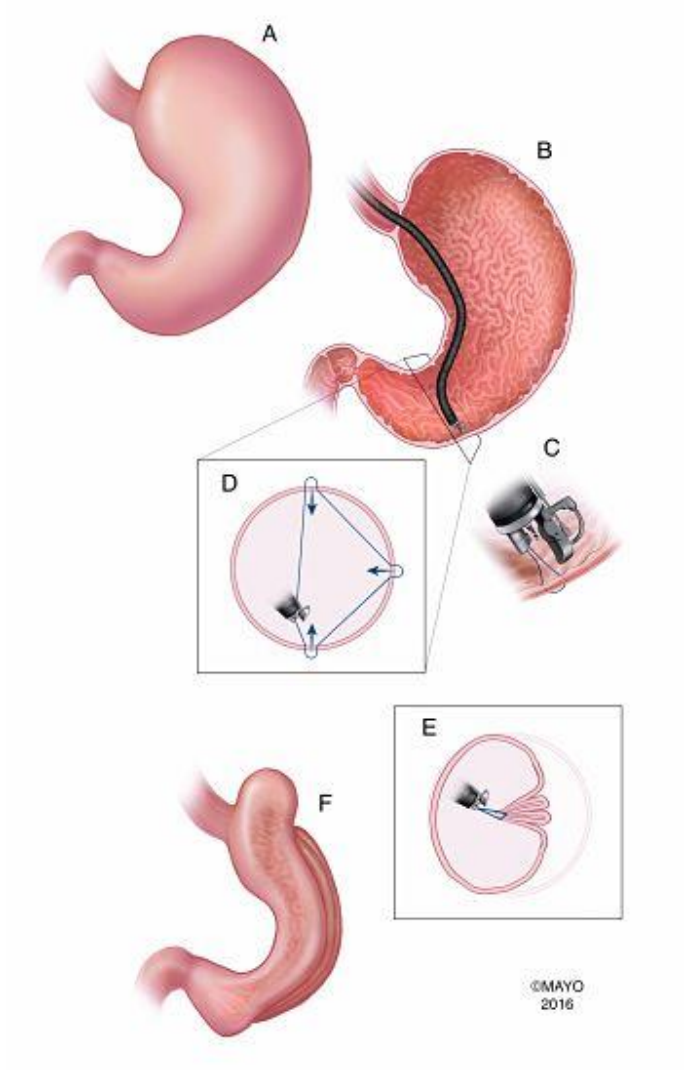
Effect of endoscopic sleeve gastroplasty on gastric emptying, motility and hormones: a comparative prospective study

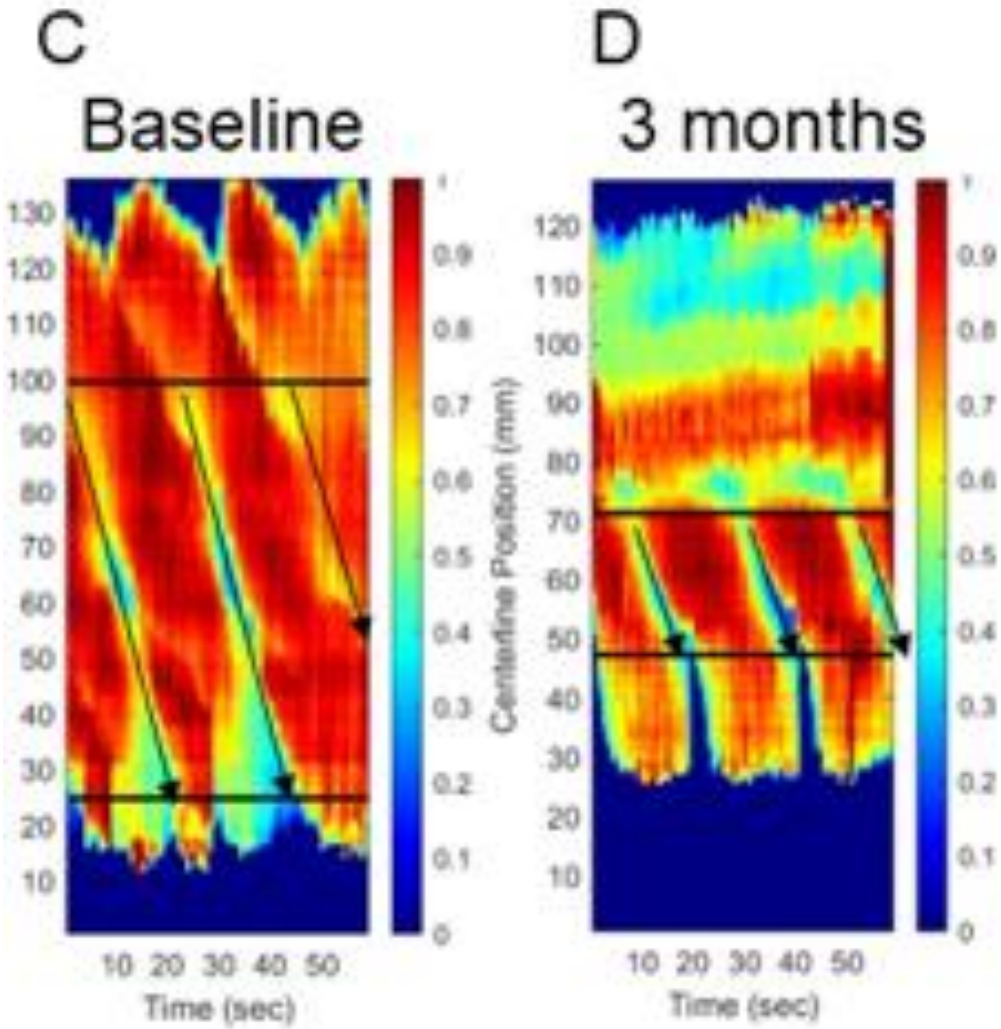
Eric J Vargas ,[1] Monika Rizk,[1] Jacky Gomez-Villa,[1] Phillip K Edwards,[2] Veeravich Jaruvongvanich,[1] Andrew C Storm,[1] Andres Acosta ,[1] David Lake,[2] Jeff Fidler,[3] Adil E Bharucha ,[1] Michael Camilleri ,[1] Barham K Abu Dayyeh [1]

Significant changes in gastric emptying at 3 and 12 months with the ESG

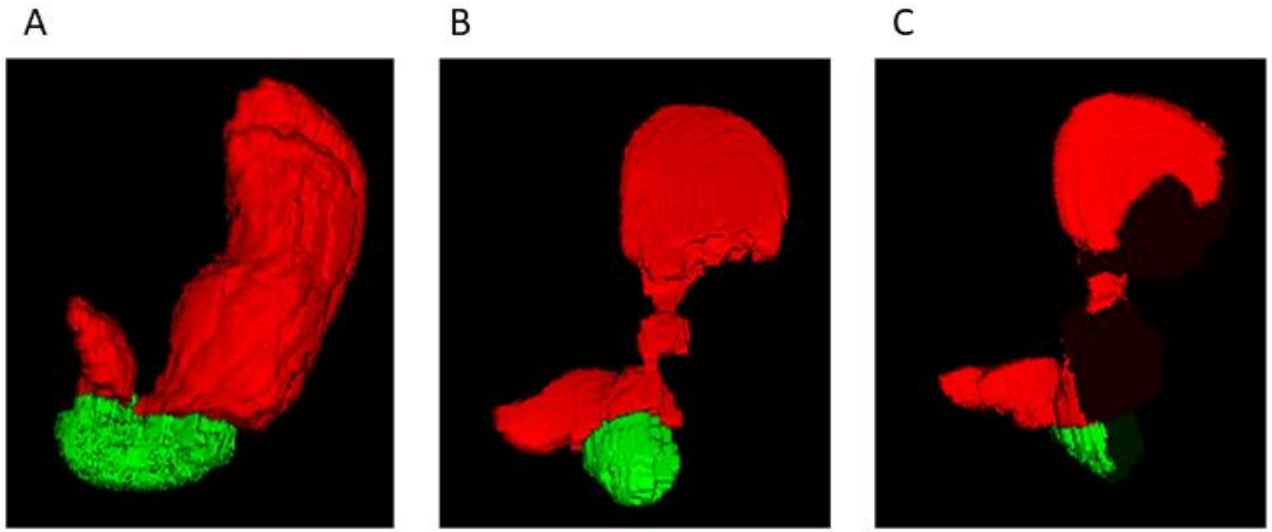


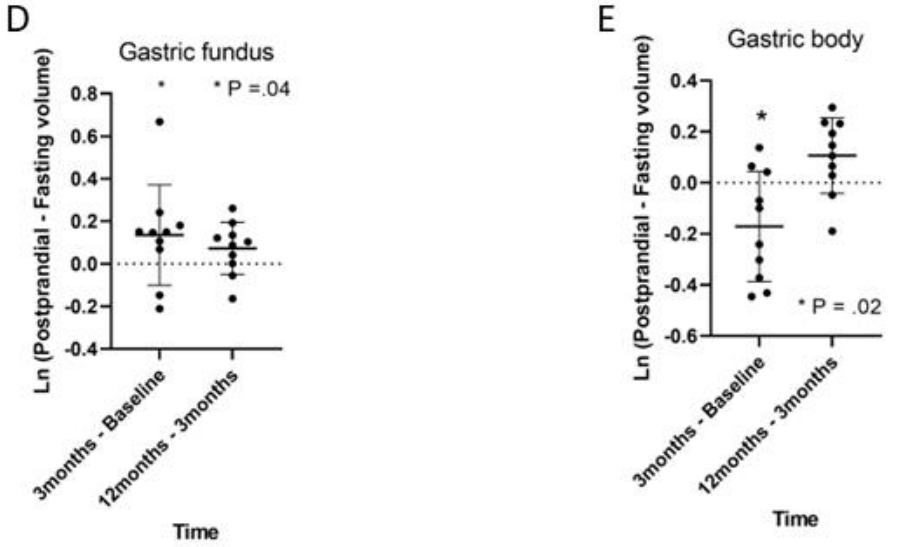
What happens to gastric motor function?





