

2<sup>nd</sup> Annual

# GI ReConnect

**June 10-11, 2022**

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SANTA FE, NEW MEXICO**

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# Obesity Management 2022: Endoscopic Approaches, Medications, and Diet Modification

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# Disclosure Statement

## **Disclosure Statement**

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# Disclosures

- Medtronic (employment)
- Boston Scientific (consulting until Oct. 2021)
- Olympus (consulting until Oct. 2021)
- Exact Sciences (consulting until Oct. 2021)
- YouTube (advisory board)
- Moderna (consulting)
- Real Chemistry (consulting)

# Agenda

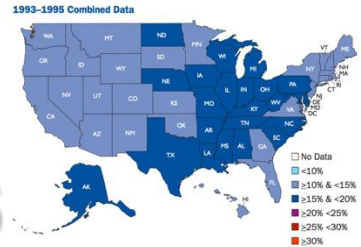
- Obesity overview
- Endoscopic Bariatric Therapies
  - Primary procedures
  - Revision procedures
- The future



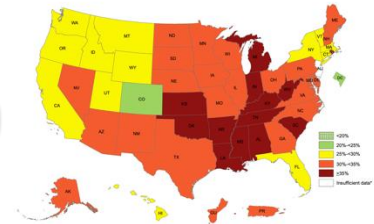
# Obesity Overview

- 1% of patients who qualify undergo surgery in US
  - 88M class I/II obesity, 228K surgeries in 2017
- Significant economic burden
- Obesity is multifactorial

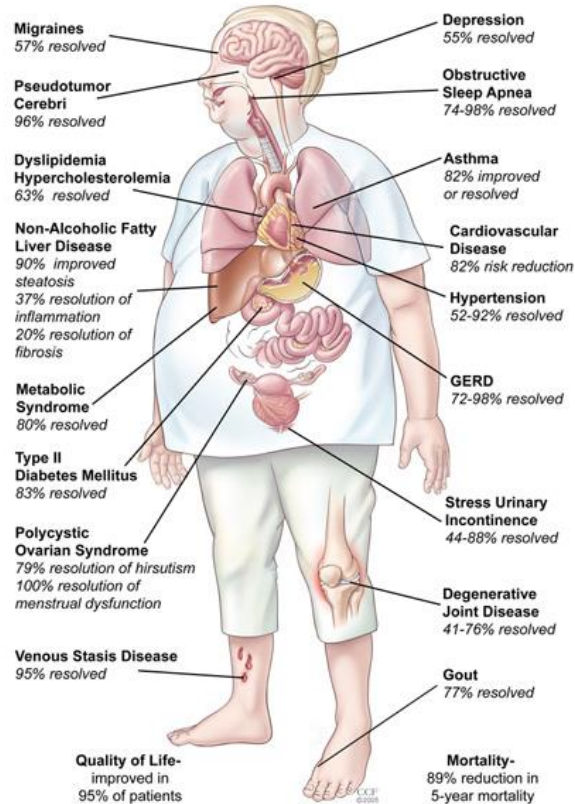
1993-1996



2017-2019



# Obesity-Related Co-Morbid Illness





# Starting Point

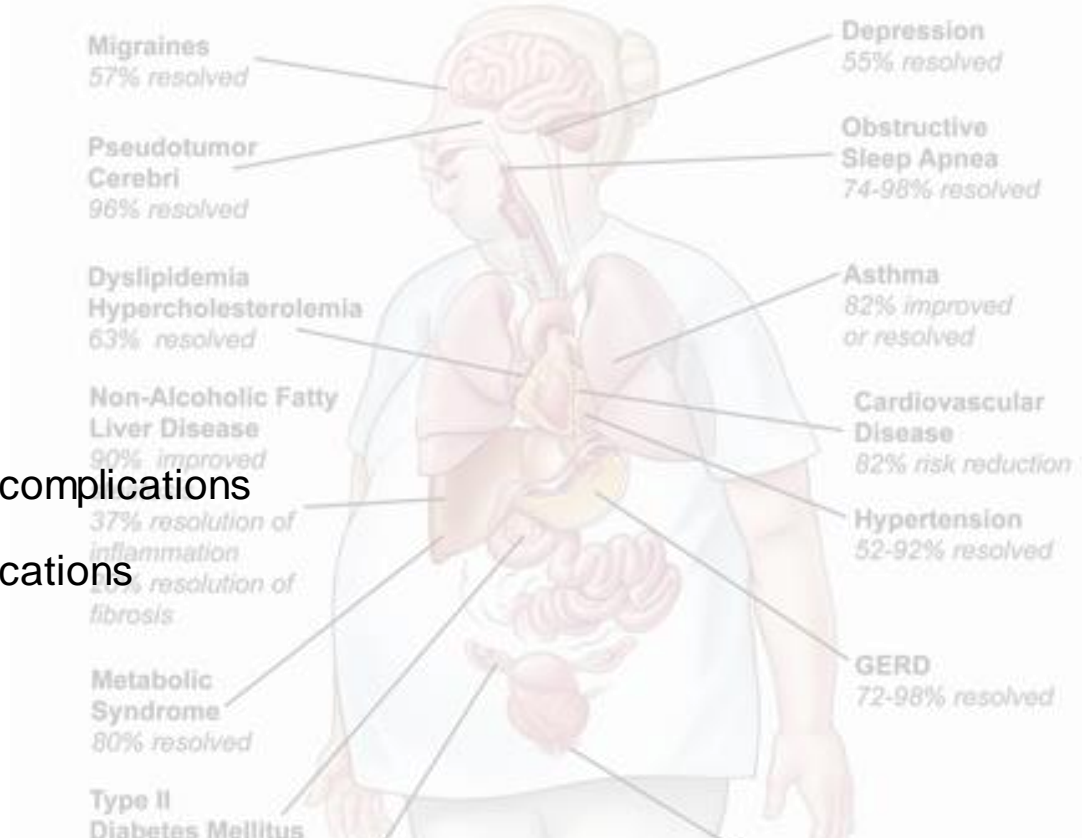
- Dietary and lifestyle modification is basis of ALL treatment!
- Treatment is multidisciplinary



