



Endoscopic Bariatric Therapies- What's Out There and Who Should Get It

Victoria Gómez, M.D., F.A.S.G.E.

**Associate Professor of Medicine
Director of Bariatric Endoscopy
Division of Gastroenterology, Mayo Clinic Florida**

Diplomate of the American Board of Obesity Medicine (ABOM)

Disclosures

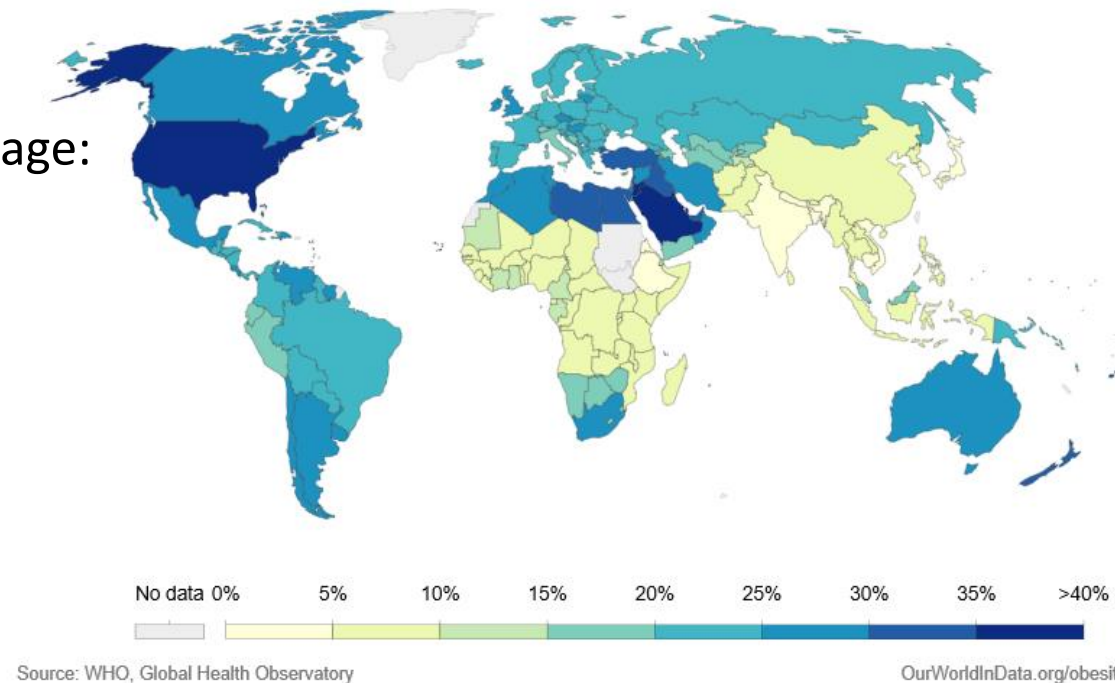
- Olympus Corporation of the Americas-
 - Consulting Work

Learning Objectives

- 1) Recognize the important role that endoscopic bariatric therapies (EBTs) play in today's management of obesity
- 2) To become familiar with FDA-approved EBTs and their mechanisms of action
- 3) Review how patients are evaluated for EBTs and the importance of a multidisciplinary framework.

Introduction: Current Global Status of Obesity

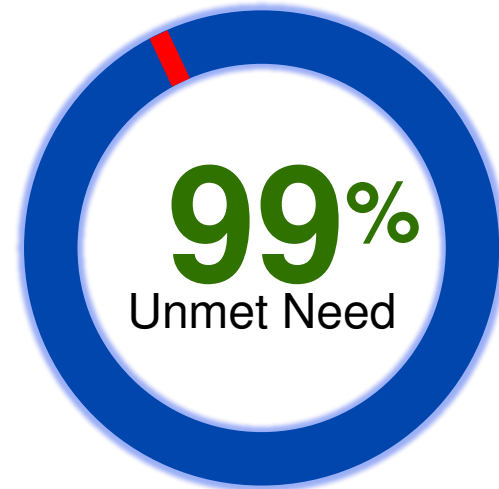
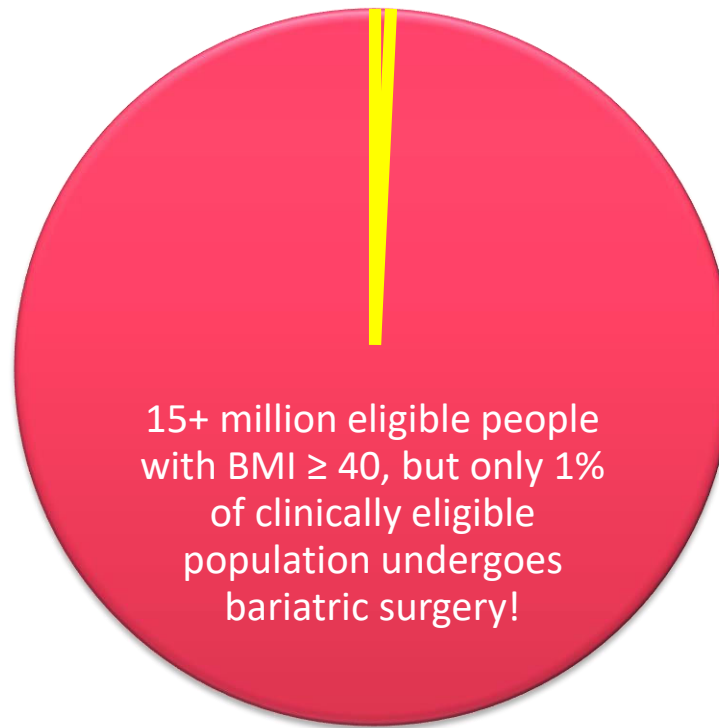
- 700 million adults with obesity (BMI* \geq 30)
- In the U.S. for adults > 20 years of age:
 - 73.6% overweight or obesity
 - 42.5% obesity
- Obesity is a major risk factor for:
 - Cardiovascular disease
 - Diabetes Mellitus
 - NAFLD/NASH/Cirrhosis/HCC
 - Cancers



