

Obesity Management



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MEDICAL MANAGEMENT OF OBESITY

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Director of Obesity Medicine VMFH

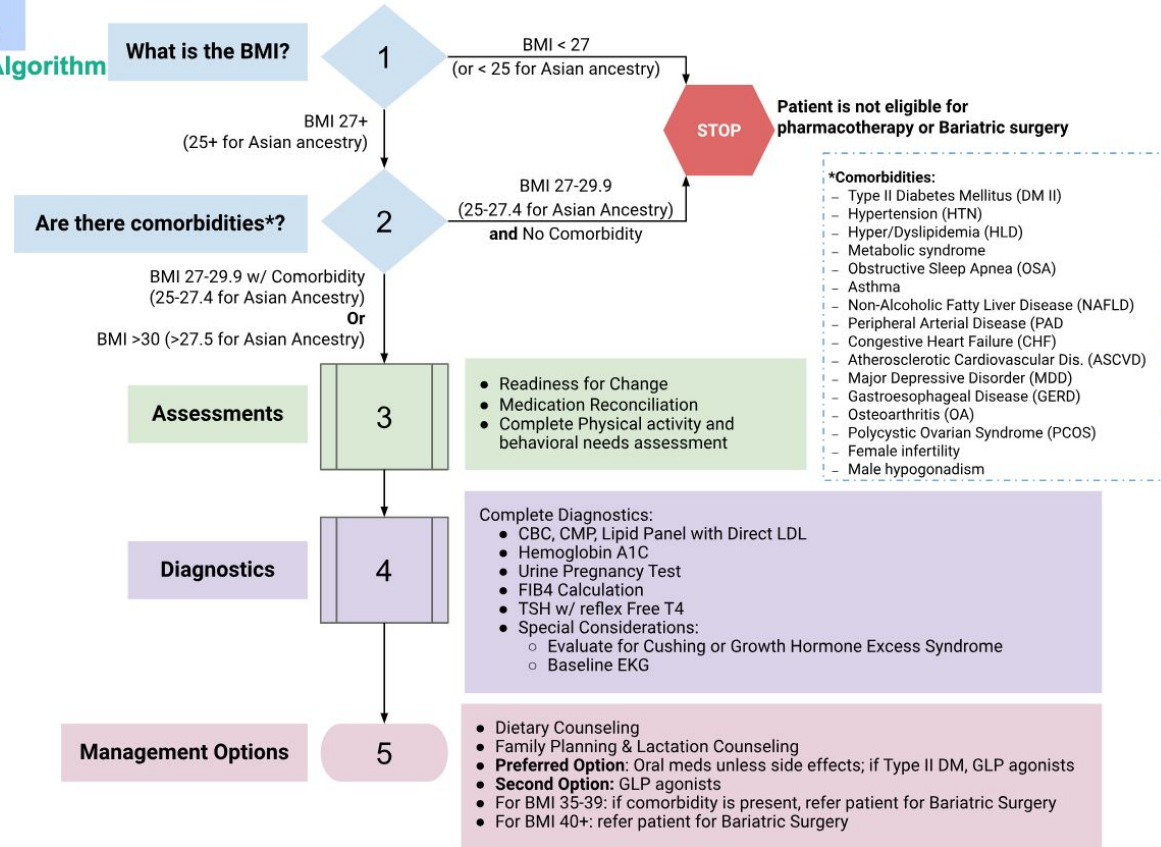
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NO DISCLOSURES

OBJECTIVES:

- Discuss evidence supporting Lifestyle that will help with weight loss
- Current Anti- obesity medications and its other uses.
- Exciting emerging Anti- obesity medications that are in trials

Figure 1:
Overall Algorithm



EVIDENCE-BASED LIFESTYLE INTERVENTIONS

- Components

1. **DIET:** Minimal difference in weight loss between diet types. Key is calorie restrictions and adherence.
 2. **PHYSICAL ACTIVITY:** > 150 minutes/ week
- **Best evidence** for 5- 10% weight loss is with **face-to-face** sessions 1-2 x/ month

AHA/ACC/TOS guidelines: Best diet for weight loss

- 17 diets reviewed- Low cal, low carb, low glycemic, vegan, lacto-ovo veg, Mediterranean, DASH, zone- like, Atkins- like and others
- For weight loss over at least 1 year there was no one superior diet.

Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. J Am Coll Cardiol 2014;63(25 Pt B):2985-3023.



Adults need a mix of physical activity to stay healthy.

Moderate-intensity aerobic activity*

Anything that gets your heart beating faster counts.



AND

Muscle-strengthening activity

Do activities that make your muscles work harder than usual.



If you prefer vigorous-intensity aerobic activity (like running), aim for at least **75 minutes a week**.

If that's more than you can do right now, **do what you can**. Even 5 minutes of physical activity has real health benefits.

Walk. Run. Dance. Play. **What's your move?**



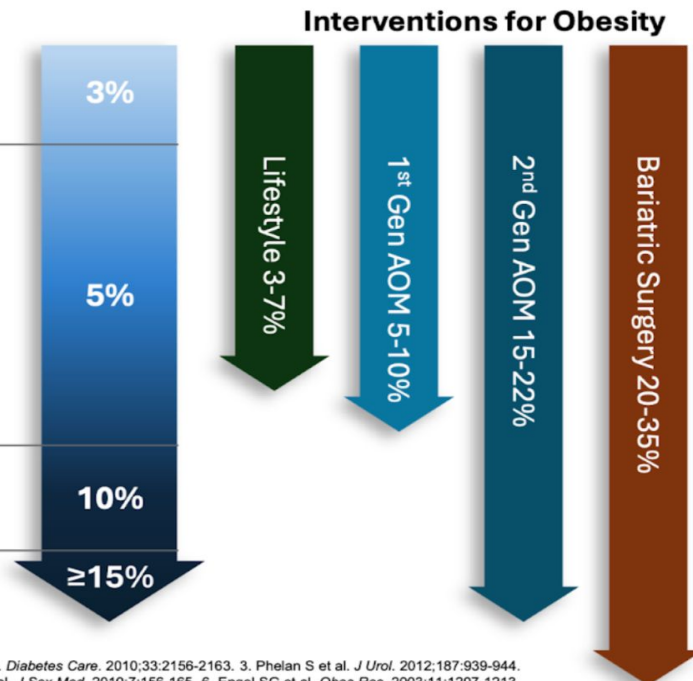
ANTI- OBESITY MEDICATIONS

GUIDELINES FOR SELECTING OBESITY TREATMENT

TREATMENT		BMI	Kg/m2		
	25- 26.9	27- 29.9	30-34.9	35-39.9	> 40
Lifestyle Therapy	+	+	+	+	+
Pharmacotherapy	-	comorbidity	+	+	+
Surgery	-	+	comorbidity	+	+

Percentage Of Weight Reduction And Health Improvements

- Blood glucose
- Triglycerides
- HDL-Cholesterol¹
- Systolic and diastolic blood pressure
- Hepatic steatosis measured by MRS²
- Measures of feeling and function
 - Symptoms of urinary stress incontinence³
 - Measures of sexual function^{4,5}
 - Quality of life measures (IWQOL)⁶
- NASH Activity Score on biopsy⁷
- OSA Apnea-Hypopnea Index⁸
- Remission of T2D, reduction in CV events, mortality



1. Wing RR et al. *Diabetes Care*. 2011;34:1481-1486. 2. Lazo M et al. *Diabetes Care*. 2010;33:2156-2163. 3. Phelan S et al. *J Urol*. 2012;187:939-944. 4. Wing RR et al. *Diabetes Care*. 2013;36:2937-2944. 5. Wing RR et al. *J Sex Med*. 2010;7:156-165. 6. Engel SG et al. *Obes Res*. 2003;11:1207-1213. 7. Promrat K et al. *Hepatology*. 2010;51:121-129. 8. Foster GD et al. *Arch Intern Med*. 2009;169:1619-1626. 9. Després JP et al. *BMJ*. 2001;322:716-720.

Orlistat

Dosing

60 mg or 120 mg

Three times daily before meals

Side Effects & Considerations

Diarrhea

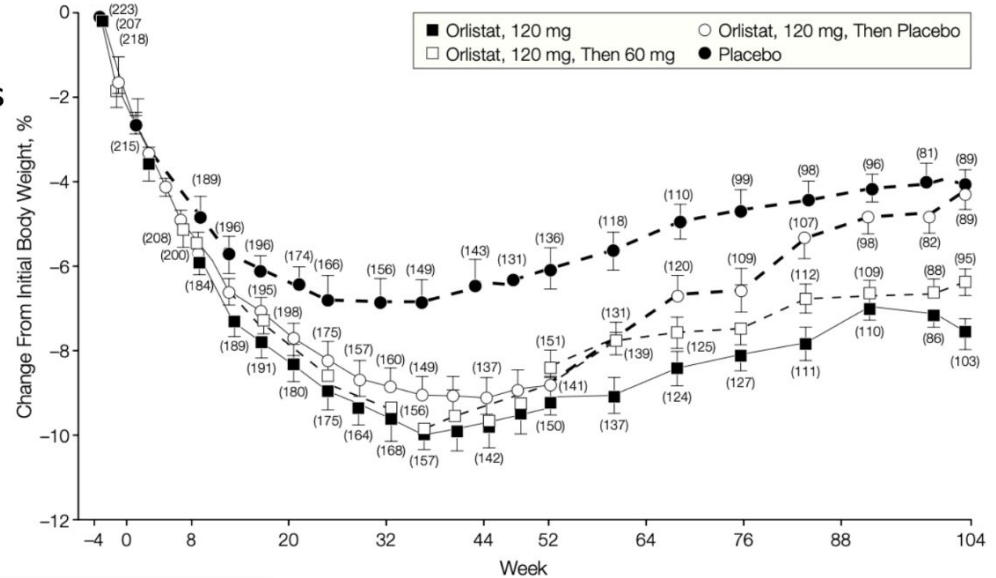
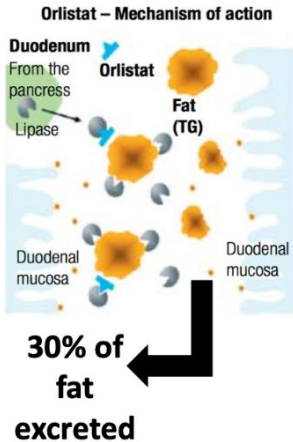
Malabsorption

Nephrolithiasis

Severe liver injury (rare)

Cost per month

\$42 (60 mg), \$556 (120 mg)



	Orlistat	Placebo
Weight loss 1 year	8.8%	5.8%
>5% weight loss	65.7%	43.6%
>10% weight loss	38.9%	24.8%

Naltrexone Bupropion ER

Dosing

8/90 mg – two tabs twice daily

Side Effects & Considerations

Gastrointestinal upset

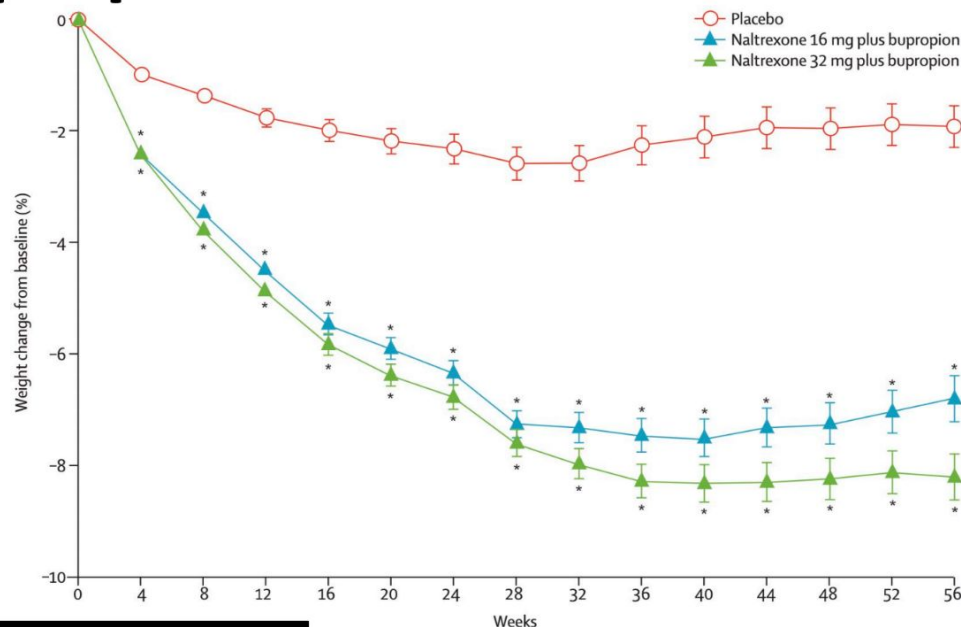
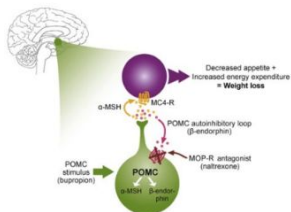
Opiates efficacy

Insomnia, mood changes

Lower seizure threshold

Average cost per month

\$231-290



	NAL/BUP	Placebo
Weight Loss	6.1%	1.3%
>5% weight loss	48%	16%
>10% weight loss	21%	7%

Naltrexone Bupropion Regimens

**Bupropion SR 150 mg
60 tablets
\$9 per month Walmart**

**Bupropion SR 150 mg daily AM for two
weeks then 150 mg BID**

**Bupropion XL 150 mg
30 tablets
\$4 per month GoodRx**

**Bupropion XL 150 mg – one daily AM
for two weeks then two daily**

**Naltrexone 50 mg
30 tablets
\$28 per month GoodRx**

COMBINATION THERAPY

**Bupropion 150 mg daily AND
Naltrexone 25 mg daily for 2 weeks
THEN INCREASE TO:**

**Bupropion SR 150 BID or XL 300 mg QD
And naltrexone 25 BID or 50 mg QD**

**Contrave 8/90 mg 2 BID
\$99 patient discount**

\$192-239 for maximum dose

Phentermine Topiramate Off Regimens

**Phentermine 15 mg
Capsules
\$14 per month**

Phentermine 15 or 18.75 mg daily AM

**Phentermine 18.75 mg
Half-37.5 mg tab
\$4.80 per month**

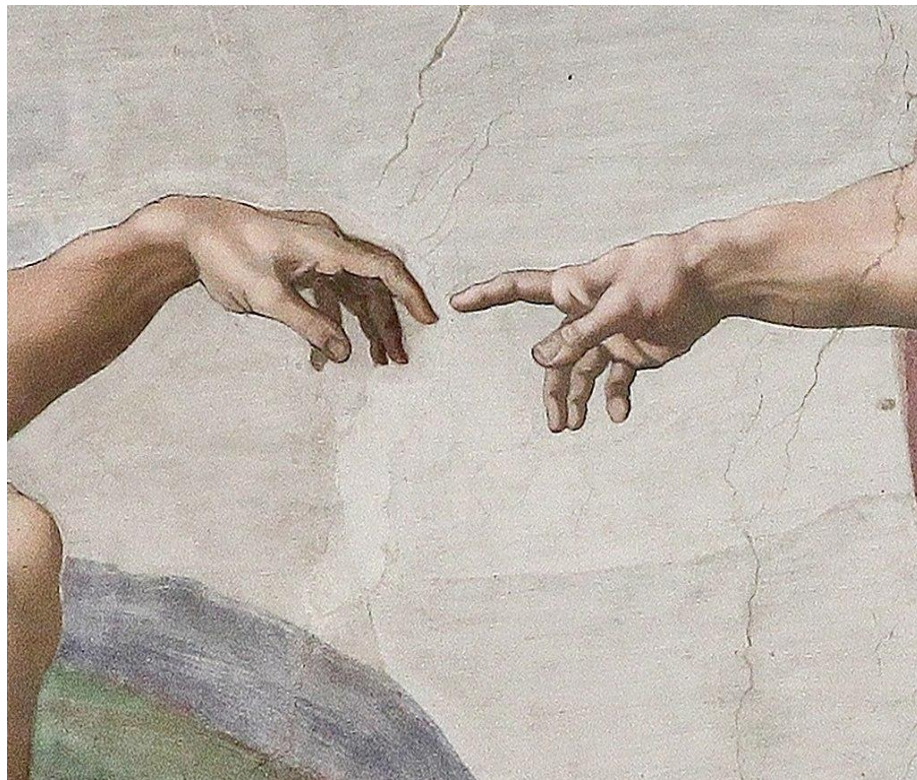
**Phentermine 15 or 18.75 mg daily AM
Topiramate 25 mg QD x 2 wks then BID**

**Topiramate 50 mg
Half or one 50 mg tab
\$4.50-9.00 per month**

**1) Topiramate 25 mg QD x 2 wks
2) Topiramate 25 mg BID x 2 wks
3) Topiramate 50 mg BID**

FACTS - GLP-1

- 1 in 8 adults have used GLP-1 for weight loss.
- More than half have trouble affording the medication
- 90 million US adults are eligible
- If all US adults eligible took GLP-1: it will cost 600 billion dollars/ year. This is equal to all other US drugs spending combined.



Harris JAMA.2024;332(1):8



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Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes

A.M. Linc [ORIGINAL ARTICLE](#) | [VOL. 390 NO. 15](#) | APR 18, 2024 | CME | 

In a trial i **Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes** .perior to
placebo ir M.N. Kosibor [ORIGINAL ARTICLE](#) | [VOL. 389 NO. 12](#) | SEP 21, 2023 | CME |  | FREE
cardiovas

Among patien **Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and**
produced grea **Obesity**

fraction... and M.N. Kosiborod and Others | N Engl J Med 2023;389:1069-1084
heart failure w

In patients with heart failure with preserved ejection fraction and obesity, semaglutide (2.4 mg) led to greater
reductions in syst [ORIGINAL ARTICLE](#) | JUN 21, 2024
impairment, esp
with preserved... **Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity**

A. Malhotra and Others | 10.1056/NEJMoa2404881

...this trial, tirzepatide reduced the apnea–hypopnea index of participants with obstructive sleep apnea and obesity....-
blind, randomized, controlled trials involving adults with moderate-to-severe obstructive sleep apnea and obesity.
Participants who were not receiving treatment with positive airway pressure (PAP) at baseline... ..mild to moderate in
severity. Among persons with moderate-to-severe obstructive...

Long-Term Management

SCIENTIFIC
AMERICAN

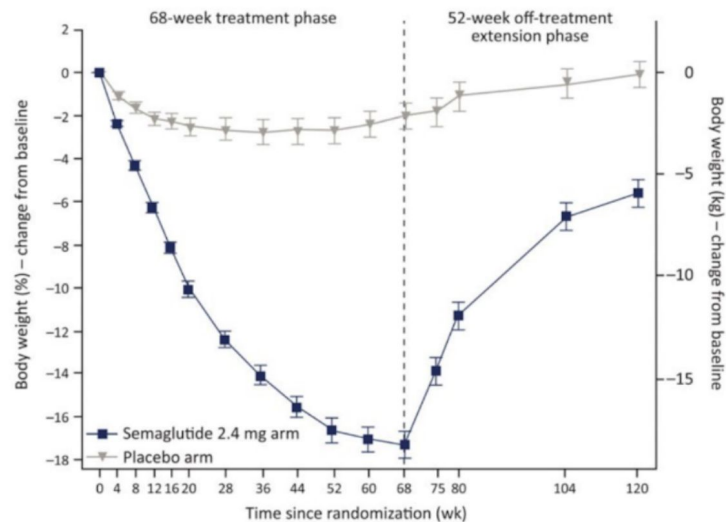
What Happens When You Quit Ozempic or Wegovy?