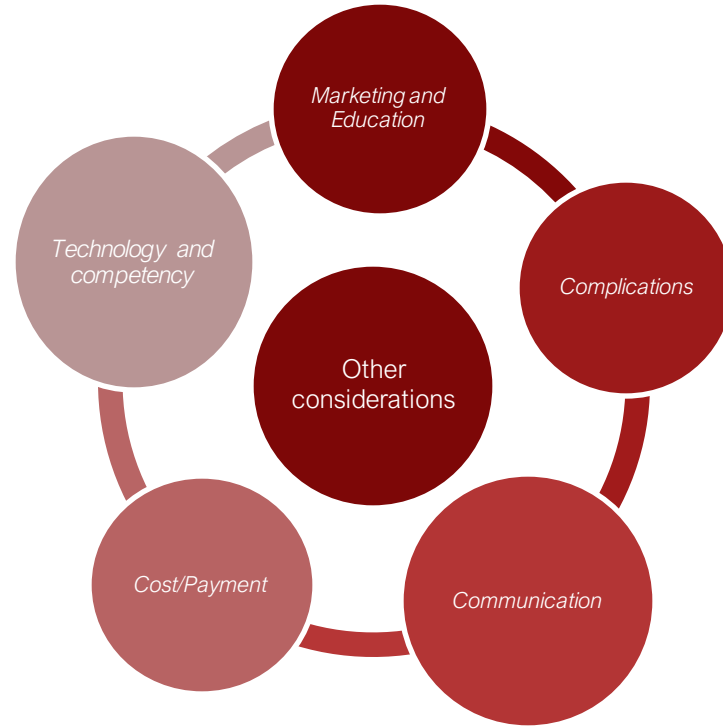
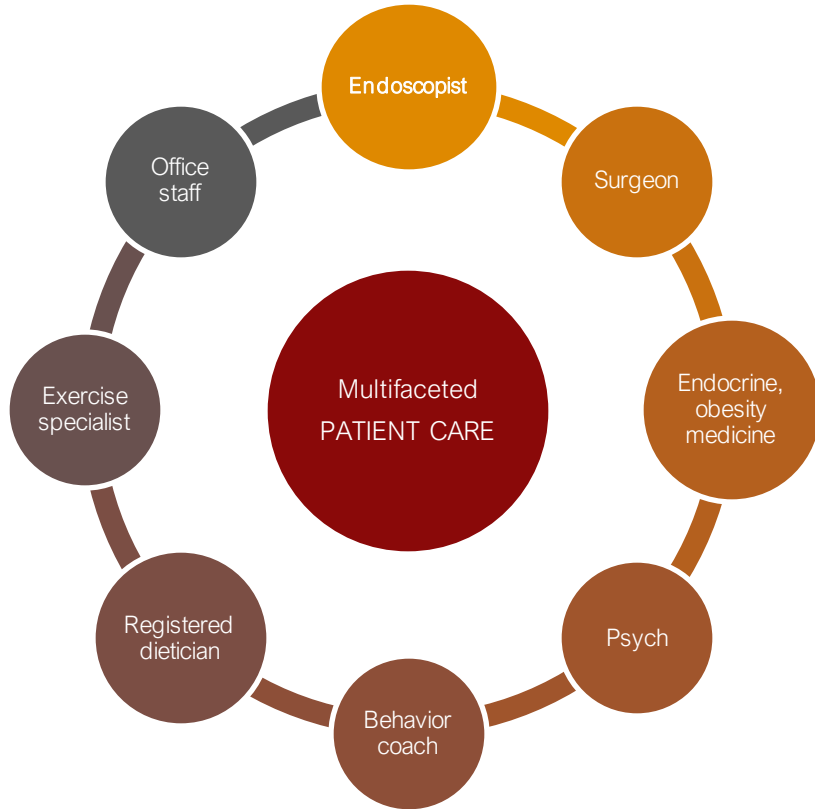


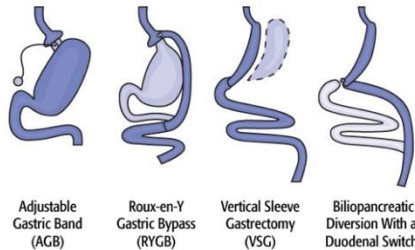
# Comprehensive Management

- Requires understanding of:
  - Pathophysiology
  - Co-morbidities
  - Nutrition
  - Physical activity
  - Pharmacotherapy and their complications
  - Procedures and their complications
  - Behavioral therapy
  - Weight bias