* Body Mass Index (BMI)- defined as kg/m^2

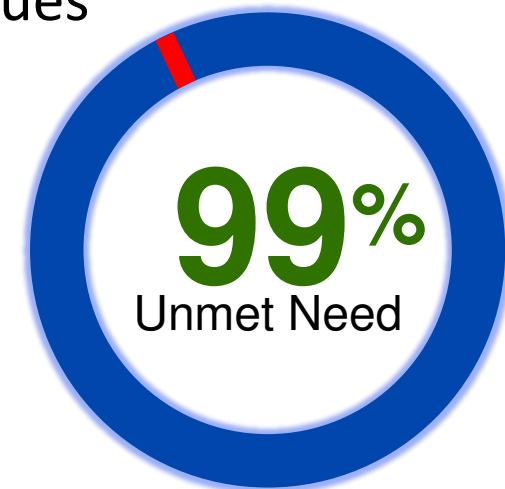
Current Status of Bariatric Surgery in USA

	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Total	158,000	173,000	179,000	193,000	196,000	216,000	228,000	252,000

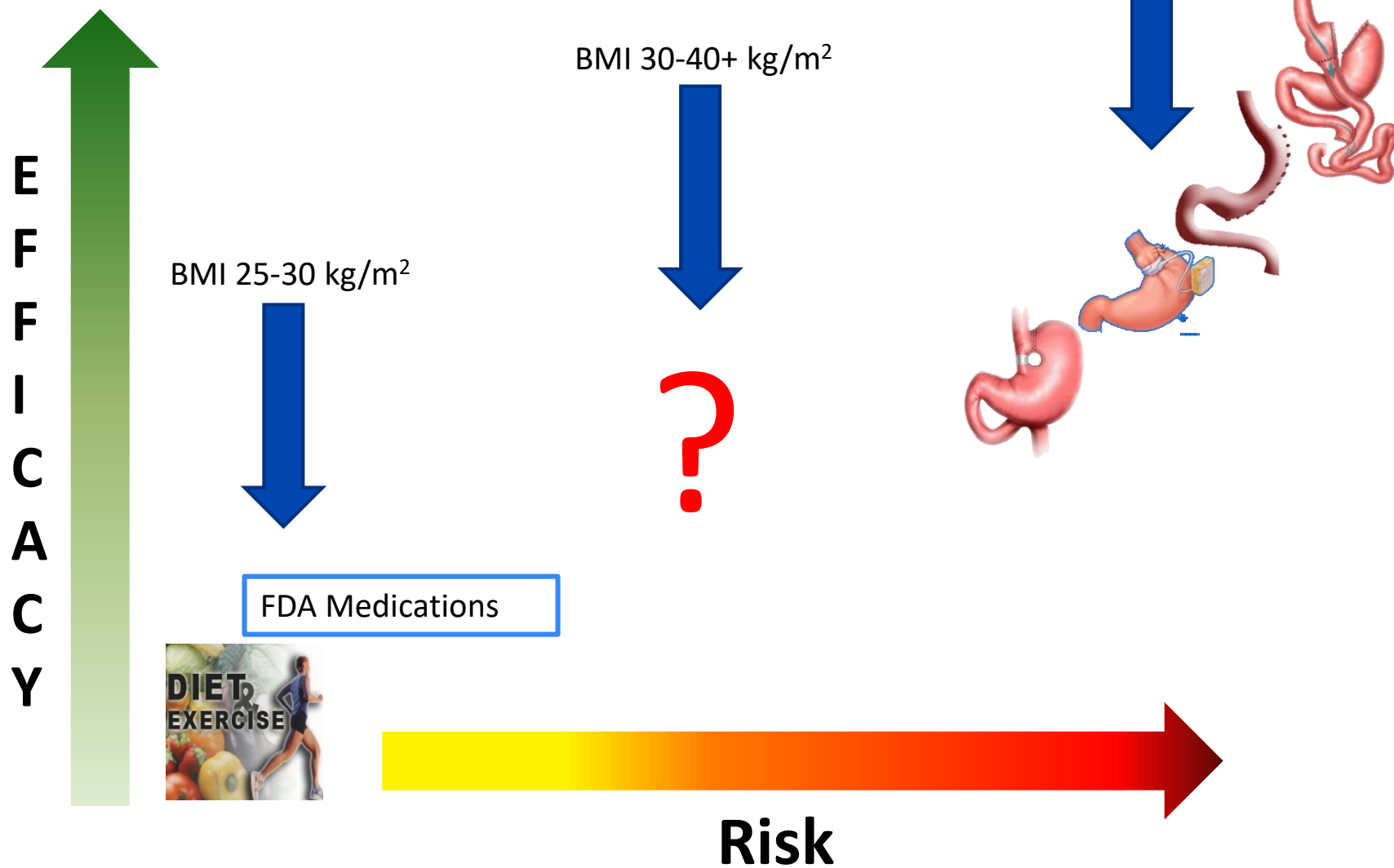


What Is Going On Here?