Many researchers think that Wegovy and Ozempic should be taken for life, but myriad factors can force people off the drugs

BY MCKENZIE PRILLAMAN & NATURE MAGAZINE



STEP-1 Extension Semaglutide

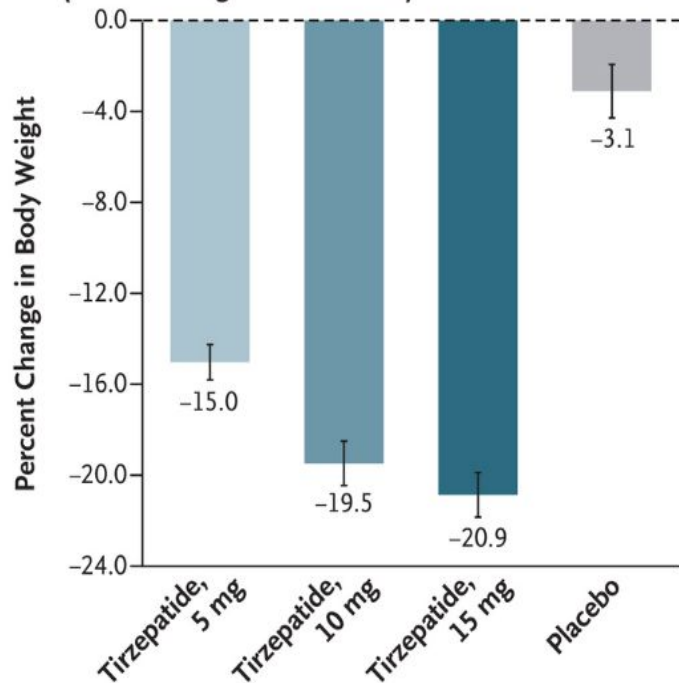


Wilding et al. Diabetes Obes Metab. 2022;24:1553–1564

SURMOUNT I – TIRZEPATIDE IN PATIENTS with OBESITY

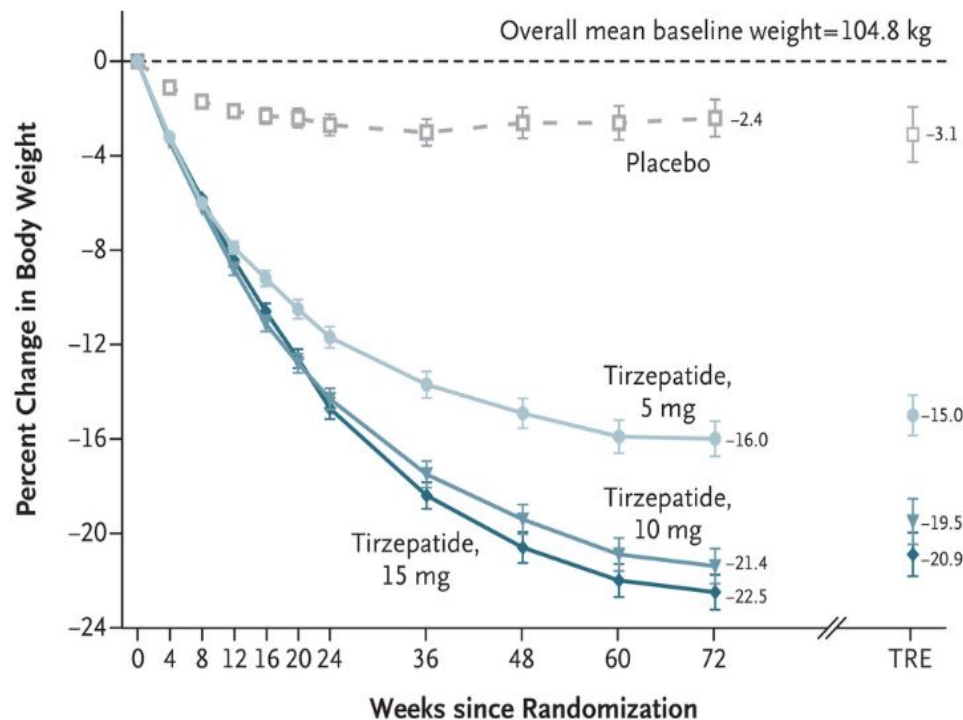
Tirzepatide, 5 mg Tirzepatide, 10 mg Tirzepatide, 15 mg Placebo

A Overall Percent Change in Body Weight from Baseline (treatment-regimen estimand)



Jastreboff et al, NEJM, JUNE 2022

B Percent Change in Body Weight by Week (efficacy estimand)



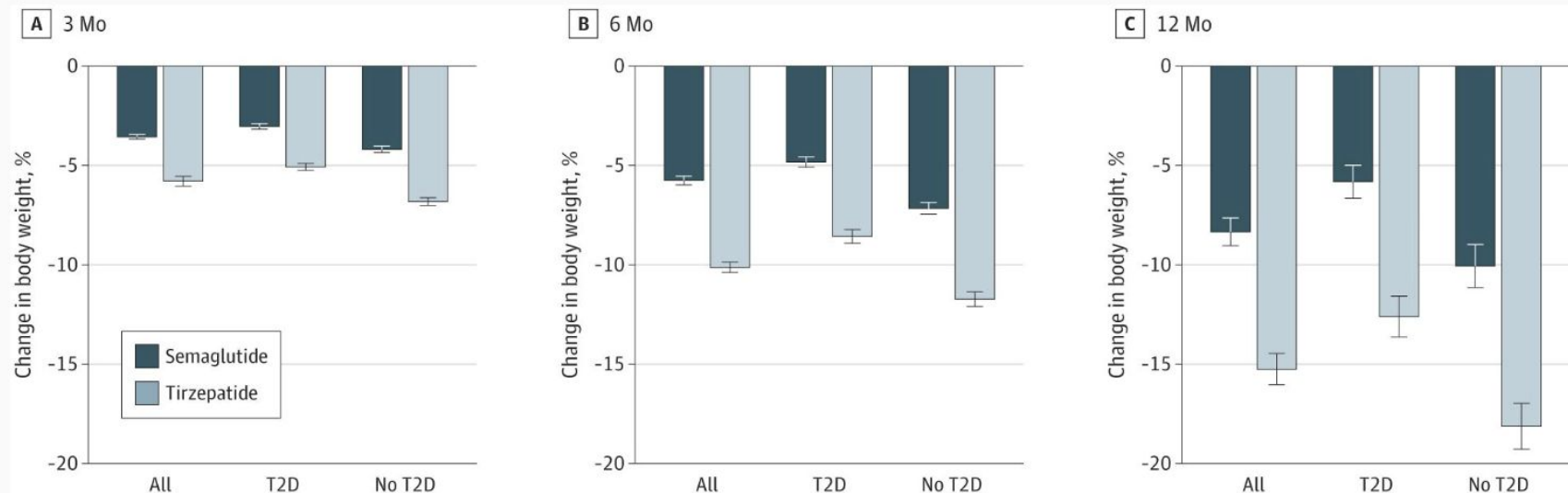


Figure 3. Mean Percentage Change in Body Weight at 3, 6, and 12 Months Receiving Treatment for the Overall Population, Those With Type 2 Diabetes (T2D), and Those Without T2D

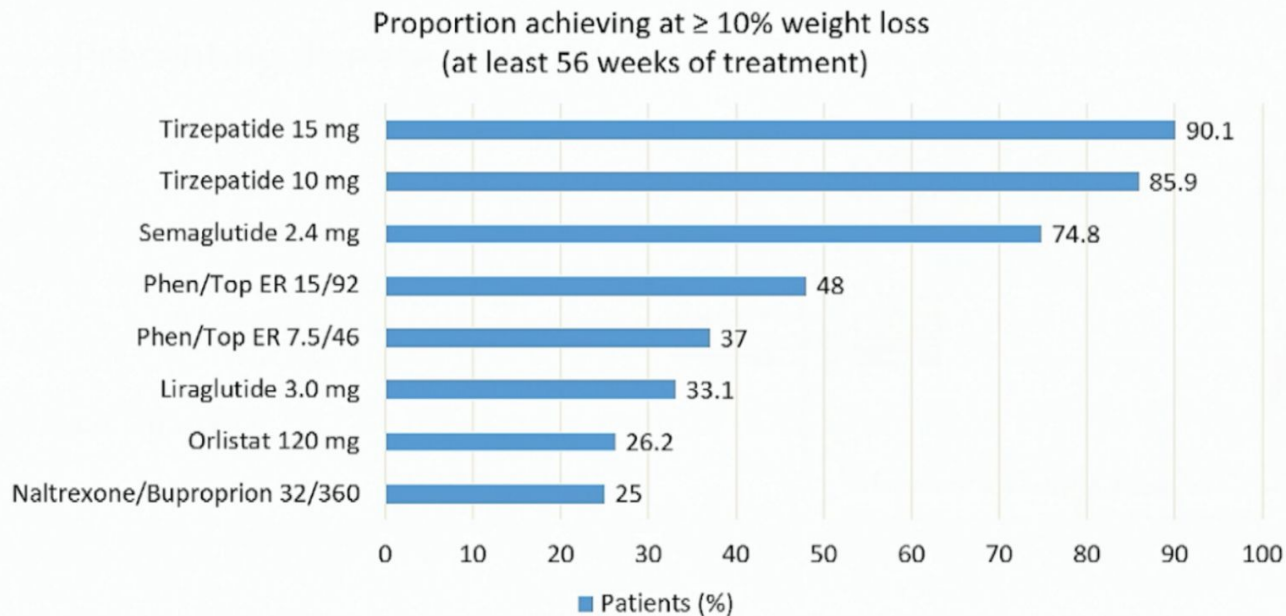
Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity.

JAMA Intern Med. August 31, 2024.

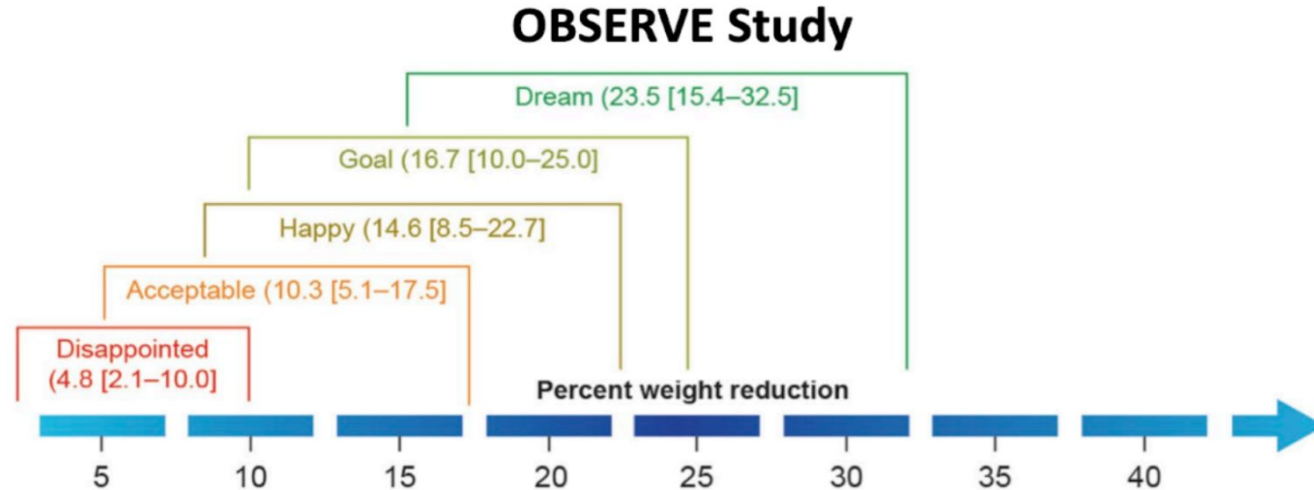
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TREATMENT EFFECTS: EXPECTATIONS



Patient preferred magnitude of weight loss



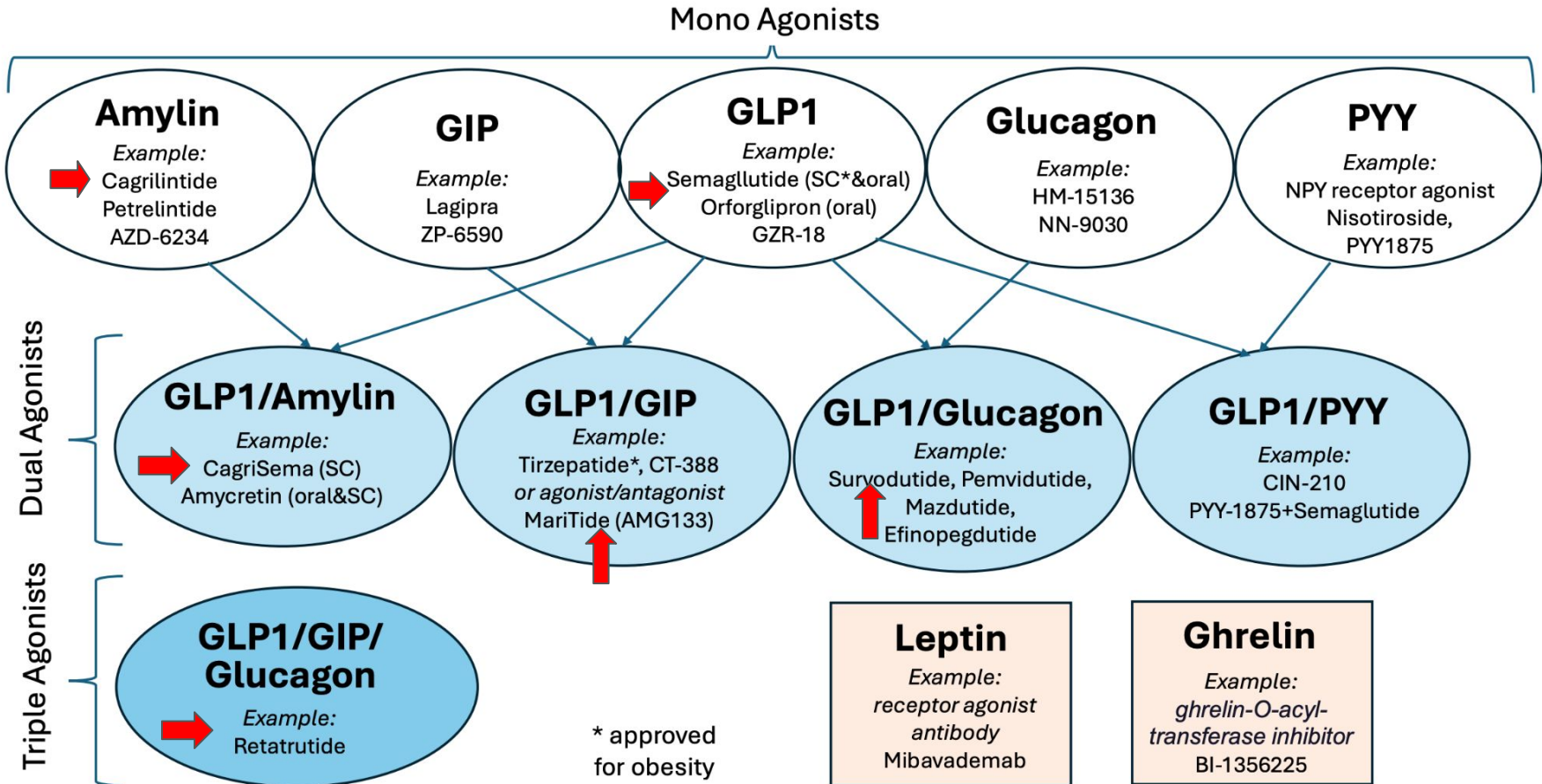
Preferred percent weight reduction by weight class					
BMI categories*	Dream	Goal	Happy	Acceptable	Disappointed
Overweight	12.3 (8.1–17.5)	8.9 (5.3–14.4)	7.4 (3.6–11.3)	4.4 (1.9–8.4)	2.3 (0.7–4.2)
Class I obesity	20.0 (13.5–26.9)	13.3 (8.5–20.0)	12.5 (6.8–18.3)	8.7 (4.4–13.6)	3.9 (1.8–6.9)
Class II obesity	27.2 (20.4–34.8)	20.0 (14.2–27.3)	17.5 (12.4–24.3)	13.0 (8.9–19.7)	6.5 (3.5–12.5)
Class III obesity	36.9 (28.0–45.1)	27.0 (20.0–36.5)	24.0 (15.5–32.7)	17.5 (10.6–27.7)	9.1 (4.8–16.5)

EMERGING THERAPIES

NUTRIENT REGULATED HORMONES

Hormone		Action	Origin
Glucagon-Like Protein-1	GLP-1	stimulated; anorexigenic	L cells, distal intestine, islets
Glucagon	GCG	stimulated; anorexigenic	alpha cells, pancreatic islets
Gastric-Inhibitory Polypeptide	GIP	stimulated; anorexigenic	K cells, duodenum and upper jejunum
Amylin		stimulated; anorexigenic	beta cells, pancreatic islets
Gherlin		suppressed; orexigenic	gastric mucosa
Peptide YY	PYY	stimulated; anorexigenic	L cells, distal intestine
Leptin	LEP	stimulated; anorexigenic	adipocytes

Obesity Medications in Development Based on Nutrient-Regulated Hormones



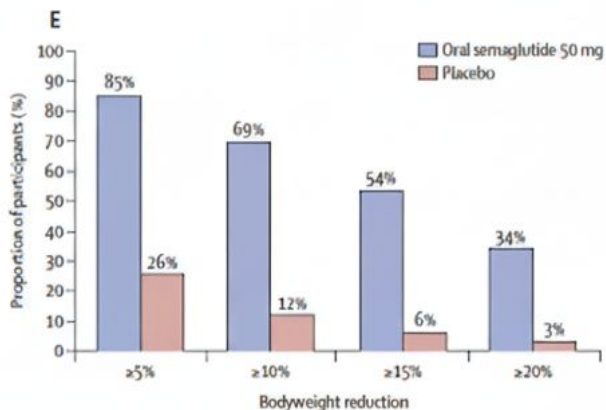
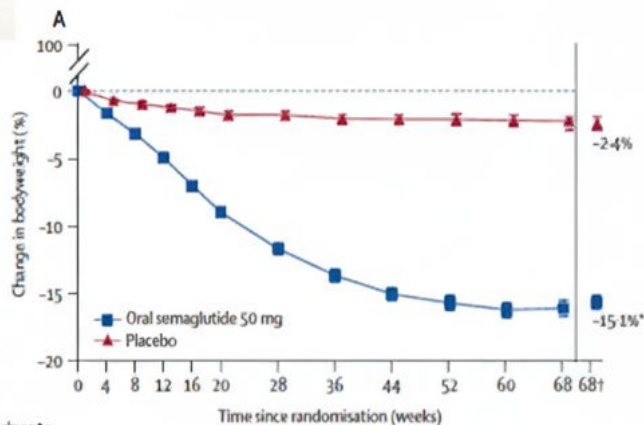
Ongoing Trials with SC Semaglutide 2.4 mg

TRIAL	POPULATION	OUTCOME	DOSE	DURATION	Number
SELECT (completed)	CVOT	MACE superiority	2.4 vs PLB	Event driven	17,604
STEP 9	Osteoarthritis	weight, WOMAC score	2.4 mg vs PLB	68 weeks	407
STEP 10	Prediabetes	weight, HbA1c	2.4 mg vs PLB	52 weeks	181
STEP UP	Obesity	weight	7.2 vs 2.4 vs PLB	72 weeks	1407
STEP UP T2D	Obesity + T2D	weight, (HbA1c)	7.2 vs 2.4 vs PLB	72 weeks	513

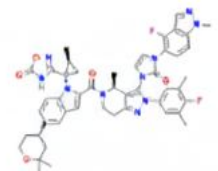
Salcaprozate sodium
(SNAC) molecule

semaglutide molecule

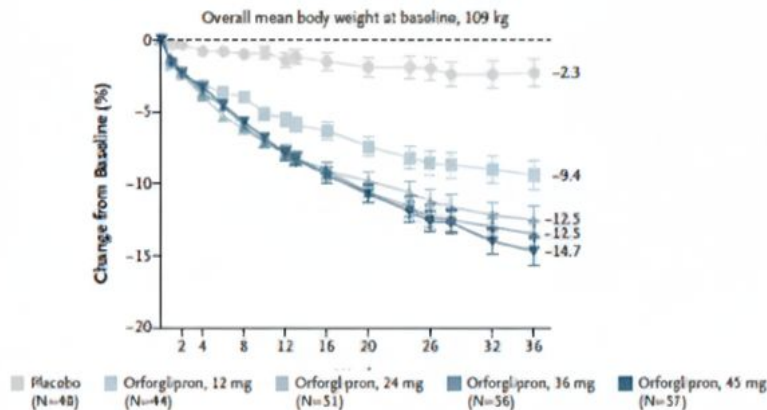
Phase 3 OASIS 1: Oral Semaglutide 50 mg



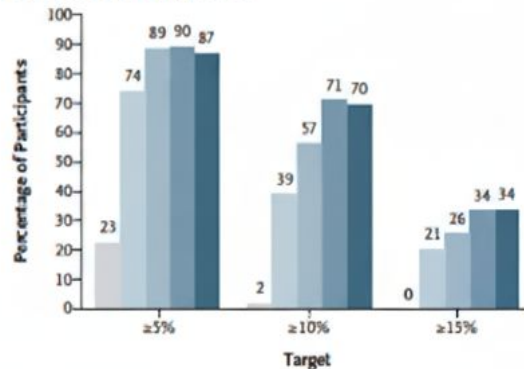
Phase 3: Oral Orforglipron



A Percentage Change in Body Weight (efficacy estimand)



