



IFSO 2023

THE MODE OF ACTION OF ESG: PHYSIOLOGY + MERIT

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DISCLOSURES

- **Consultant:** Boston Scientific, Metamodix, BFKW, Apollo Endosurgery, Medtronic, Endogenex
- **Cofounder:** Endogenex
- **Research Support:** Apollo Endosurgery, USGI, Endogastric Solutions, Boston Scientific, Medtronic, Spatz, Cairn.
- **Speaker:** Johnson & Johnson, Olympus, Endogastric Solutions

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THE UNMET NEED

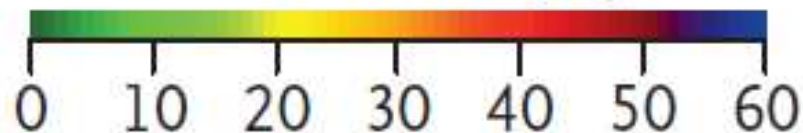


SPECIAL ARTICLE

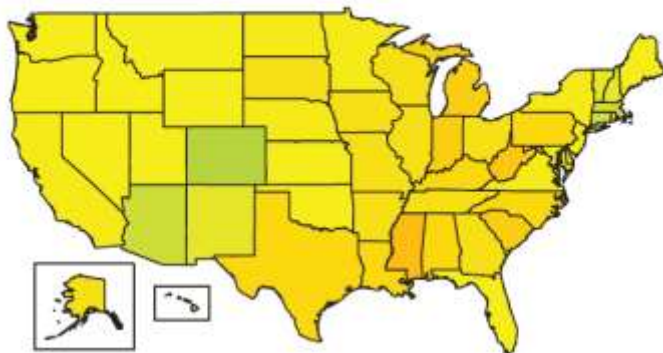
Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity

Zachary J. Ward, M.P.H., Sara N. Bleich, Ph.D., Angie L. Cradock, Sc.D.,
Jessica L. Barrett, M.P.H., Catherine M. Giles, M.P.H., Chasmine Flax, M.P.H.,
Michael W. Long, Sc.D., and Steven L. Gortmaker, Ph.D.

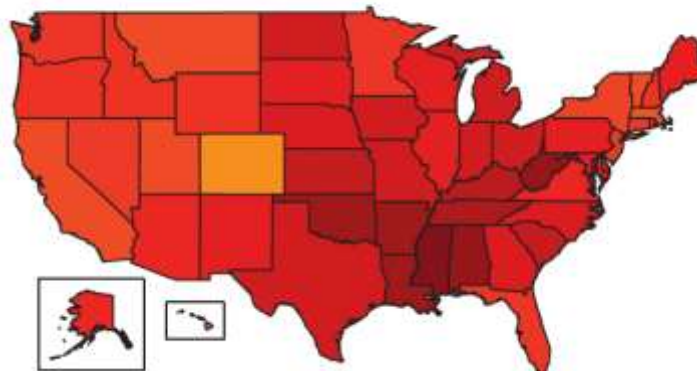
Prevalence (%)



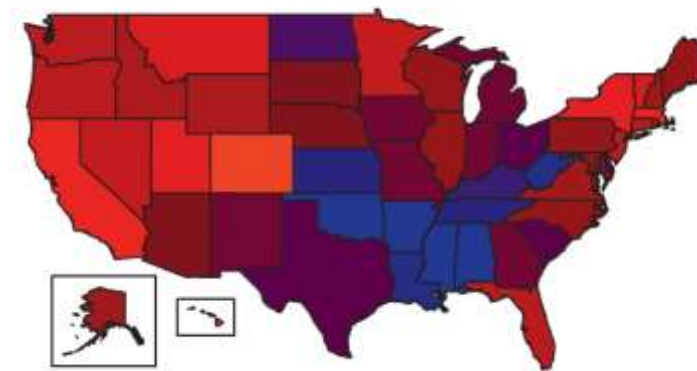
Prevalence of Overall Obesity (BMI, ≥ 30)
1990