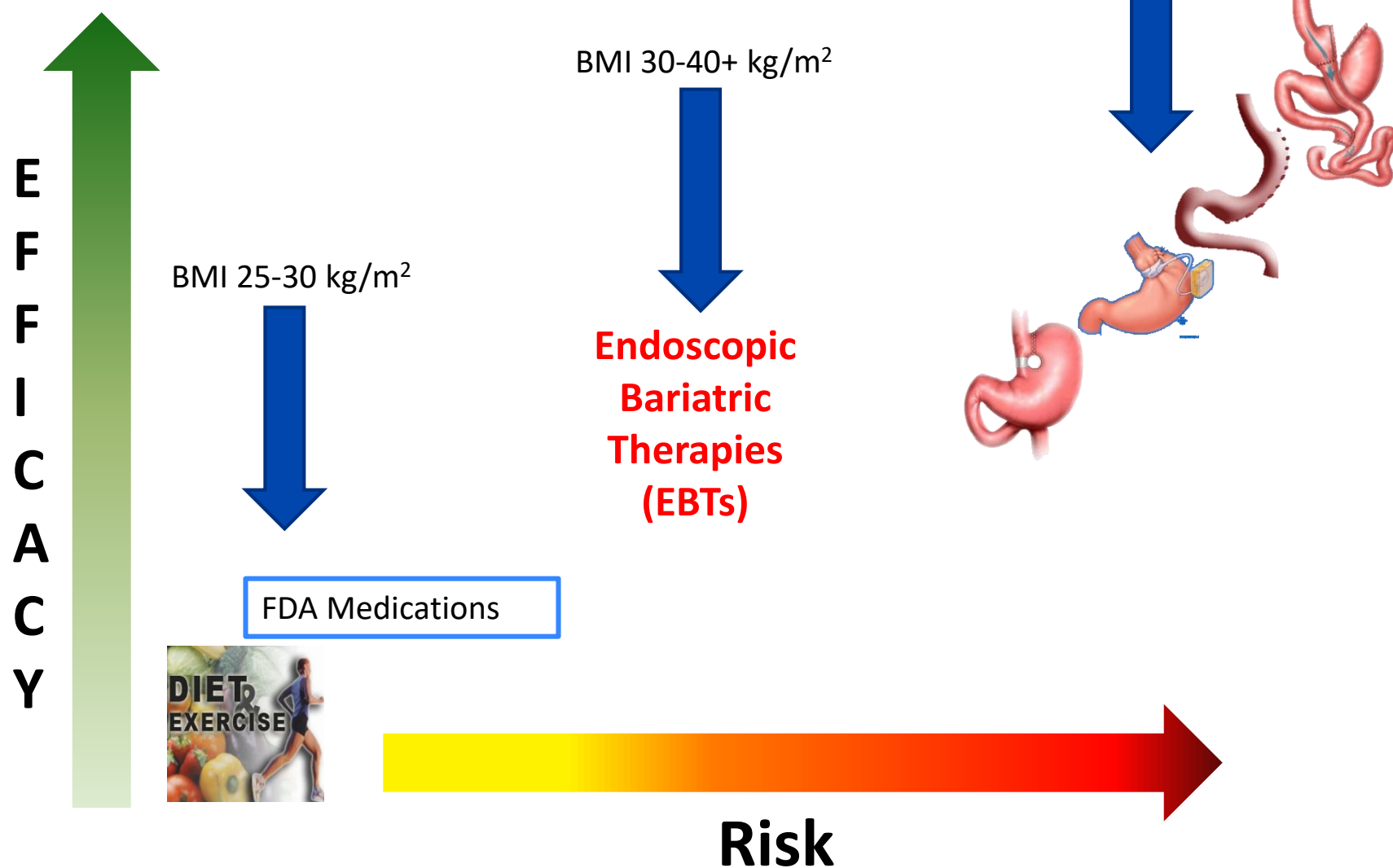
- Fear of surgery
- Lack of insurance coverage
- BMI not high enough
- Not enough/lack of obesity-related comorbidities
- Patient misperceptions of weight status and issues



Treatments for Obesity



Treatments for Obesity



Types of EBTs

Space occupying

- Intra-gastric balloons ★
- TransPyloric Shuttle ★
- Full Sense

Gastric Remodeling/ Plication

- Endoscopic Sleeve Gastroplasty (ESG) ★
- Primary Obesity Surgery Endoluminal Procedure 2 (POSE2)

Malabsorption/Aspiration

- Aspiration Therapy ★
- Gastrointestinal bypass sleeves
- Duodenal mucosal resurfacing
- Small bowel magnets

★ FDA approved device or therapy

Intragastric Balloon (IGB)

IGB

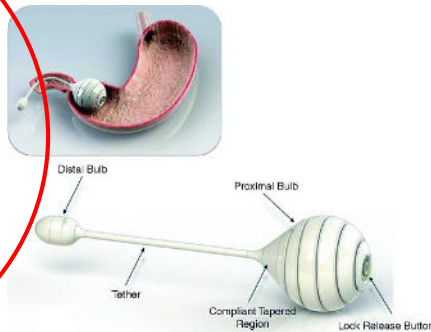
- Four approved by FDA:
 - Orbera
 - TransPyloric Shuttle
 - Obalon IGB
 - ReShape Duo
 - *Spatz3 (under review by FDA)- longer term balloon up to 12 months*
- Mechanisms of action:
 - Delays gastric emptying
 - Early satiety due to space occupying device

FDA approved for 6-month duration

Orbera



TransPyloric Shuttle



Obalon



Reshape Duo



Spatz3



An endoscopic view showing the placement of an intragastric balloon. The balloon is being inserted into the stomach through the pylorus. The surrounding mucosal tissue is visible.