# Comprehensive Care



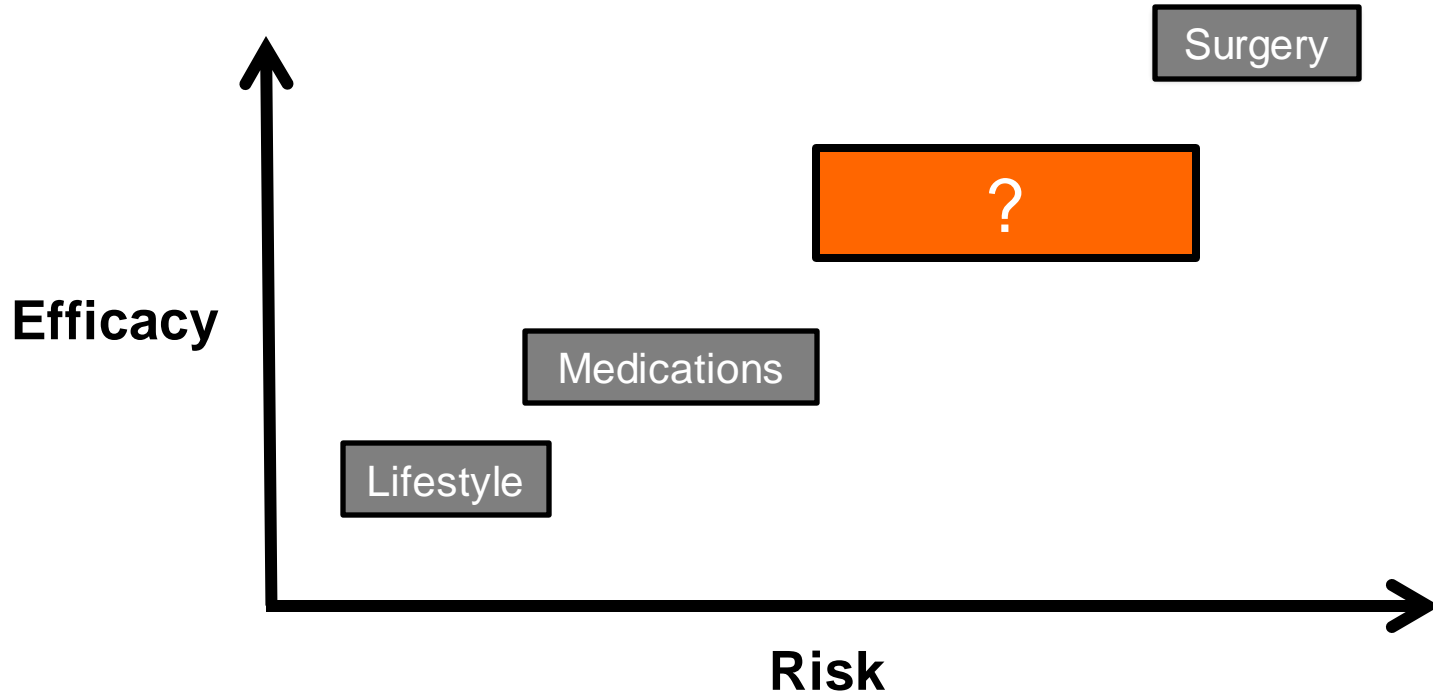


## Estimate of Bariatric Surgery Numbers, 2011-2017

Published June 2018

	2011	2012	2013	2014	2015	2016	2017
<b>Total</b>	<b>158,000</b>	<b>173,000</b>	<b>179,000</b>	<b>193,000</b>	<b>196,000</b>	<b>216,000</b>	<b>228,000</b>
<b>Sleeve</b>	17.80%	33.00%	42.10%	51.70%	53.61%	58.11%	<b>59.39%</b>
<b>RYGB</b>	36.70%	37.50%	34.20%	26.80%	23.02%	18.69%	<b>17.80%</b>
<b>Band</b>	35.40%	20.20%	14.00%	9.50%	5.68%	3.39%	<b>2.77%</b>
<b>BPD-DS</b>	0.90%	1.00%	1.00%	0.40%	0.60%	0.57%	<b>0.70%</b>
<b>Revision</b>	6.00%	6.00%	6.00%	11.50%	13.55%	13.95%	<b>14.14%</b>
<b>Other</b>	3.20%	2.30%	2.70%	0.10%	3.19%	2.63%	<b>2.46%</b>
<b>Balloons</b>	—	—	—	—	0.36%	2.66%	<b>2.75%</b>

# Bridging the Weight Loss Gap





# Indications by BMI

Intervention	BMI				
	25-26.9	27-29.9	30-34.9	35-39.9	≥40
Lifestyle	X	X	X	X	X
Medications		with co-morbidities	X	X	X
<b>Bariatric Endoscopy</b>			X	X	X
Surgery				with co-morbidities	X