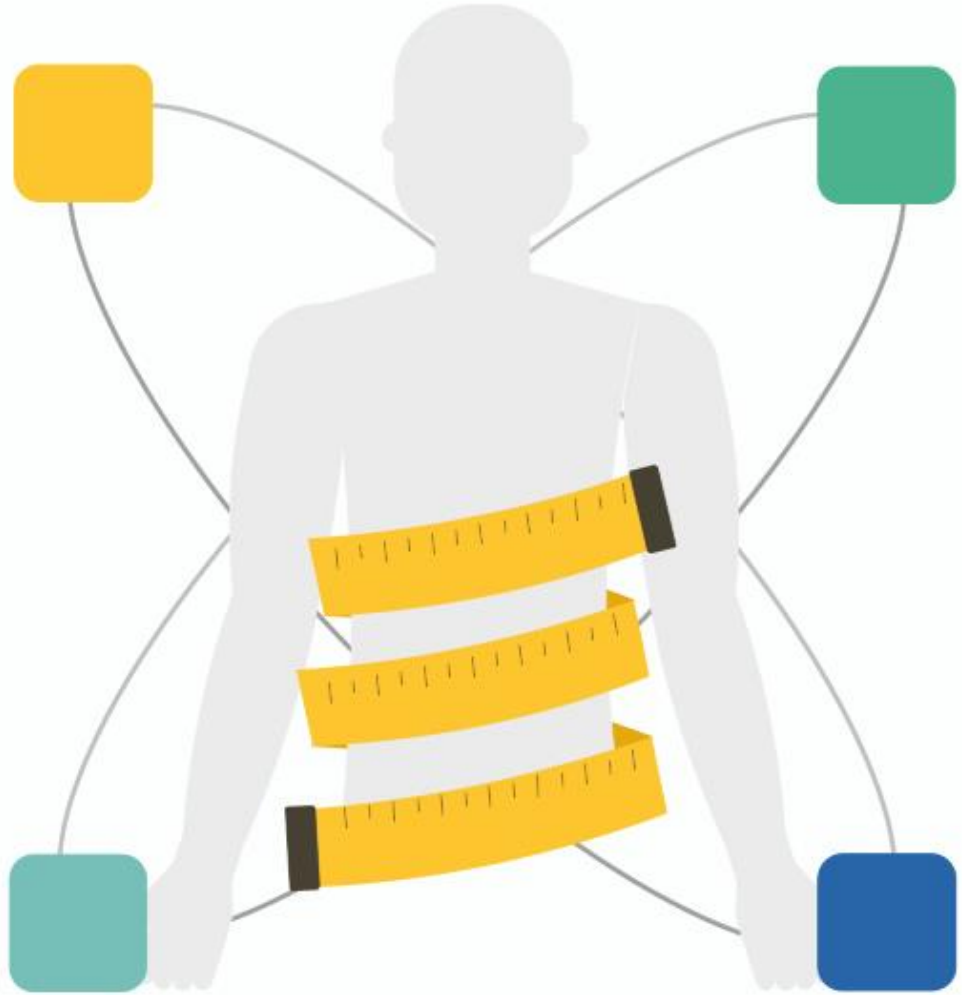
Changes in gastric accommodation after ESG





Organ Sparing

Safe Effective



No Long-Term Consequences

Minimal Disruption

STATE OF THE EVIDENCE

New Authorizations + Landmark Publication

FDA MARKET AUTHORIZATION

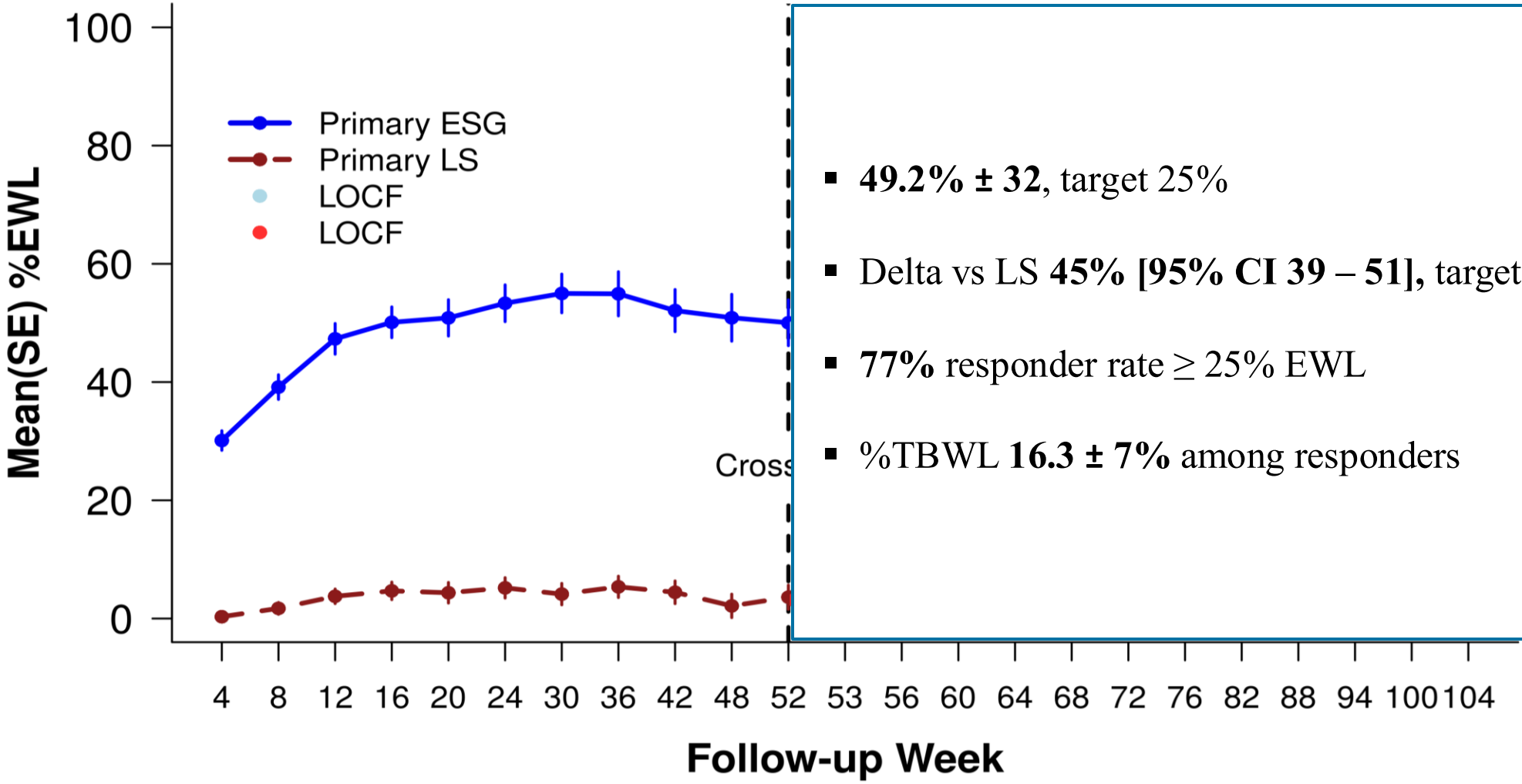
The FDA authorized for marketing the Apollo ESG & Revise Systems, the **first FDA-authorized systems for endoscopic sleeve gastroplasty**, a minimally invasive procedure **to facilitate weight loss**. It is intended for adults with obesity **(BMI 30-50 kg/m^2)** who have not been able to lose weight 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 Thaemert, 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

Efficacy & Durability



- **49.2% ± 32**, target 25%
- Delta vs LS **45% [95% CI 39 – 51],** target 15%
- **77%** responder rate ≥ 25% EWL
- %TBWL **16.3 ± 7%** among responders

Significant Impact on Comorbidities

ESG compared to standard of care

	ESG		SoC		p
	Improve	Worsen	Improve	Worsen	
Diabetes Mellitus Type II (DMII)	**93%**	0%	**15%**	44%	<0.001
Metabolic Syndrome	**83%**	0%	**35%**	38%	<0.001
Hypertension (HTN)	**67%**	6%	**40%**	23%	=0.01

DMII Parameters

ESG	Improve	Worsen	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

NAFLD+ Inflammation

ESG	Improve	Worsen	p
Hepatic Steatosis Index	-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

