

# A Fresh Look at Obesity and the Role of Bariatric Surgery

## Enhancing Your Benefit Design Approach

National Alliance of Healthcare Purchaser Coalitions

Educational Webinar, May 2, 2019



# TODAY'S SPEAKERS



**Scott Kahan, MD, MPH**  
Director  
National Center for Weight  
and Wellness



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Therapeutic Area, Lead  
Metabolics  
Johnson & Johnson



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President and CEO  
Greater Philadelphia  
Business Coalition on Health

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# Outline for Today's Presentation

1. Obesity is a disease: prevalence, health impact, and economic impact, and overall approaches to treatment
2. Bariatric surgery: how does it work and what do we know about effectiveness and safety?
3. Employer considerations in designing and monitoring the bariatric surgery benefit
4. Questions and answers/discussion

# *A Brief Overview of Obesity Treatments*

Scott Kahan, MD, MPH, FTOS

Director, National Center for Weight and Wellness

Department of Health Policy & Management

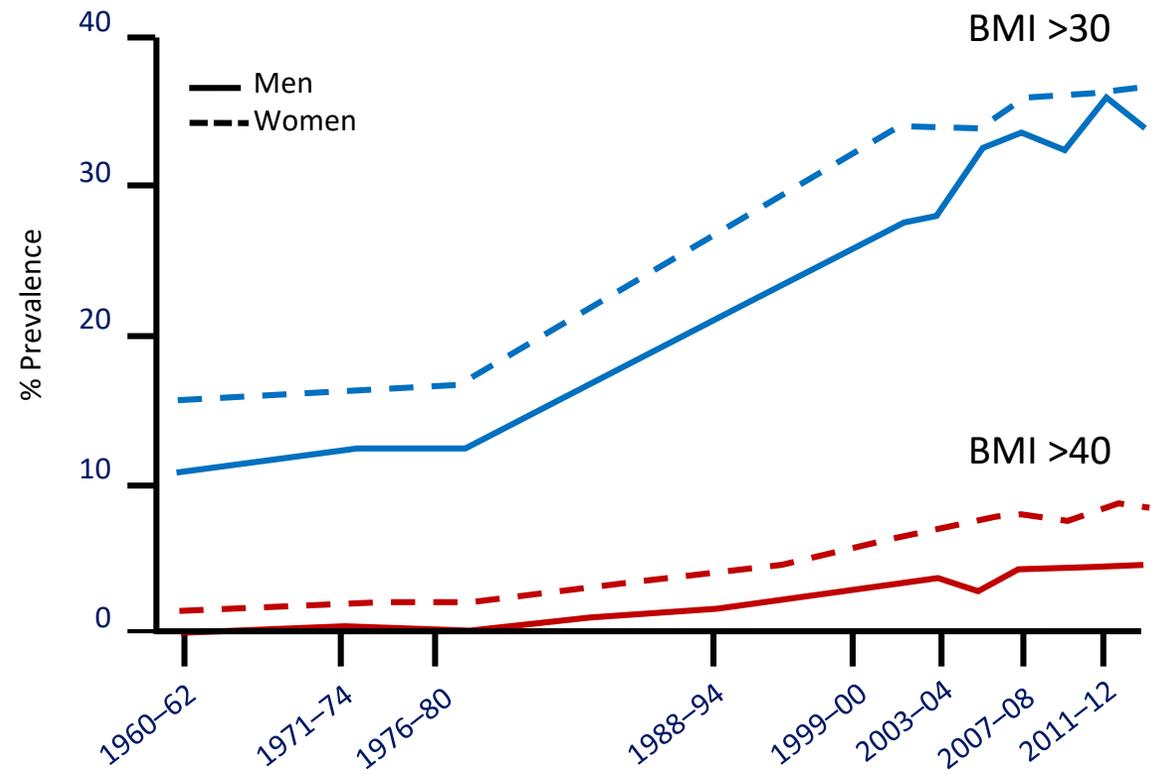
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# Disclosures