C Weight Reduction by Week 26



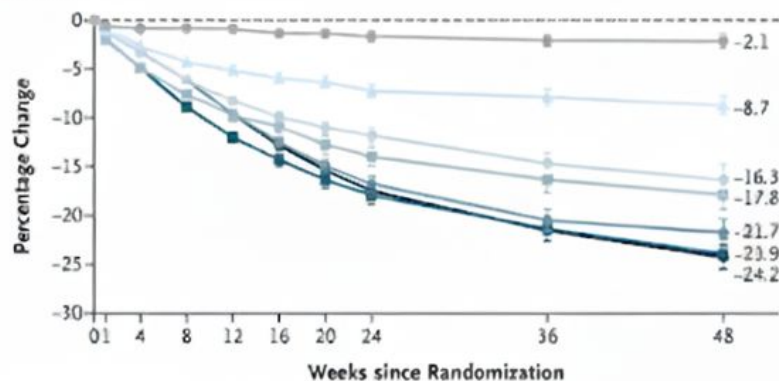
Knop FK et al.
Lancet
2023;402:705
Wharton S et al.
NEJM
2023;389:877

Phase 3: GLP-1/GIP/Glucagon Receptor Agonist Retatrutide

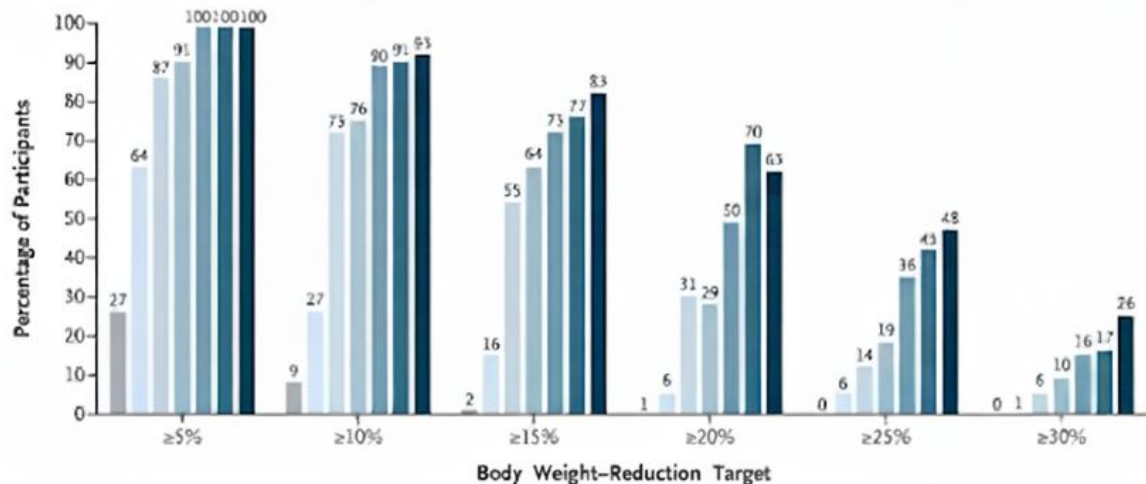
338 adults with
overweight/obesity
randomized to retratrutide at
various starting and ending
doses vs placebo

Placebo Retatrutide, 1 mg Retatrutide, 4 mg (ID, 2 mg) Retatrutide, 4 mg (ID, 4 mg) Retatrutide, 8 mg (ID, 2 mg) Retatrutide, 8 mg (ID, 4 mg) Retatrutide, 12 mg (ID, 2 mg)

A Changes in Body Weight



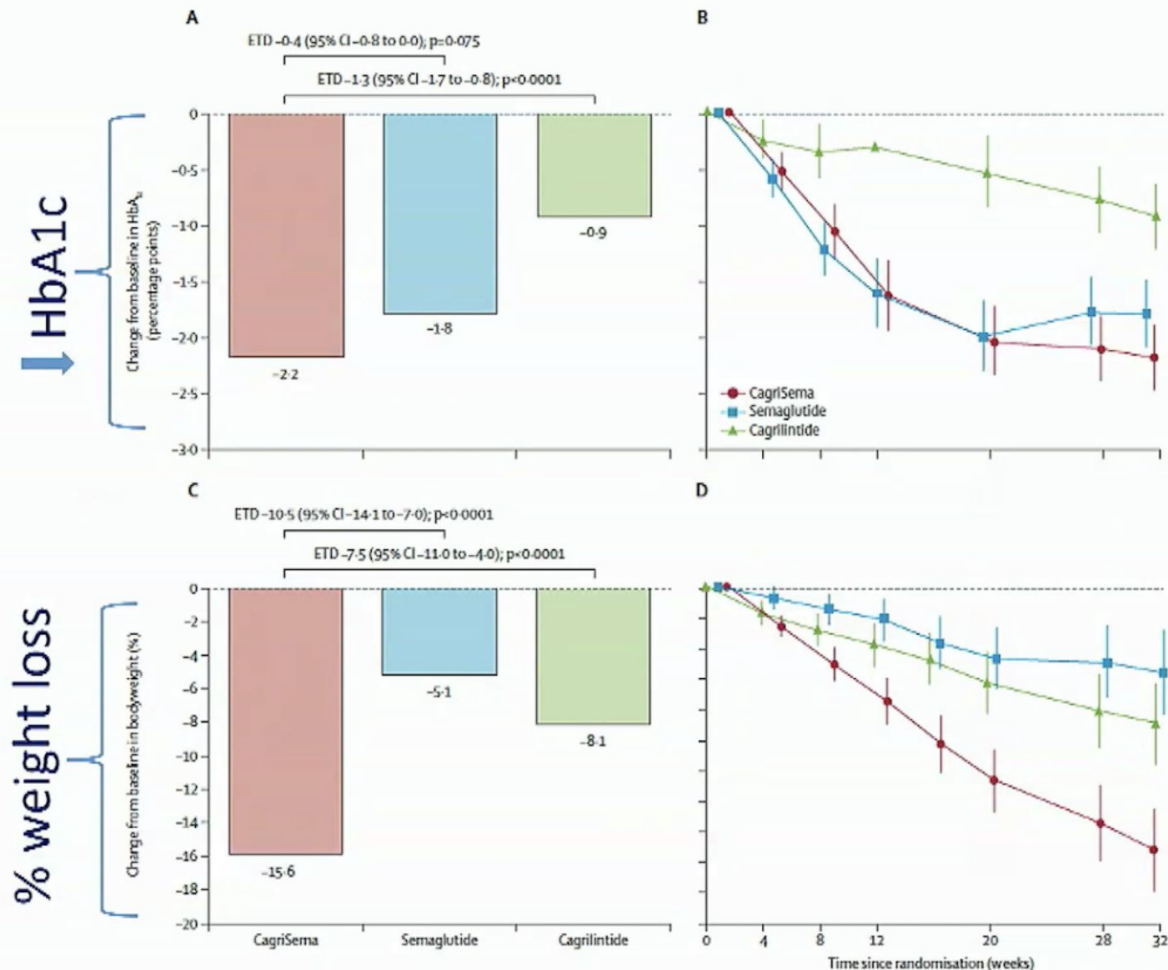
B Attainment of Weight-Reduction Targets



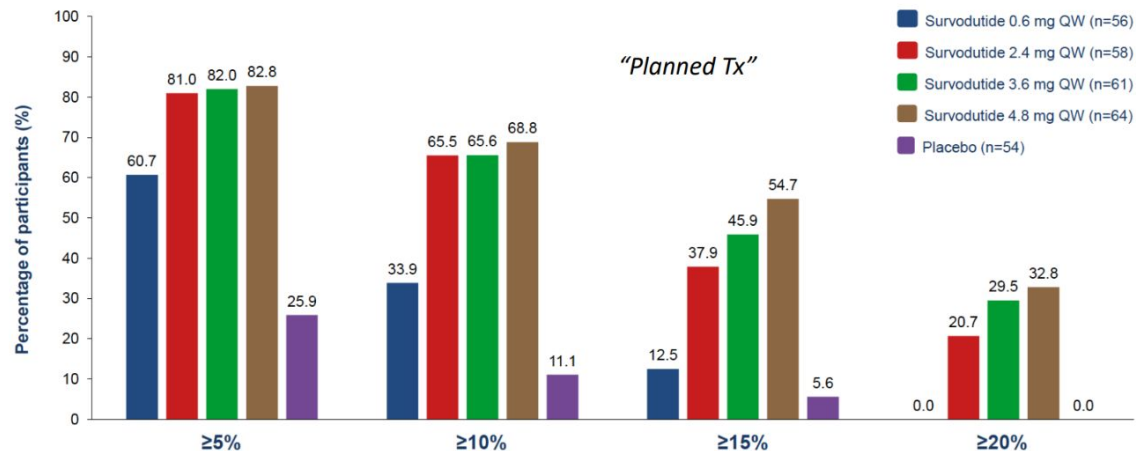
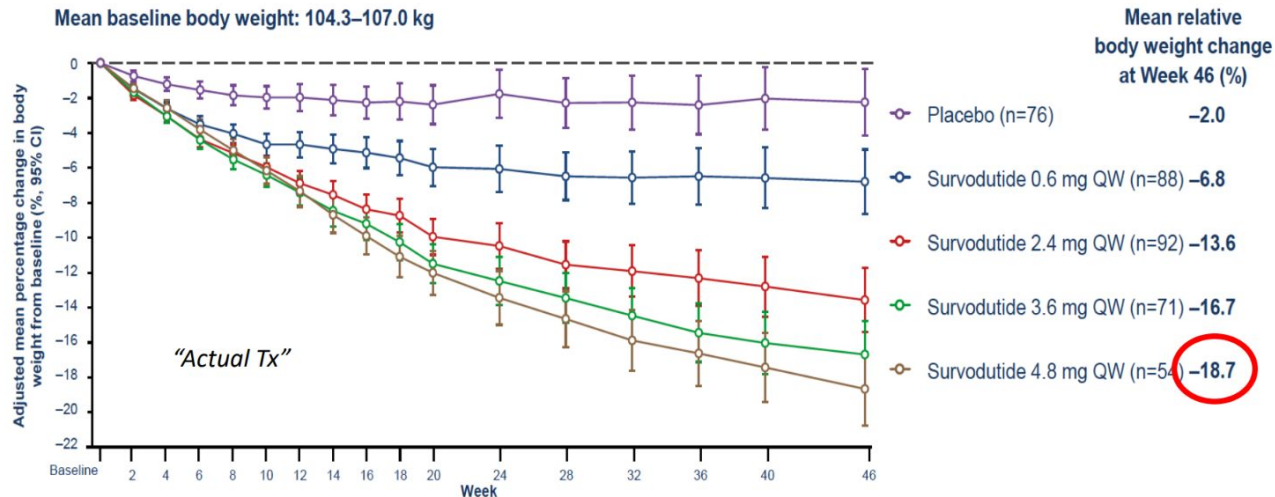
Efficacy of Semaglutide 2.4 mg/Cagrinlitide 2.4 mg in patients with Obesity and T2D

A phase 3 trial

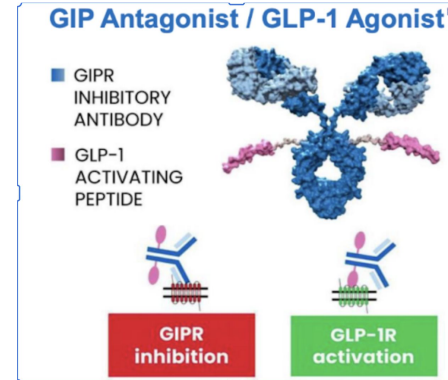
Frias JP et al, Lancet 2023;402(10403):720-730



Effectiveness of Survodutide (GLP1/GCGR dual agonist) in Patients with Obesity: a Phase 2 Trial

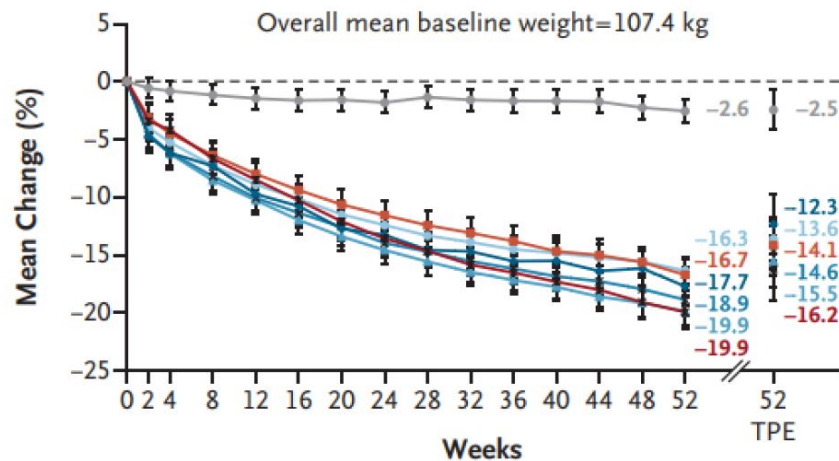


Once-Monthly Maridebart Cafraglutide for the Treatment of Obesity — A Phase 2 Trial

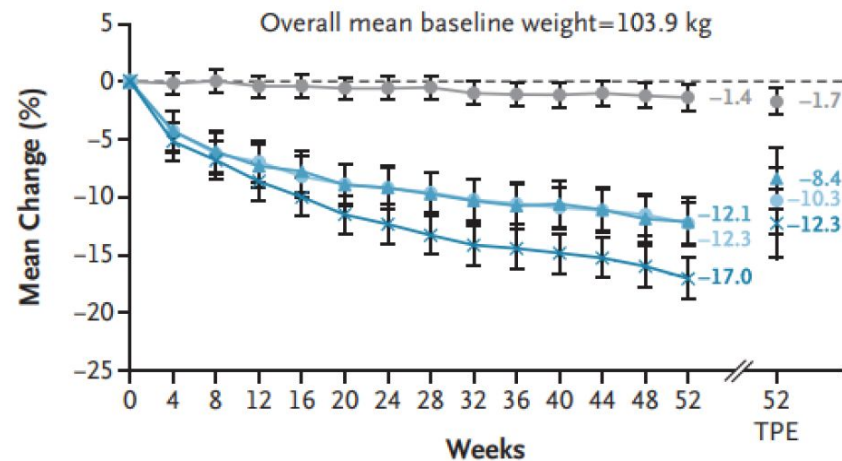


● 140 mg every 4 wk (no DE) ▲ 280 mg every 4 wk (no DE) × 420 mg every 4 wk (no DE) ◆ 420 mg every 8 wk (no DE)
 ■ 420 mg every 4 wk, with 4-wk DE * 420 mg every 4 wk, with 12-wk DE ● Placebo

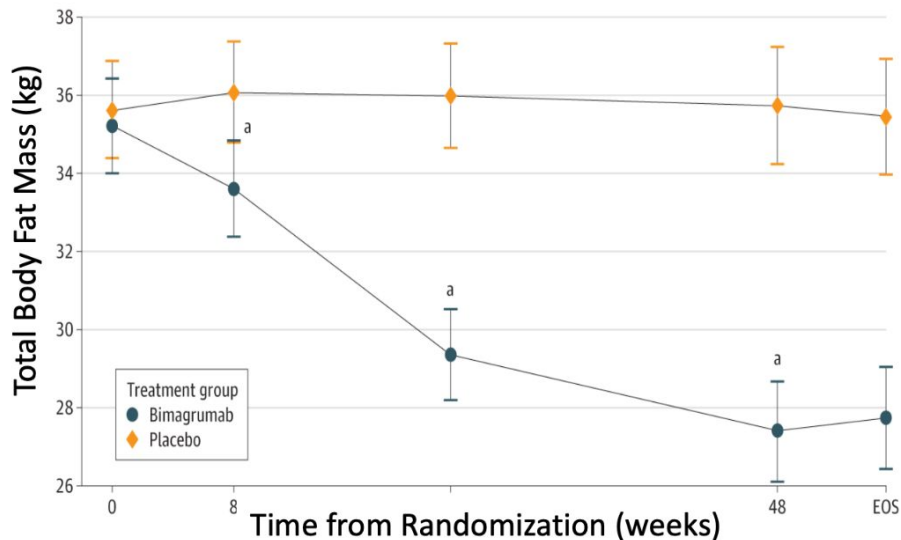
A Change in Body Weight in the Obesity Cohort



B Change in Body Weight in the Obesity–Diabetes Cohort



Activin Type II Receptor Blocking Biologic (Bimagrumab) Decreases Fat Mass, Increases Lean Mass in Patients with Obesity and T2D © 2021 Novo Nordisk®



Parameter	Bimagrumab	Placebo
Body Weight (%)	-6.5%	-0.8%
Fat Mass (%)	-20.5%	-0.5%
Lean Mass (%)	+3.6%	-0.8%
% Losing ≥15% Fat Mass	77%	10%
HbA1c (% units)	-0.76%	-0.04%

Heymsfield SB, et al.. Effect of Bimagrumab vs Placebo on Body Fat Mass Among Adults With Type 2 Diabetes and Obesity: A Phase 2 Randomized Clinical Trial. JAMA Netw Open. 2021 Jan 4;4(1):e2033457.

eTable. Medications Currently Available in the US and Agents in Phase 3 of Development

Name	Mechanism	Dosing and frequency	Magnitude of weight reduction compared with placebo ^a	Common adverse events ^{b,c}
Agents available in the US (FDA approved) ^a				
Liraglutide ¹	Peptide agonist of GLP-1 receptor	3.0 mg SC daily	56 wk, 5.40%	Adverse reactions occurring in ≥5% of patients include: nausea, diarrhea, vomiting, constipation, abdominal pain, injection site reactions, headache, fatigue, dyspepsia, dizziness, abdominal distention, belching, hypoglycemia in type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, hypersensitivity reactions, and hair loss
Semaglutide ²	Peptide agonist of GLP-1 receptor	1.7 mg and 2.4 mg SC weekly	68 wk, 12.50%	
Tirzepatide ³	Peptide agonist of GIP and GLP-1 receptors	5 mg, 10 mg, and 15 mg SC weekly	72 wk, 17.80%	
Agents in phase 3 with published phase 2 data ^a				
Cagrilintide-semaglutide ⁴	Peptide agonist of GLP-1, amylin, and calcitonin receptors	SC weekly	68 wk, 17.30%	Agents that are not FDA approved have similar adverse reaction profiles, with no additional adverse reactions than those noted above
Survodutide ⁵	Peptide agonist of GLP-1 and glucagon receptors	SC weekly	46 wk, 12.1%	
Retatrutide ⁶	Peptide agonist of GLP-1, GIP, and glucagon receptors	SC weekly	48 wk, 22.1%	
Maridebart-cafraglutide ⁷	Monoclonal antibody antagonist to GIP conjugated with 2 GLP-1 receptor–targeted peptides	SC monthly or less frequently	52 wk, 13.80%	
Semaglutide (25	Peptide agonist of	25 mg, 50 mg	68 wk, 12.7%	
Orforglipron ⁹	Small-molecule agonist of GLP-1 receptor	Orally daily	36 wk, 12.4%	

THE NEED FOR A NATIONAL DIALOGUE

Second generation medications are expensive- \$500

US pays more for these medications than other countries.
\$169 in Japan and \$96 in Sweden.

Many insurance companies and employers do not cover evidence- based obesity care or medications. Medicare is prohibited from covering medications.

Counterfeit or compounded medications are largely produced in unregulated facilities in SE Asia. According to partnership for safe medicine, this has been linked to severe hypoglycemia, seizures and thrombosis.

WW and Noom make weight loss medications available using online providers without a physical exam or evaluation of the complications.