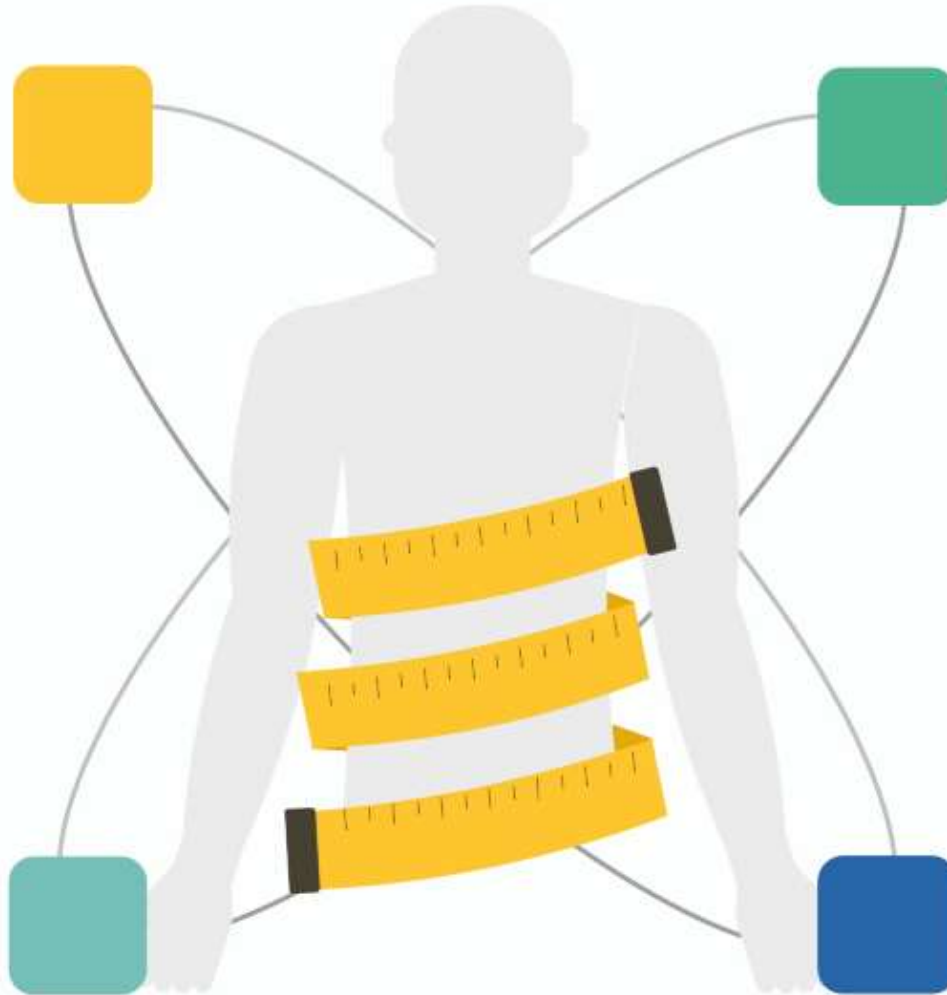
2020



2030



**Organ
Sparing**



**Safe
Effective**

**No Long-Term
Consequences**

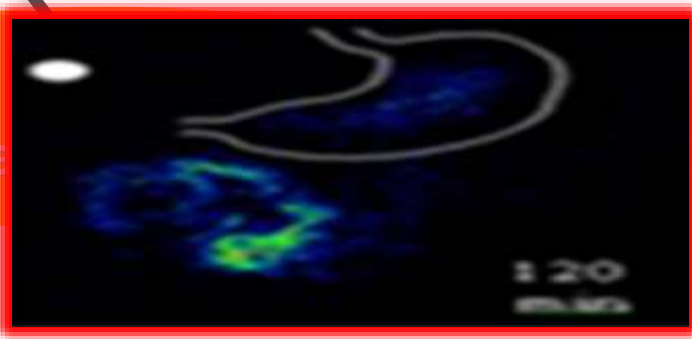
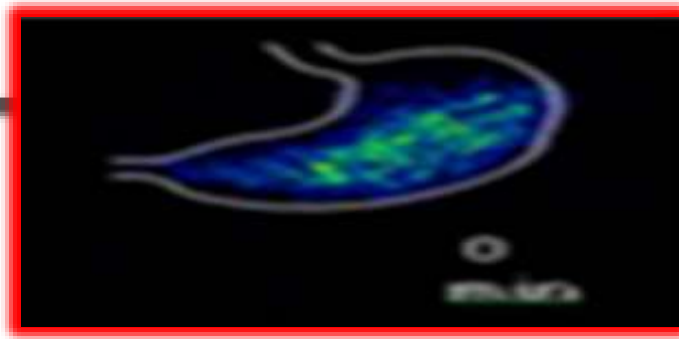
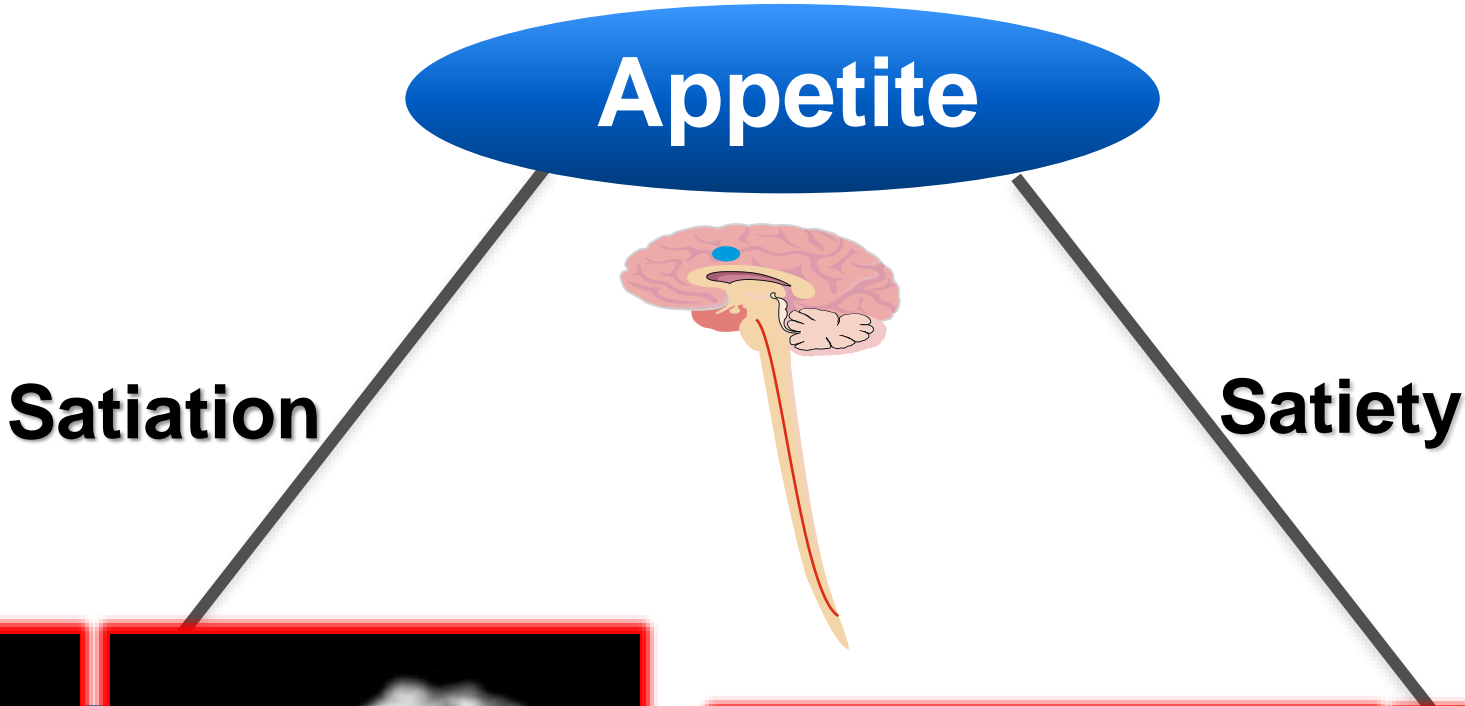
**Minimal
Disruption**