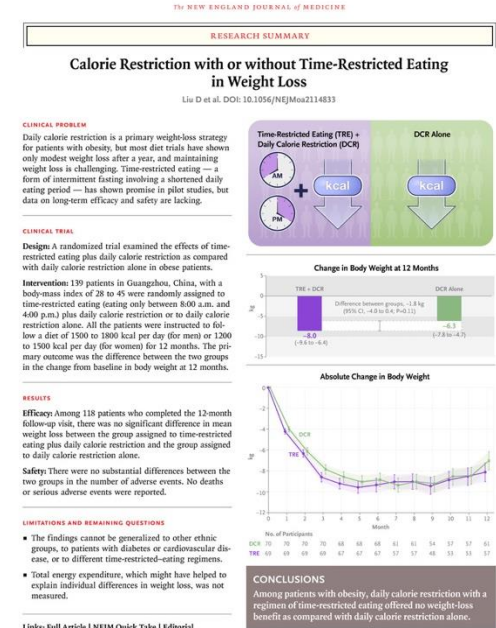
# Lifestyle Modifications

## Best weight loss diets per USNews?

1. Flexitarian
2. Volumetrics
3. WW
4. Vegan
5. Jenny Craig
6. Mayo Clinic

## Intermittent fasting?

- Time restricted eating
- Alternate day fasting
- Modified fasting



# Pharmacotherapy

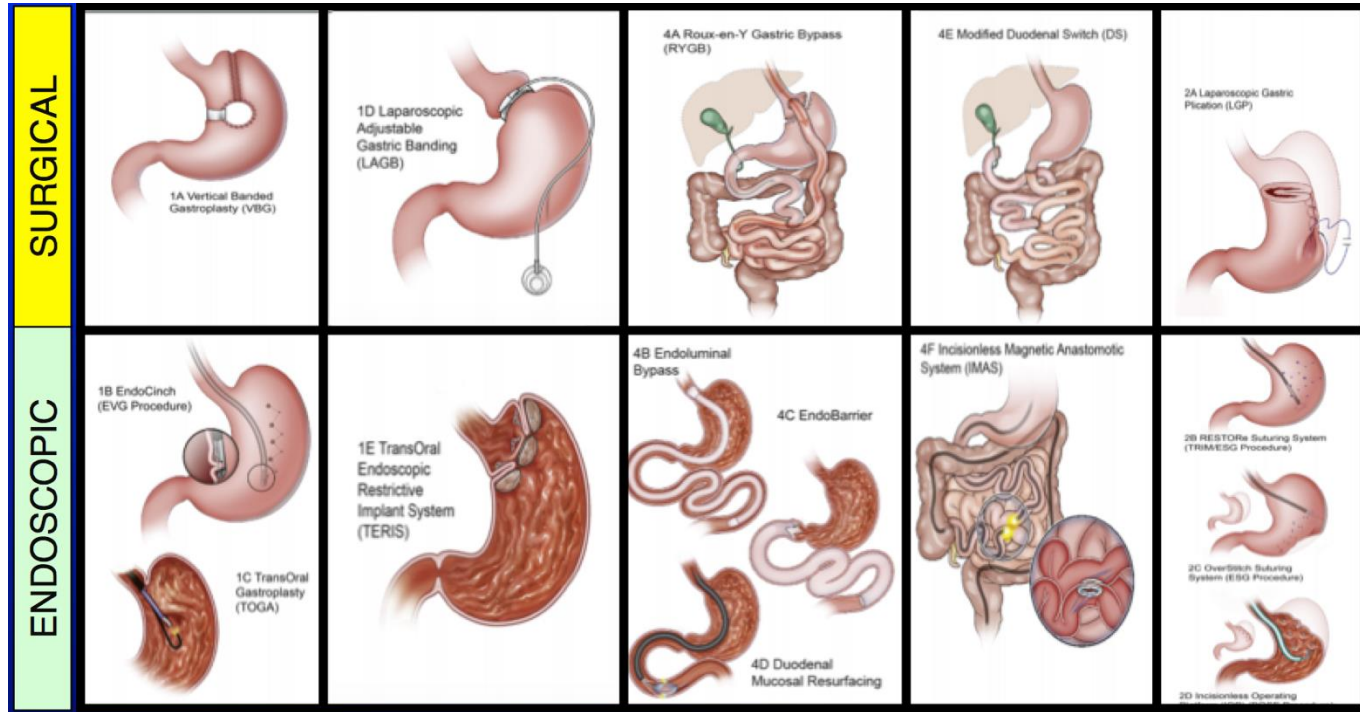
Medication	Route	FDA approval year	Mechanism	Pivotal trial	Mean weight loss
Orlistat	PO	1999	Lipase inhib.		10.2% (@ 120mg, 56 weeks)
Phentermine/topiramate	PO	2012	Sympathomimetic, anticonvulsant	CONQUER	12.4% (@ 15/92mg, 56 weeks)
Naltrexone/bupropion	PO	2014	Opioid antagonist, antidepressant	COR-1	6.1% (@ 32mg, 56 weeks)
Liraglutide	SQ	2014	GLP-1 agonist	SCALE	8.0% (@ 3.0mg, 56 weeks)
Semaglutide	SQ	2021	GLP-1 agonist	STEP1	14.9% (@ 2.4mg, 68 weeks)
Tirzepatide	SQ	2022	GLP-1/GIP agonist	SURMOUNT-1	22.5% (@ 15mg, 72 weeks)

# What Is “Bariatric Endoscopy”?

- Primary weight loss
- Treating complications of bariatric surgery
  - **Weight regain**, leaks, fistulas, ulcerations, choledocholithiasis
- Targeted metabolic therapy
- Bridge to bariatric surgery or other therapy