MERIT RESULTS: SAFETY

✓ Met primary safety endpoint

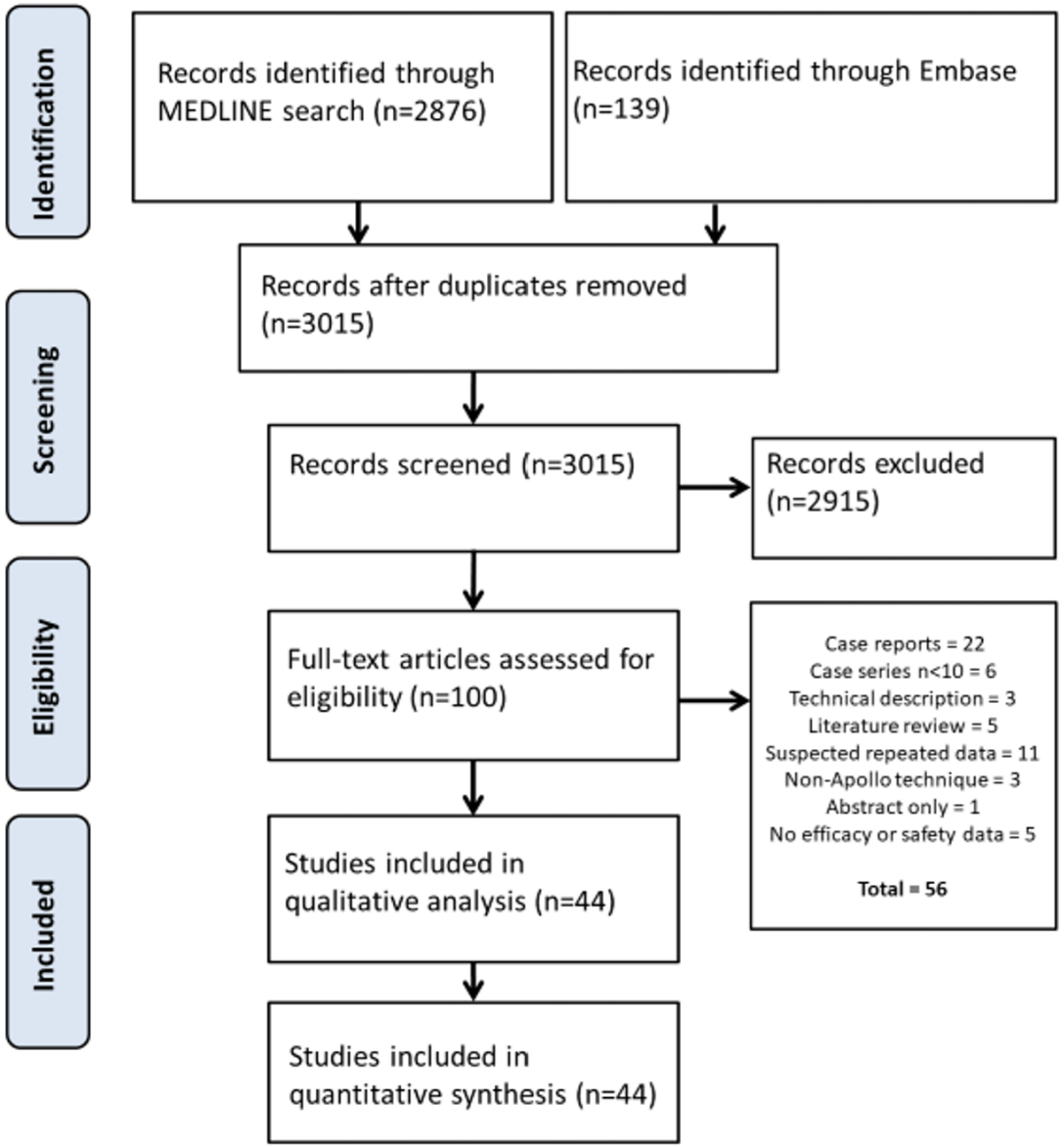
2%

SAE rate among all ESG completers n=150
All recovered

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

Peri-Gastric Abscess	**Upper GI Bleed**	**Malnutrition**
Endoscopy	Endoscopy	Endoscopic Reversal
Antibiotics	No transfusion	

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



N= 15,714 ESG in Peer-Reviewed Literature

Pooled **SAE** rate of **1.25%**

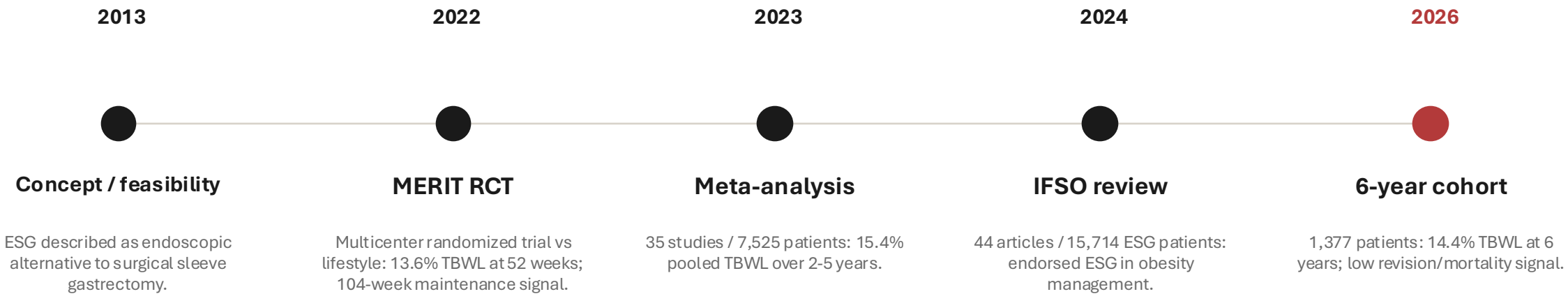
12 Months: %TBWL: **17.56%** (SE 0.39, 4118 patients)

24 Months: TBWL: **15.2%** (SE 0.93, 2123 patients)

36 Months: %TBWL: **14.07%** (SE 0.39), 922 patients)

EVIDENCE TIMELINE

Evidence base has matured from feasibility to longitudinal outcomes



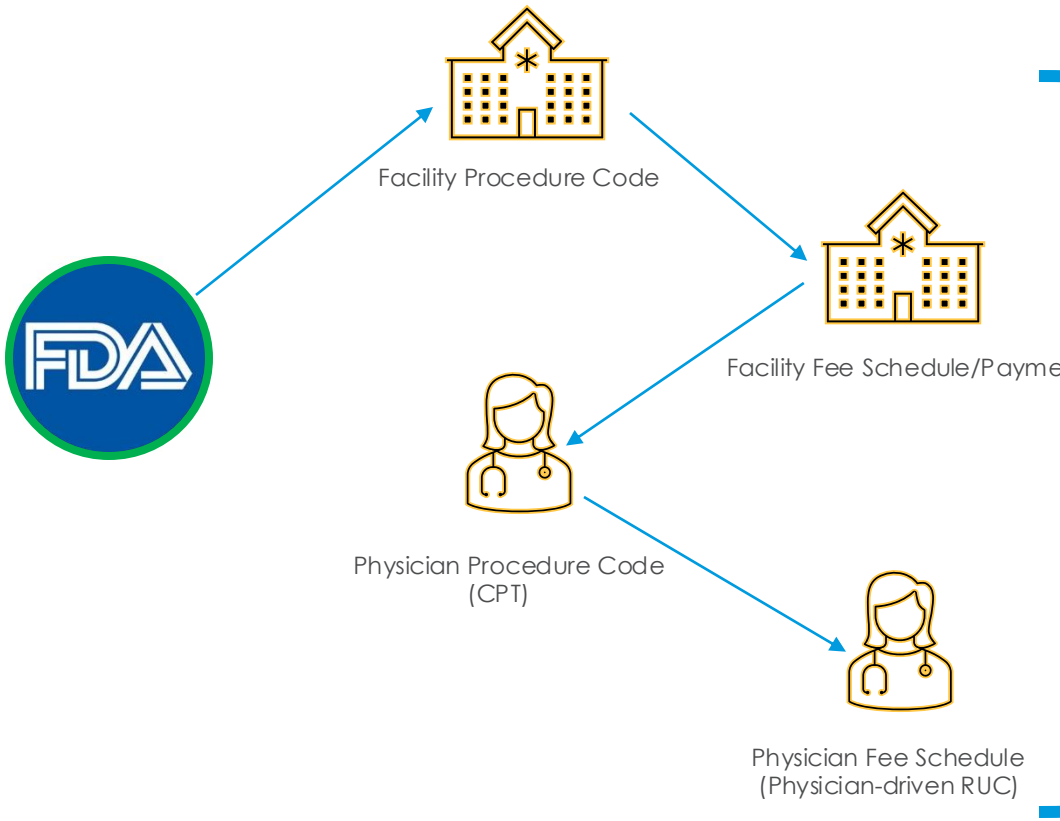
Sources: IFSO 2024 (PMID: 39482444); The LANCET MERIT 2022 (PMID: 35908555) ; Fehervari 2023 (PMID10602997) ; Neto 2026 (PMID41703242)