2

ESG: ANATOMY & PHYSIOLOGY

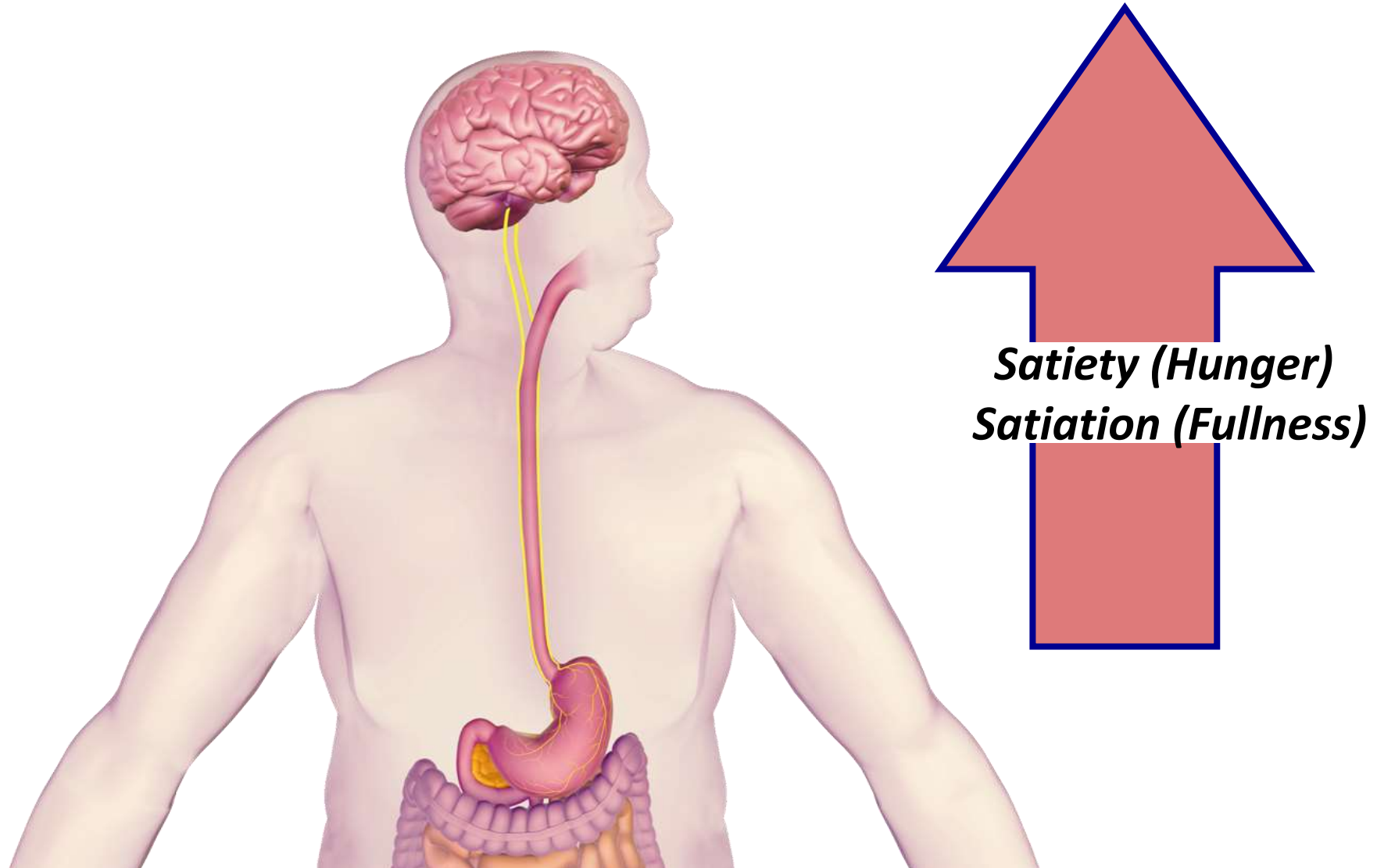


Human Appetite / Physiology

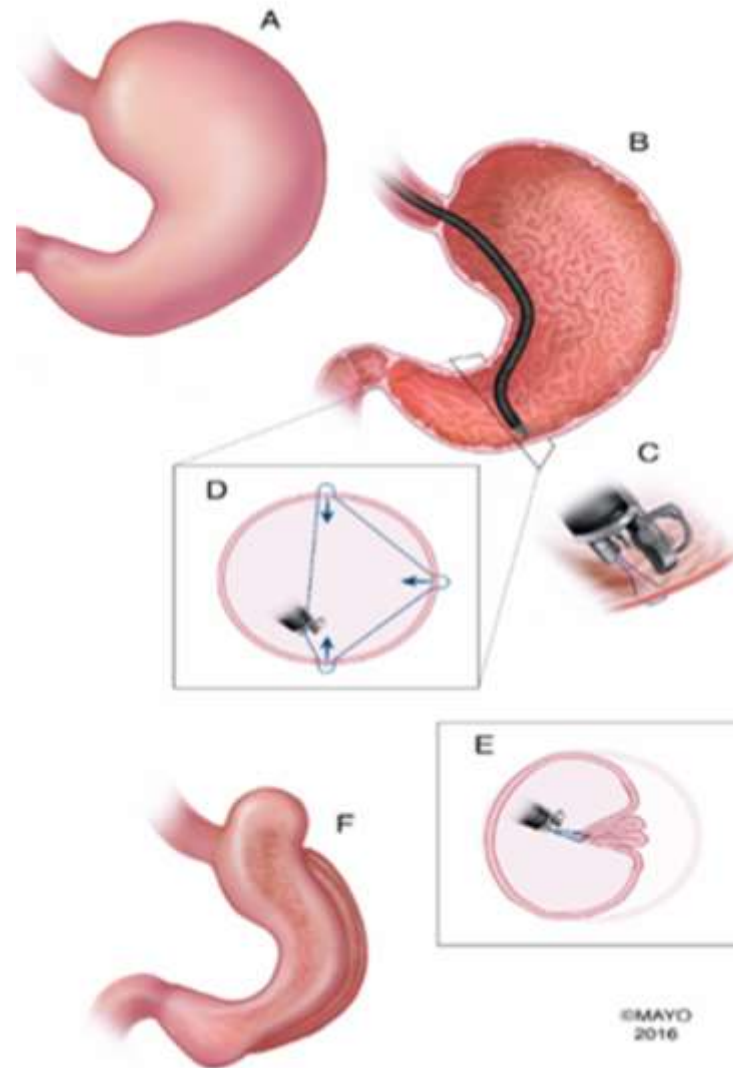


Cummings and Overduin J Clin Invest. 2007; 117: 13–23