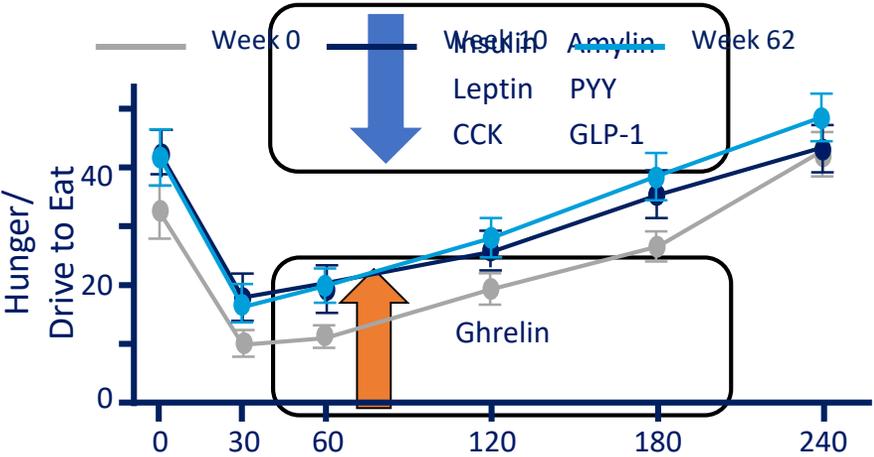
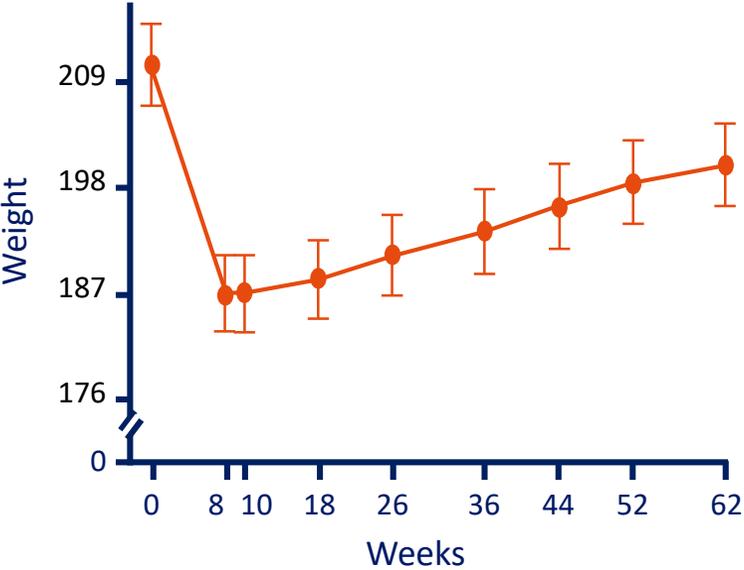
- Consulting: Novo Nordisk, Novartis, Amgen, Orexigen, Bausch, Vivus, Google, Optum, Anthem, Express Scripts, Health Monitor, Medscape, WebMD, Phenomix, Flo, Biologix, KVK Tech, McKinsey, Johns Hopkins Healthcare
- Board of Directors/Advisors: American Board of Obesity Medicine, The Obesity Society, Obesity Action Coalition, Obesity Treatment Foundation, True Health Initiative, Playworks DC, Global Liver Institute, NASH Council
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# Obesity Prevalence in US Adults