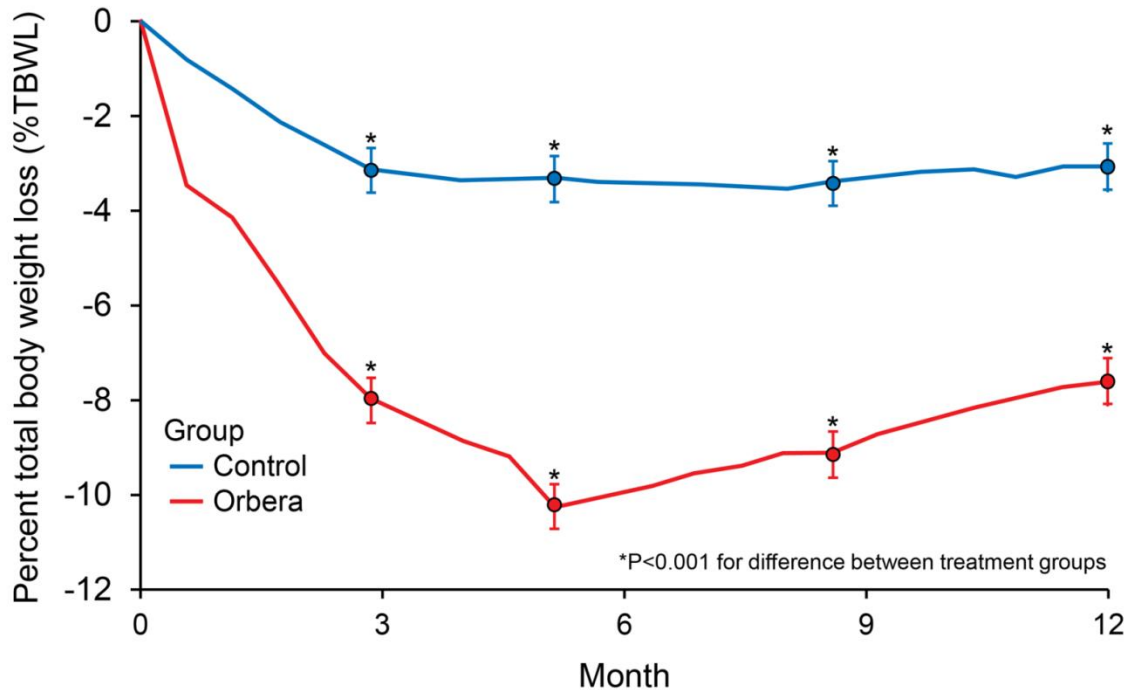
Intragastric
Balloon
Placement

□An endoscopic view showing the removal of an intragastric balloon. The balloon is being deflated and pulled out of the stomach. The surrounding mucosal tissue is visible.

Intragastric
Balloon
Removal

□

% TBWL with Orbera: US Pivotal Trial (ITT) N= 255



- ✓ IGB+ LIP patient can achieve 3 x weight loss at 6 months compared to LIP alone
- ✓ Majority of weight loss occurs in the first 3 months

IGB- intragastric balloon
LIP- lifestyle intervention program

IGB Therapy Induces Significant Metabolic and Histologic Improvement in Patients with Nonalcoholic Steatohepatitis (NASH)