The Vagus Nerve



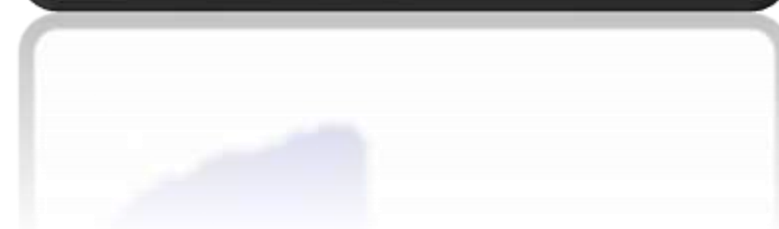
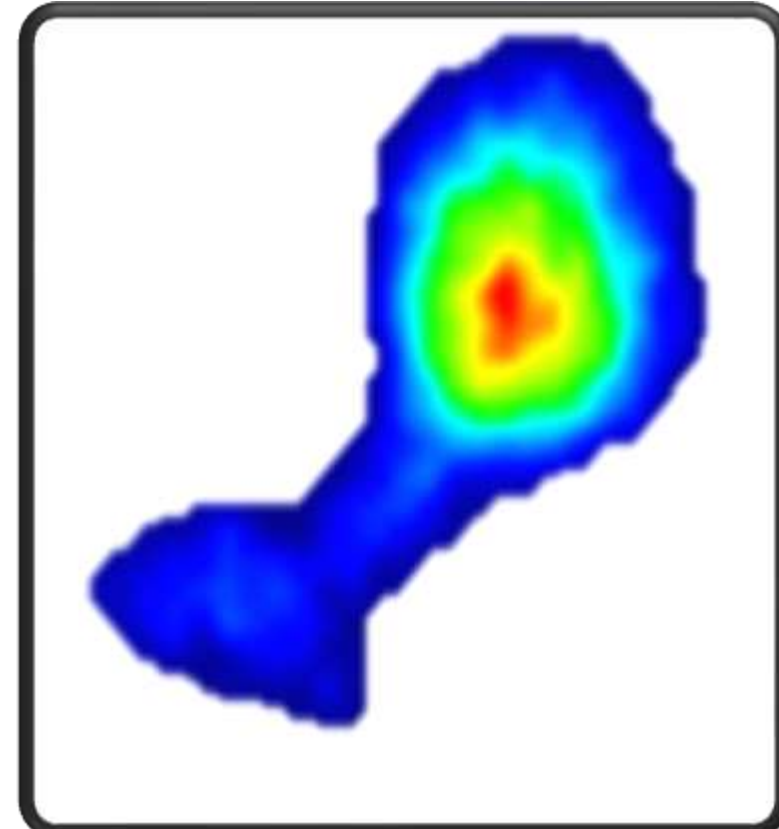
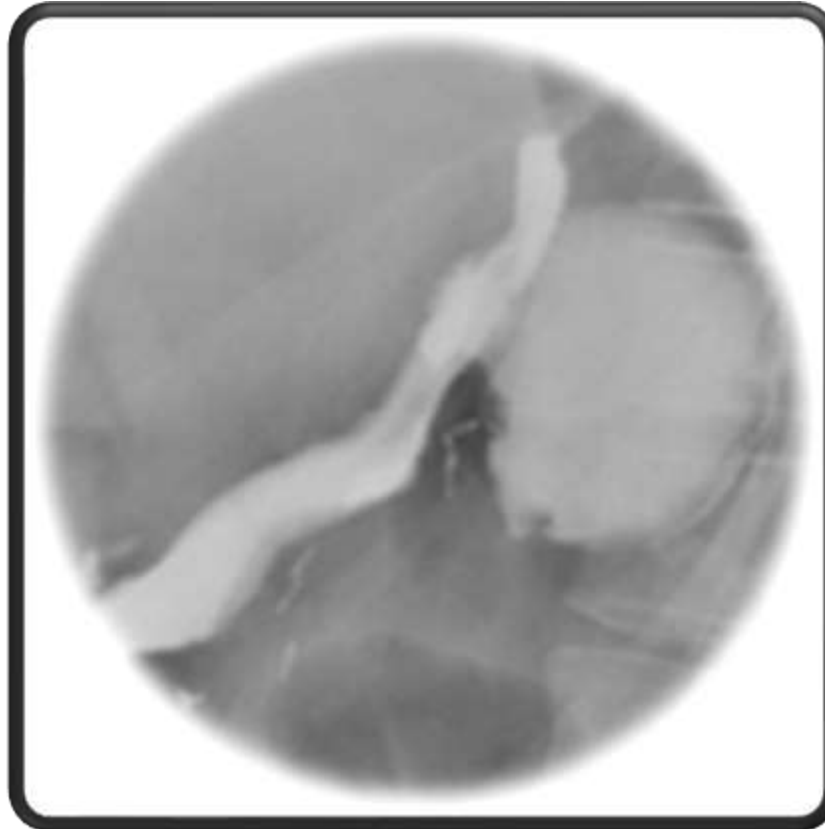
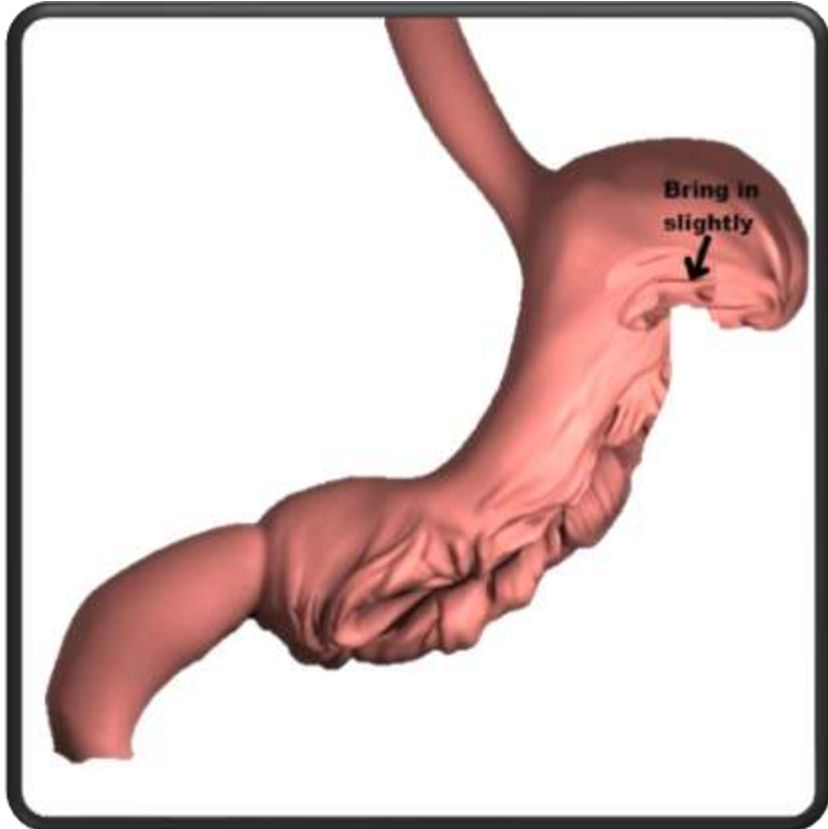
Endoscopic Sleeve Gastroplasty