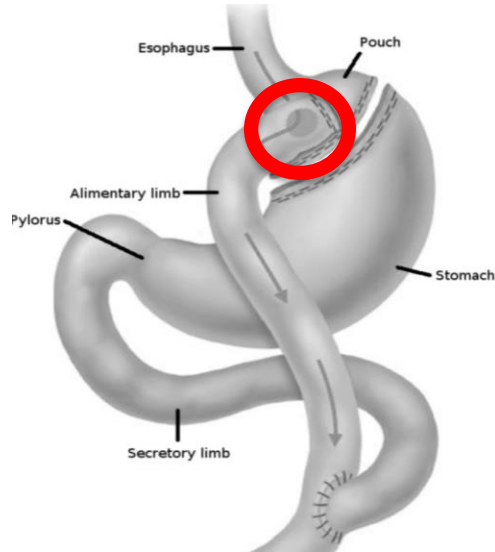


# Endoscopic Therapies Often Surgical Analogues



# Approved Endoscopic Bariatric Therapies

## Revision Therapies



Stoma reduction

## Primary Therapies



Intragastric Balloons



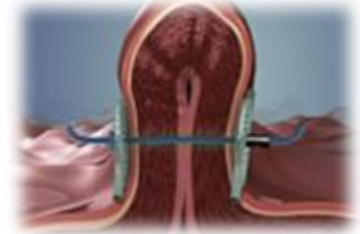
Sleeve Gastropasty



Aspiration therapy

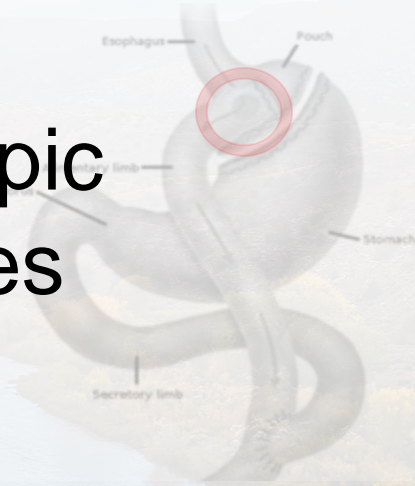


Transpyloric shuttle



Gastric plications

# Revision Endoscopic Bariatric Therapies





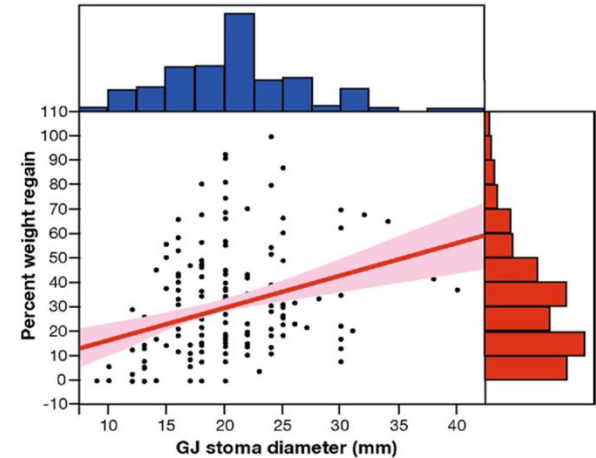
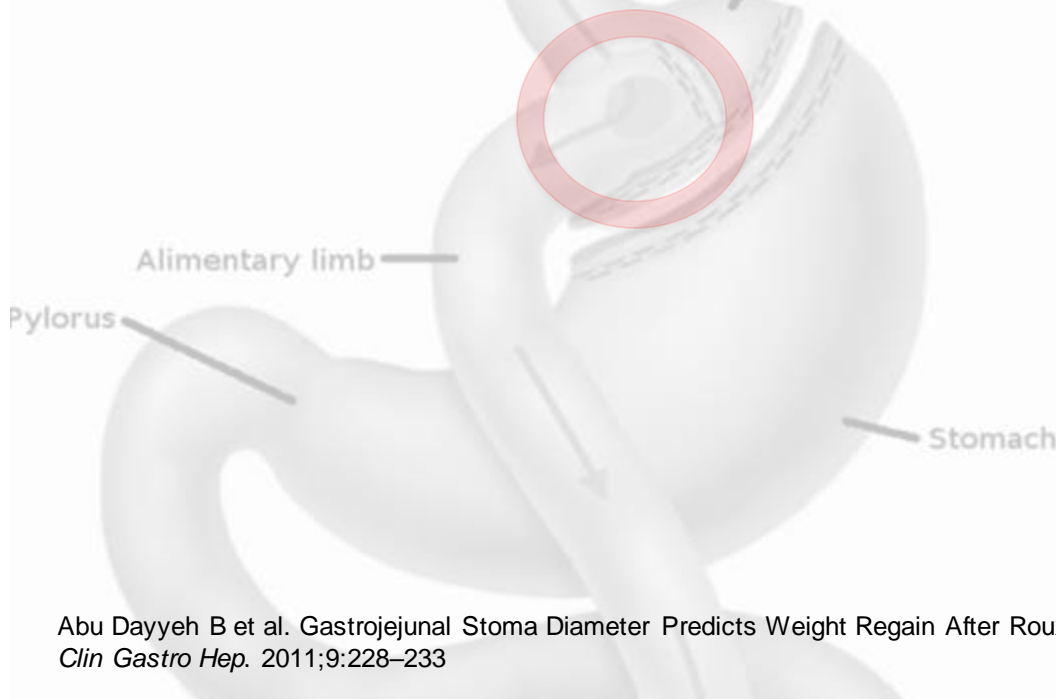
# GJ Stomal Diameter Is Associated With Weight Regain