Boston Scientific
Advancing science for life™

apollo endosurgery

APOLLO ESG™ SYSTEM
APOLLO REVISE™ SYSTEM
REIMBURSEMENT UPDATE JUNE 2023

REIMBURSEMENT PROCESS STEPS



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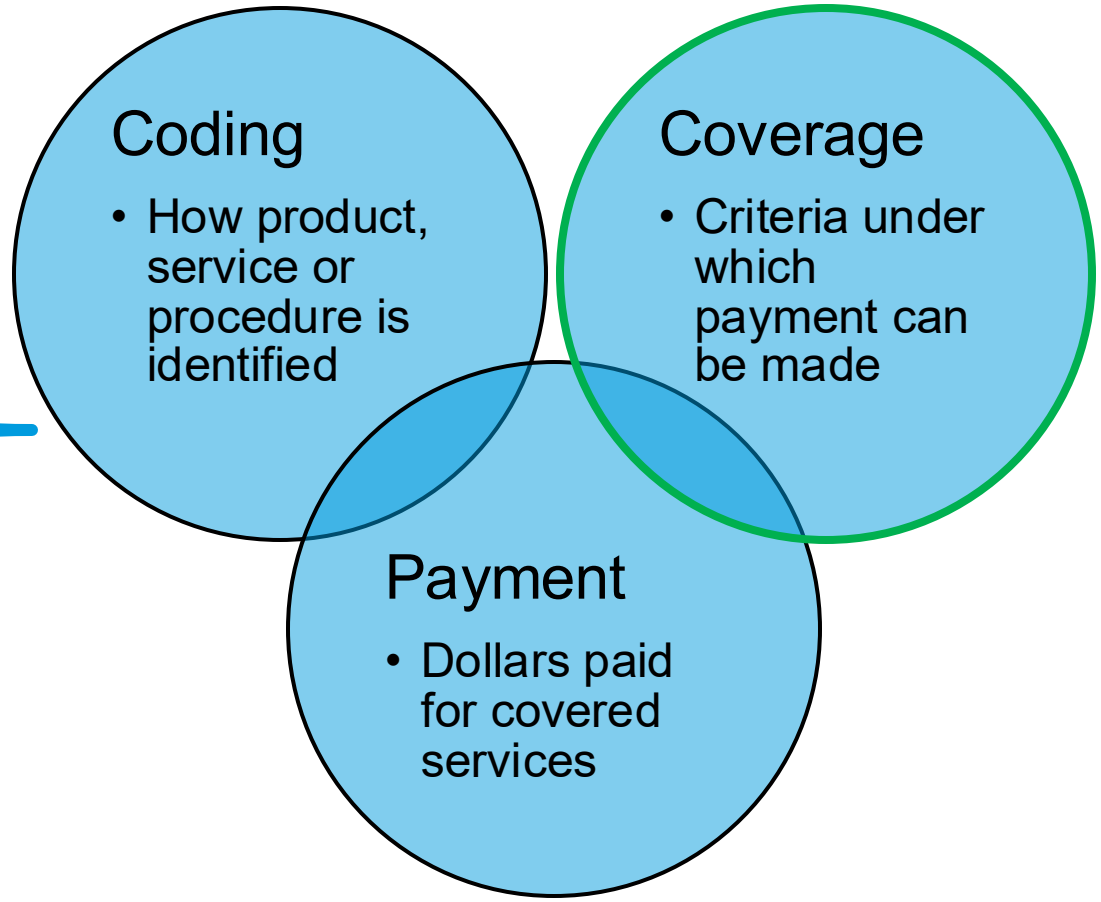


CPT Cat 1 Code 43889

Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed

Anthem

Clinical UM Guideline

Subject: Bariatric Surgery and Other Treatments for Clinically Severe Obesity
Guideline #: CG-SURG-83
Status: Revised
Publish Date: 12/18/2025
Last Review Date: 11/06/2025

Description

This document addresses surgical and other treatments for clinically severe obesity. Clinically severe obesity is a result of persistent and uncontrollable weight gain that constitutes a present or potential threat to life. There are a variety of surgical procedures and other treatment modalities intended for the treatment of clinically severe obesity.

Note: For additional information, please see:

- CG-MED-59 Upper Gastrointestinal Endoscopy in Adults
- CG-SURG-92 Paraesophageal Hernia Repair

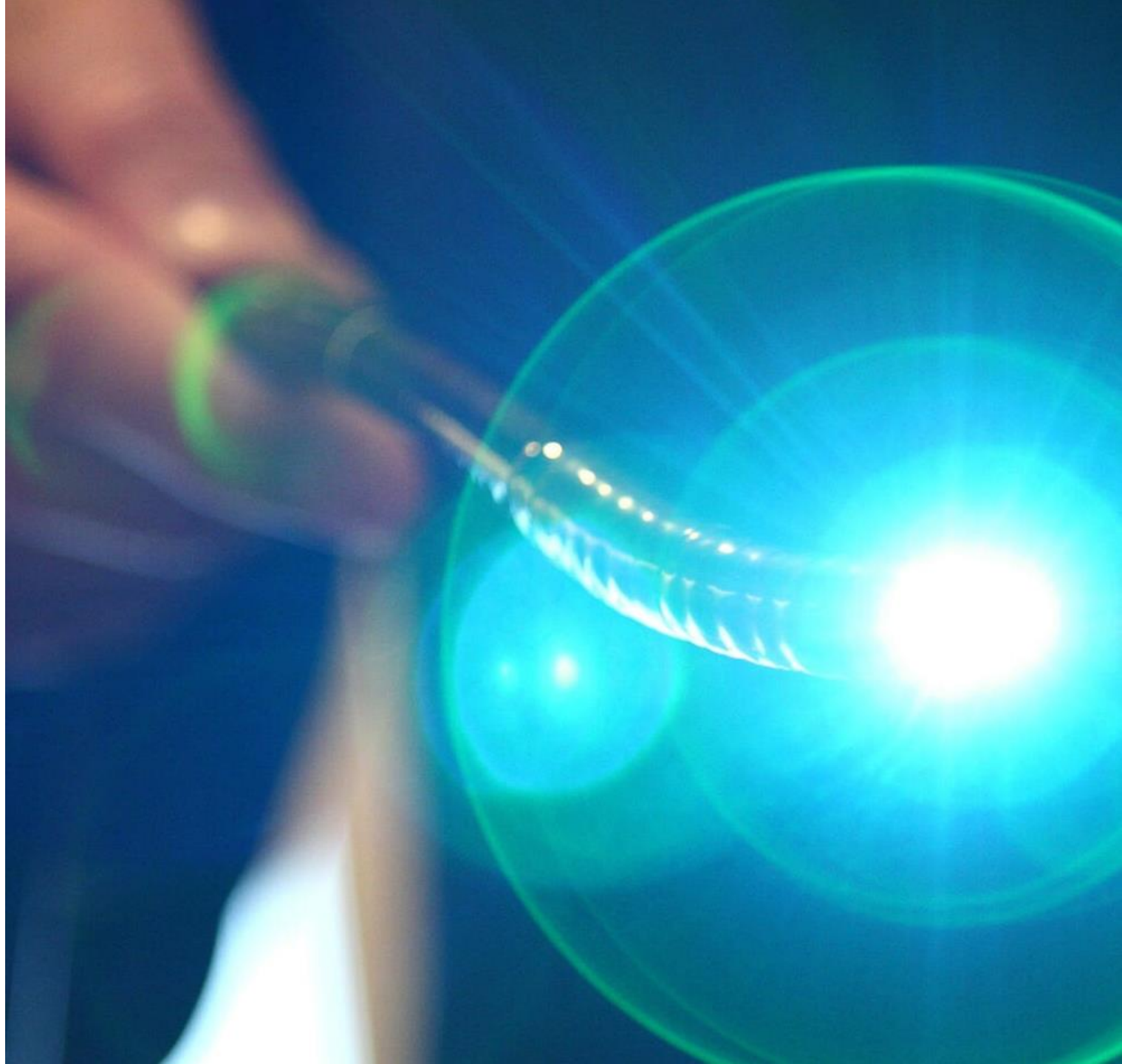
Clinical Indications

Medically Necessary:

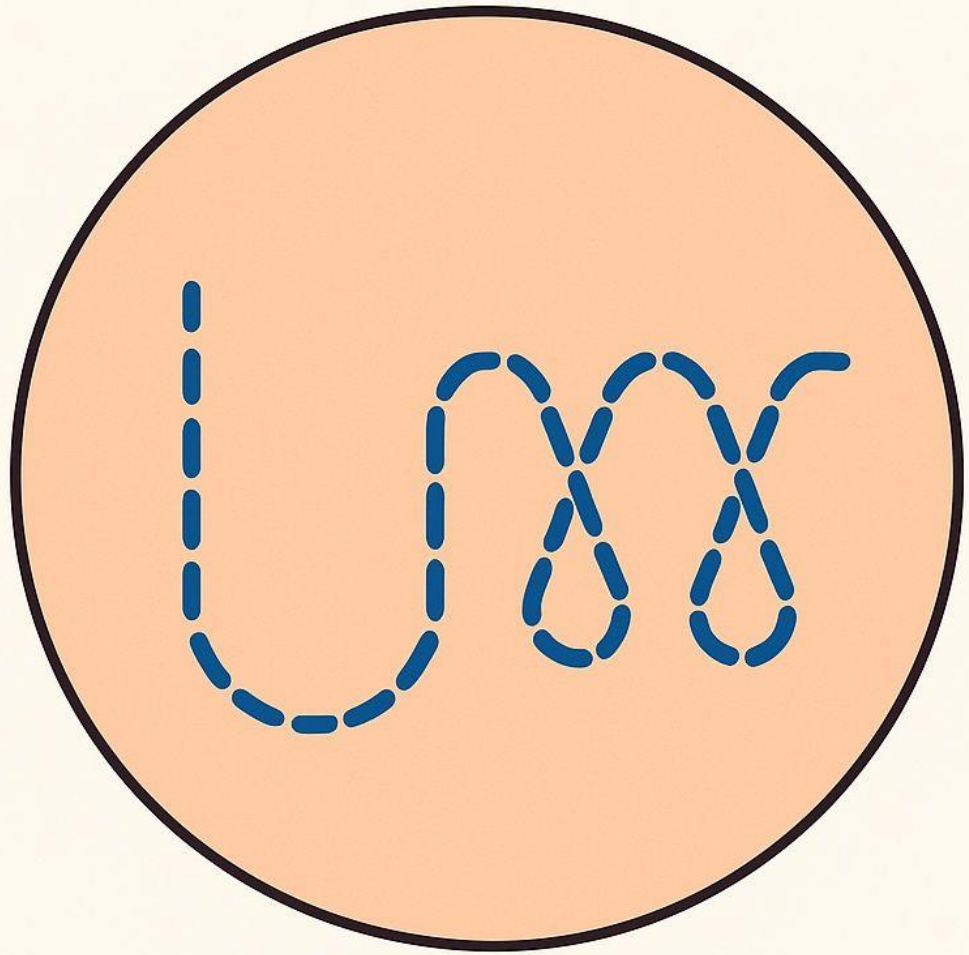
Gastric bypass and gastric restrictive procedures are considered **medically necessary** when **all** of the following criteria are met:

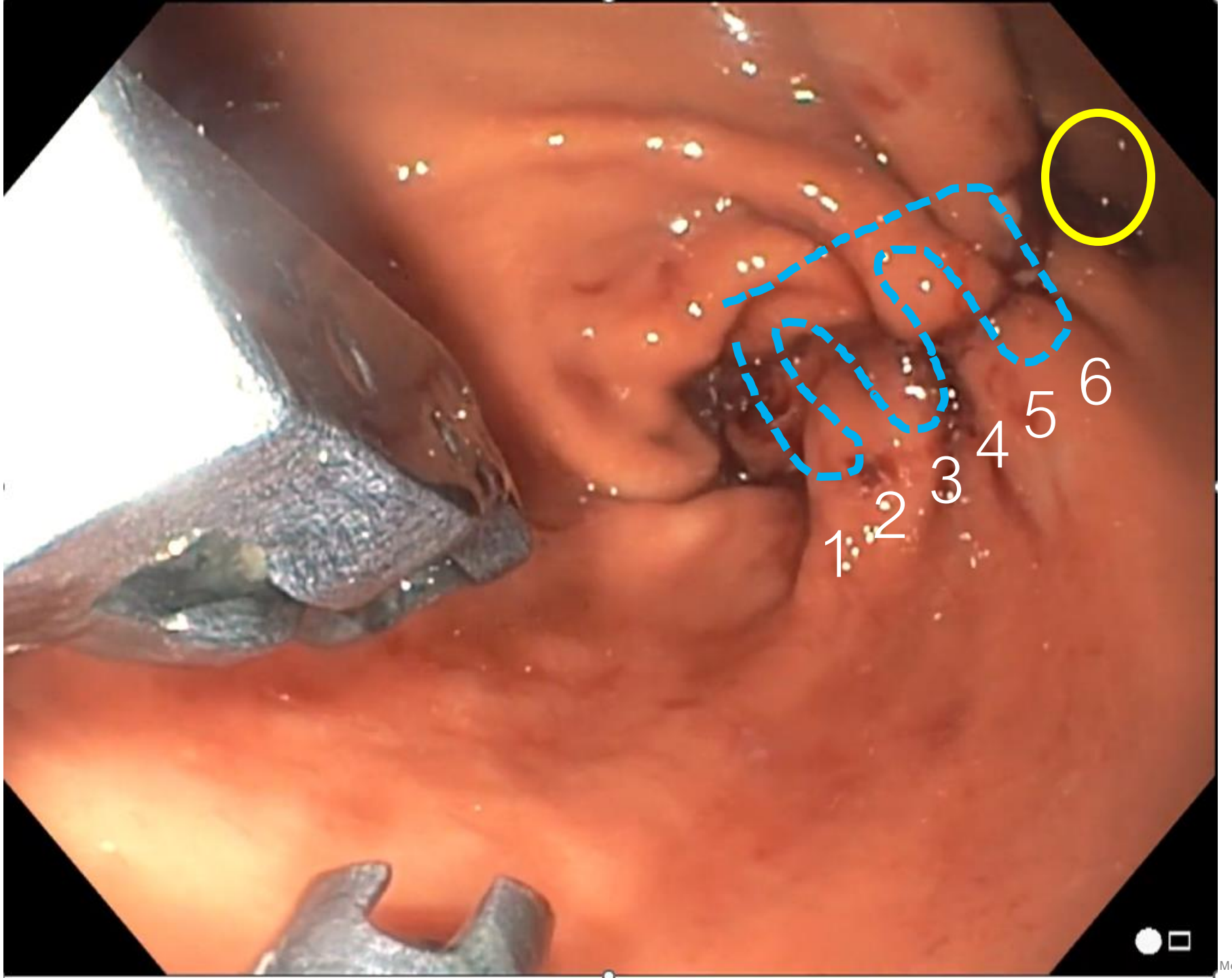
A. Individual is age 18 years or older; **and**
B. The recommended surgery is one of the following procedures:
    1. Biliopancreatic bypass with duodenal switch; **or**
    2. Endoscopic sleeve gastroplasty; **or**
    3. Laparoscopic adjustable gastric banding; **or**
    4. Roux-en-Y procedure up to 150 cm; **or**
    5. Single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S); **or**
    6. Duodenal jejunal bypass with gastric sleeve (DJB-SG); **or**
    7. Sleeve gastrectomy;
    and

INNOVATION & NEW BOUNDARIES



Interlocking ESG (iESG)