THANK YOU

An Overview of Bariatric Endoscopy

By Oviea Akpotaire, MD

Nov 15, 2025

Disclosures



I have no disclosures
or conflicts of interest

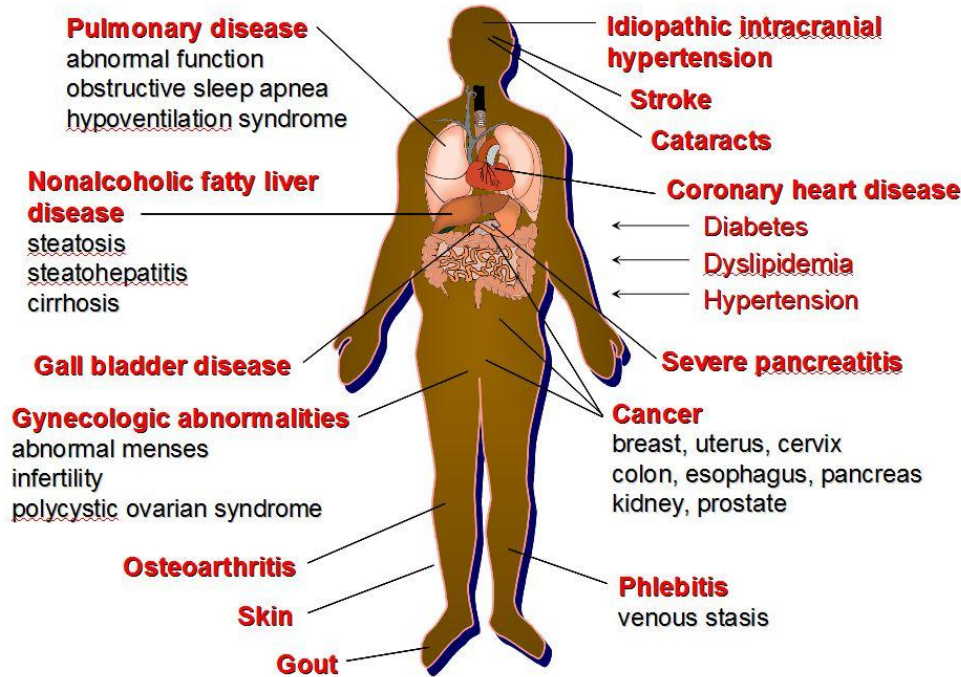
Objectives

- Review available endoscopic bariatric therapies (EBTs) mechanisms & efficacies
- Discuss roles of GI providers in obesity medicine



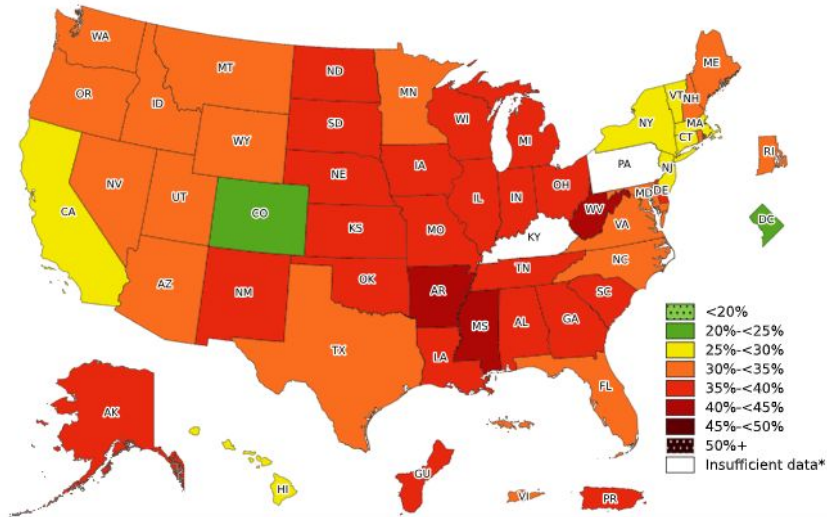
Obesity Epidemic^{1,2,3}

Medical Complications of Obesity



- Increases cardiovascular & cerebrovascular disease risks
- Linked to gallstones, GERD, Fatty Liver/ Cirrhosis, & pancreatitis

Obesity Epidemic Prevalence³



CDC 2023 Obesity Map

2017 to 2020 CDC data on US adults

- >70% US overweight or obese (42%)

Washington State Obesity prevalence:

- 2018 = 29%
- 2022 = 32%
- 2023 = 31%

TWL % is the Preferred Measurement

Excess Weight Loss (EWL) %

1. Ideal Body Weight (IBW) = Weight at which BMI is 25
2. Excess Body Weight = Preoperative weight – IBW

Therefore EWL % =

Weight Loss

Excess Body Weight

X 100%



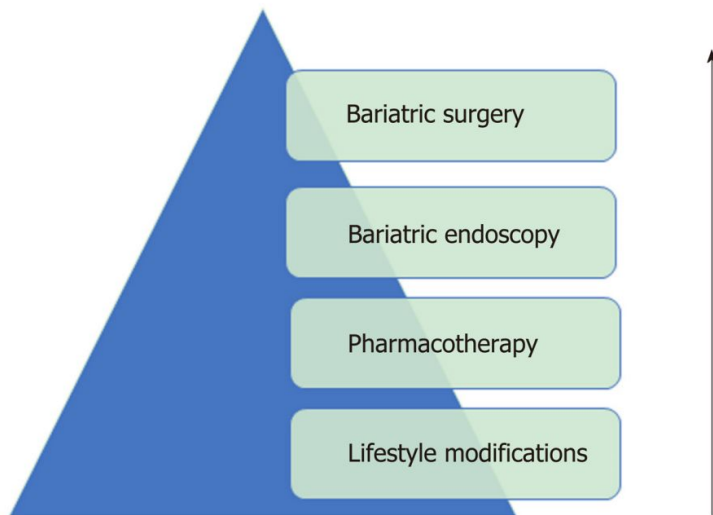
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Total Weight Loss (TWL) %

$$= \frac{\text{Weight Lost}}{\text{Starting Weight}} \times 100\%$$

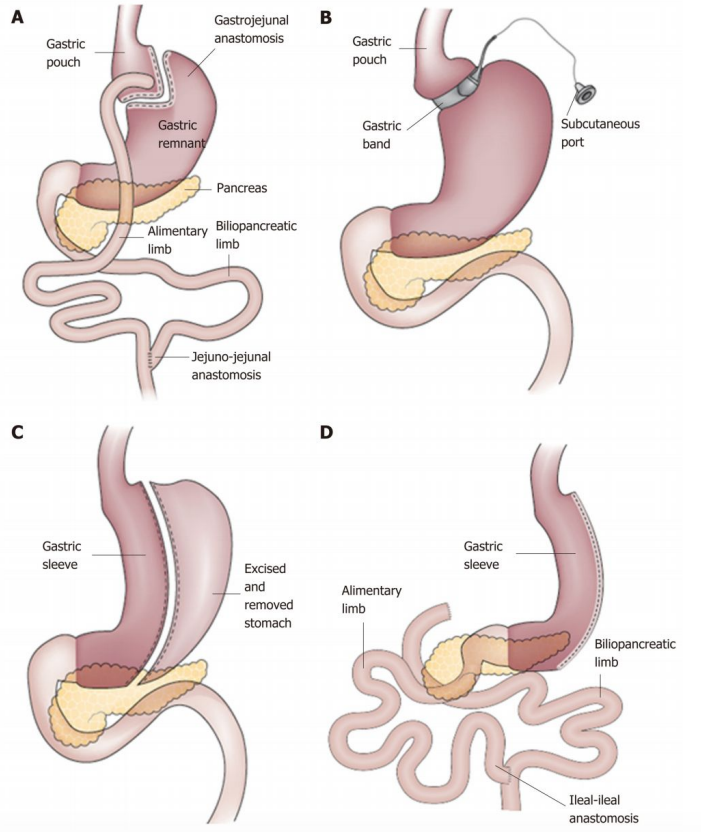
- **10% TWL reduces CVD risks**
National Heart Lung and Blood Institute
- Bariatric literature since late 2010's supports using TWL%

Obesity Treatments Options^{2, 4, 5, 6, 7, 8}



- Lifestyle modification (diet & exercise)
 - Variable efficacy (3 to 5% TWL) & adherence
- Pharmacotherapy
 - 5 to 20% TWL depending on medication
 - **Highest with GLP1 agonists**
 - FDA approved for Semaglutide & Tirzepatide for weight loss in 2021 (Wegovy) & 2023 (Zepbound) respectively
 - Hindered by cost/ insurance coverage, 2022 to 2025 FDA drug shortage, & side effects

Obesity Treatments Options^{5, 6, 7, 8}



- Surgery most effective and durable
 - 25 - 30% TWL sustained (5 – 10 yrs)
 - Risk of complications
 - **Low utilization**
 - < 1% of eligible patients had surgery in 2016

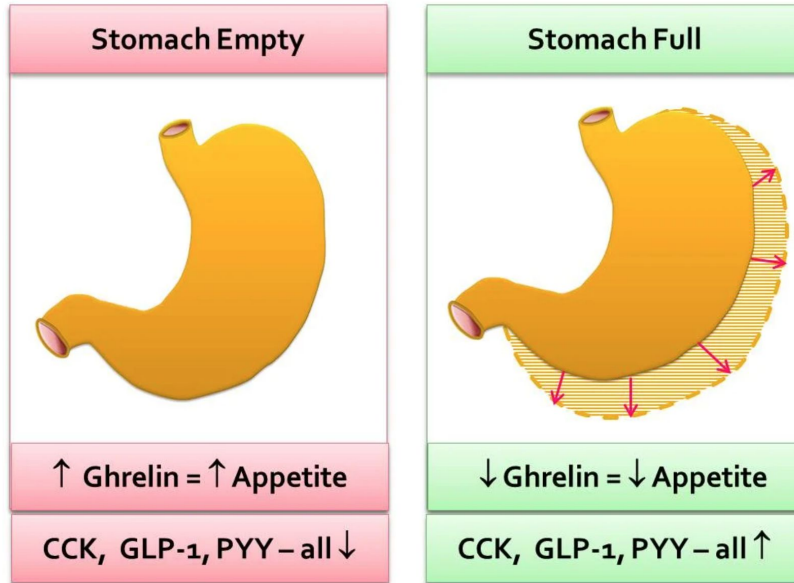
ORIGINAL ARTICLE

Changes in Utilization of Bariatric Surgery in the United States From 1993 to 2016

Guilherme M. Campos, MD, PhD, ✉ Jad Khoraki, MD, Matthew G. Browning, PhD, Bernardo M. Pessoa, MD, Guilherme S. Mazzini, MD, PhD, and Luke Wolfe, MS



Surgical Mechanisms of Weight Loss ^{5, 6, 7}

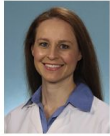


- **Restriction** of caloric intake by reducing gastric volume
- **Malabsorption** with small bowel surface area reduction
 - Risks protein calorie malnutrition & micronutrient deficiencies
- **Neurohormonal** effects of anatomic changes reduce appetite
 - Ghrelin reduced
 - GLP1 & CCK increased after surgery

Obesity Treatments Options^{8, 9, 10}

Endoscopic Bariatric and Metabolic Therapies: New and Emerging Technologies *Gastroenterology*

2017



Shelby Sullivan¹



Steven A. Edmundowicz¹



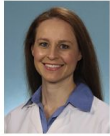
Christopher C. Thompson²

- Endoscopy Bariatric Therapy (EBT)
 - Aims for durability of surgery, but less invasive & optimally reversible
- Lower postoperative events

Potential Benefits of EBTs^{8, 9, 10}

Endoscopic Bariatric and Metabolic Therapies: New and Emerging Technologies *Gastroenterology*

2017



Shelby Sullivan¹



Steven A. Edmundowicz¹



Christopher C. Thompson²

New Era: Endoscopic treatment options in obesity—a paradigm shift *World Journal of Gastro, 2019 (UTSW)*

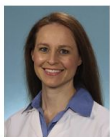
Jason Glass, Ahson Chaudhry, Muhammad S Zeeshan, Zeeshan Ramzan

- Endoscopy Bariatric Therapy (EBT)
 - **Aims for durability of surgery, but less invasive & optimally reversible**
- Lower postop events
- Earlier ambulation
- Reduced LOS

Drawbacks of EBTs^{8, 9, 10}

Endoscopic Bariatric and Metabolic Therapies: New and Emerging Technologies *Gastroenterology*

2017



Shelby Sullivan¹



Steven A. Edmundowicz¹



Christopher C. Thompson²

- Could be a “bridge to surgery” to reduce obesity related operative risks in patients with BMI > 50
 - Hip replacement example

BUT...

- Training/ exposure limited
- Not covered by insurance

New Era: Endoscopic treatment options in obesity—a paradigm shift

World Journal of Gastro, 2019

Jason Glass, Ahson Chaudhry, Muhammad S Zeeshan, Zeeshan Ramzan

Endoscopic bariatric therapies for treating obesity: a learning curve for gastroenterologists

Vahe Shahnazarian¹, Daryl Ramai², Avik Sarkar³



Translational Gastroenterology & Hepatology

Member of CommonSpirit

2019

2024 ASGE – ESGE Guidelines on EBTs¹¹

Article published online: 2024-04-19

Guideline

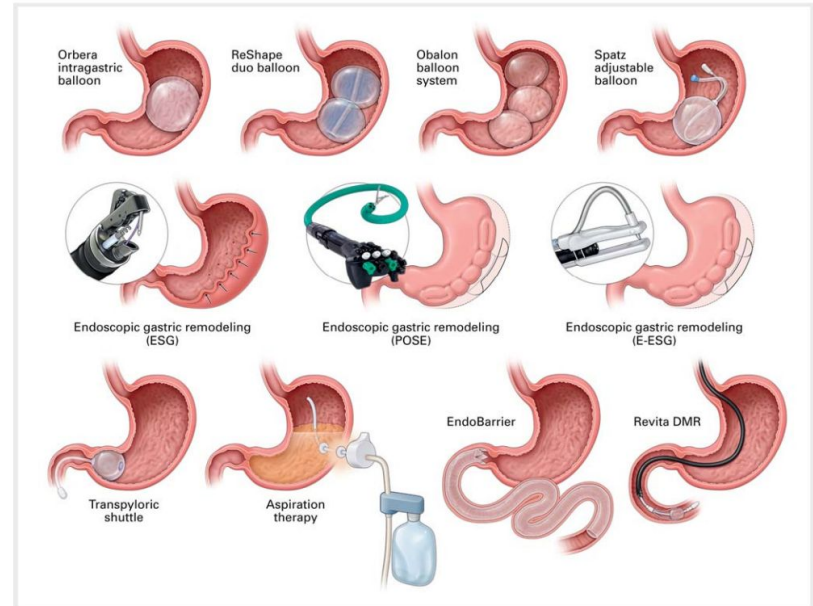
Thieme

American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity



- I. For primary obesity therapies in patients with obesity class I, II, and III, a minimum goal of 25% excess weight loss at 12 months
- II. For nonprimary EBMTs including metabolic therapy, bridging to surgery, and early intervention, a goal of $\geq 5\%$ total weight loss
- III. For serious adverse events, $\leq 5\%$ is recommended for all EBMTs

- **First set of EBT guidelines to summarize efficacies of available therapies and provide evidence-based practice**



Endoscopy Approaches Proposed ^{8, 9, 10, 11, 12}

Gastric EBTs:

- Space-occupying devices
 - Intragastric Balloons
- Anatomy altering devices
 - Endoscopic sleeve gastropasty
 - POSE
 - Aspiration device

Small bowel EBTs:

- Duodenojejunal bypass liners
- Duodenal mucosal remodeling
- Magnetic compression

Aspire Assist Device Withdrawn in 2022¹²

Gastric EBTs:

- Space-occupying devices
 - Intragastric Balloons
- Anatomy altering devices
 - Endoscopic sleeve gastroplasty
 - POSE
 - ~~Aspiration device~~ was FDA approved in 2016 & was used at VM, but the company shut down in 2022, citing financial impact of COVID 19. 15% TWL



POSE Not FDA Approved^{11, 12}

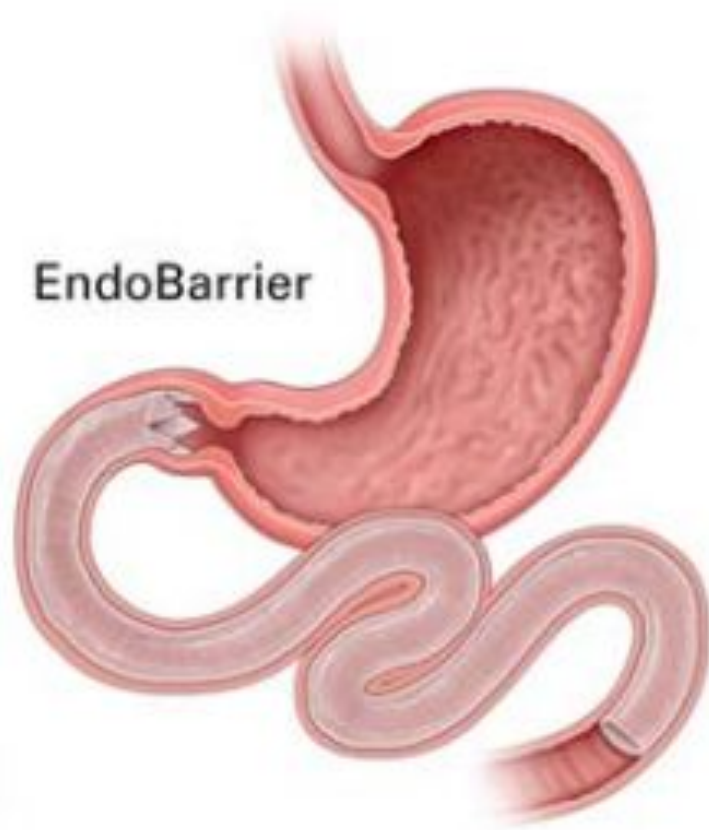
Gastric EBTs:

- Space-occupying devices
 - Intra gastric Balloons
 - Anatomy altering devices
 - Endoscopic sleeve gastroplasty
 - ~~POSE~~ Not FDA approved
- Primary Obesity Surgery EndoLuminal creates folds (plications) along the greater curvature of the stomach. 15 % TWL



Endoscopic gastric remodeling (POSE)

DJBL Not FDA Approved^{11, 12}



Small bowel EBTs:

- Duodenojejunal bypass ~~liners~~

Not FDA approved

- Duodenal mucosal remodeling
DJBL have shown efficacy in reducing A1c (0.5 to 1%) & TWL (5 to 18%)

- Magnetic compression

However, the 1st RCT in the US was stopped due to adverse events such as hepatic abscesses



DMR Not FDA Approved^{11, 12}



Small bowel EBTs:

- Duodenojejunal bypass ~~X~~ liners

Not FDA approved

- Duodenal mucosal remodeling ~~X~~

Not FDA approved

- Intestinal compression
0.5 - 1% A1c reduction, No significant TWL (< 3%)
However...

DMR Not FDA Approved^{11, 12}



Small bowel EBTs:

- Duodenojejunal bypass **X**

Not FDA approved

- Duodenal mucosal remodeling **X**

Not FDA approved

- Intestinal compression
0.5 - 1% A1c reduction, No significant TWL (< 3%)

However...