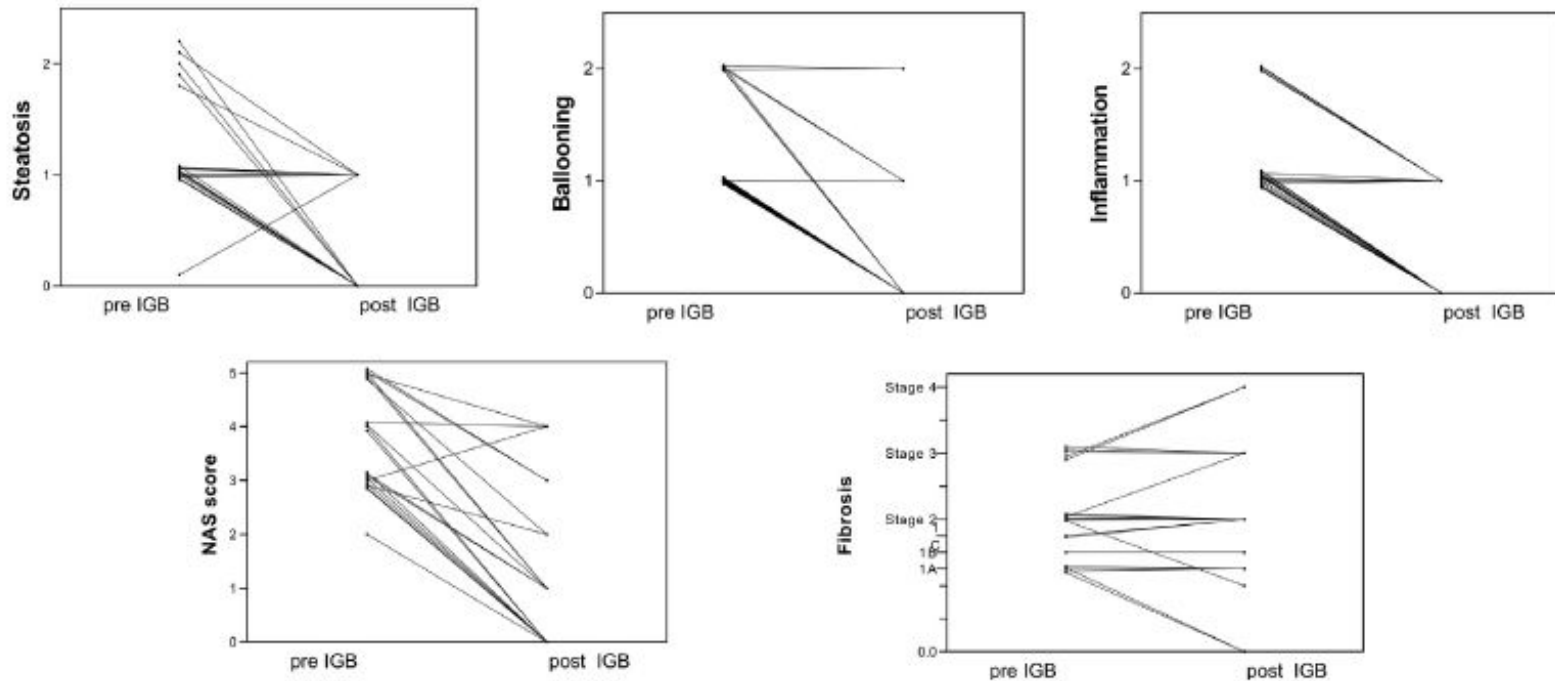


Figure 2. Individual patient change in NAS and fibrosis pre- and post-IGB therapy.

CLINICAL PRACTICE GUIDELINES

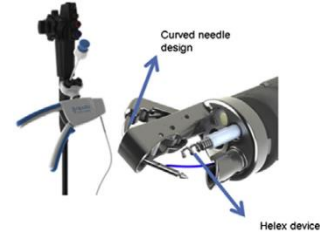
AGA Clinical Practice Guidelines on Intragastic Balloons in the Management of Obesity



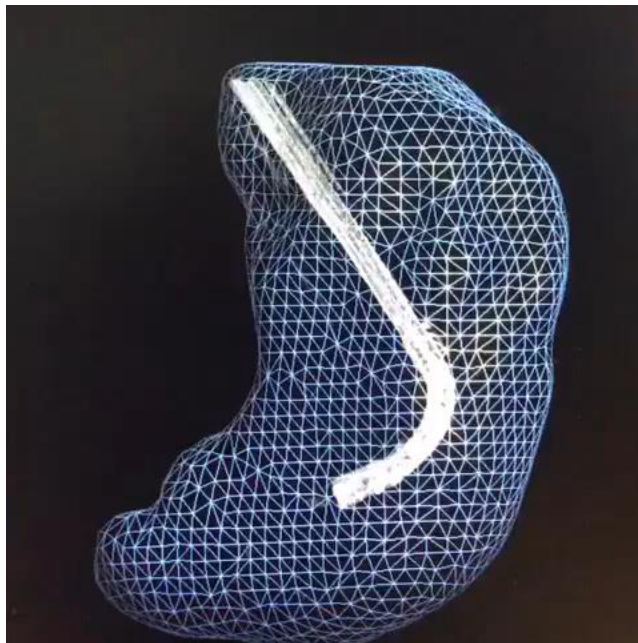
Thiruvengadam Muniraj,¹ Lukejohn W. Day,² Levi M. Teigen,³ Edith Y. Ho,⁴ Shahnaz Sultan,⁶ Perica Davitkov,^{5,7} Raj Shah,^{5,7,8} and M. Hassan Murad⁹

Endoscopic Sleeve Gastroplasty (ESG)

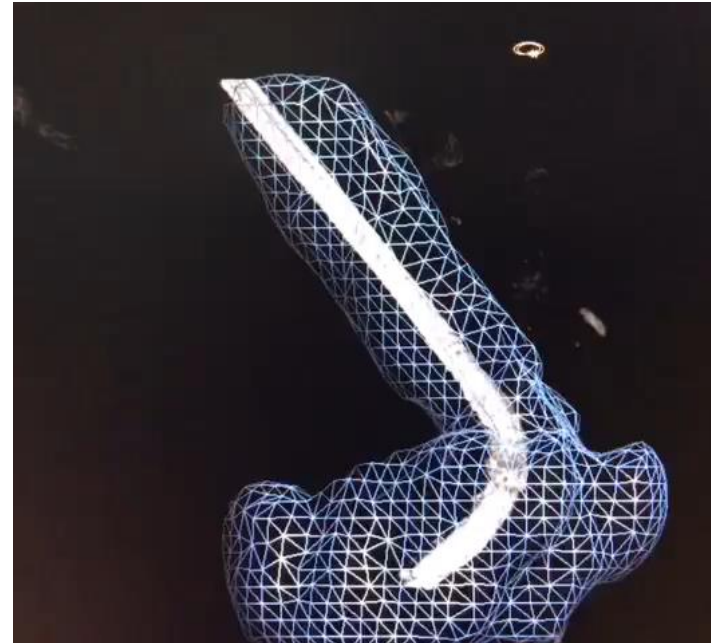
Endoscopic Sleeve Gastroplasty (ESG)



- Reduction of stomach area (> 70%) along greater curvature by endoscopic placement of full-thickness sutures, creating sleeve
- Induces early satiety
- Delays gastric emptying