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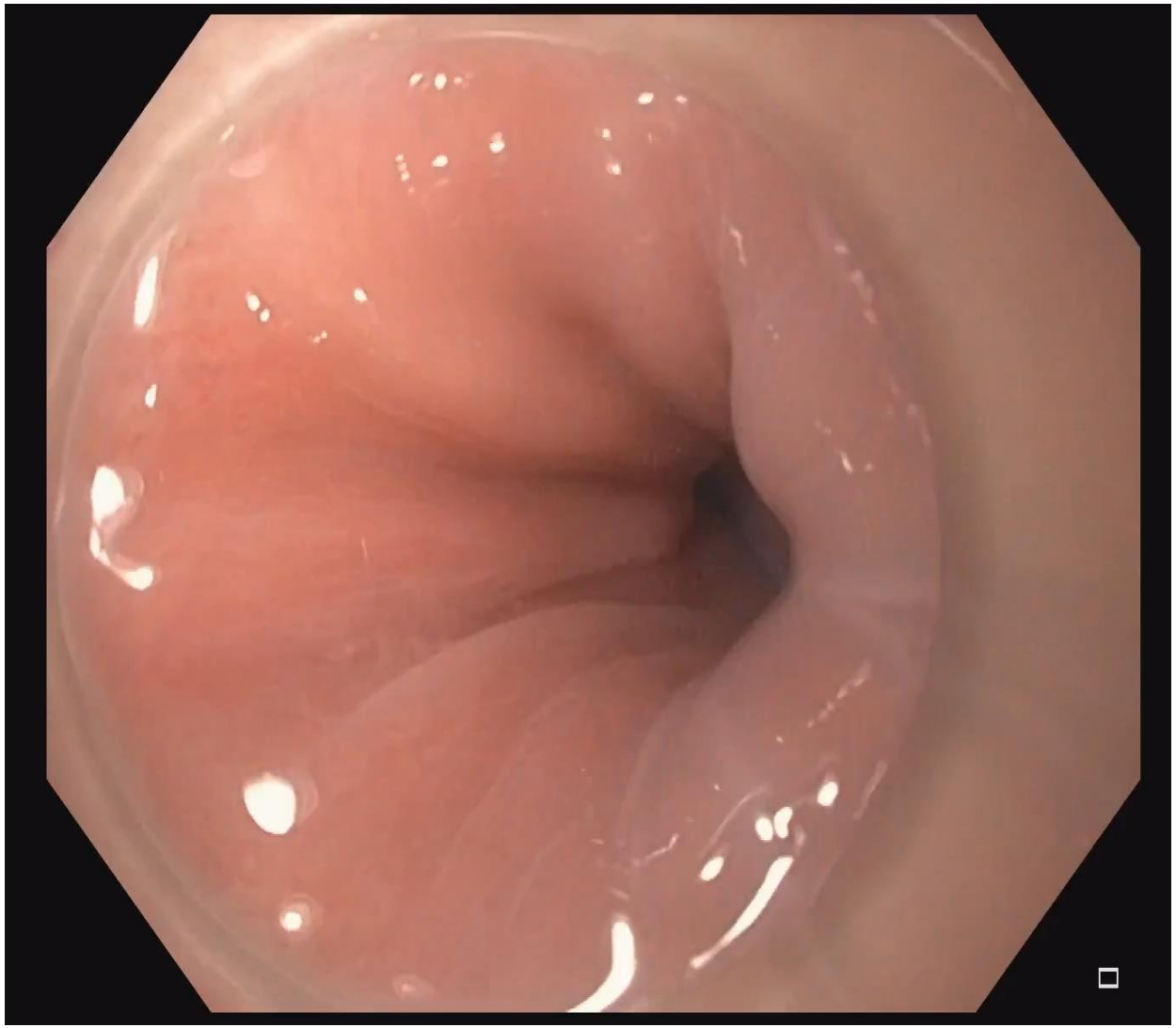
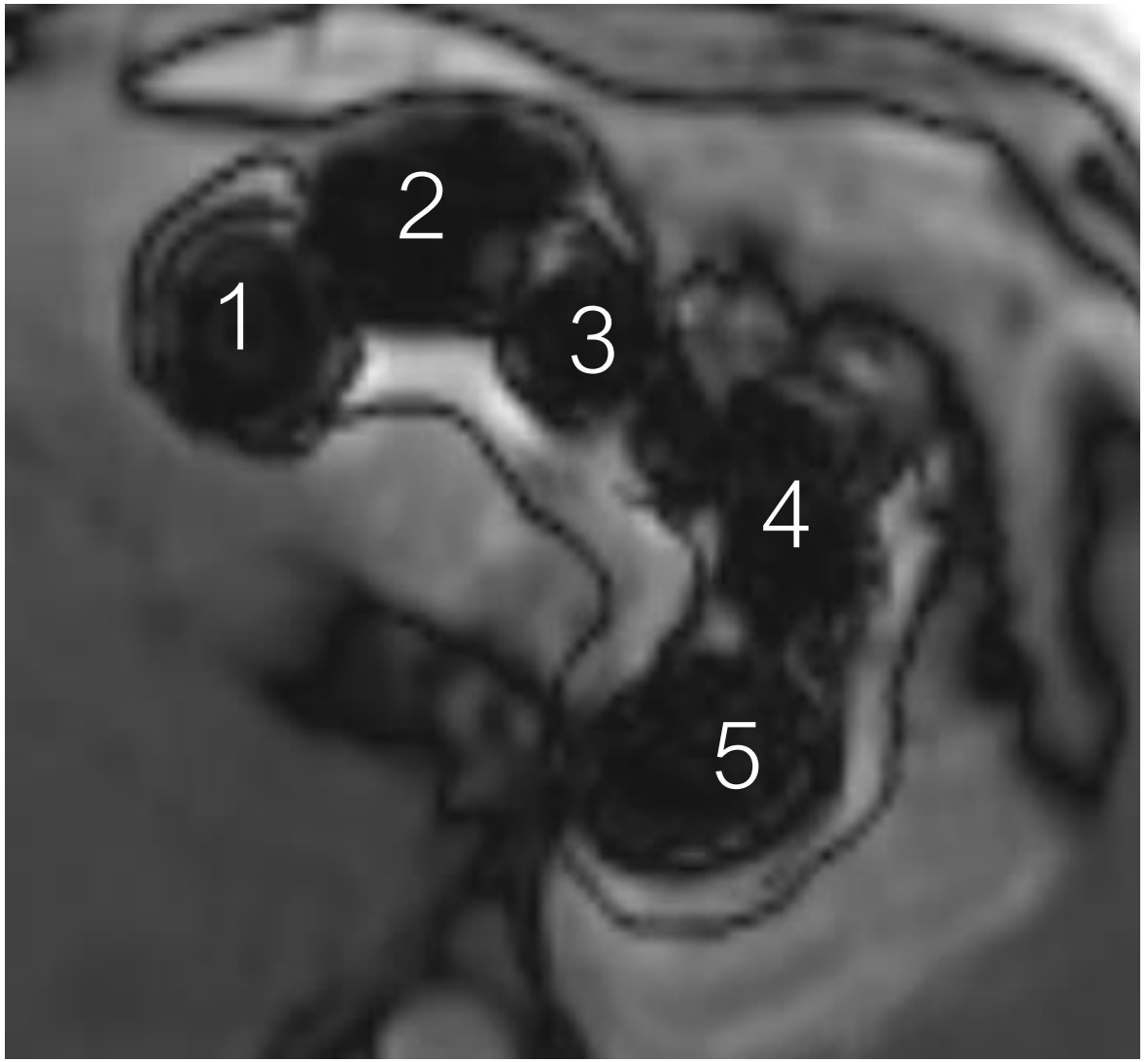
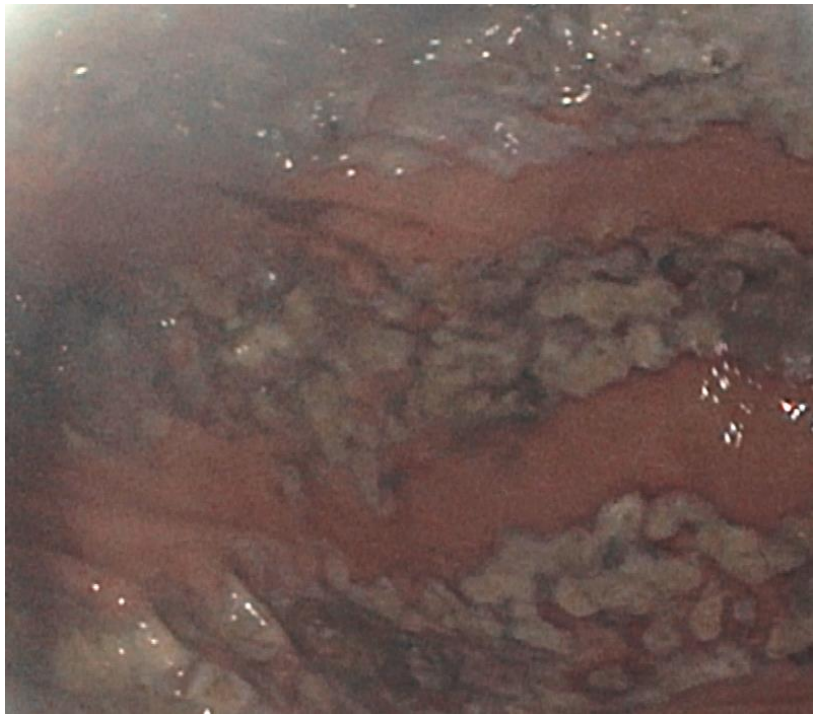


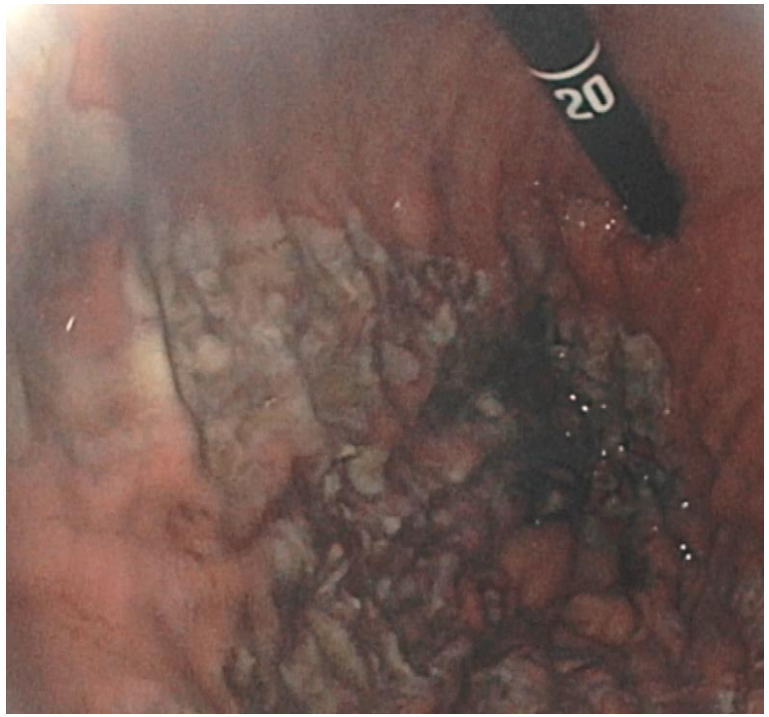


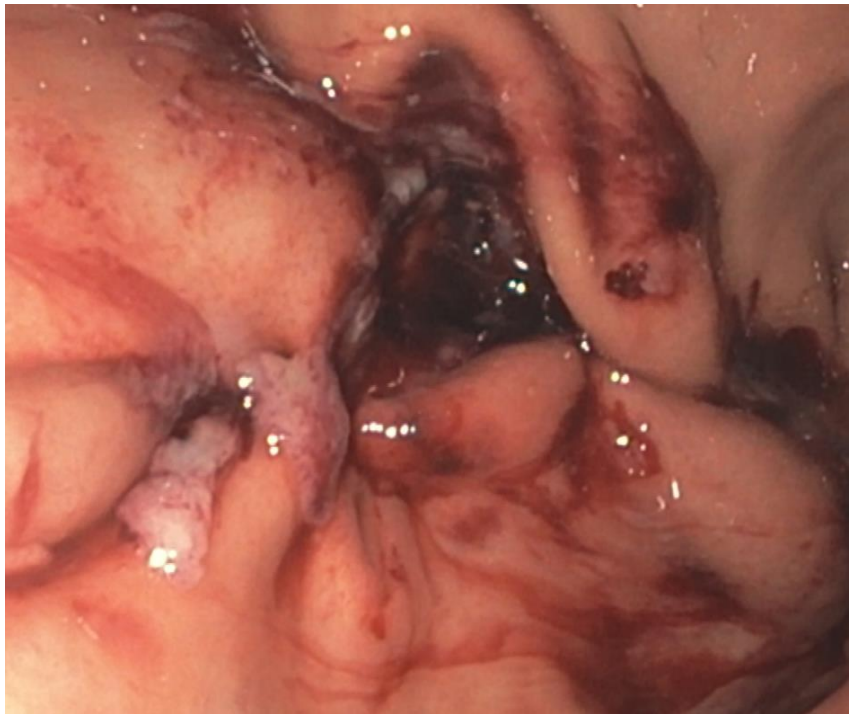
TBWL **23%** at 6 months

HYBRID GMA + ESG

- Wide-field HAPC from fundus to incisura
- Interlocking suture pattern







- Pilot randomized controlled trial (NCT05559866)