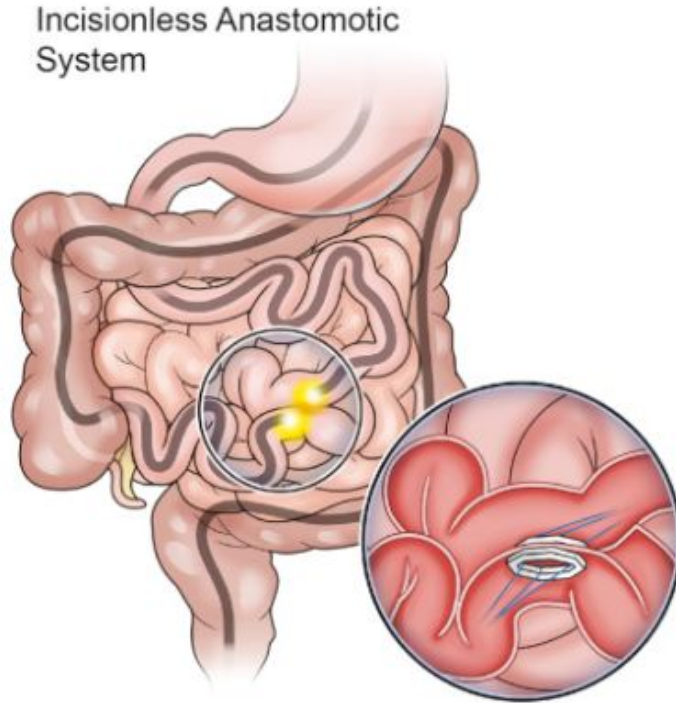


Fractyl Health Receives FDA Breakthrough Device Designation for Revita in Weight Maintenance for People with Obesity Who Discontinue GLP-1 Based Drugs

July 30, 2024

Breakthrough Device Designations are granted by the U.S. FDA to expedite review of promising technologies that address high unmet needs and may improve the lives of people with life-threatening or debilitating conditions

IAC Not FDA Approved for Wt Loss^{10, 11, 12}



Small bowel EBTs:

- Duodenojejunal bypass **X**

Not FDA approved

- Duodenal mucosal remodeling **X**

Not FDA approved

- **Magnetic compression** **X**

FDA approved (BUT NOT for weight loss)
Simultaneous endoscopic deployment of magnets in the small bowel leads to incisionless duodeno-ileal anastomosis.
10% TWL in pilot studies

FDA Approved EBT's 2025^{10, 11, 12}

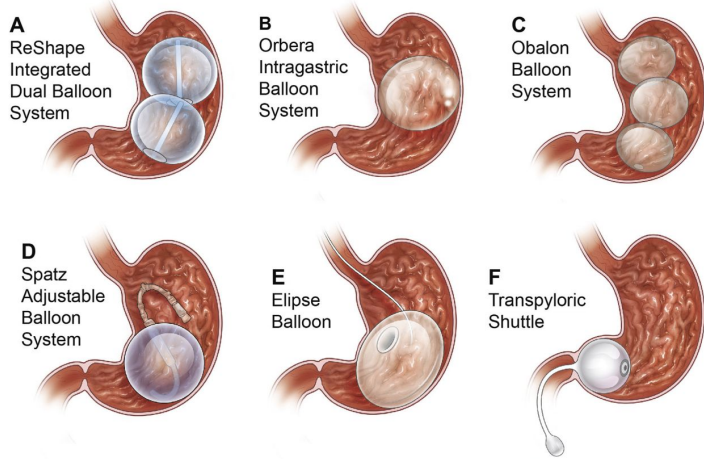
Gastric EBTs:

- Space-occupying devices
 - **Intragastric Balloons**
- Anatomy altering devices
 - **Endoscopic sleeve gastroplasty**
 - POSE
 - ~~Aspiration device~~ **X** Not FDA approved
was FDA approved,
but the company shut down in 2022

Small bowel EBTs:

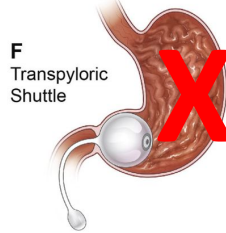
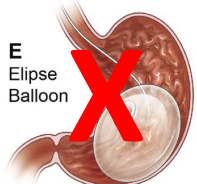
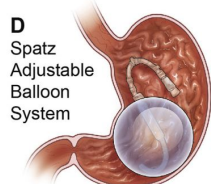
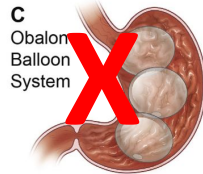
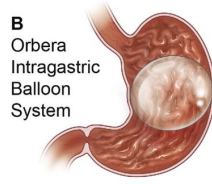
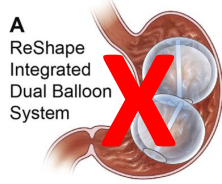
- Duodenojejunal bypass **X**
Not FDA approved
- Duodenal mucosal remodeling **X**
Not FDA approved
- Magnetic compression **X**
FDA approved (BUT NOT for weight loss)

Intragastric Balloons (IGBs) ⁸



- Deflated balloon (s) placed in the fundus endoscopically
- Inflation > 400 mL of fluid -> satiety
- > 6 month retention & hyperinflation raised risks of rupture & migration with SBO, pancreatitis, gastric ulceration, or bowel perforation
 - Methylene blue solution produces blue- green urine in case of balloon rupture

Intragastric Balloons (IGBs) ^{8,12}



- FDA Approved:
 - **Orbera 2015 – Available**
 - ~~Obalon (3 gas filled balloons) 2016, withdrawn 2021~~
 - **Spatz (Adjustable) 2019 – Available**
 - ~~Transpyloric Shuttle 2019, currently not manufactured~~
 - ~~ReShape Duo (2 balloons) withdrawn 2019~~
 - Not FDA Approved
 - Ellipse (swallowed & degradable), available outside US
- **FDA warning!!!**
 - **18 deaths worldwide 2016 to 2020 from IGBs**

IGB vs Lifestyle Changes ¹³

ORIGINAL ARTICLE

Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial

A Courcoulas¹, BK Abu Dayyeh², L Eaton³, J Robinson⁴, G Woodman⁵, M Fusco⁶, V Shayani⁷, H Billy⁸, D Pambianco⁹ and C Gostout^{2,10}

BACKGROUND/OBJECTIVES: This trial evaluated the safety and effectiveness of the Orbera Intragastric Balloon as an adjunct to lifestyle intervention.

SUBJECTS/METHODS: In this multicenter, randomized, open-label clinical trial, 255 adults with a body mass index of 30–40 kg m⁻² were treated and outcomes were assessed up to 12 months. Participants were randomized to endoscopic placement of an intragastric balloon plus lifestyle or lifestyle intervention alone. Balloons were removed at 6 months and lifestyle intervention continued for both groups through 12 months. At 9 months, coprimary end points were two measures of weight loss.

RESULTS: At 6 months, weight loss was –3.3% of total body weight (–3.2 kg) in the lifestyle arm vs –10.2% (–9.9 kg) in the balloon plus lifestyle arm ($P < 0.001$); at 9 months (3 months postballoon removal), weight loss was –3.4% (–3.2 kg) vs –9.1% (–8.8 kg, $P \leq 0.001$); and at 12 months, –3.1% (–2.9 kg) vs –7.6% (–7.4 kg, $P \leq 0.001$). For the primary end points, at 9 months, mean percent loss of weight in excess of ideal body weight (s.d.) at 9 months was 26.5% (20.7) ($P = 0.32$) and 9.7% (15.1) in the balloon and control groups, respectively. Also, 45.6% (36.7, 54.8) of the subjects randomized to the balloon achieved at least 15% loss of weight in excess of ideal body weight greater than the control group ($P < 0.001$). The majority of balloon subjects experienced adverse events; 86.9% nausea, 75.6% vomiting, 57.5% abdominal pain and 18.8% had their device removed before 6 months because of an adverse event or subject request. Five subjects (3.1%) in the balloon group had a gastric abnormality at the time of device removal, and no ulcers were found.

CONCLUSIONS AND RELEVANCE: Intragastric balloon achieved greater short-term weight loss at 3 and 6 months postballoon removal than lifestyle intervention alone. Adverse gastrointestinal events were common.

International Journal of Obesity (2017) **41**, 427–433; doi:10.1038/ijo.2016.229

- Multicentered, RCT
- BUT open-label, industry sponsored
- N = 255 Total (125 IGB)
- Measured TWL % 3 months after Orbera removal (6 month) vs Lifestyle (1200 cal/d)
- **9.1% (20 lb) vs 3.4% (7 lb), $p < 0.001$**
- 1 yr IGB TWL (7.6%) from weight gain
- Similar efficacy in large metaanalyses

Courcoulas Et. Al., International Journal of Obesity

2017



A member of CommonSpirit

IGB Poorly tolerated¹³

Table 2a. Device-related AEs with frequency ≥ 1% IGB group (N = 160)

Event	Total, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)
At least one device-related AE	157 (98.1%)	95 (59.4%)	57 (35.6%)	5 (3.1%)
Nausea	139 (86.9%)	73 (45.6%)	59 (36.9%)	7 (4.4%)
Vomiting	121 (75.6%)	54 (33.8%)	61 (38.1%)	6 (3.8%)
Abdominal pain	92 (57.5%)	44 (27.5%)	43 (26.9%)	5 (3.1%)
Gastroesophageal reflux disease	48 (30.0%)	31 (19.4%)	12 (7.5%)	5 (3.1%)
Eructation	39 (24.4%)	35 (21.9%)	4 (2.5%)	0 (0.0%)
Dyspepsia	34 (21.3%)	24 (15.0%)	8 (5.0%)	2 (1.3%)
Constipation	32 (20.0%)	29 (18.1%)	3 (1.9%)	0 (0.0%)
Abdominal pain upper	29 (18.1%)	18 (11.3%)	11 (6.9%)	0 (0.0%)
Abdominal distension	28 (17.5%)	24 (15.0%)	3 (1.9%)	1 (0.6%)
Dehydration	23 (14.4%)	9 (5.6%)	11 (6.9%)	3 (1.9%)
Diarrhea	21 (13.1%)	15 (9.4%)	6 (3.8%)	0 (0.0%)
Flatulence	18 (11.3%)	14 (8.8%)	4 (2.5%)	0 (0.0%)
Impaired gastric emptying	14 (8.8%)	13 (8.1%)	1 (0.6%)	0 (0.0%)
Abdominal discomfort	10 (6.3%)	9 (5.6%)	1 (0.6%)	0 (0.0%)
Asthenia	8 (5.0%)	3 (1.9%)	4 (2.5%)	1 (0.6%)
Postprocedural pain	8 (5.0%)	7 (4.4%)	1 (0.6%)	0 (0.0%)
Headache	8 (5.0%)	6 (3.8%)	2 (1.3%)	0 (0.0%)
Fatigue	7 (4.4%)			
Halitosis	6 (3.8%)			
Abdominal rigidity	5 (3.1%)			
Gastrointestinal pain	5 (3.1%)			
Vitamin B1 decreased	5 (3.1%)			
Pharyngolaryngeal pain	5 (3.1%)			
Esophagitis	4 (2.5%)			
Hiccups	4 (2.5%)			
Gastritis	3 (1.9%)			
Anorexia	3 (1.9%)			
Anemia	2 (1.3%)			
Epigastric discomfort	2 (1.3%)			
Fecal incontinence	2 (1.3%)			
Migraine	2 (1.3%)			
Alopecia	2 (1.3%)			

- N/V, abdominal pain, & GERD = most common AEs
- 5 SAEs: 1 perforation. 1 GOO. 3 PUD. No deaths
- 30 patient had balloon removed before 6 months
 - 15 for notable AEs + 15 per patient request

IGB Poorly tolerated¹⁴

Obesity Surgery (2024) 34:1971–1974
<https://doi.org/10.1007/s11695-024-07128-1>



Methods

The MAUDE database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>) tracks adverse event reports involving FDA-approved medical devices. Reports contain information on the device, manufacture, and event details, including report date, device problems, patient complications, and free-texted narratives.

MAUDE was queried for entries on Orbera and Spatz3 IGBs submitted between December 2020 and September 2023. Search terms included Spatz3, Spatz FGIA, and Orbera, Apollo Endosurgery.

BRIEF COMMUNICATION

Patient Complications and Device Issues Associated With FDA-Approved Intra gastric Balloons Available in the USA: A Maude Database Study

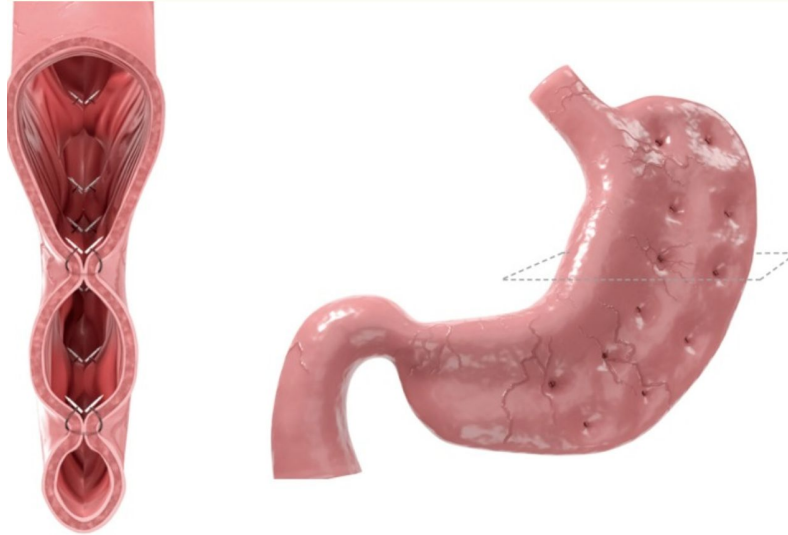
Morgan C. Goodman¹  · Patrick Chang¹ · William Minter¹ · Denis Nguyen² · Kalpana Gopalkrishnan² · Jennifer Phan¹

Received: 30 November 2023 / Revised: 19 February 2024 / Accepted: 22 February 2024 / Published online: 11 March 2024
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Results

During the study period, 728 cases (Orbera = 354, Spatz3 = 374) with 1099 device issues and 1021 patient complications were reported to MAUDE.

Endoscopic Sleeve Gastroplasty (ESG)^{8, 9, 10}



- Gastric volume restricted ~ 70% with full thickness sutures placed endoscopically in 2 rows along greater curvature
- **18 - 21% TWL at 12 – 24 months**
- Similar neurohormonal effects as bariatric sleeve & significant, sustained reductions in A1c & BP

ESG by Apollo Overstitch device FDA approved
7/2022

No assigned CPT code

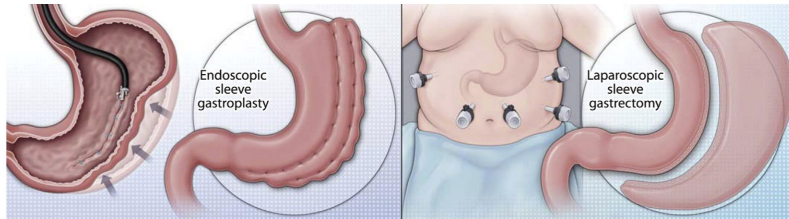
ESG vs Laparoscopic Sleeve Gastrectomy (LSG)¹⁵

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

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 Paranj, MD,¹ Sepehr Lalezari, MD,³
Anthony N. Kalloo, MD,¹ Mouen A. Khashab, MD,¹ Vivek Kumbhari, MD¹

Baltimore, Maryland, USA

GRAPHICAL ABSTRACT



- Retrospective study of consecutive patients at Hopkins (2015 – 2017)
- 54 ESG & 83 LSG patients matched
- 6 month TWL: ESG (17%, 44 lbs) vs LSG (24%, 70 lbs). $P < 0.01$.
- 5% AEs in ESG (LSG 17%). $P < 0.05$.
- 2% new onset GERD in ESG (LSG 14%)

TABLE 2. Total body weight lost and percent reduction in body mass index at 1 and 6 months

	1 Month				P value	6 Months				P value
	ESG group		LSG group			ESG group		LSG group		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Total body weight lost, lbs	24.98	6.68	19.33	8.02	<.001	44.92	6.68	69.62	28.96	<.001
Reduction in body mass index, %	9.40	2.42	6.65	2.41	<.001	17.2	5.56	23.72	7.62	<.001

Endoscopic Bariatric Therapies & Techniques^{11, 16}

Primary Weight Loss Endoscopic Therapies

- Intra gastric Balloons
 - Easily deployed & reversible
 - 7 to 9% TWL at 9 to 12 months
 - Poorly tolerated. FDA warnings
- Endoscopic sleeve gastropasty
 - 18 to 21% TWL at 12 to 24 months
 - Not covered by insurance

Endoscopic Bariatric Surgery Revision Techniques (for wt regain)

- Argon Plasma Coagulation (APC)
 - Scars the GJ anastomosis to reduce outlet size
 - 6 – 10% TWL at 12 months
- Transoral Outlet Reduction (TORe)
 - Uses APC + Endoscopic suturing to reduce GJ diameter to 8 to 10 mm
 - 9% TWL to 1 to 5 YEARS
 - >12% TWL if GLP1 therapy used too

Conclusion



- 10% TWL significantly reduces CVD risk, but a large number of eligible patients are unlikely to undergo bariatric surgery or may not tolerate pharmacotherapy
- EBTs offer novel & less invasive approaches to achieving clinically significant & sustained TWL
- Further studies are needed to compare long term efficacy, assess AEs, & shape guidelines.
- Insurance coverage might increase access and utilization.

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The Evolving Role of Surgery in the Treatment of Metabolic Disease: Indications, Techniques and Outcomes

Troy P. Houseworth, MD

November 15, 2025

Disclosures

- ❖ No disclosures or conflicts of interest

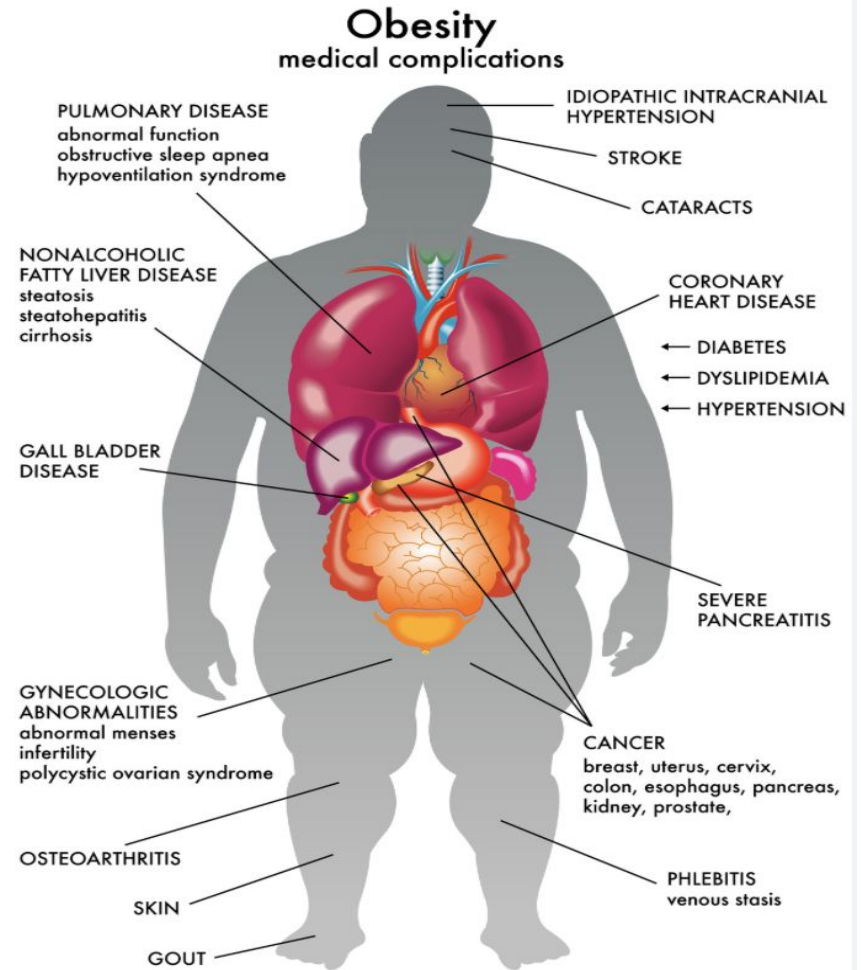
Objectives:



- ❖ Brief history of MBS
- ❖ Indications for Surgery
- ❖ Long-term Outcomes
- ❖ Future possibilities

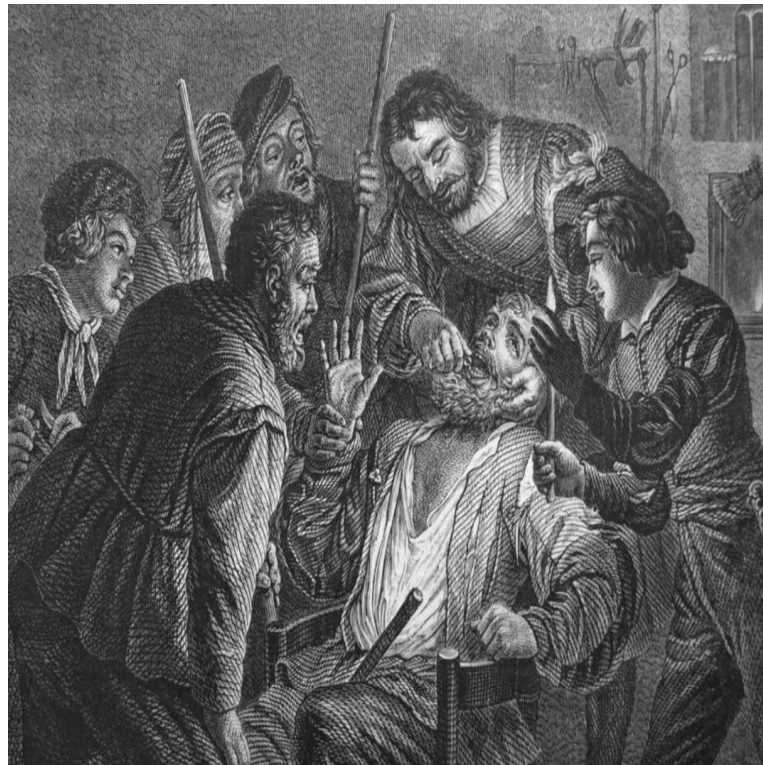
The Disease

- ❖ Obesity is a chronic, multifactorial disease that is highly resistant to treatment
- ❖ It is the underpinning cause of multiple other chronic diseases
- ❖ It is an epidemic and is growing at an alarming rate
- ❖ It affects every aspect of the patient's life and wellbeing



History and Evolution of Bariatric Surgery

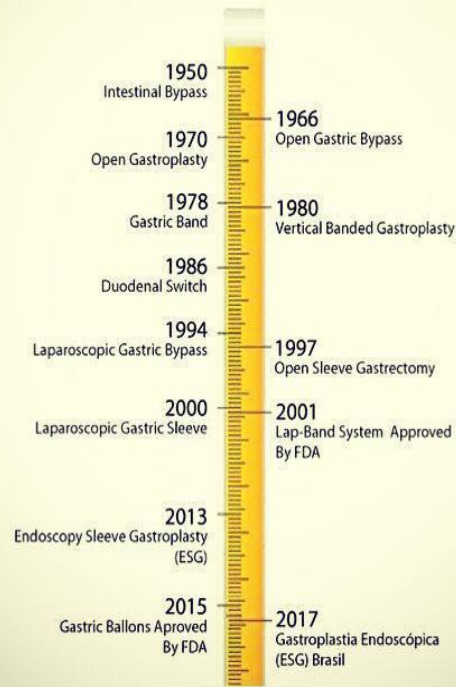
- ❖ First invasive procedure intended to produce weight loss was performed in the 10th century
- ❖ Modern Bariatric Surgery era dates back to the 1950s and 1960s – Edward Mason
- ❖ ASMBS – 1983



History and Evolution of Bariatric Surgery

- ❖ NIH Consensus Statement in 1991
- ❖ Started transition to laparoscopy in mid-1990s
- ❖ First Robotic 2002 at U.C Davis
- ❖ 2022– ASMBS/IFSO updates NIH Criteria

HISTORY OF BARIATRIC SURGERY



Robotics



Robotics

- ❖ Much better vision
- ❖ Full range of motion
- ❖ Scaled motion
- ❖ Stable Platform
- ❖ More Surgeon Autonomy
- ❖ Some Haptics



3D HD Vision



Instrumentation



Motion

Laparoscopic versus robotic Roux-en-Y gastric bypass: lessons and long-term follow-up learned from a large prospective monocentric study

Nicolas C Buchs¹, Philippe Morel, Dan E Azagury, Minoa Jung, Gilles Chassot, Olivier Huber, Monika E Hagen, François Pugin

Methods: 777 consecutive cases. 389 LRYGB (50.1 %) 388 RRYGB (49.9 %). Data was prospectively collected.