Pre- ESG



After ESG

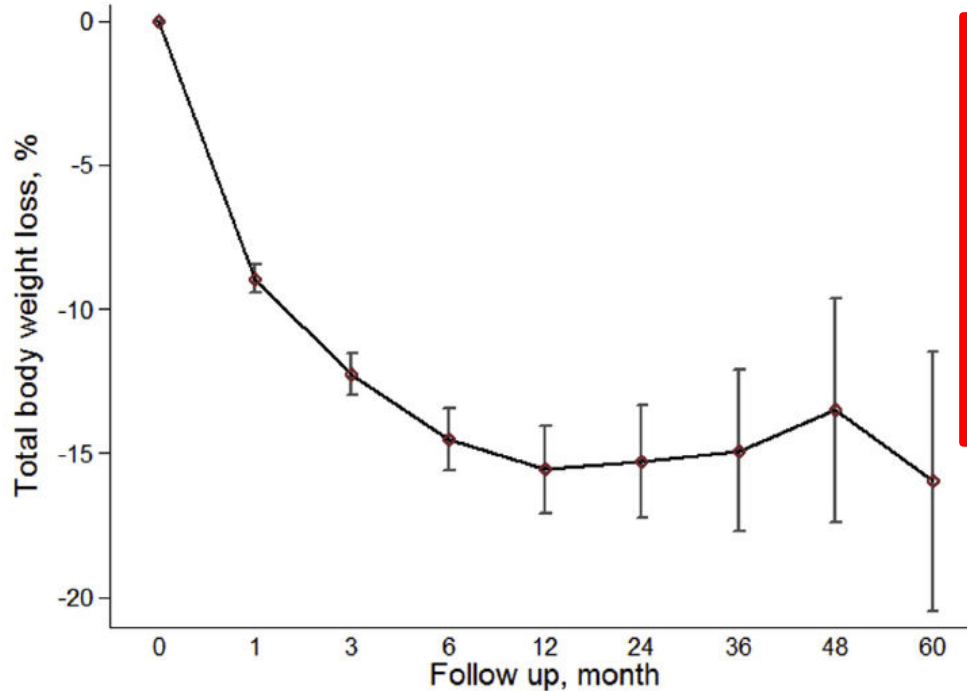
ESG %TWL Outcomes at 5 Years, N=216 patients

Weill Cornell/New York-Presbyterian Hospital

68% female

Mean age 46 ± 13 years

Mean baseline BMI 39 ± 6 kg/m²



%TBWL 6 mos = 14.5%

% TBWL 12 mos = 15.6%

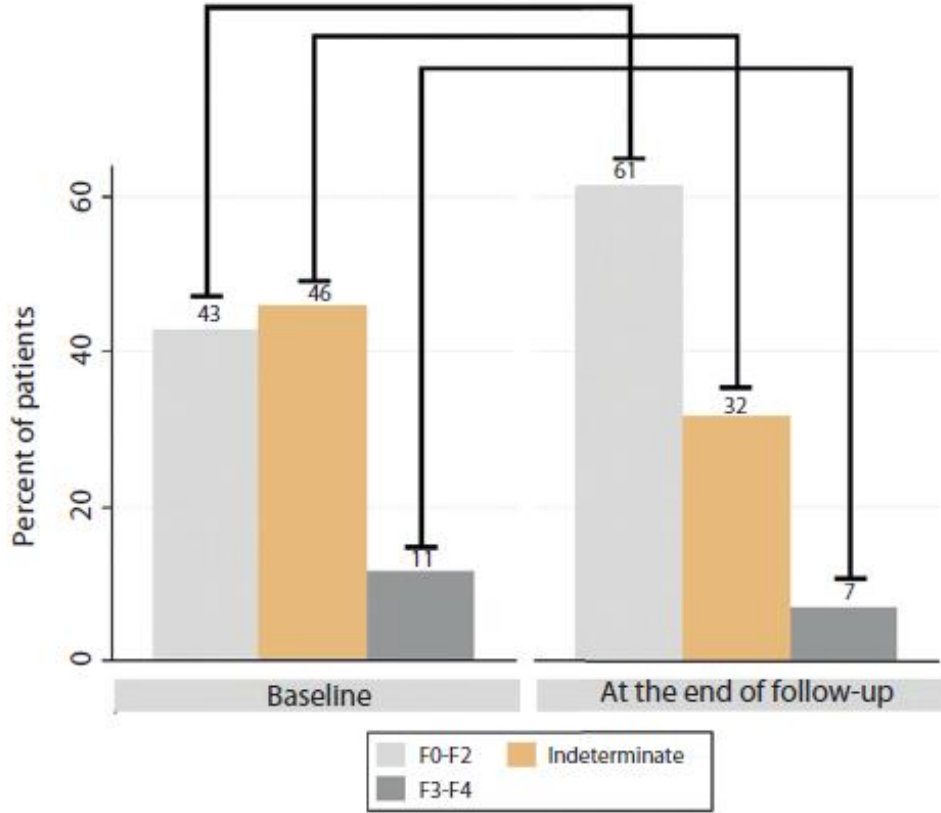
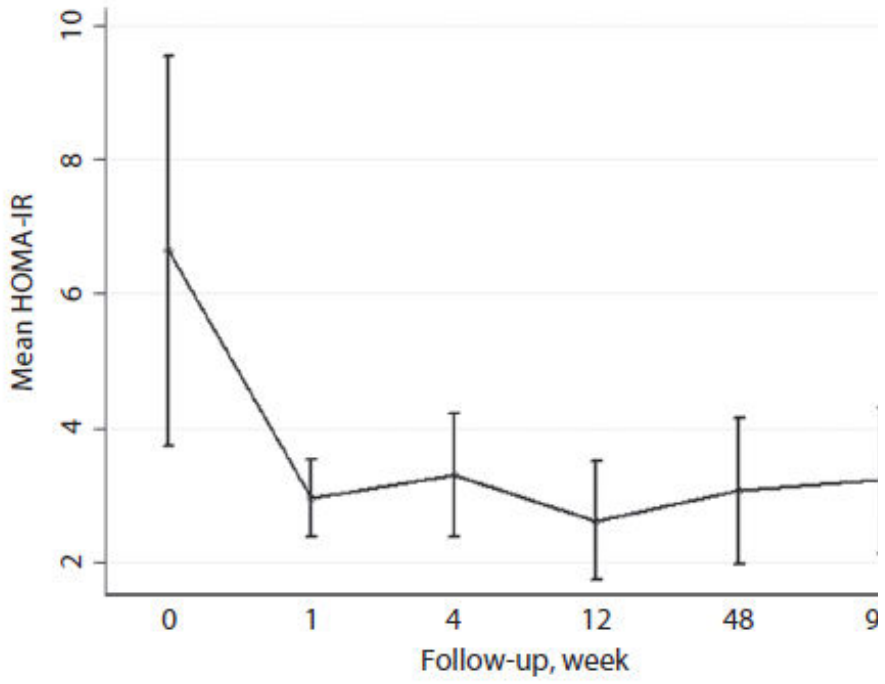
% TBWL 24 mos = 15.3%