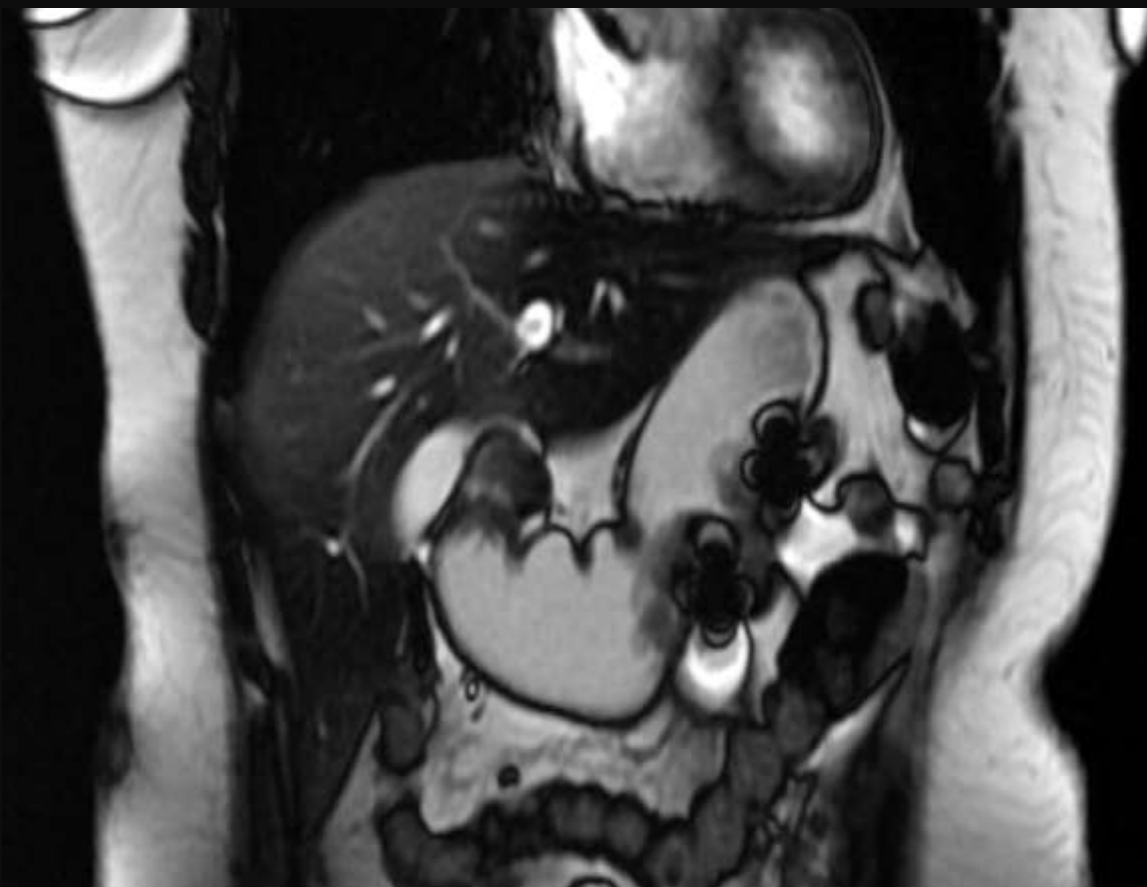


Abu Dayyeh and Gostout GIE 2013 Sep;78(3):530-5

Endoscopic Sleeve Gastroplasty




Final Anatomic and Physiological Manipulation



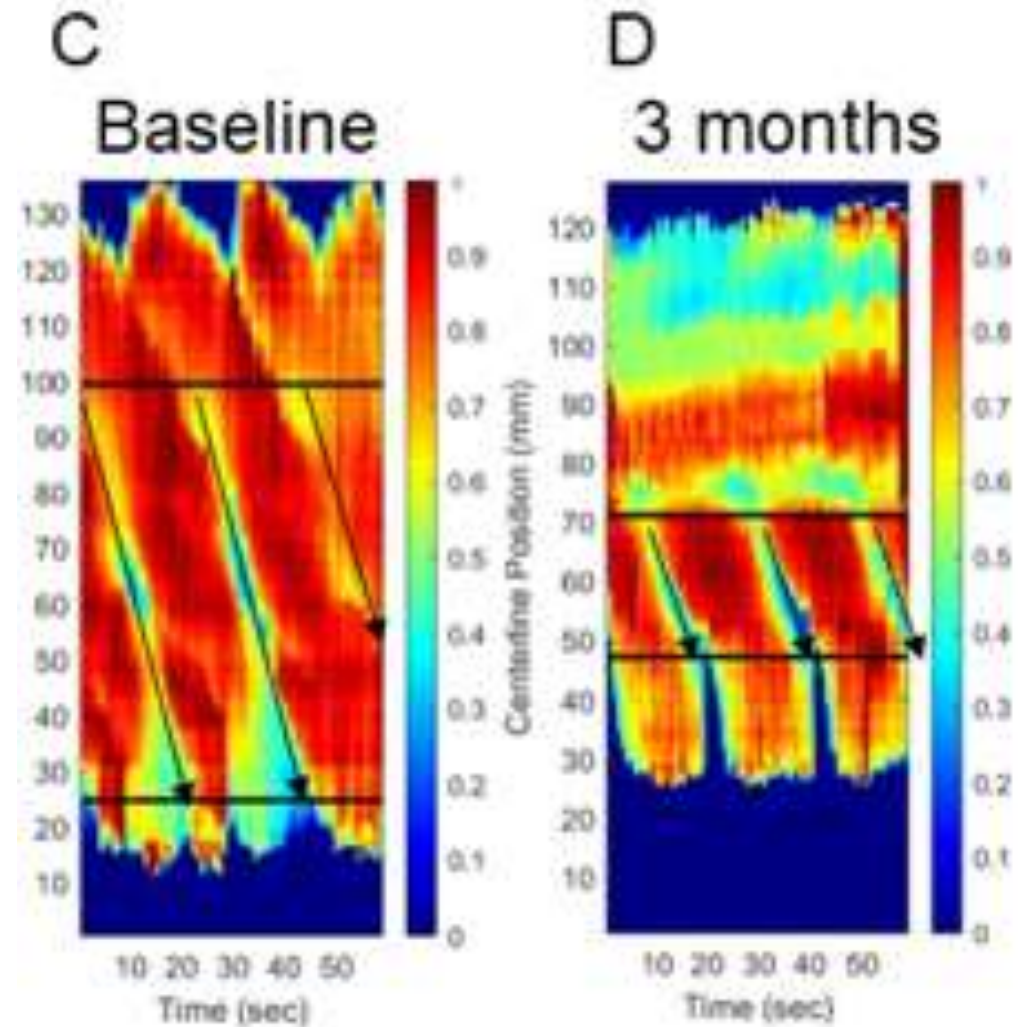
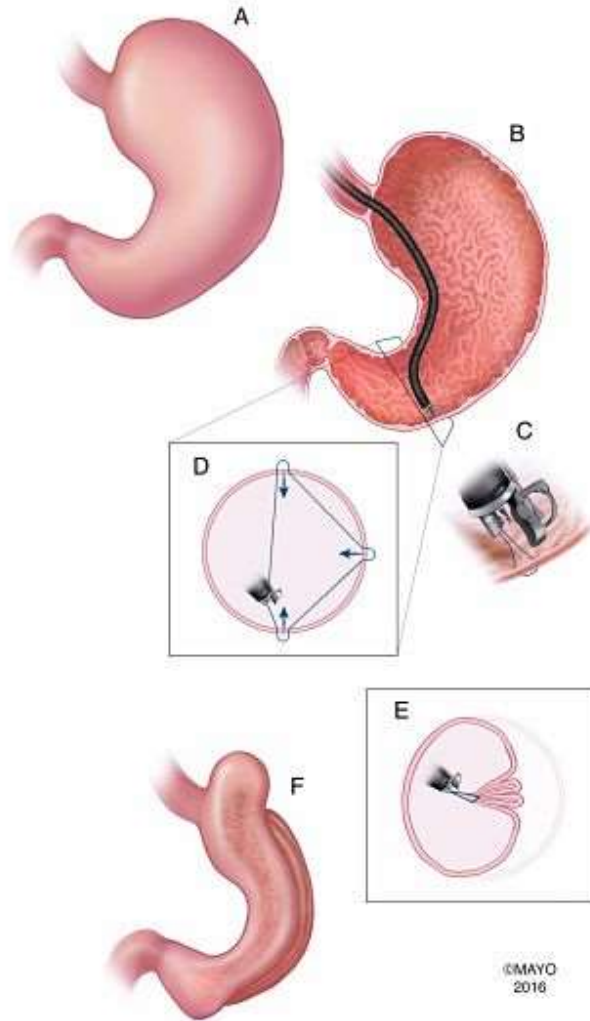