Baseline Screening & Enrollment

BMI ≥ 30 and ≤40 kg/m² with history of failure with non-surgical weight loss methods

Baseline assessment and tests
Informed consent

Single-Blind Randomization

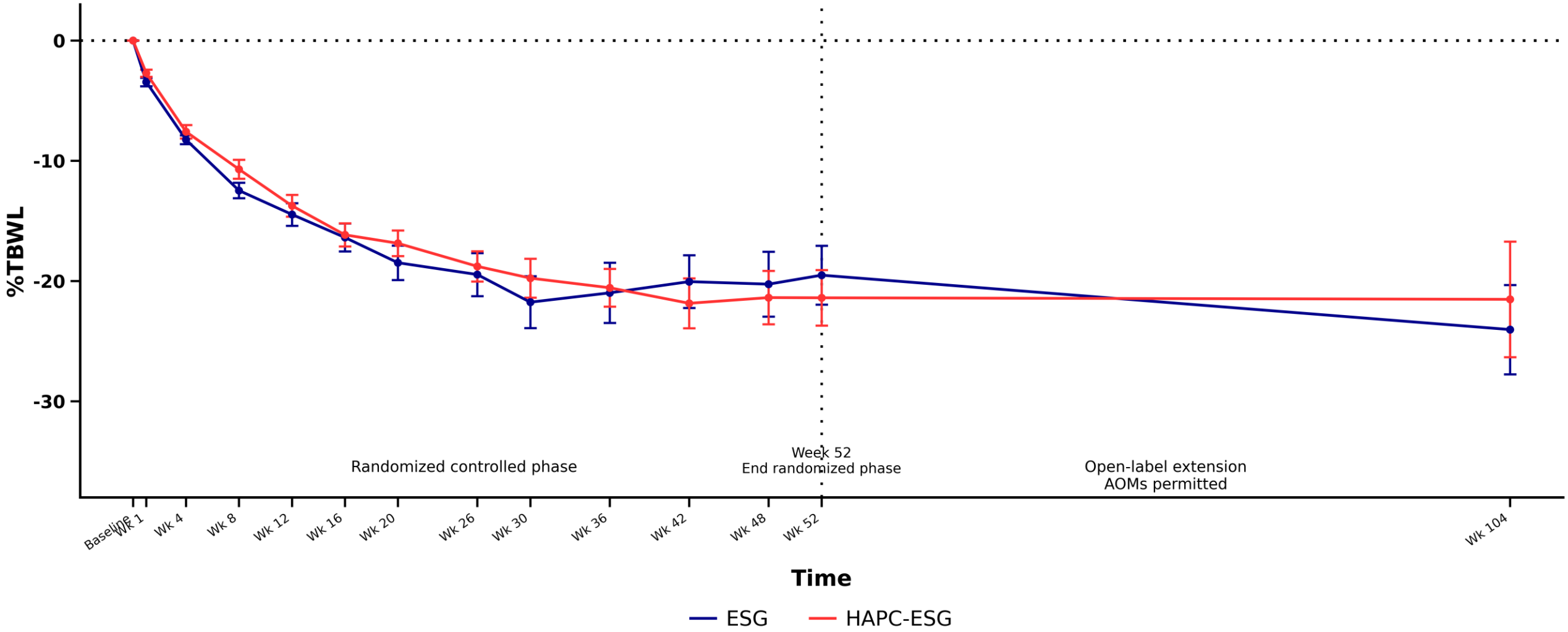
1:1 randomization to either ESG or HAPC-ESG

ESG (n = 12) | **HAPC-ESG** (n = 12)

Follow-up: week 1, 4, every 4 weeks following till 52 weeks

Baseline assessment & tests

- Weight, height, BMI, waist and hip measurements
- Nutritional assessment
- Psychological assessment
- Pregnancy test if indicated
- EKG for all patients
- Questionnaires
- Post-enrollment nutrition/exertion/satiety counseling and assessment
- Laboratory tests
- H-Pylori breath test
- Gastric MRI
- Gastric emptying scintigraphy



	0	1	4	8	12	16	20	26	30	36	42	48	52	104
ESG	0.0% (n=12)	3.5% (n=12)	8.3% (n=12)	12.5% (n=12)	14.5% (n=12)	16.4% (n=12)	18.5% (n=12)	19.5% (n=12)	21.8% (n=9)	21.0% (n=9)	20.1% (n=11)	20.3% (n=9)	19.5% (n=11)	24.0% (n=9)
HAPC-ESG	0.0% (n=12)	2.7% (n=12)	7.6% (n=12)	10.7% (n=11)	13.7% (n=12)	16.2% (n=11)	16.9% (n=12)	18.8% (n=12)	19.8% (n=11)	20.6% (n=12)	21.9% (n=12)	21.4% (n=12)	21.4% (n=12)	21.5% (n=7)

Table values show mean %TBWL and number evaluated at each time point. Error bars show standard error.

VALUE ADDED TO METABOLIC DISEASE CARE

Scalable

Durable

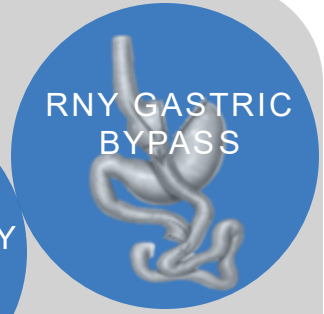
Value

EFFICACY & DURABILITY

ESG +

Medications

ESG



SURGICAL OPTIONS

INVASIVENESS

GLP-1s Adverse Events

nature medicine

Article

https://doi.org/10.1038/s41591-024-03412-w

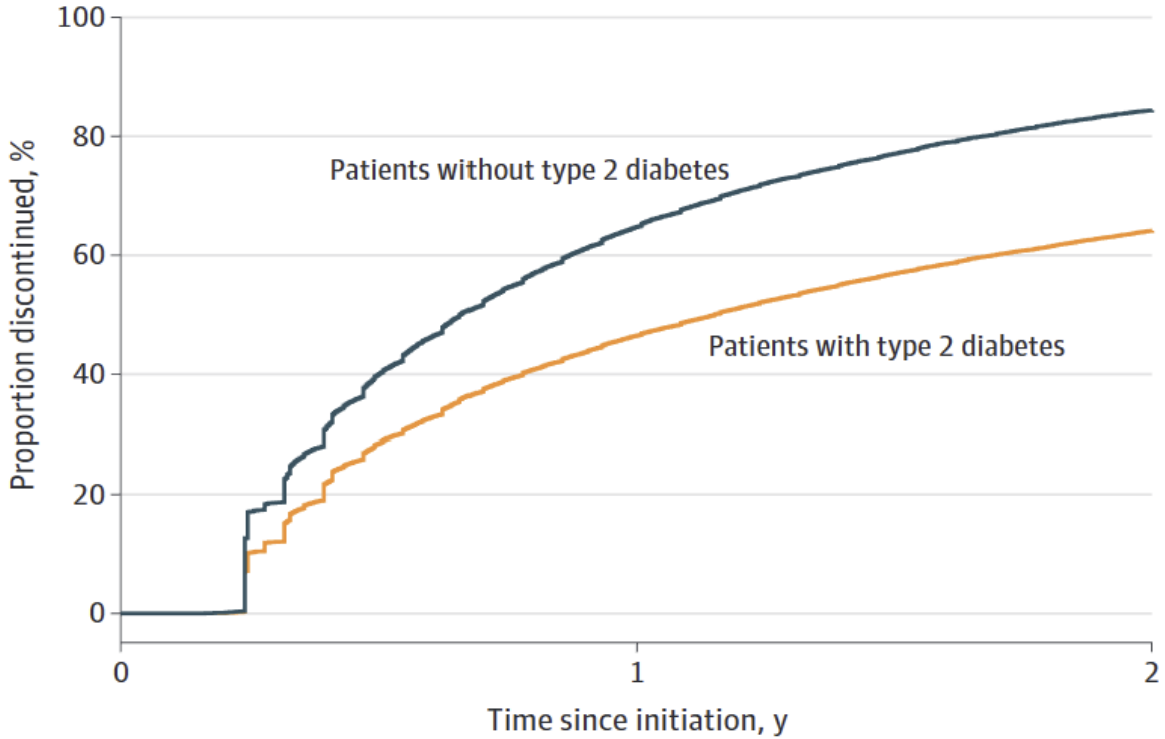
Mapping the effectiveness and risks of GLP-1 receptor agonists

Received: 14 June 2024

Yan Xie[1,2,3,4], Taeyoung Choi[1,2] & Ziyad Al-Aly[1,2,5,6,7]

- **Study Design:** VA databases to compare GLP-1RA (n=215,970) with other diabetes treatments and usual care across 175 health outcomes.
- **Benefits:** GLP-1RA use reduced risks of neurocognitive disorders, cardiometabolic disorders, infectious diseases, and respiratory conditions.
- **Risks:** Increased risks of GI disorders, hypotension, syncope, nephrolithiasis, and pancreatitis.

GLP-1s Discontinuation



No. at risk			
Patients with type 2 diabetes	76 524	36 709	10 774
Patients without type 2 diabetes	48 950	15 696	2750

GLP-1s Resistance

Diabetologia. 2025 May 22. doi: 10.1007/s00125-025-06448-w. Online ahead of print.