Results: Robotic approach had **longer op times** (+30 min; $p=0.0001$), **a lower conversion rate** (0.8 vs. 4.9 %; $p=0.0007$), and **less complications** (11.6 % vs. 16.7 %; $p=0.05$), **less gastrointestinal leaks** (0.3 vs. 3.6 %; $p=0.0009$). There were also **less early reoperations** (1 vs. 3.3 %; $p=0.05$) and a **shorter hospital stay** in the **robotic group** ($p=0.0001$). Operative time and hospital stay, were shorter for the last 100 cases.

Conclusions: Robotic RYGB is not only safe and feasible, but also a valid option in comparison to laparoscopy. At the cost of a longer operative time, we observed better short-term outcomes with the robotic approach.

Gastric Bypass Outcomes by Surgical Technique

N= 1939

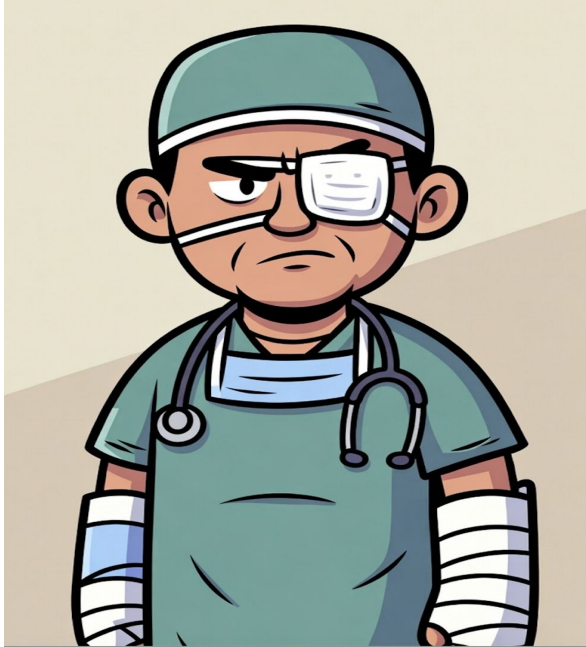
Procedure Primary	Modality	Number of Records	*Avg. LOS Days	Avg. Readmit Rate	Avg. Conversion ..	* Avg. Mortality R..	Avg. SSI Rate	* Avg. ICU Admit Rate	Avg. OR Time Mins	* Avg. transfusion r..
Gastric Bypass	Da Vinci	574	1.6	4.36%	0.00%	0.00%	0.00%	0.52%	204	0.87%
	Lap	1,251	2.4	4.24%	0.48%	0.32%	0.08%	1.76%	209	1.60%
	Open	114	12.0	6.14%	0.00%	3.51%	3.51%	21.05%	231	7.02%
Grand Total		1,939	2.7	4.38%	0.31%	0.41%	0.26%	2.53%	209	1.70%

CHA Data Includes Hospitals that have completed at least 400 Bypass/Gastrectomy in any modality

**p value
>.05*

The Limitations of Laparoscopy are Obvious

Laparoscopic



Robotic



INDICATIONS FOR SURGICAL TREATMENT



NIH Consensus Statement 1991

- ❖ Patient must meet the following criteria for consideration for bariatric surgery:
 - BMI > 40 or BMI > 35 with an associated medical comorbidity
 - Failed dietary therapy
 - Psychiatrically stable without ETOH dependence or illegal drug use
 - Knowledgeable about the operation and its sequelae
 - Motivated individual
 - Medical problems not precluding probable survival from surgery

Major 2022 ASMBS/IFSO updates to the 1991 NIH Consensus Statement

- ❖ BMI ≥ 35 , regardless of presence, absence, or severity of comorbidities
- ❖ BMI 30–34.9 with metabolic disease
- ❖ BMI ≥ 25 suggests clinical obesity in the Asian Population, and individuals with BMI ≥ 27.5 should be offered MBS
- ❖ Appropriately selected children and adolescents should be considered for MBS (metabolic bariatric surgery)

Other 2022 ASMBS/IFSO updates to the 1991 NIH Consensus Statement

- ❖ **Children** and adolescents with **BMI > 120% of the 95th percentile and a major comorbidity, or BMI > 140 percentile**, should be considered for MBS after Evaluation by a multidisciplinary team in a specialty center
- ❖ There is **no upper patient-age limit to MBS**
 - Older individual who could benefit for MBS should be considered for surgery after careful assessment of co-morbidities and frailty
- ❖ Severe obesity is a chronic disease requiring long term management after primary MBS. This may include revisional surgery or other adjuvant therapy to achieve desired effect
- ❖ MBS is safe in pts with BMI >70 – preferred treatment for extreme BMIs.

Long-term Outcomes

- ❖ **Safe** with **durable** weight loss for years after surgery
- ❖ **Weight loss** is consistently reported at greater than **25% TBW** or **60% EBW**
 - Some variation depending on the specific operation
- ❖ Results in significant **improvement or remission** of most weight related comorbidities
- ❖ Greater weight loss, improvement in T2D, HTN, and HLP demonstrated beyond ten years compared with non-surgical treatments

Long-term Outcomes – Safety

Table 2. Adverse Outcomes within 30 Days after Surgery, According to Surgical Procedure.

Outcome	Total (N=4610)*	Laparoscopic Adjustable Gastric Banding (N=1198)	Laparoscopic Roux-en-Y Gastric Bypass (N=2975)	Open Roux-en-Y Gastric Bypass (N=437)	P Value†
		number (percent)			
Death	15 (0.3)	0	6 (0.2)	9 (2.1)	<0.001
Deep-vein thrombosis or venous thromboembolism	20 (0.4)	3 (0.3)	12 (0.4)	5 (1.1)	0.05
Tracheal reintubation	20 (0.4)	2 (0.2)	12 (0.4)	6 (1.4)	0.004
Endoscopy	51 (1.1)	1 (0.1)	45 (1.5)	5 (1.1)	<0.001
Operation					
Tracheostomy	11 (0.2)	0	6 (0.2)	5 (1.1)	0.001
Placement of percutaneous drain	16 (0.3)	0	13 (0.4)	3 (0.7)	0.48
Abdominal operation	118 (2.6)	9 (0.8)	94 (3.2)	15 (3.4)	<0.001
Failure to be discharged by day 30	17 (0.4)	0	13 (0.4)	4 (0.9)	0.02
Composite end point‡	189 (4.1)	12 (1.0)	143 (4.8)	34 (7.8)	<0.0001

* The total excludes 166 procedures, including 117 sleeve gastrectomies, 47 biliopancreatic diversions with or without a duodenal switch, 1 vertical banded gastroplasty, and 1 open adjustable gastric banding.

† P values are for the comparison between treatment groups. Values were calculated with the use of the chi-square test.

‡ This end point is a composite of death; deep-vein thrombosis or venous thromboembolism; reintervention with the use of a percutaneous, endoscopic, or operative technique; or failure to be discharged from the hospital within 30 days after surgery.

The NEW ENGLAND JOURNAL of MEDICINE

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JULY 30, 2009

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Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium

ABSTRACT

BACKGROUND

To improve decision making in the treatment of extreme obesity, the risks of bariatric surgical procedures require further characterization.

METHODS

We performed a prospective, multicenter, observational study of 30-day outcomes in consecutive patients undergoing bariatric surgical procedures at 10 clinical sites in the United States from 2005 through 2007. A composite end point of 30-day major adverse outcomes (including death; venous thromboembolism; percutaneous, endoscopic, or operative reintervention; and failure to be discharged from the hospital) was evaluated among patients undergoing first-time bariatric surgery.

RESULTS

There were 4776 patients who had a first-time bariatric procedure (mean age, 44.5 years; 21.1% men; 10.9% nonwhite; median body-mass index [the weight in kilograms divided by the square of the height in meters], 46.5). More than half had at least two coexisting conditions. A Roux-en-Y gastric bypass was performed in 3412 patients (with 87.2% of the procedures performed laparoscopically), and laparoscopic adjustable gastric banding was performed in 1198 patients; 166 patients underwent other procedures and were not included in the analysis. The 30-day rate of death among patients who underwent a Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding was 0.3%; a total of 4.3% of patients had at least one major adverse outcome. A history of deep-vein thrombosis or pulmonary embolus, a diagnosis of obstructive sleep apnea, and impaired functional status were each independently associated with an increased risk of the composite end point. Extreme values of body-mass index were significantly associated with an increased risk of the composite end point, whereas age, sex, race, ethnic group, and other coexisting conditions were not.

CONCLUSIONS

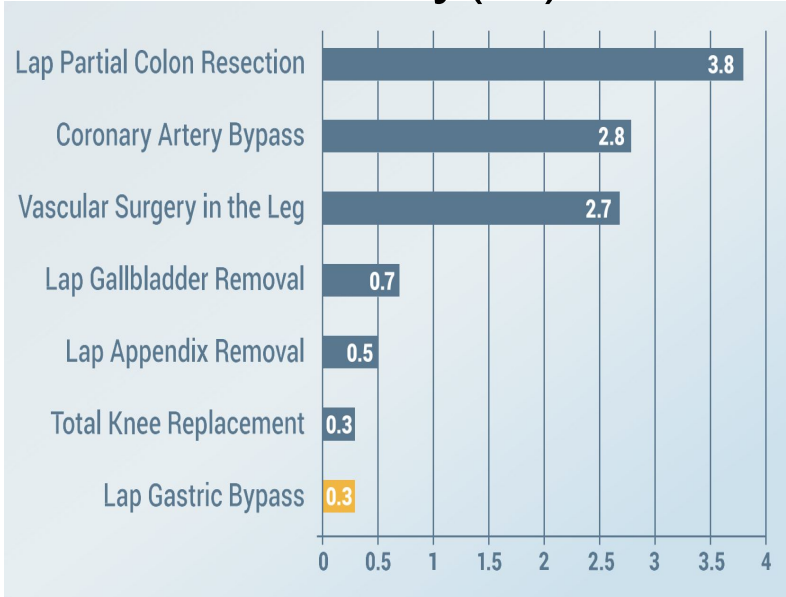
The overall risk of death and other adverse outcomes after bariatric surgery was low and varied considerably according to patient characteristics. In helping patients make appropriate choices, short-term safety should be considered in conjunction with both the long-term effects of bariatric surgery and the risks associated with being extremely obese. (ClinicalTrials.gov number, NCT00433810.)

The LABS writing group assumes responsibility for the content of this article. Members of the LABS writing group are listed in the Appendix. Address reprint requests to Dr. David R. Flum at the Surgical Outcomes Research Center, Department of Surgery, University of Washington, Box 356410, Seattle, WA 98195-6410, or at sorce@u.washington.edu.

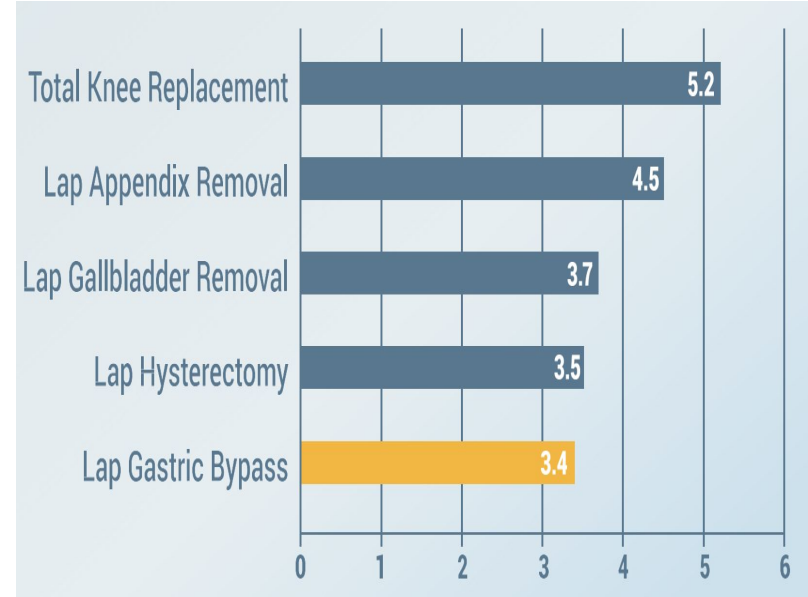
N Engl J Med 2009;361:445-54.
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Long-term Outcomes

Mortality(%)



Morbidity(%)



Long-term outcomes – Weight Loss

TBWL %

Procedure	1 year	3 years	5 years
RYGB	31.2%	29%	25.5%
Sleeve	25.2%	21%	18.8%
AGB	13.7%	12.7%	11.7%

RYGB = 32,208

Sleeve = 29,693

P<0.001

Annals of Internal Medicine

ORIGINAL RESEARCH

Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss

A PCORnet Cohort Study

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Background: There has been a dramatic shift in use of bariatric procedures, but little is known about their long-term comparative effectiveness.

Objective: To compare weight loss and safety among bariatric procedures.

Design: Retrospective observational cohort study, January 2005 to September 2015. (ClinicalTrials.gov: NCT02741674)

Setting: 41 health systems in the National Patient-Centered Clinical Research Network.

Participants: 65 093 patients aged 20 to 79 years with body mass index (BMI) of 35 kg/m² or greater who had bariatric procedures.

Intervention: 32 208 Roux-en-Y gastric bypass (RYGB), 29 693 sleeve gastrectomy (SG), and 3192 adjustable gastric banding (AGB) procedures.

Measurements: Estimated percent total weight loss (TWL) at 1, 3, and 5 years; 30-day rates of major adverse events.

Results: Total numbers of eligible patients with weight measures at 1, 3, and 5 years were 44 978 (84%), 20 783 (68%), and 7159 (69%), respectively. Thirty-day rates of major adverse events were 5.0% for RYGB, 2.6% for SG, and 2.9% for AGB. One-year mean TWLs were 31.2% (95% CI, 31.1% to 31.3%) for RYGB, 25.2% (CI, 25.1% to 25.4%) for SG, and 13.7% (CI, 13.3%

to 14.0%) for AGB. At 1 year, RYGB patients lost 5.9 (CI, 5.8 to 6.1) percentage points more weight than SG patients and 17.7 (CI, 17.3 to 18.1) percentage points more than AGB patients, and SG patients lost 12.0 (CI, 11.6 to 12.5) percentage points more than AGB patients. Five-year mean TWLs were 25.5% (CI, 25.1% to 25.9%) for RYGB, 18.8% (CI, 18.0% to 19.6%) for SG, and 11.7% (CI, 10.2% to 13.1%) for AGB. Patients with diabetes, those with BMI less than 50 kg/m², those aged 65 years or older, African American patients, and Hispanic patients lost less weight than patients without those characteristics.

Limitation: Potential unobserved confounding due to nonrandomized design; electronic health record databases had missing outcome data.

Conclusion: Adults lost more weight with RYGB than with SG or AGB at 1, 3, and 5 years; however, RYGB had the highest 30-day rate of major adverse events. Small subgroup differences in weight loss outcomes were observed.

Primary Funding Source: Patient-Centered Outcomes Research Institute.

Ann Intern Med. doi:10.7326/M17-2786

For author affiliations, see end of text.

This article was published at Annals.org on 30 October 2018.

* For key investigators and stakeholders in the PCORnet Bariatric Study Collaborative, see the Appendix (available at Annals.org).

Annals.org

Retrospective observational cohort

Long Term Outcomes Sleeve vs RYGB

Effect of Laparoscopic Sleeve Gastrectomy vs Roux-en-Y Gastric Bypass on Weight Loss, Comorbidities, and Reflux at 10 Years in Adult Patients With Obesity The SLEEVEPASS Randomized Clinical Trial

Paulina Salminen, MD, PhD^{1,2}; Sofia Grönroos, MD^{1,2}; Mika Helmiö, MD, PhD^{1,2}; [et al](#)

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JAMA Surg

Published Online: June 22, 2022

240 randomized patients (121 randomized to LSG and 119 to LRYGB)

Results There was no statistically significant difference in type 2 diabetes remission (26% and 33%, respectively; $P = .63$), dyslipidemia (19% and 35%, respectively; $P = .23$), or obstructive sleep apnea (16% and 31%, respectively; $P = .30$). **Hypertension remission was superior after LRYGB (8% vs 24%; $P = .04$). Esophagitis was more prevalent after LSG (31% vs 7%; $P < .001$)** with no statistically significant difference in BE (4% vs 4%; $P = .29$). The overall reoperation rate was 15.7% for LSG and 18.5% for LRYGB ($P = .57$).

Long Term Outcomes – Weight Loss

- ❖ DM remission
- ❖ RYGB 33 %
- ❖ Sleeve 26 %

- ❖ OSA Remission
- ❖ RYGB 31%
- ❖ Sleeve 16%

- ❖ HTN Remission
- ❖ RYGB 24%
- ❖ Sleeve 8%
- p<0.04

- ❖ Reflux:
- ❖ RYGB 7%
- ❖ Sleeve 31%
- p<0.001



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JAMA Surgery

RCT: Effect of Laparoscopic Sleeve Gastrectomy vs Roux-en-Y Gastric Bypass on Weight Loss, Comorbidities, and Reflux at 10 Years in Adult Patients With Obesity

POPULATION

73 Men, 167 Women



Adults aged 18-60 y with body mass index (BMI) ≥ 40 (or ≥ 35 with obesity-related comorbidity) and prior nonsurgical treatment

Mean age, 48.4 y; mean BMI, 44.6

INTERVENTION

240 Patients randomized

193 Analyzed for 10-y weight loss outcome



98 LSG

Laparoscopic sleeve gastrectomy

95 LRYGB

Laparoscopic Roux-en-Y gastric bypass

SETTINGS/LOCATIONS



3 Hospitals in Finland

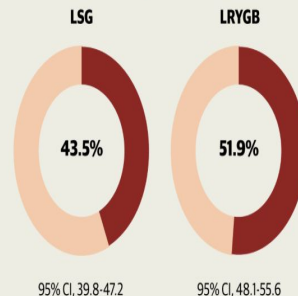
PRIMARY OUTCOME

10-y Percentage excess weight loss (%EWL), defined as the difference between initial weight and follow-up weight divided by the difference between initial weight and ideal weight for BMI of 25, multiplied by 100

FINDINGS

Both LSG and LRYGB resulted in sustainable weight loss, but 10-y %EWL was not equivalent between the 2 groups

10-y %EWL



Between-group difference in mean 10-y %EWL:
8.4 Percentage points (95% CI, 3.1-13.6)

Salminen P, Grönroos S, Helmiö M, et al. Long-term effect of laparoscopic sleeve gastrectomy vs Roux-en-Y gastric bypass on weight loss, comorbidities, and reflux in adult patients with obesity: the SLEEVEPASS randomized clinical trial. *JAMA Surg*. Published online June 22, 2022. doi:10.1001/jamasurg.2022.2229

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Long Term Outcomes –Weight Loss

Original Investigation

FREE



Metrics

Bariatric Surgery and Long-term Durability of Weight Loss

Matthew L. Maciejewski, PhD^{1,2}; David E. Arterburn, MD, MPH^{3,4}; Lynn Van Scoy-
oc, BA¹ ; [et al](#)

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JAMA Surg

Published Online: November 2016

2016;151;(11):1046-1055. doi:10.1001/jama-surg.2016.2317

Large, Multi-site, retrospective, cohort study
(1787 RYBG, 379 sleeve and 5304 controls)

Long Term Outcomes – Weight Loss

Figure 3. Differences in Estimated Percentage of Weight Change From Baseline by Surgical Procedure Type