Original research

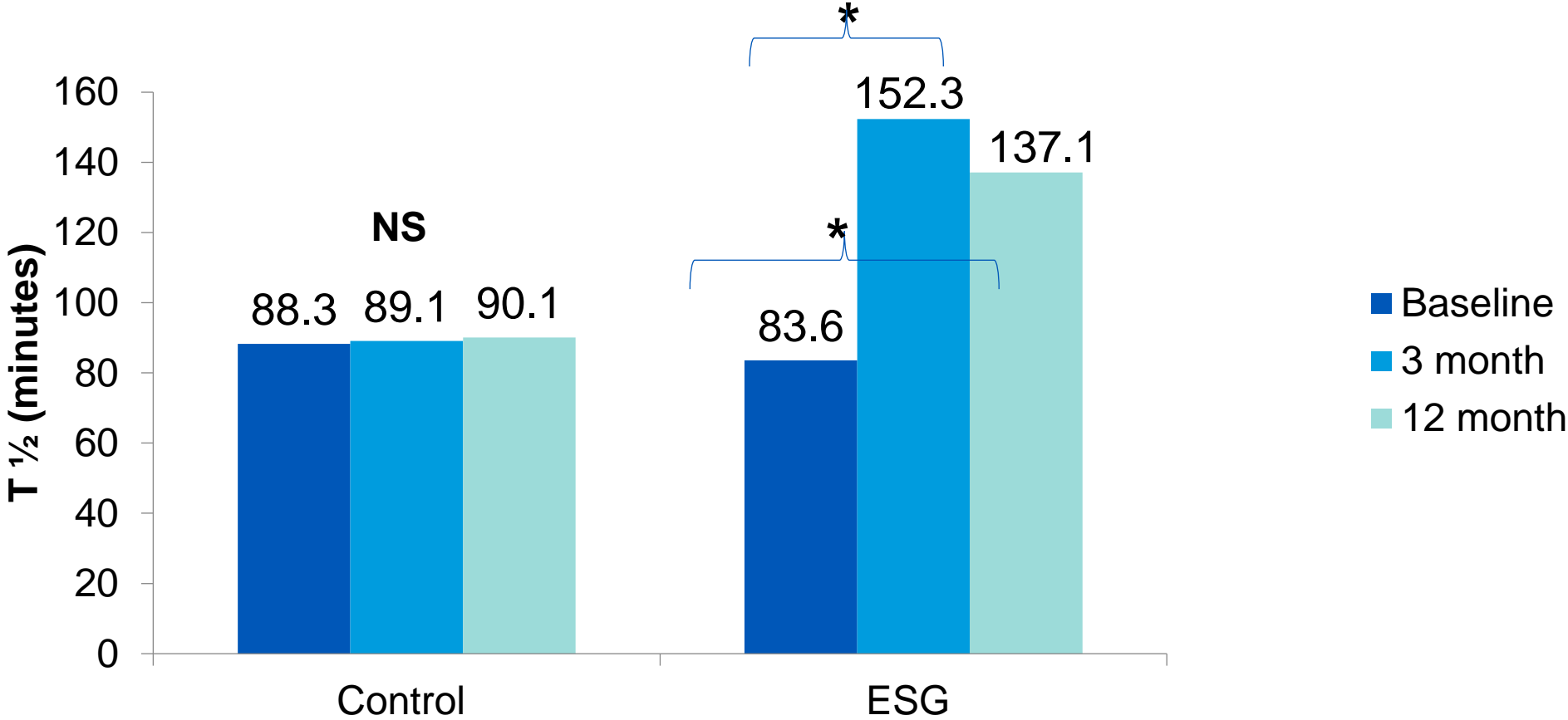
Effect of endoscopic sleeve gastroplasty on gastric emptying, motility and hormones: a comparative prospective study