Heterogeneity in response to GLP-1 receptor agonists in type 2 diabetes in real-world clinical practice: insights from the DPV register - an IMI-SOPHIA study

Martin Heni [1 2], Lisa Frühwald [3], Wolfram Karges [4], Michael Naudorf [5], Kathrin Niemöller [6], Frank Pagnia [7], Jörg Reindel [8], Jochen Seufert [9], Gisa Ufer [10], Christian Wagner [11], Reinhard W Holl [12 13], Nicole Prinz [12 13]

4,467 adults with type 2 diabetes starting GLP-1 receptor agonist (GLP-1 RA) therapy

Patient Response Groups at 6 Months

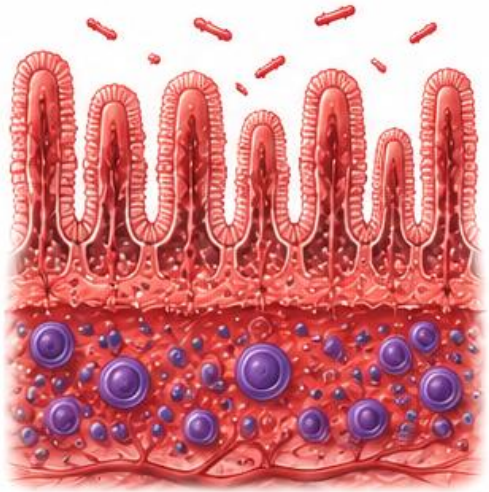
Response Group	% of Patients	Median HbA1c Reduction (%)
Both HbA1c & Weight Loss	14%	≥0.5%
HbA1c Reduction Only	36%	≥0.5%
Weight Loss Only	7%	<0.5%
Neither	43%	<0.5%

Reprogrammable Biology


AI

1. DISEASE BEGINS IN TISSUE

Metabolic Duodenopathy



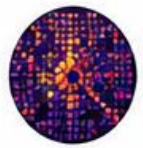
↑ INFLAMMATION

- Dysbiosis (imbalanced microbiome)
- Loose / leaky tight junctions
- Increased permeability (leaky barrier)
- Immune cell infiltration
- Inflamed submucosa

2. MULTIMODAL INTELLIGENCE

See What Matters

Endoscopic Imaging

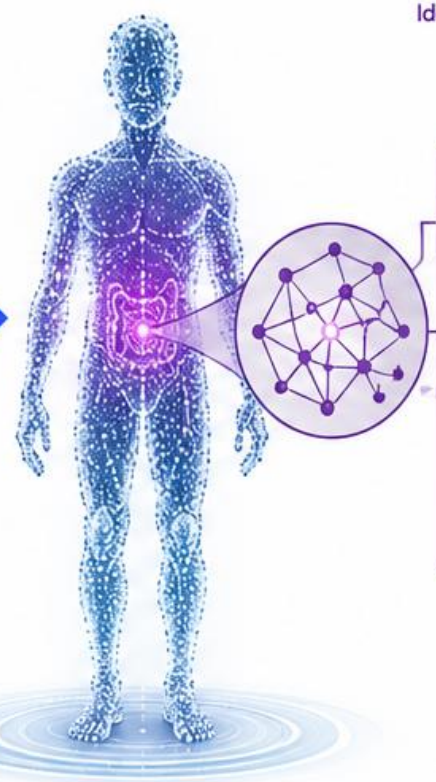


Spatial Molecular Biology

Clinical & Phenotypic Data

3. DIGITAL BIOLOGICAL TWIN

Your Avatar



4. PREDICTED DISEASE MECHANISM

Identify the Dominant Driver

- Inflammation
- Metabolic Dysfunction
- Tissue Remodeling

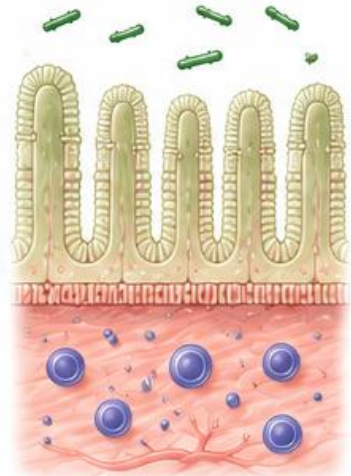
5. OPTIMAL THERAPY

Reprogram the Biology

- Endoscopic Therapy
- Endoscopic Regenerative Modalities
- Metabolic Surgery

6. TISSUE RESTORED

Metabolic Health



↓ INFLAMMATION RESOLVED

- Healthy microbiome
- Normal tight junctions
- Intact barrier (normal permeability)
- Reduced immune activation
- Healthy submucosa

THE OLD PARADIGM

Manage the Consequences

Measure Numbers → Treat Symptoms → Manage Disease

Temporary control. Disease persists.

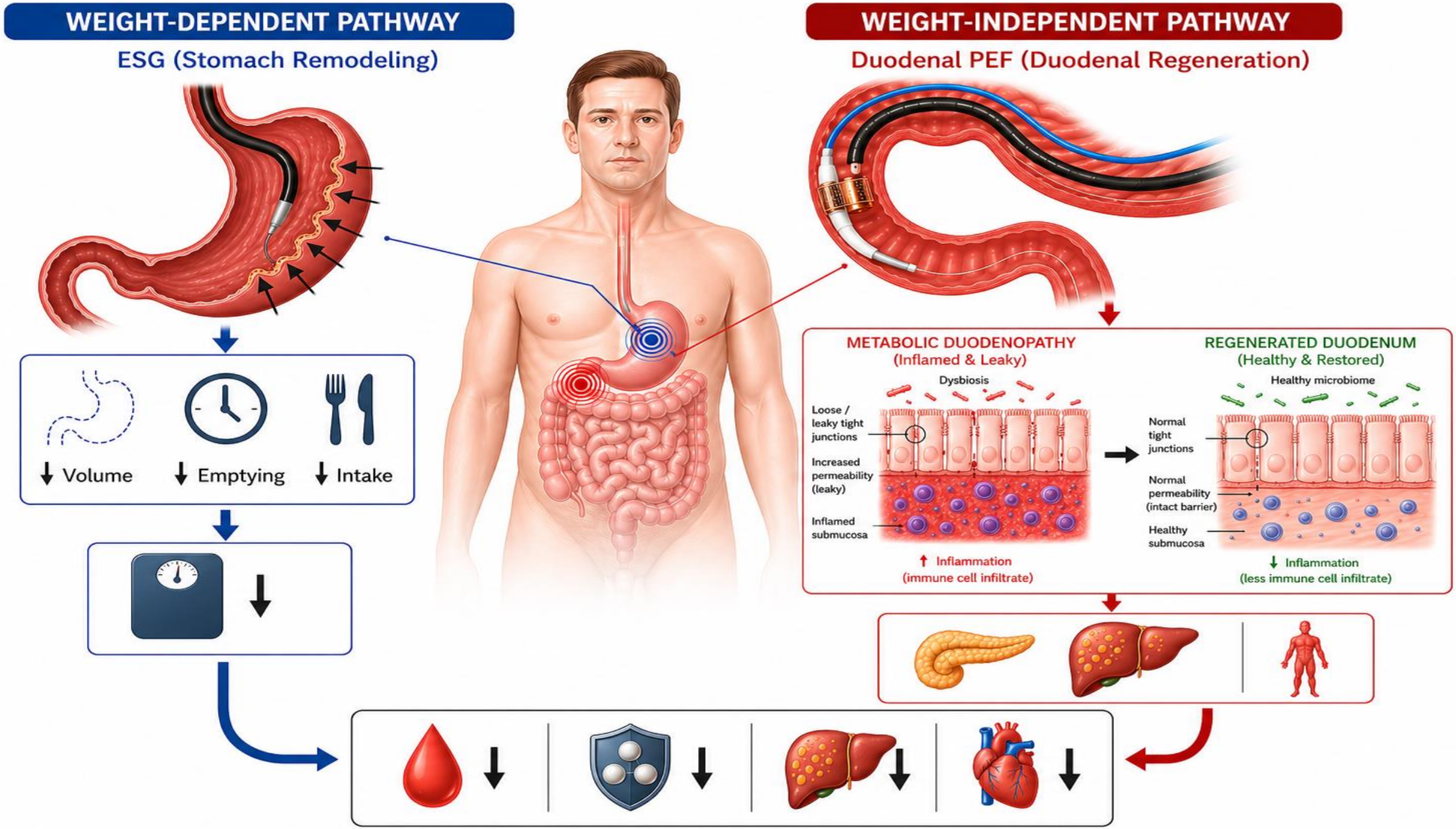
»

THE NEW HORIZON

Reprogram the Biology

Understand Tissue Biology → Identify Root Cause → Reprogram Biology → Reverse Disease

Address the cause. Restore health.


WEIGHT-DEPENDENT PATHWAY
ESG (Stomach Remodeling)
WEIGHT-INDEPENDENT PATHWAY
Duodenal PEF (Duodenal Regeneration)
↓ Volume
↓ Emptying
↓ Intake
METABOLIC DUODENOPATHY
(Inflamed & Leaky)
Dysbiosis
Loose / leaky tight junctions
Increased permeability (leaky)
Inflamed submucosa
↑ Inflammation
(immune cell infiltrate)
REGENERATED DUODENUM
(Healthy & Restored)
Healthy microbiome
Normal tight junctions
Normal permeability (intact barrier)
Healthy submucosa
↓ Inflammation
(less immune cell infiltrate)

Questions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