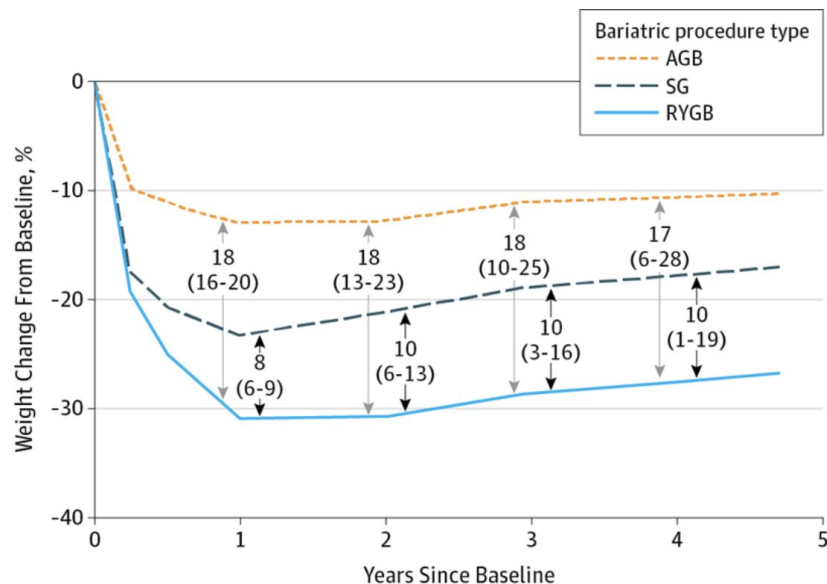
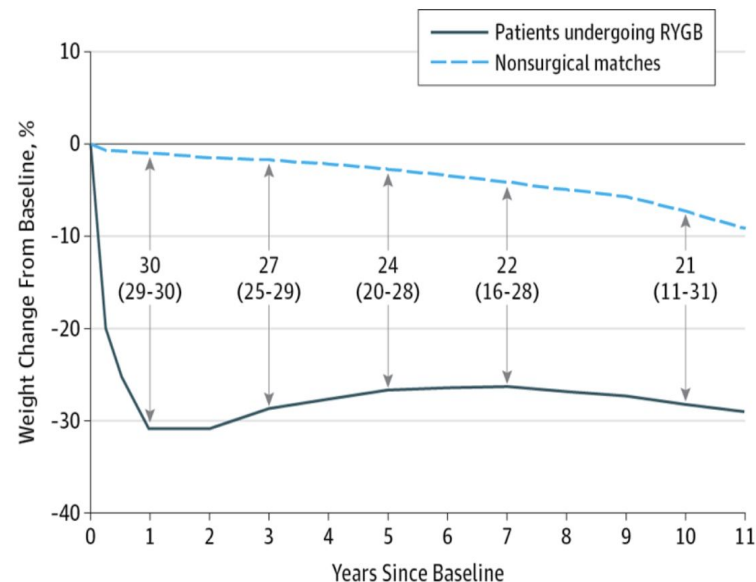
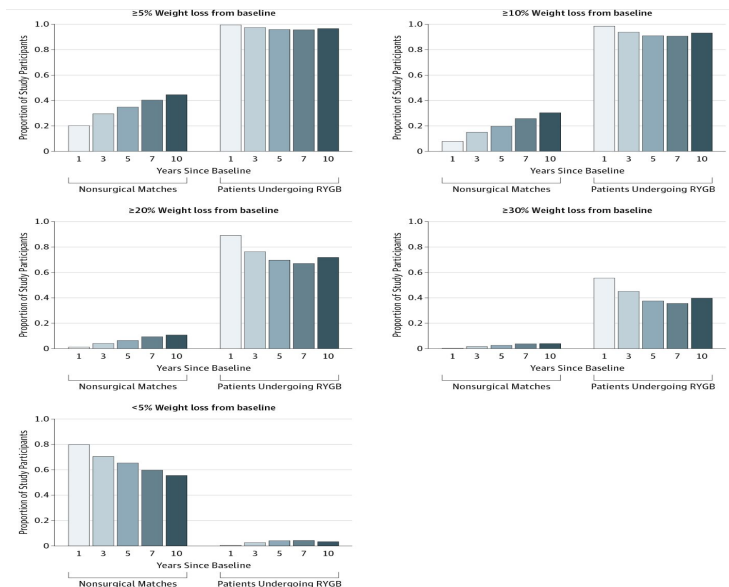


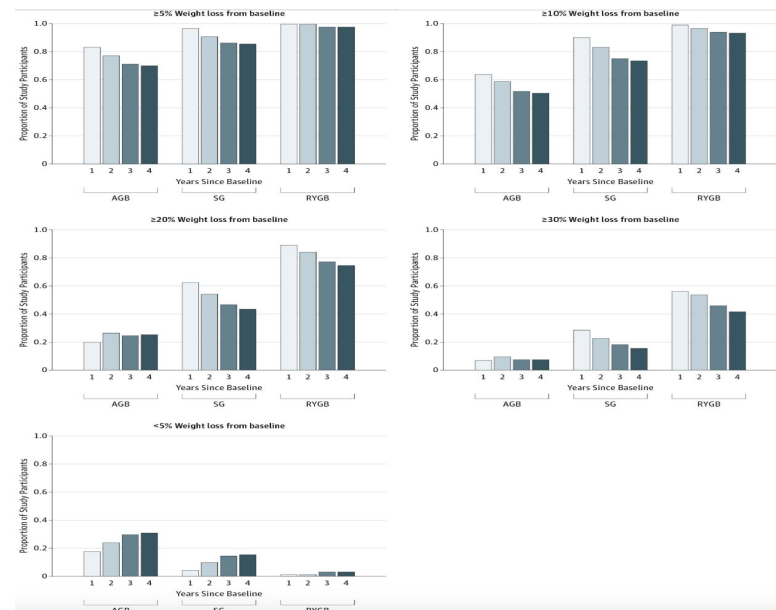
Figure 1. Differences in Estimated Weight Changes Among Patients Undergoing Roux-en-Y Gastric Bypass (RYGB) and Nonsurgical Matches



Long Term Outcomes – Weight Loss



71.8% of RYGB had 20% TBWL at 10 yrs
39.7% of RYGB pts had 30% TBWL at 10 years
3.4% regained to 5% of original weight



At 4-years 14.6% of sleeve pts
regained to 5% of original weight vs
only 2.5% in the RYGB group

Long Term Outcomes – Weight & Co-morbidities

The NEW ENGLAND JOURNAL of MEDICINE

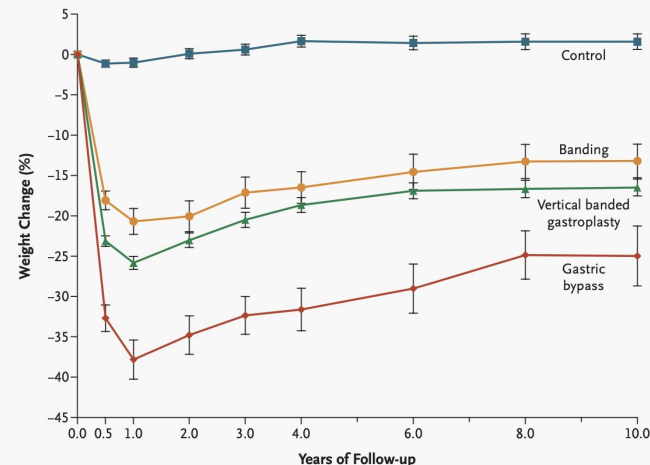
ESTABLISHED IN 1812

DECEMBER 23, 2004

VOL. 351 NO. 26

Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery

Lars Sjöström, M.D., Ph.D., Anna-Karin Lindroos, Ph.D., Markku Peltonen, Ph.D., Jarl Torgerson, M.D., Ph.D., Claude Bouchard, Ph.D., Björn Carlsson, M.D., Ph.D., Sven Dahlgren, M.D., Ph.D., Bo Larsson, M.D., Ph.D., Kristina Narbro, Ph.D., Carl David Sjöström, M.D., Ph.D., Marianne Sullivan, Ph.D., and Hans Wedel, Ph.D.,
for the Swedish Obese Subjects Study Scientific Group*



No. of Subjects

Control	627	585	594	587	577	563	542	535	627
Banding	156	150	154	153	149	150	147	144	156
Vertical banded gastroplasty	451	438	438	438	429	417	412	401	451
Gastric bypass	34	34	34	34	33	32	32	29	34

Figure 1. Weight Changes among Subjects in the SOS Study over a 10-Year Period.

All data are for subjects who completed 10 years of the study. The average weight change in the entire group of surgically treated subjects was almost identical to that in the subgroup of subjects who underwent vertical banded gastroplasty. The I bars represent the 95 percent confidence intervals.

Long Term Outcomes – Life-style / comorbidity

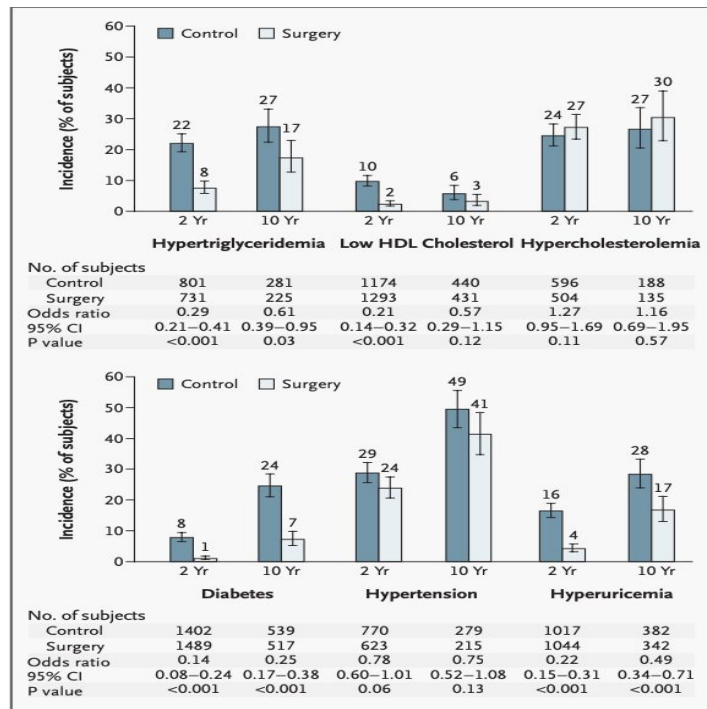
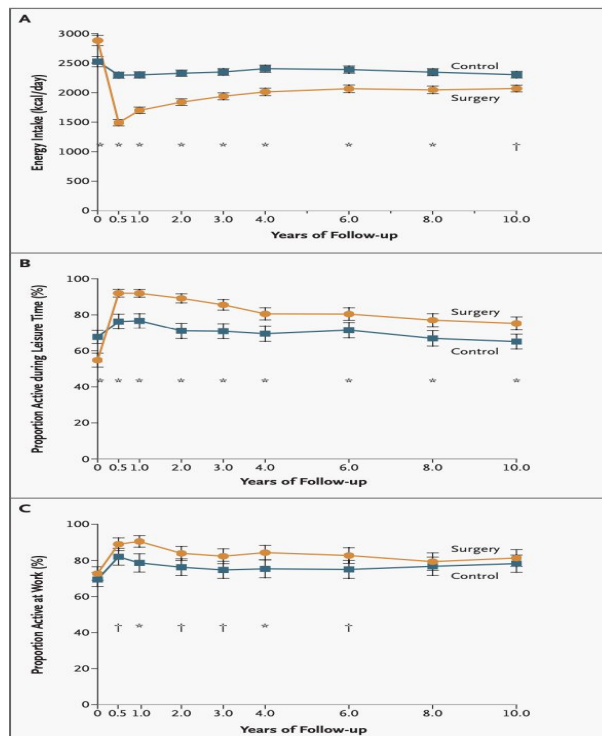


Figure 3. Incidence of Diabetes, Lipid Disturbances, Hypertension, and Hyperuricemia among Subjects in the SOS Study over 2- and 10-Year Periods.

Data are for subjects who completed 2 years and 10 years of the study. The bars and the values above the bars indicate unadjusted incidence rates; I bars represent the corresponding 95 percent confidence intervals (CIs). The odds ratios, 95 percent CIs for the odds ratios, and P values have been adjusted for sex, age, and body-mass index at the time of inclusion in the intervention study.

Long-term Outcomes Randomized Controlled Trials

❖ **STAMPEDE TRIAL (N Engl J)**

- Medical therapy combined with MBS is superior to medical therapy only
- ❖ MBS vs conventional medical treatment in obese patients with T2D; 5 yr follow-up (Mingrone et al. Lancet 2015;386(997):964–73)
 - Superiority of MBS to medical therapy in the management of T2D 5 years after surgery.
- ❖ Effect of gastric bypass vs best medical treatment on early-stage chronic kidney disease in patient with T2D and obesity (Cohen et al JAMA surg 2020;155(8))

Long-term Outcomes

STAMPEDE TRIAL

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes

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Kathy Wolski, M.P.H., Ali Aminian, M.D., Stacy A. Brethauer, M.D.,
Sankar D. Navaneethan, M.D., M.P.H., Rishi P. Singh, M.D., Claire E. Pothier, M.P.H.,
Steven E. Nissen, M.D., and Sangeeta R. Kashyap, M.D.,
for the STAMPEDE Investigators*

ABSTRACT

BACKGROUND Long-term results from randomized, controlled trials that compare medical therapy with surgical therapy in patients with type 2 diabetes are limited.

METHODS We assessed outcomes 5 years after 150 patients who had type 2 diabetes and a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 27 to 43 were randomly assigned to receive intensive medical therapy alone or intensive medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy. The primary outcome was a glycated hemoglobin level of 6.0% or less with or without the use of diabetes medications.

RESULTS Of the 150 patients who underwent randomization, 1 patient died during the 5-year follow-up period; 134 of the remaining 149 patients (90%) completed 5 years of follow-up. At baseline, the mean (±SD) age of the 134 patients was 49±8 years, 66% were women, the mean glycated hemoglobin level was 9.2±1.5%, and the mean BMI was 37±3.5. At 5 years, the criterion for the primary end point was met by 2 of 38 patients (5%) who received medical therapy alone, as compared with 14 of 49 patients (29%) who underwent gastric bypass (unadjusted P=0.01, adjusted P=0.03, P=0.08 in the intention-to-treat analysis) and 11 of 47 patients (23%) who underwent sleeve gastrectomy (unadjusted P=0.03, adjusted P=0.07, P=0.17 in the intention-to-treat analysis). Patients who underwent surgical procedures had a greater percentage reduction from baseline in glycated hemoglobin level than did patients who received medical therapy alone (2.1% vs. 0.3%, P=0.003). At 5 years, changes from baseline observed in the gastric-bypass and sleeve-gastrectomy groups were superior to the changes seen in the medical-therapy group with respect to body weight (−23%, −19%, and −5% in the gastric-bypass, sleeve-gastrectomy, and medical-therapy groups, respectively), triglyceride level (−40%, −29%, and −8%), high-density lipoprotein cholesterol level (32%, 30%, and 7%), use of insulin (−35%, −34%, and −13%), and quality-of-life measures (general health score increases of 17, 16, and 0.3; scores on the RAND 36-Item Health Survey ranged from 0 to 100, with higher scores indicating better health) (P<0.05 for all comparisons). No major late surgical complications were reported except for one reoperation.

CONCLUSIONS Five-year outcome data showed that, among patients with type 2 diabetes and a BMI of 27 to 43, bariatric surgery plus intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia. (Funded by Ethicon Endo-Surgery and others; STAMPEDE ClinicalTrials.gov number, NCT00432805.)

N. ENGL J MED 376:7 NEJM.ORG FEBRUARY 16, 2017



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- ◆ **Randomized, controlled, 150 obese patients with type II DM (50 RYGB + IMT, 50 Sleeve + IMT and 50 IMT only)**
- ◆ **Five-year f/u: 90%**
- ◆ **Criteria: Age (20–60 yrs), HA1c >7 (mean 9.2), BMI 27 to 43**
- ◆ **Primary outcome: HA1c < 6 with or without medication**
- ◆ **Secondary outcomes: Glycemic control, weight loss, lipid levels, renal function, medication use, QOL (RAND 36–item HS)**

Long-term Outcomes

STAMPEDE TRIAL

- ❖ **Mean BMI 37**
- ❖ **37% had BMIs < 35**
- ❖ Mean HA1c 9.2
- ❖ Mean duration of diabetes 8.4 years
- ❖ 44% required insulin at baseline
- ❖ **No significant differences at baseline between group**

Long-term Outcomes

STAMPEDE TRIAL

❖ Primary Outcome HA1c <6

Medical group (2 of 38) - **5%** met primary outcome

RYGB (14 of 49) – **29%** met primary outcome ($p < 0.01$)

Sleeve (11 of 47 – **23%** met primary outcome ($p < 0.03$))

❖ Significant predictors of achieving HA1c of < 6

Duration of diabetes < 8 years

Random assignment of RYGB

Long-term Outcomes

STAMPEDE TRIAL

- ❖ The two surgical groups were superior to medical therapy alone in achieving HA1c of < 6 without meds, < 6.5 with or without meds or < 7 with or without meds ($p < 0.05$)
- ❖ There was more rapid, larger and more sustained reductions of HA1c levels, fasting glucose levels, BMI and the use of medications in the two surgical groups

Long-term Outcomes

STAMPEDE TRIAL

- ❖ Greater reduction in weight, BMI, waist circumference and waist to hip ratios with RYGB and sleeve ($p < 0.05$)
- ❖ The decrease of baseline in triglyceride levels and the increase of baseline in HDL levels were significantly greater in the two surgical groups
- ❖ Reduction in body weight was greater after gastric bypass than after sleeve ($p < 0.01$)

Long-Term Outcomes

❖ Observational Cohort

3,392 Total patients

1,657 in the **MBS group**
(RYGB 61.3%, sleeve 38.7%)

2,275 in the **GLP-1 group**

❖ Median F/U – 5.9 years

GLP-1 group: Liraglutide 1,488 (65.4%), dulaglutide 1,106 (48.6%), exenatide 740 (32.5%), semaglutide 602 (26.5%), tirzepatide 101 (4.4%), lixisenatide 65 (2.9%)

Macrovascular and microvascular outcomes of metabolic surgery versus GLP-1 receptor agonists in patients with diabetes and obesity

[Hamlet Gasoyan](#), [Mohammad Hesam Alavi](#), [Alexander Zajichek](#), [Nicholas J. Casacchia](#), [Abdullah Al Jabri](#), [James Bena](#), [Xiaoxi Feng](#), [Rickesha Wilson](#), [Ricard Corcelles](#), [W. Scott Butsch](#), [Rishi P. Singh](#), [Nikhil Das](#), [Hejin Jeong](#), [Amgad Mentias](#), [W. H. Wilson Tang](#), [Bartolome Burguera](#), [Raul J. Rosenthal](#), [Steven E. Nissen](#) , [Michael B. Rothberg](#) & [Ali Aminian](#) 

[Nature Medicine](#) **31**, 3341–3349 (2025) | [Cite this article](#)

Long-term Outcomes

Macrovascular and microvascular
outcomes of metabolic surgery Versus GLP-1 receptors agonists in patients with
diabetes and obesity

Nature M/vol. 31/Oct 2025 3341–3349

❖ All cause mortality at 10 years

MBS group – 9.0%

GLP-1 group – 12.4%

Adjusted Absolute risk difference – **3.8%** ($p < 0.028$)

Long-term Outcomes

Macrovascular and Microvascular outcomes of MBS Versus GLP-1 receptors agonists in patients with diabetes and obesity

Nature M/vol. 31/Oct 2025 3341–3349

❖ MACE at 10 years

MBS group – 23.7%

GLP-1 group – 34%

P < 0.001

❖ Retinopathy at 10 years

MBS – 5.5%

GLP-1 group – 15.9%

P < 0.002

❖ Nephropathy at 10 years

MBS -21.4%

GLP-1 group – 37%

P < 0.001

Long-term Outcomes

Macrovascular and microvascular outcomes of MBS Versus GLP-1 receptors agonists in patients with diabetes and obesity

Nature M/vol. 31/Oct 2025 3341–3349

❖ Mean body weight reduction

- ❑ **MBS group - 21.6%**
- ❑ GLP-1 group – 6.8%
- ❑ Mean difference in overlap weighted analysis was **14.8%** ($p < 0.001$)

❖ Absolute change in HA1c

- ❑ **MBS group - 0.86%**
- ❑ GLP-1 group - 0.23%
- ❑ Mean between group difference in overlap weighted analysis was **-0.63**
($p < 0.001$)

Long-term Outcomes

Macrovascular and microvascular outcomes of MBS Versus GLP-1 receptors agonists
in patients with diabetes and obesity

Nature M /vol. 31/Oct 2025 3341–3349

Conclusion:

These findings indicate that even with the availability of GLP-1 RAs, **metabolic surgery remains superior to medical treatment**. Future studies should compare the cardiometabolic outcomes of metabolic surgery with newer GLP-1 RAs that are more effective for weight reduction.