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

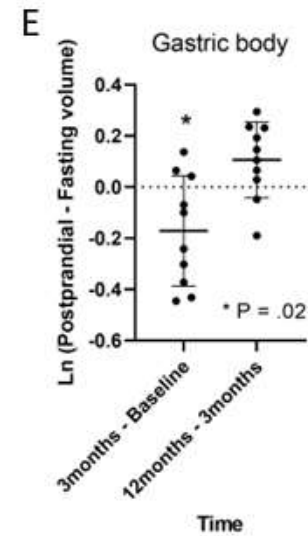
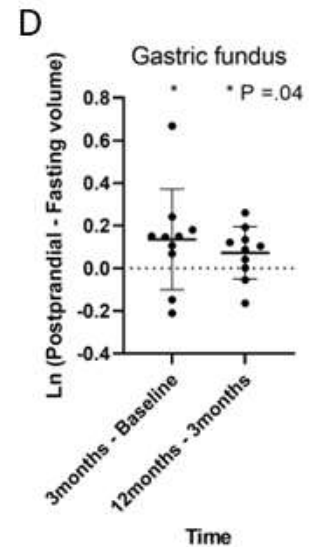
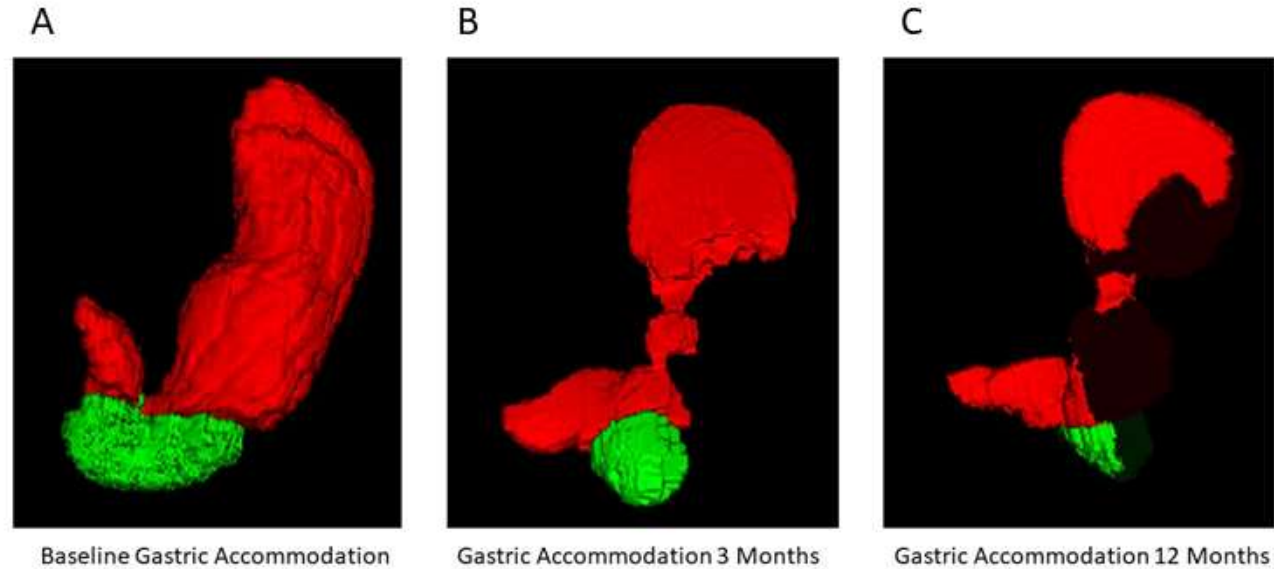
What happens to gastric motor function?



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



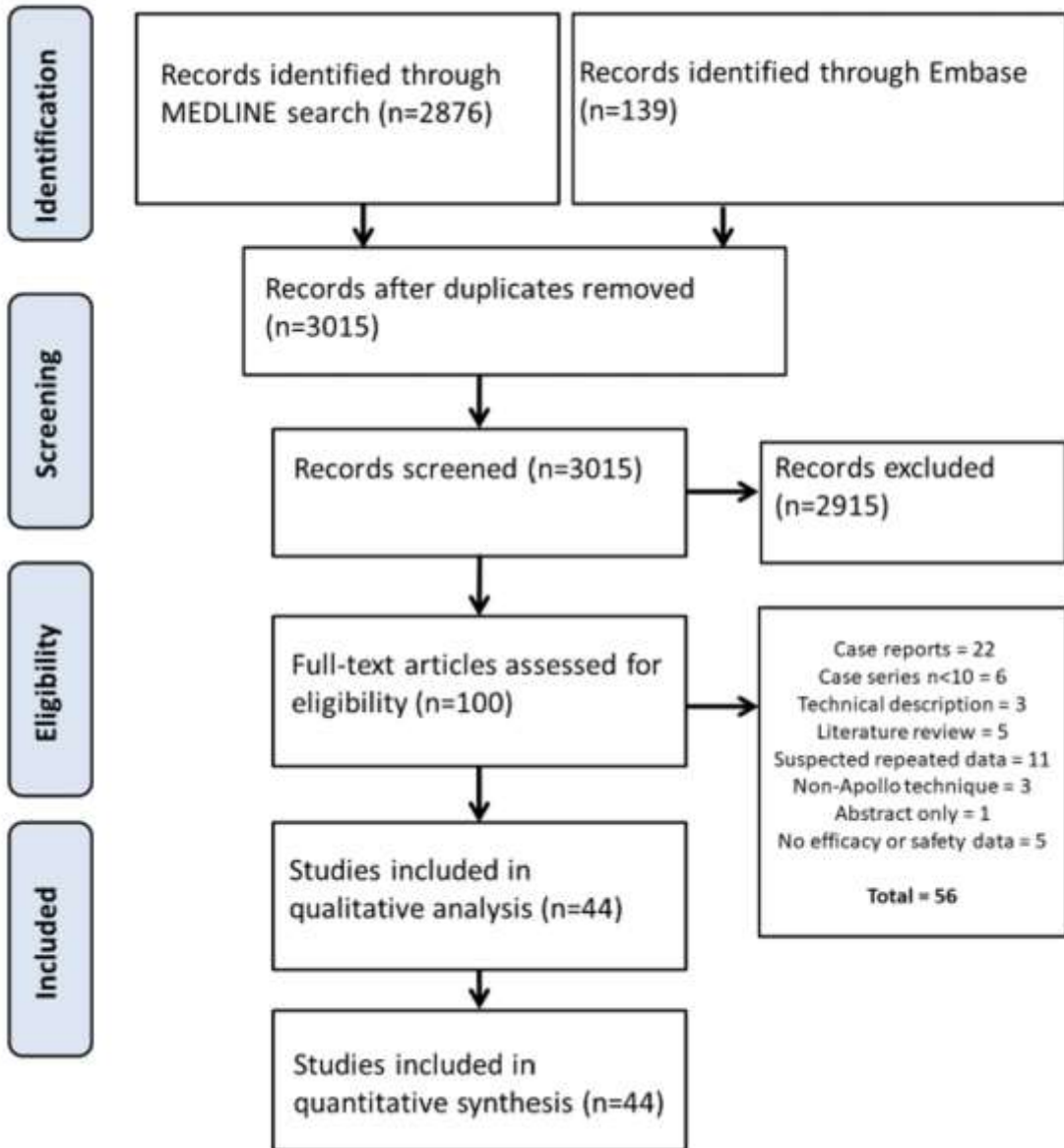
Changes in gastric accommodation after ESG



3

STATE OF THE EVIDENCE





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)

New Authorizations + Landmark Publication

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.