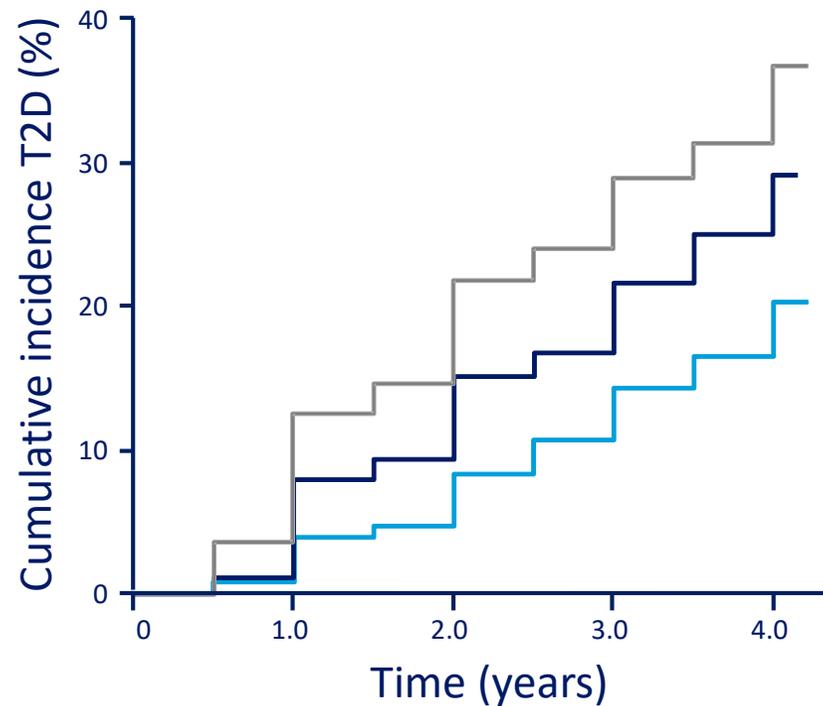
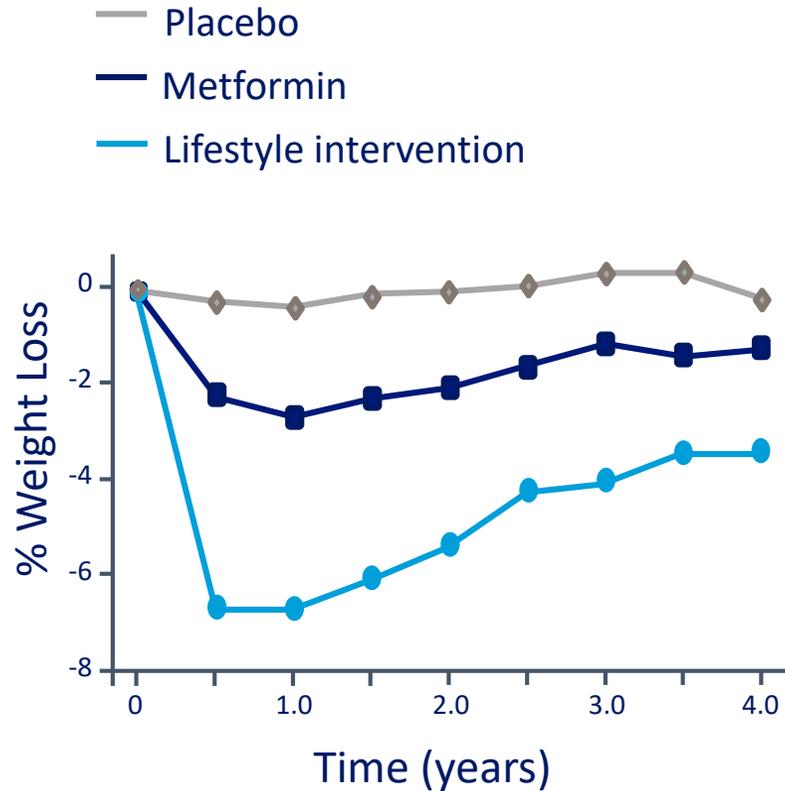