## Clinical Gastroenterology and Hepatology

### Gastrojejunal Stoma Diameter Predicts Weight Regain After Roux-en-Y Gastric Bypass

BARHAM K. ABU DAYYEH,<sup>1,2</sup> DAVID B. LAUTZ,<sup>3</sup> and CHRISTOPHER C. THOMPSON<sup>1,2</sup>

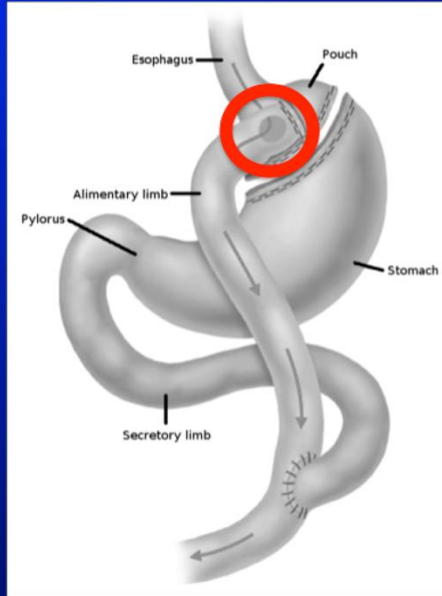
<sup>1</sup>Gastrointestinal Unit, Massachusetts General Hospital, Boston; <sup>2</sup>Department of Medicine, Harvard Medical School, Boston; <sup>3</sup>Department of Surgery, Brigham and Women's Hospital, Boston; <sup>4</sup>Gastroenterology Division, Brigham and Women's Hospital, Boston, Massachusetts



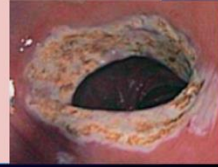
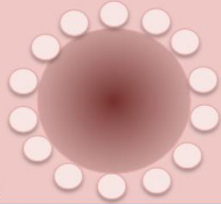
**Figure 2.** Scatter plot with best-fit linear regression line and 95% confidence intervals of the association between the GJ stoma diameter in millimeters and percentage of maximal weight lost after RYGB that was regained. The normal distribution of each of the continuous variables is also shown.



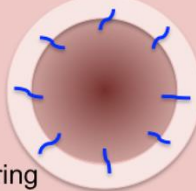
# Transoral Outlet Reduction (TORe)



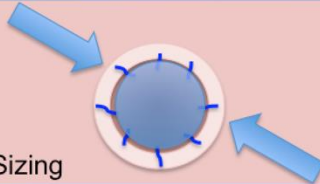
Step 1: APC



Step 2: Suturing



Step 3: Sizing



Step 4: Post-procedural diet



# Weight Regain: Transoral Outlet Reduction



Transoral outlet reduction for weight regain after gastric bypass:  
long-term follow-up CME

Nitin Kumar, MD,<sup>1</sup> Christopher C. Thompson, MD<sup>2</sup>  
Boston, Massachusetts, USA

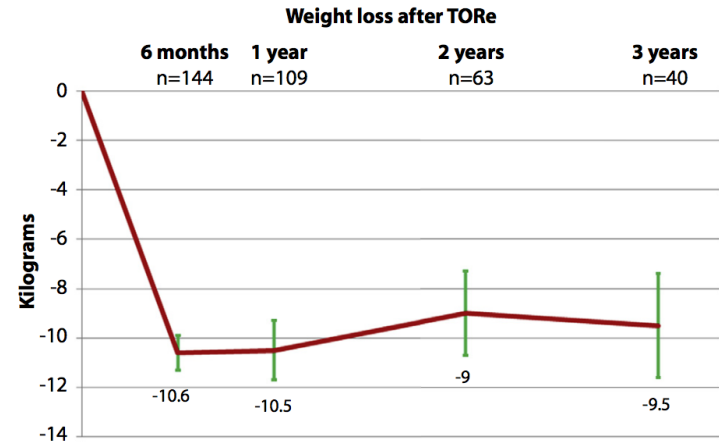
- 1 year:  $24.9 \pm 2.6\%$  excess weight loss
- **3 years:  $19.2 \pm 4.6\%$  excess weight loss**
- NNT for  $\geq 5$  kg weight loss = 1.5 at 1 year, 2.0 at 3 years



Purse-string transoral outlet reduction (TORe) is effective at inducing weight loss and improvement in metabolic comorbidities after Roux-en-Y gastric bypass

Pichamol Jirapinyo, Paul T. Kröner, Christopher C. Thompson

- BP, HbA1c, ALT improved after 1 year



**Figure 2.** Weight loss trend. *TORe*, transoral outlet reduction.

The background of the slide is a composite image. The top half shows a vast, arid landscape with rolling hills under a bright blue sky with scattered white clouds. The bottom half shows a river flowing through a valley with trees displaying vibrant yellow autumn foliage. Overlaid on the right side of the landscape is a semi-transparent image of two hands, one holding a small white pill.