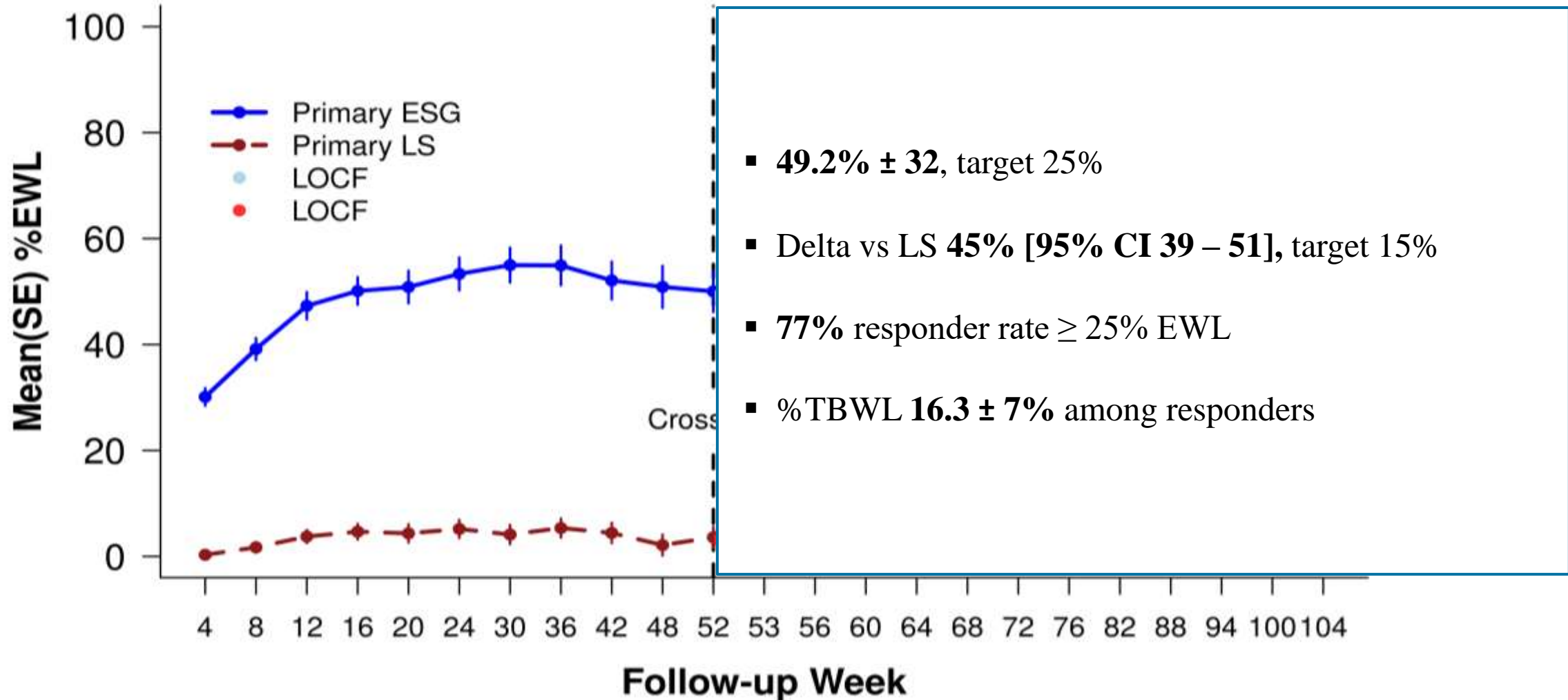
THE LANCET

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 Thamer, 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



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

NAFLD+ Inflammation

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

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

Endoscopy
Antibiotics

Upper GI Bleed

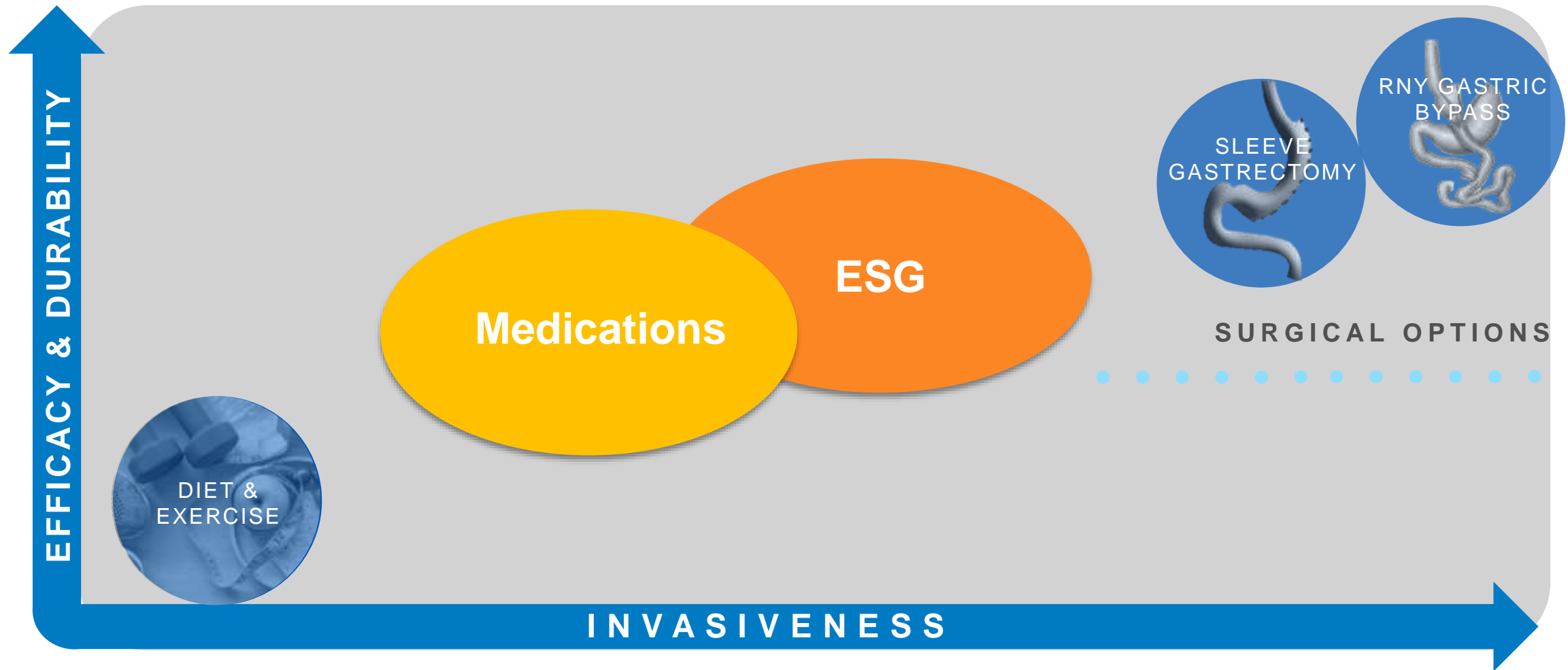
Endoscopy
No transfusion

Malnutrition

Endoscopic Reversal

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

#Pushing the Boundaries (Value Proposition)



CONCLUSIONS

- 1- ESG alters human appetite pathways to induce weight loss (gastric emptying and accommodation)
- 2- ESG is associated with clinically relevant weight loss
- 3- ESG is a safe, effective, and scalable option to help manage obesity



THANK YOU