Long-term Outcomes Mortality

❖ Prospective, controlled study:

□ Decrease overall mortality of 30.7% in 2010 MBS patients 10 years after surgery

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Effects of Bariatric Surgery on Mortality in Swedish Obese Subjects

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ABSTRACT

BACKGROUND

Obesity is associated with increased mortality. Weight loss improves cardiovascular risk factors, but no prospective interventional studies have reported whether weight loss decreases overall mortality. In fact, many observational studies suggest that weight reduction is associated with increased mortality.

METHODS

The prospective, controlled Swedish Obese Subjects study involved 4047 obese subjects. Of these subjects, 2010 underwent bariatric surgery (surgery group) and 2037 received conventional treatment (matched control group). We report on overall mortality during an average of 10.9 years of follow-up. At the time of the analysis (November 1, 2005), vital status was known for all but three subjects (follow-up rate, 99.9%).

RESULTS

The average weight change in control subjects was less than $\pm 2\%$ during the period of up to 15 years during which weights were recorded. Maximum weight losses in the surgical subgroups were observed after 1 to 2 years: gastric bypass, 32%; vertical-banded gastroplasty, 25%; and banding, 20%. After 10 years, the weight losses from baseline were stabilized at 25%, 16%, and 14%, respectively. There were 129 deaths in the control group and 101 deaths in the surgery group. The unadjusted overall hazard ratio was 0.76 in the surgery group ($P=0.04$), as compared with the control group, and the hazard ratio adjusted for sex, age, and risk factors was 0.71 ($P=0.01$). The most common causes of death were myocardial infarction (control group, 25 subjects; surgery group, 13 subjects) and cancer (control group, 47; surgery group, 29).

CONCLUSIONS

Bariatric surgery for severe obesity is associated with long-term weight loss and decreased overall mortality.

From the Institutes of Medicine (L.-S., K.N., K.K., T.L., M.S., B.C., A.G., P.J., J.K., K.S., L.M.S.C.), Anesthesiology (C.D.S., B.L.), Surgery (H.L., T.O.), and Primary Health Care (C. Bengtsson), Sahlgrenska Academy, Gothenburg University, Gothenburg; Nordic School of Public Health, Gothenburg (H.W.); Børjegatan 10B, Uppsala (S.D.); Department of Surgery, University Hospital, Örebro (I.N., G.A.); and Department of Medicine, Northern Älvsborg Hospital, Trollhättan (J.T.)—all in Sweden; Pennington Biomedical Research Center, Louisiana State University System, Baton Rouge (L.S., C. Bouchard); and Medical Research Council Human Nutrition Research, Elsie Widdowson Laboratory, Cambridge University, Cambridge, United Kingdom (A.-K.L.). Address reprint requests to Dr. L. Sjöström at the Swedish Obese Subjects Secretariat, Vita stråket 15, Sahlgrenska University Hospital, S-413 45 Gothenburg, Sweden, or at lars.sjostrom@medfak.gu.se.

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Long-term Outcomes Mortality

- ❖ Retrospective Cohort study of 9949 patients
- Decreased mortality after Gastric bypass by 40% with mean f/u of 7 years

ORIGINAL ARTICLE

Long-Term Mortality after Gastric Bypass Surgery

Ted D. Adams, Ph.D., M.P.H., Richard E. Gress, M.A., Sherman C. Smith, M.D., R. Chad Halverson, M.D., Steven C. Simper, M.D., Wayne D. Rosamond, Ph.D., Michael J. LaMonte, Ph.D., M.P.H., Antoinette M. Stroup, Ph.D., and Steven C. Hunt, Ph.D.

ABSTRACT

BACKGROUND

Although gastric bypass surgery accounts for 80% of bariatric surgery in the United States, only limited long-term data are available on mortality among patients who have undergone this procedure as compared with severely obese persons from a general population.

METHODS

In this retrospective cohort study, we determined the long-term mortality (from 1984 to 2002) among 9949 patients who had undergone gastric bypass surgery and 9628 severely obese persons who applied for driver's licenses. From these subjects, 7925 surgical patients and 7925 severely obese control subjects were matched for age, sex, and body-mass index. We determined the rates of death from any cause and from specific causes with the use of the National Death Index.

RESULTS

During a mean follow-up of 7.1 years, adjusted long-term mortality from any cause in the surgery group decreased by 40%, as compared with that in the control group (37.6 vs. 57.1 deaths per 10,000 person-years, $P<0.001$); cause-specific mortality in the surgery group decreased by 56% for coronary artery disease (2.6 vs. 5.9 per 10,000 person-years, $P=0.006$), by 92% for diabetes (0.4 vs. 3.4 per 10,000 person-years, $P=0.005$), and by 60% for cancer (5.5 vs. 13.3 per 10,000 person-years, $P<0.001$). However, rates of death not caused by disease, such as accidents and suicide, were 58% higher in the surgery group than in the control group (11.1 vs. 6.4 per 10,000 person-years, $P=0.04$).

CONCLUSIONS

Long-term total mortality after gastric bypass surgery was significantly reduced, particularly deaths from diabetes, heart disease, and cancer. However, the rate of death from causes other than disease was higher in the surgery group than in the control group.

Long-term Outcomes – Mortality

Original Investigation

FREE



Metrics

Association Between Bariatric Surgery and Long-term Survival

David E. Arterburn, MD, MPH^{1,2}; Maren K. Olsen, PhD^{3,4}; Valerie A. Smith, MS³; [et al](#)

JAMA

Published Online: January 6, 2015

2015;313;(1):62-70.

doi:10.1001/jama.2014.16968

Retrospective cohort study (2500 male MBS patients and 7462 controls)

□ Mortality Rates:	<u>5 years</u>	<u>10 years</u>
MBS:	6.6%	13.8%
Controls:	10.4%	23.9%
	P< 0.05	P< 0.05

Long-term Outcomes –Cardiovascular

(Mentias et al. J AM Coll Cardiol 2022;79(15):1429-37)

Long-Term Cardiovascular Outcomes After Bariatric Surgery in the Medicare Population



Amgad Mentias, MD, MS,^a Ali Aminian, MD,^b Dalia Youssef, MD,^c Ambarish Pandey, MD,^d Venu Menon, MD,^a
Leslie Cho, MD,^a Steven E. Nissen, MD,^a Milind Y. Desai, MD, MBA^a

Retrospective, matched cohort

Total Patients 189,779

Surgical: 94,885, matched controls: 94,885

Propensity score matching on 87 variables

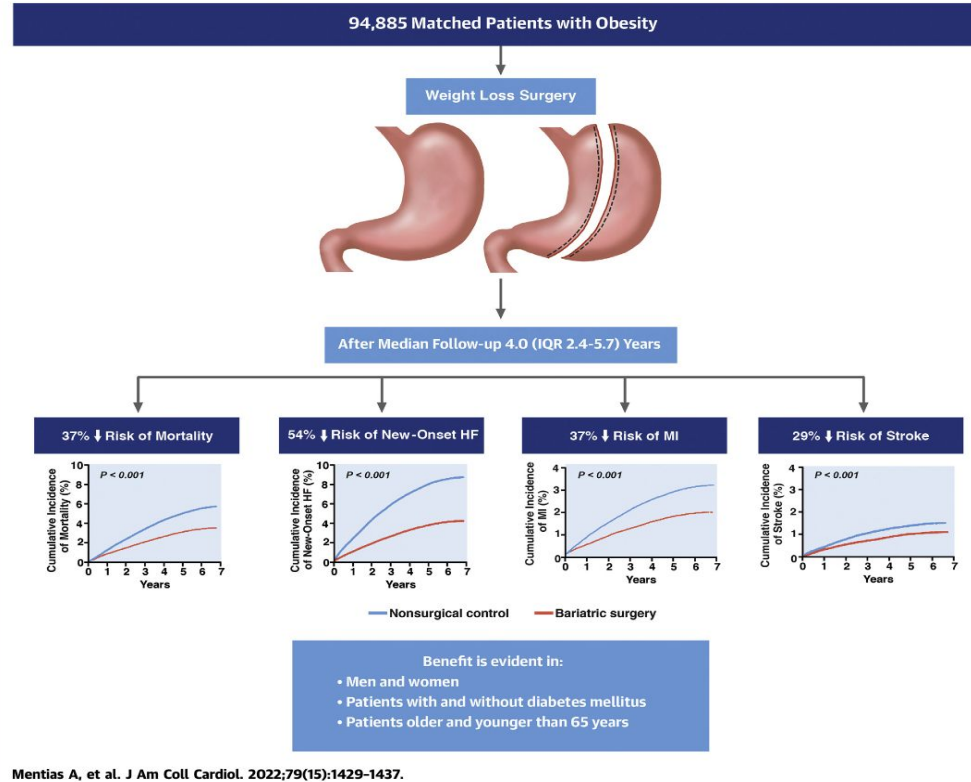
Long-term Outcomes –Cardiovascular

TABLE 2 Incidence Rates and Cause-Specific HRs for Study Endpoints After Propensity Score Matching

Outcome	Bariatric Surgery Group	Nonsurgical Control Group	Cause-Specific HR (95% CI)	P Value
	Incidence Rate per 1,000 Person-Years			
All-cause mortality	9.2	14.7	0.63 (0.60-0.66)	<0.001
Heart failure	13.3	27.0	0.46 (0.44-0.49)	<0.001
Myocardial infarction	6.1	9.5	0.63 (0.59-0.68)	<0.001
Ischemic stroke	3.5	4.6	0.71 (0.65-0.79)	<0.001

(Mentias et al. J AM Coll Cardiol 2022;79(15):1429-37)

CENTRAL ILLUSTRATION Summary of Study Findings



Mentias A, et al. J Am Coll Cardiol. 2022;79(15):1429-1437.

Association of bariatric surgery with long-term cardiovascular outcomes. HF = heart failure, MI = myocardial infarction.

Bariatric Surgery and Long-term Cardiovascular Events

Lars Sjöström, MD, PhD; Markku Peltonen, PhD; Peter Jacobson, MD, PhD ; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

JAMA

Published Online: January 4, 2012

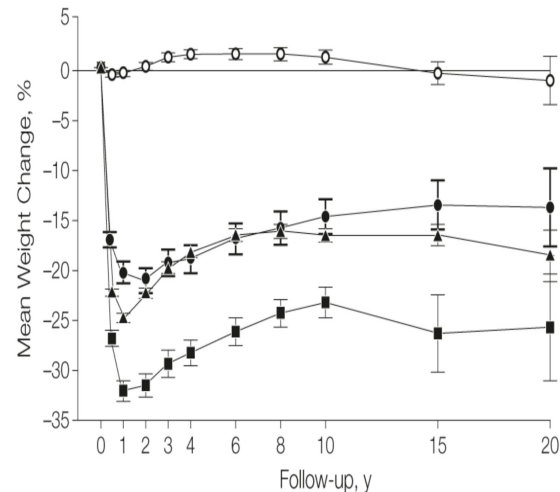
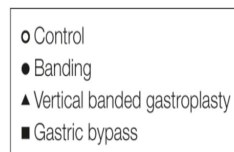
2012;307;(1):56-65. doi:10.1001/jama.2011.1914

◆ **Non-randomized, matched, prospective controlled SOS study (median f/u -14.7 years)**
 2010 MBS patients (18.7% gastric bands, 68.1% VBG, 13.2% gastric bypass)

Changes in body weight at 2, 10, 15 and 20 years - 23%, 17%, 16% and 18% in the MBS group and 0%, 1%, -1% and -1% in the control group

□ **53% reduction in Cardiovascular related deaths**

□ **33% reduction in cardiac events**



No. of patients						
Control	2037	1490	1242	1267	556	176
Banding	376	333	284	284	150	50
Vertical banded gastroplasty	1369	1086	987	1007	489	82
Gastric bypass	265	209	184	180	37	13

Long-term Outcomes Mortality in HF patients

- ❖ Retrospective review of Medicare patients, Propensity-matched analysis
- ❖ 298,101 pt with HF and BMI >34.9
- ❖ 2594 underwent bariatric surgery (3069 controls, 1944 MBS)
- ❖ 74.3% sleeve gastrectomy and 24.8% bypass
- ❖ f/u 4.7 years



Trends and Outcomes Associated With Bariatric Surgery and Pharmacotherapies With Weight Loss Effects Among Patients With Heart Failure and Obesity

Amgad Mentias¹, MD, MS; Milind Y. Desai², MD, MBA; Ali Aminian, MD; Kershaw V. Patel³, MD, MSCS; Neil Keshvani⁴, MD; Subodh Verma⁵, MD; Leslie Cho⁶, MD; Miriam Jacob⁷, MD; Paulino Alvarez, MD, PhD; A. Michael Lincoff⁸, MD; Harriette G.C. Van Spall⁹, MD, MPH; Carolyn S.P. Lam¹⁰, MBBS, PhD; Javed Butler¹¹, MD, MPH, MBA; Steven E. Nissen¹², MD; Ambarish Pandey¹³, MD, MSCS

BACKGROUND: Utilization patterns of bariatric surgery among older patients with heart failure (HF), and the associations with cardiovascular outcomes, are not well known.

METHODS: Medicare beneficiaries with HF and at least class II obesity from 2013 to 2020 were identified with Medicare Provider Analysis and Review 100% inpatient files and Medicare 5% outpatient files. Patients who underwent bariatric surgery were matched to controls in a 1:2 ratio (matched on exact age, sex, race, body mass index, HF encounter year, and HF hospitalization rate pre-surgery/matched period). In an exploratory analysis, patients prescribed pharmacotherapies with weight loss effects (semaglutide, liraglutide, naltrexone-bupropion, or orlistat) were identified and matched to controls with a similar strategy in addition to HF medical therapy data. Cox models evaluated associations between weight loss therapies (as a time-varying covariate) and mortality risk and HF hospitalization rate (calculated as the rate of HF hospitalizations following index HF encounter per 100 person-months) during follow-up.

RESULTS: Of 298 101 patients with HF and body mass index ≥ 35 kg/m², 2594 (0.9%) underwent bariatric surgery (45% men; mean age, 56.2 years; mean body mass index, 51.5 kg/m²). In propensity-matched analyses over a median follow-up of 4.7 years, bariatric surgery was associated with lower risk of all-cause mortality (HR, 0.55 [95% CI, 0.49–0.63]; $P < 0.001$), greater reduction in HF hospitalization rate (rate ratio, 0.72 [95% CI, 0.67–0.77]; $P < 0.001$), and lower atrial fibrillation risk (HR, 0.78 [95% CI, 0.65–0.93]; $P = 0.006$). Use of pharmacotherapies with weight loss effects was low (4.8%), with 96.3% prescribed GLP-1 (glucagon-like peptide-1) agonists (semaglutide, 23.6%; liraglutide, 72.7%). In propensity-matched analysis over a median follow-up of 2.8 years, patients receiving pharmacotherapies with weight loss effects (versus matched controls) had a lower risk of all-cause mortality (HR, 0.82 [95% CI, 0.71–0.95]; $P = 0.007$) and HF hospitalization rate (rate ratio, 0.87 [95% CI, 0.77–0.99]; $P = 0.04$).

CONCLUSIONS: Bariatric surgery and pharmacotherapies with weight loss effects are associated with a lower risk of adverse outcomes among older patients with HF and obesity; however, overall utilization remains low.

Long-term Outcomes in HF patients

- ❖ **45% lower risk of all cause mortality**
- ❖ **38% reduction in HF hospitalization**
- ❖ **22% reduction In new onset Atrial fibrillation**
- ❖ **30-day mortality in surgical group was 1.3%**

Long-term Outcomes

Cancer risk

- ❖ Multiple studies demonstrate MBS **reduces the risk** of developing cancer in patients with class II/III obesity , **ranging from 11% to 50%**

Long-term Outcomes – Cancer risk

Original Investigation

FREE



Metrics



Comments

Association of Bariatric Surgery With Cancer Risk and Mortality in Adults With Obesity

Ali Aminian, MD¹; Rickesha Wilson, MD¹; Abbas Al-Kurd, MD¹; [et al](#)

JAMA

Published Online: June 3, 2022

2022;327;(24):2423-2433.

doi:10.1001/jama.2022.9009

Conclusions and Relevance Among adults with obesity, bariatric surgery compared with no surgery was associated with a significantly lower incidence of obesity-associated cancer and cancer-related mortality.

- ❖ Retrospective cohort study of >30,000 patients with median f/u of 6 years found adults with obesity who underwent MBS had **32% lower risk of cancer and 48% lower risk of cancer related death** compared with a matched cohort who did not have surgery (Aminian et al. JAMA 2022;327(24);2423–33)

Current Procedures

Sleeve Gastrectomy 54.3%

Resect approximately
three-fourths of
the stomach



Roux-en-Y Gastric Bypass 43%

Bypass a portion
of the small intestine
and create a 15-30cc
stomach pouch



Single- Anastomosis Duodenal Switch 2.7%

Sleeve gastrectomy
with bypass portion
of small intestine



Revisional Surgery

Converting one form
of bariatric surgery
to another form

Alternative Procedures

- Gastric Band
- Intra-gastric Balloon
- Others

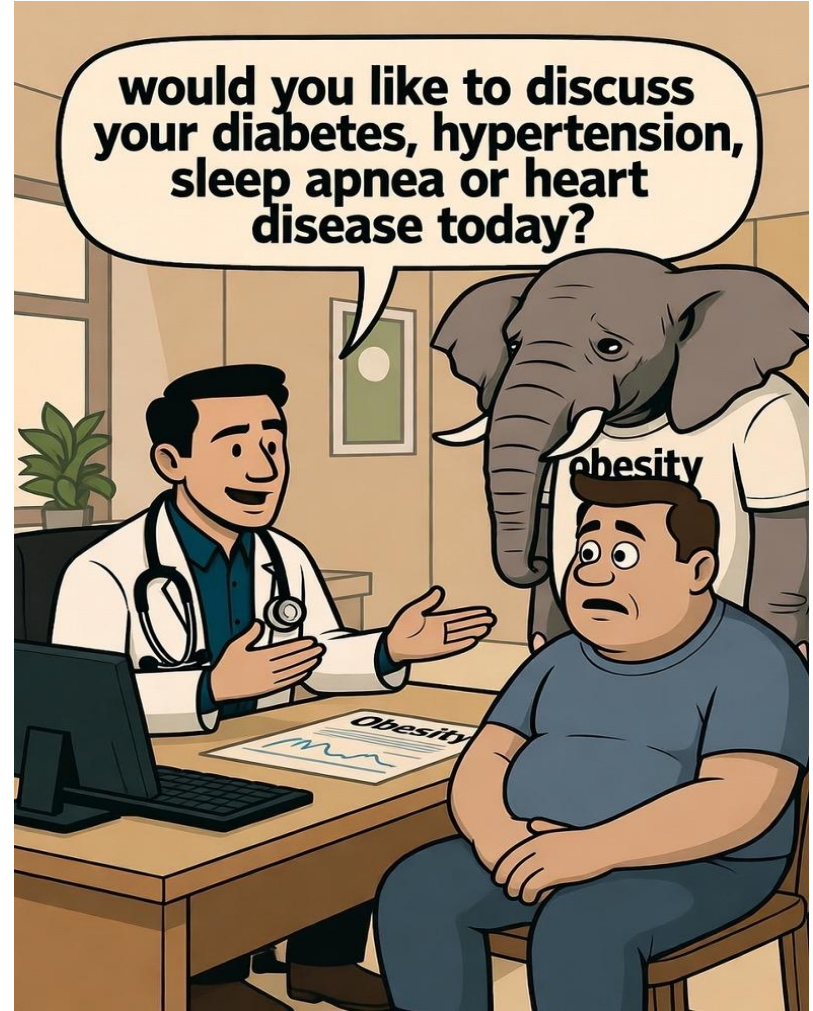


Procedures

Procedure	Risk	Wt loss	Co-morbidities	GERD	Maintenance	Ulcer	Long Term WL
Sleeve	Very low	+++	+++	-	Minimal	Very Low	++
RGB	low	++++	++++	++++	Moderate	High	+++
MRGB	Moderate	+++++	+++++	++++	High	High	++++
SADIS	Moderate	+++++	+++++	-	High	Moderate	++++

The Future

- ❖ Need to take obesity seriously as a chronic disease
- ❖ There is a need to make significant environmental changes (public health, education and policy)
- ❖ Discuss diet/exercise /medication very early
- ❖ Neoadjuvant (Medications/Gastric Balloon)
- ❖ Combined (Adjuvant therapy) with medication after surgery.
- ❖ Multiple operations may be required



Thank you

Question & Answer

Live Audience: Please raise your hand and a mic will come to you.

Virtual Attendees: Please click on the Q&A button to enter your question.



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