# Primary Endoscopic Bariatric Therapies

# Endoscopic Sleeve Gastroplasty (ESG)

- 1000 patient series (baseline BMI 33.3)<sup>1</sup>:
  - 18 months (n=54): 14.8%  $\pm$  8.5% total weight loss
- 5-year results (N=218)<sup>2</sup>
  - 3 years: 15.9% total body weight loss
  - Moderate adverse event 1.3% (fibrosis, leak), no SAE

## Five-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity

Reem Z. Sharaiha,<sup>\*</sup> Kaveh Hajifathalian,<sup>\*</sup> Rekha Kumar,<sup>‡</sup> Katherine Saunders,<sup>‡</sup> Amit Mehta,<sup>\*</sup> Bryan Ang,<sup>§</sup> Daniel Skaf,<sup>§</sup> Shawn Shah,<sup>\*</sup> Andrea Herr,<sup>\*</sup> Leon Igel,<sup>‡</sup> Qais Dawod,<sup>\*</sup> Enad Dawod,<sup>§</sup> Kartik Sampath,<sup>\*</sup> David Carr-Locke,<sup>\*</sup> Robert Brown,<sup>\*</sup> David Cohen,<sup>\*</sup> Andrew J. Dannenberg,<sup>||</sup> Srihari Mahadev,<sup>\*</sup> Alpana Shukla,<sup>‡</sup> and Louis J. Aronne<sup>‡</sup>

<sup>\*</sup>Division of Gastroenterology and Hepatology, Weill Cornell Medicine, New York-Presbyterian Hospital, New York, New York;

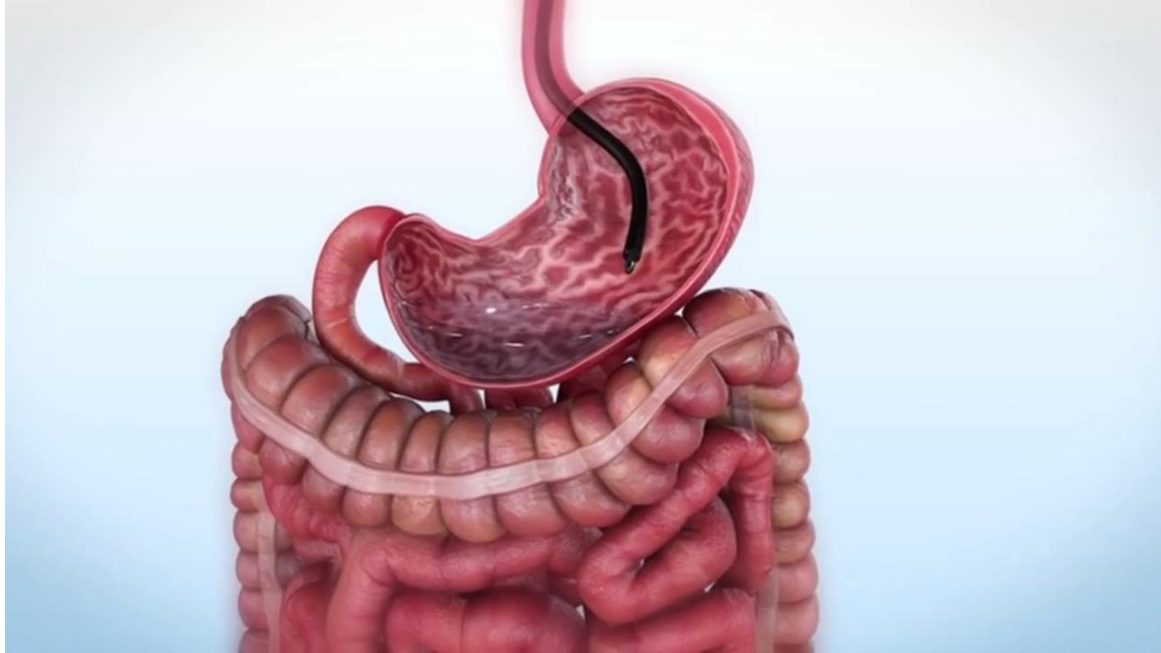
<sup>‡</sup>Division of Endocrinology Diabetes and Metabolism, Weill Cornell Medicine, New York-Presbyterian Hospital, New York, New York; <sup>§</sup>Joan & Sanford I. Weill Medical College of Cornell University, New York, New York; and <sup>||</sup>Department of Medicine, Weill Cornell Medicine, New York-Presbyterian Hospital, New York, New York





# Endoscopic Sleeve Gastroplasty (ESG)

**Apollo Endosurgery**



# FDA-Approved Intragastric Balloons



# FDA-Approved Intragastric Balloons



## Orbera (Apollo Endosurgery)

- Saline-filled + methylene blue (400-700cc)
- 6 month implantation
- 300000+ placed worldwide



## Obalon (Obalon Therapeutics)

- 3 separate 250cc gas filled balloons
- 6 month implantation, endoscopy only for removal
- Commercial data 1343 patients at 1 year published 2019



## Spatz3 (Spatz)

- Adjustable saline-filled balloon
- Approved by FDA Oct. 2021

# FDA-Approved Intragastric Balloons



## Orbera (Apollo Endosurgery)

- **11.3%** total, **25.4%** excess weight loss 6 mos after removal
- At 5 years **23% patients >20% EWL**