% TBWL 36 mos = 14.9%

% TBWL 60 mos = 15.9%

90% and 61% of patients maintained 5% and 10% TWL, respectively

ESG Improves Insulin Resistance and Steatohepatitis



ESG: Prospective Studies

- Multi-center ESG randomized interventional Trial (MERIT-Trial) with estimated 200 participants completed, data to be presented in 2021

Patient Selection

Patient Selection

- Struggled with weight for years
 - Off and on dieting
 - Successful weight loss followed by weight regain
 - Embarrassing for patients- be sensitive and compassionate

- Body Mass Index:
 - Overweight BMI 27-30 with comorbidities
 - Metabolic syndrome
 - BMI 30+ with/without obesity related comorbidities

Patient Selection: Additional Indications for EBTs

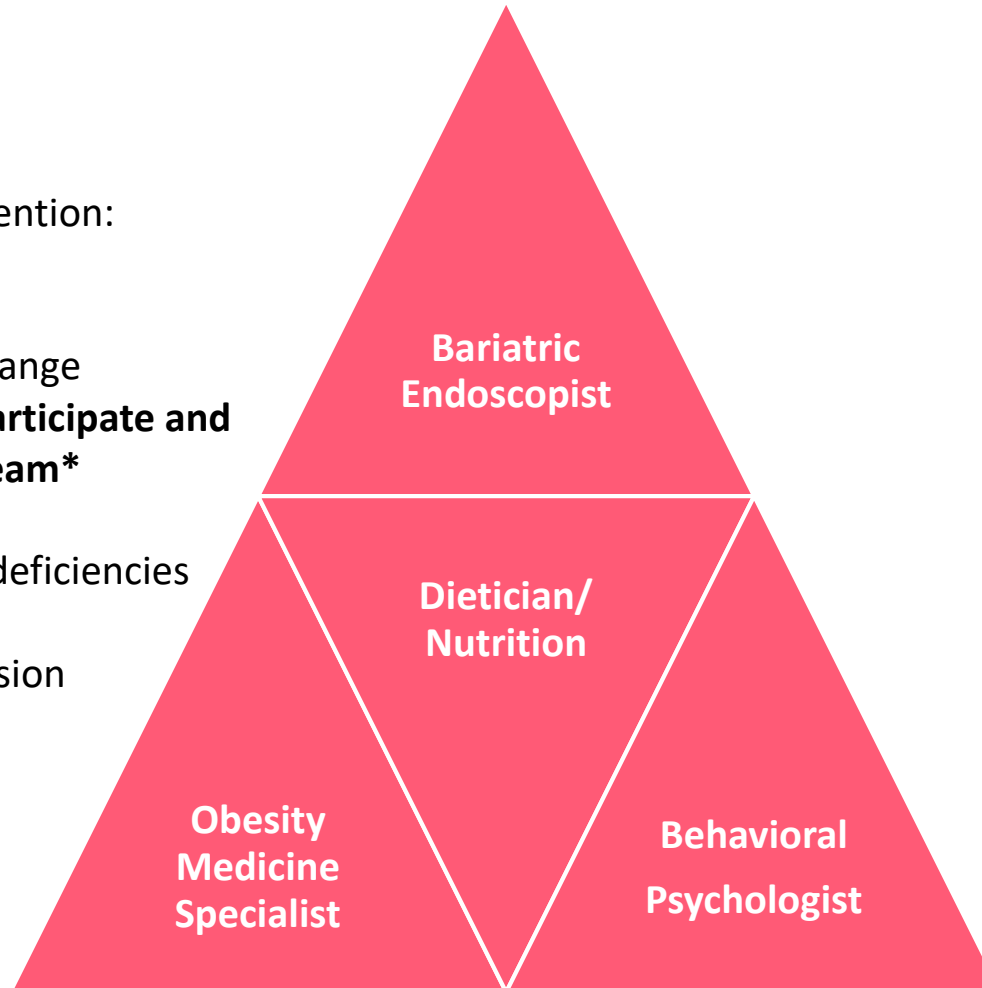
- Bridge to surgery when surgery may not be safe
 - Bariatric surgery
 - Non-bariatric surgery
 - Orthopedic, Neurosurgical, Colorectal
- Bridge to weight loss for organ transplant
 - Heart transplant patients with LVADs*