# Why Is It So Hard to Lose Weight and Keep It Off?!



# Modest Weight Loss Improves Health and Risks



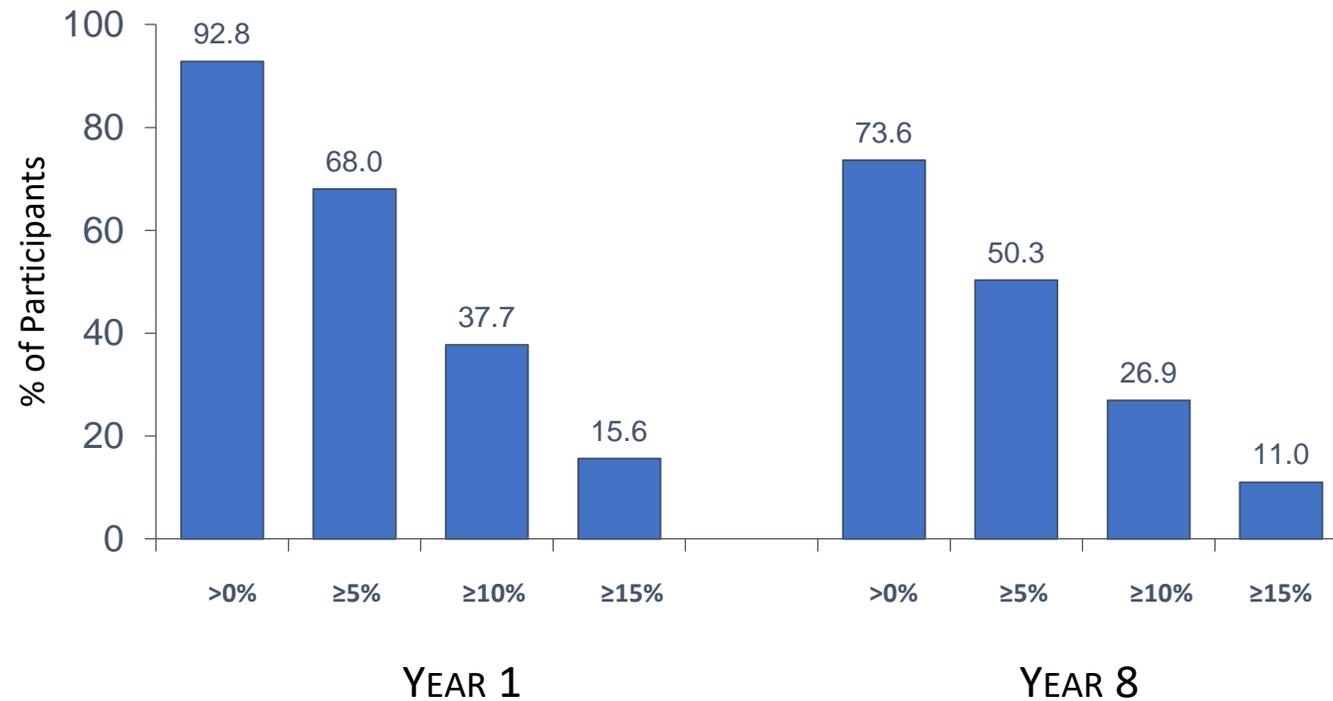
# Modest Weight Loss Improves Health and Risks

Weight-related Condition	% Weight Loss for Therapeutic Benefit	References
Diabetes Prevention	3% to 10%	DPP (Lancet, 2009) SEQUEL (Garvey et al, 2013)
Hypertension	5% to >15%	Look AHEAD (Wing, 2011)
Dyslipidemia	3% to >15%	Look AHEAD (Wing, 2011)
HbA1c	3% to >15%	Look AHEAD (Wing, 2011)
NAFLD	10%	Assy et al, 2007; Dixon et al, 2004; Anish et al, 2009
Sleep Apnea	10%	Sleep AHEAD (Foster, 2009) Winslow et al, 2012
Osteoarthritis	5-10%	Christensen et al, 2007; Felson et al, 1992; Aaboe et al, 2011
Stress Incontinence	5-10%	Burgio et al, 2007 Leslee et al, 2009
GERD	5-10% (women) 10% (men)	Singh et al, 2013 Tutujian R, 2011
PCOS	5-15% (>10% optimal)	Panidis D et al, 2008; Norman et al, 2002; Moran et al, 2013