## Obalon (Obalon Therapeutics)

- **6.9%** vs. 3.6% TBWL at 6 months
- **10.0%** vs. 3.6% total body weight loss at 1 year



## Spatz3 (Spatz Medical)

- **15%** vs. 3.3% TBWL at 32 weeks
- 80% underwent adjustment (with average -5.2% TBWL)
- 21/288 pts had downward adjustment
- 31/288 had removal for intolerance

Adjustable intragastric balloon for treatment of obesity:  
a multicentre, open-label, randomised clinical trial

Barham K Abu Dayyeh, Daniel B Maull, Babuvaraj Raju, Thomas Levin, Mark Nasir, Hisham Hassan, Christopher C Chapman, Violetta Popov, Pichamol Jongsri, Andres Acosta, Eric J Vargas, Andrew C Storm, Fatih Bazerachi, Marvin Ryan, Matthew French, Sabrina Norris, Daniel Mulline, Christopher C Thompson

Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss

Shelby Sullivan, M.D. • James Swain, M.D. • George Woodman, M.D. • ... Kumar Krishnan, M.D. • Juan Carlos Buzcoba, M.D. • Aurora Pryor, M.D. • Show all authors

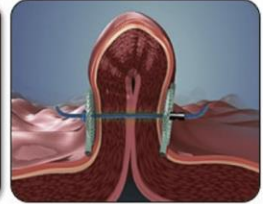
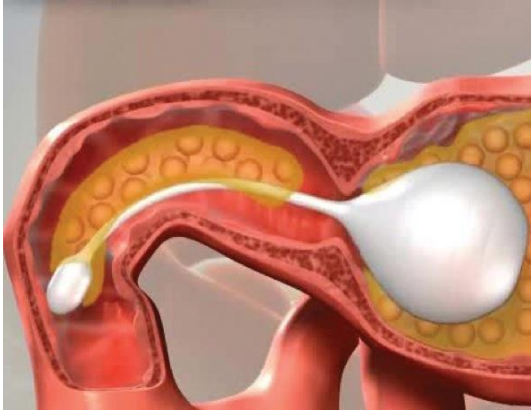
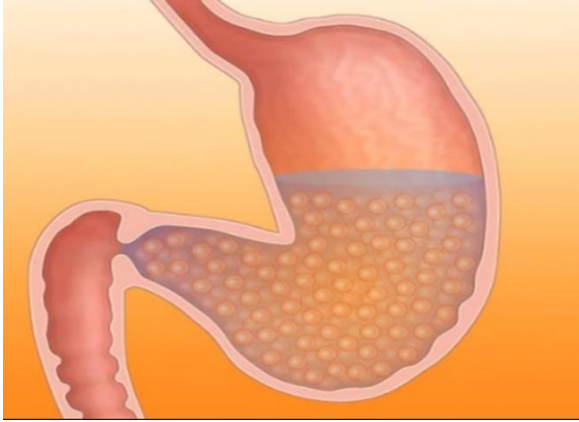
Published: September 28, 2018 • DOI: <https://doi.org/10.1016/j.soard.2018.09.486> • Check for updates

# Balloons vs. ESG

- Fayad, et al (2019)
  - 47 Balloons vs. 58 ESG
  - Mean BMI 34.5 vs. 41.5 kg/m<sup>2</sup>
- Singh, et al (2020)
  - Meta-analysis of 28 studies, only 1 study above was direct comparison
  - At 12 months, mean %TBWL:
    - ESG vs. IGB: mean TWL was **17.51% vs. 10.35%**

%TBWL IGB vs. ESG			
Months	IGB	ESG	<i>p</i>
1	6.6	9.9	<0.001
3	11.1	14.3	0.004
6	15.0	19.5	0.01
12	13.9	21.3	0.005

# More FDA-Approved Therapies

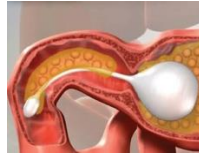


# More FDA-Approved Therapies



Gelesis  
(Plenity™)

- GLOW pivotal
  - 6 months: **6.6% vs. 4.4%** (p=0.0007) in treatment vs. placebo<sup>1</sup>
- “Hydrogel” = cellulose and citric acid
- 3 capsules taken BID



BaroNova

- ENDOBESITY II trial
  - 12 months: **9.5% vs. 2.8%** (p<0.0001) in treatment vs. placebo
- Solid silicone
- 12 month duration



POSE

- MILEPOST trial
  - 12 months: **12.6% vs. 5.3%** in treatment vs. placebo
- Gastric plications



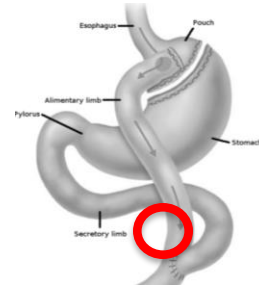
# Take Home Points

Bariatric endoscopy is one part of a multidisciplinary effort

Endoscopy may help bridge gap between low risk/low efficacy medical therapies and high risk/high efficacy surgical approaches

Endoscopic methods seek to mimic mechanisms of surgery

Multiple FDA approved endoscopic devices





@austinchiangmd