Important Considerations and Barriers

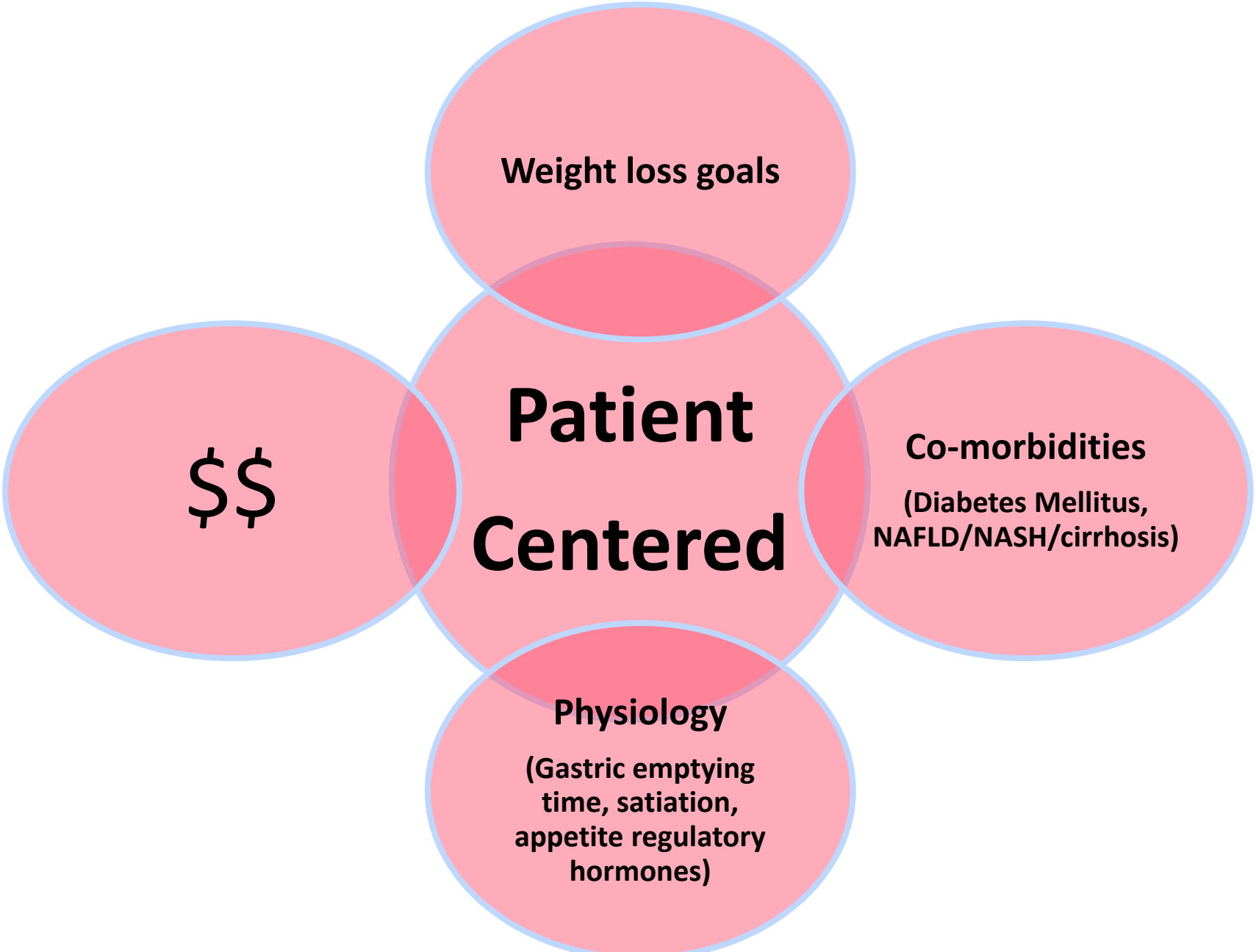
- EBTs are not for everyone!
 - Class III Obesity
 - Many obesity-related comorbidities
 - Poorly controlled Type 2 Diabetes Mellitus
- Patient and medical professional misperceptions about obesity:
 - Lack of knowledge about severity of obesity
 - Providing up to date recommendations
 - Realizing the obesity is a chronic medical condition

EBT Infrastructure: Multidisciplinary Team

- Intense lifestyle intervention:
 - Eating behaviors
 - Physical activity
 - Willingness to change
 - **Willingness to participate and follow up with team***
- Macro/micronutrient deficiencies
- GI anatomy
- NASH/portal hypertension



Which EBT to Choose?



Conclusions

- Bariatric endoscopy is rapidly evolving and gaining momentum
- EBT weight loss data shows that these interventions are
 - Durable
 - Improve metabolic outcomes
 - Play a crucial role in the management of obesity and metabolic diseases
- EBTs must be incorporated into a comprehensive weight management program

Muchas Gracias!

Gomez.victoria@mayo.edu



Check out my YouTube Channel!

<https://www.youtube.com/channel/UCV6sIOdsZlejx5VTDVBEBAAQ>