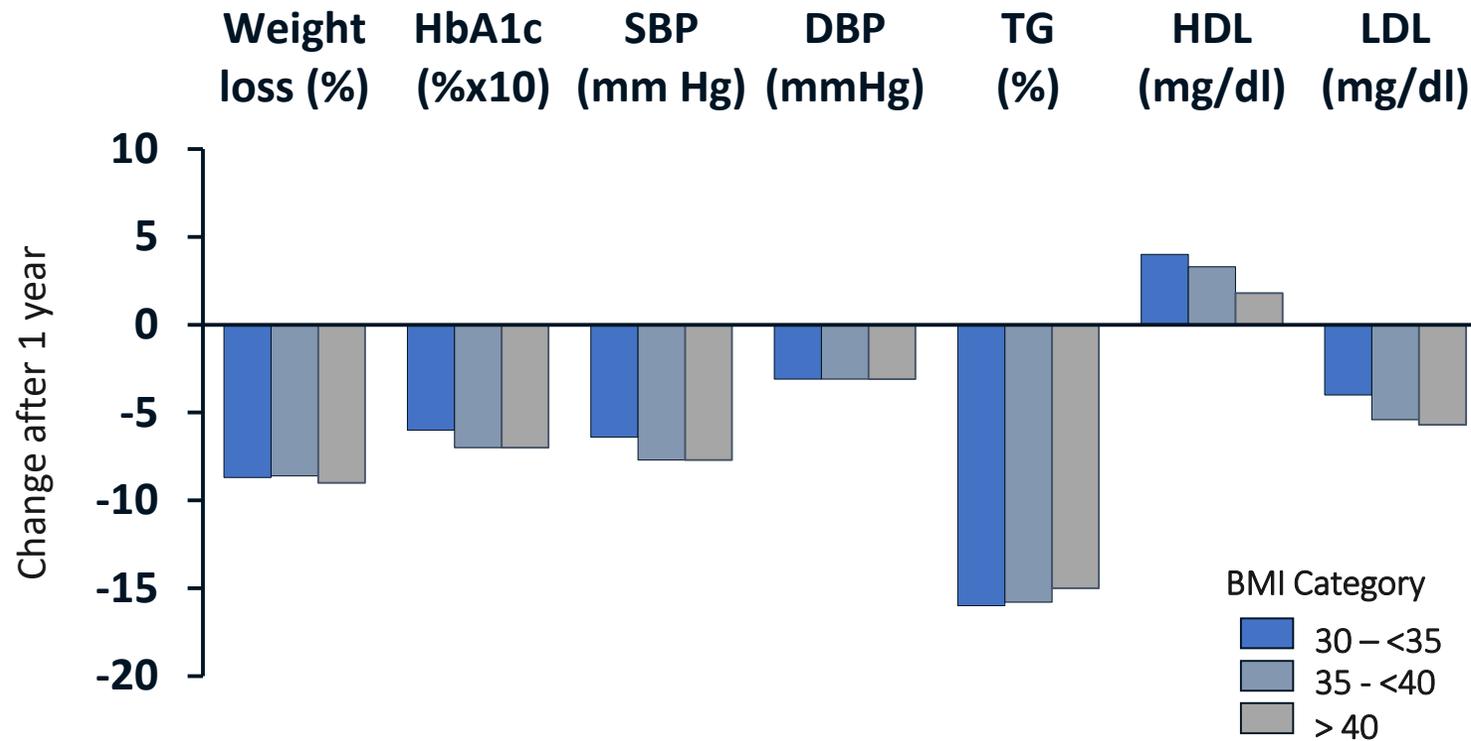
# Obesity Treatment Options

- Behavioral treatment
- Structured diets
- Pharmacotherapy
- Medical devices/procedures
- Bariatric surgery

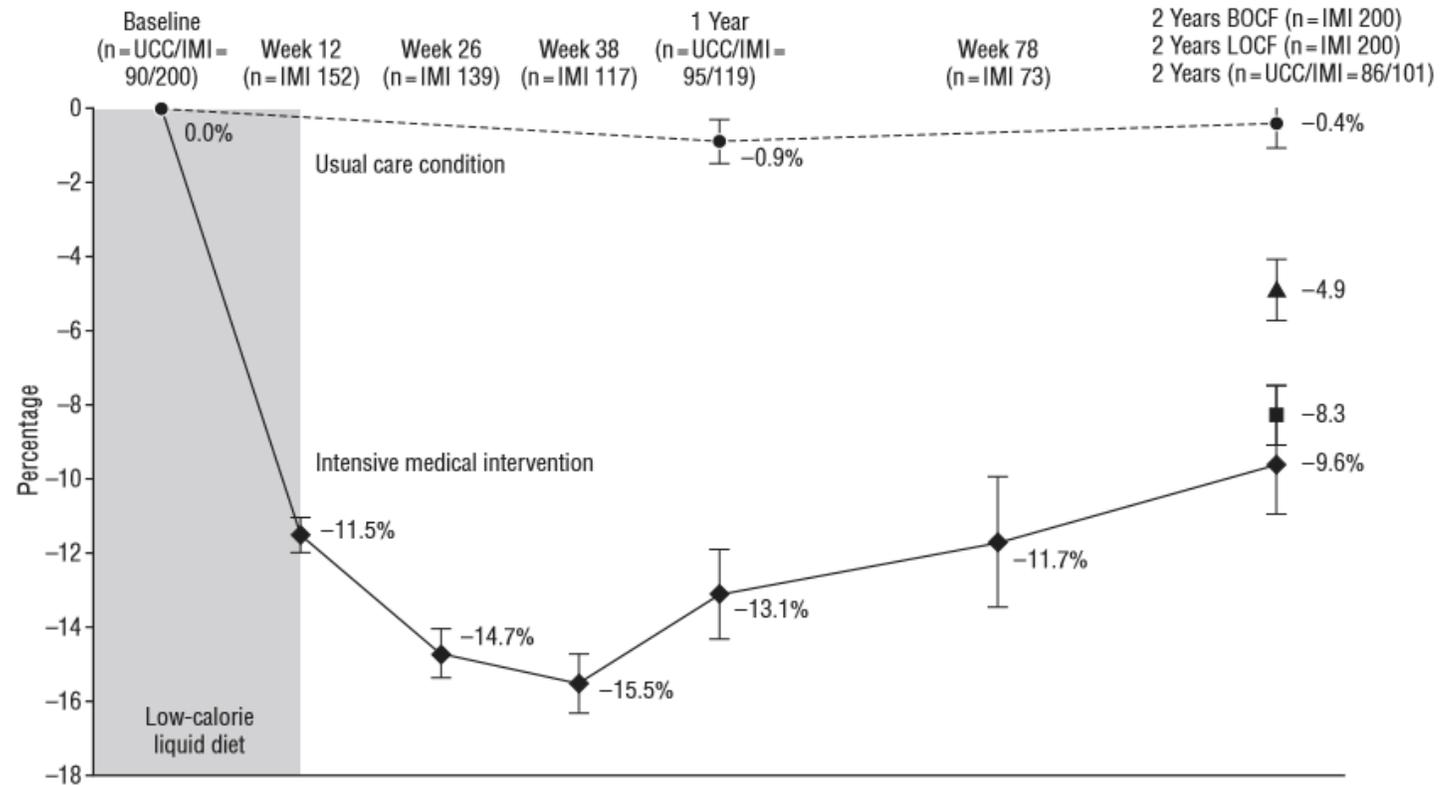
# Behavioral Therapy in Obesity/Diabetes



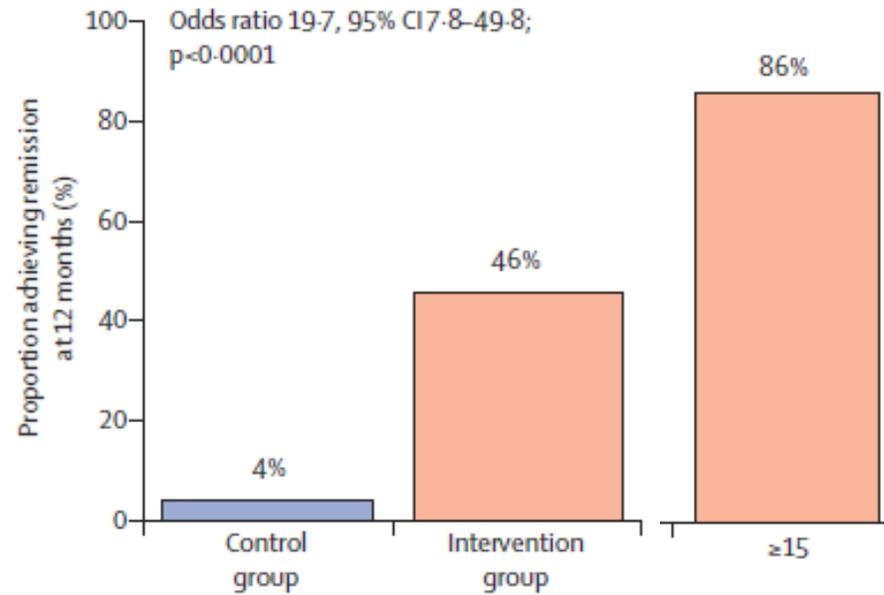
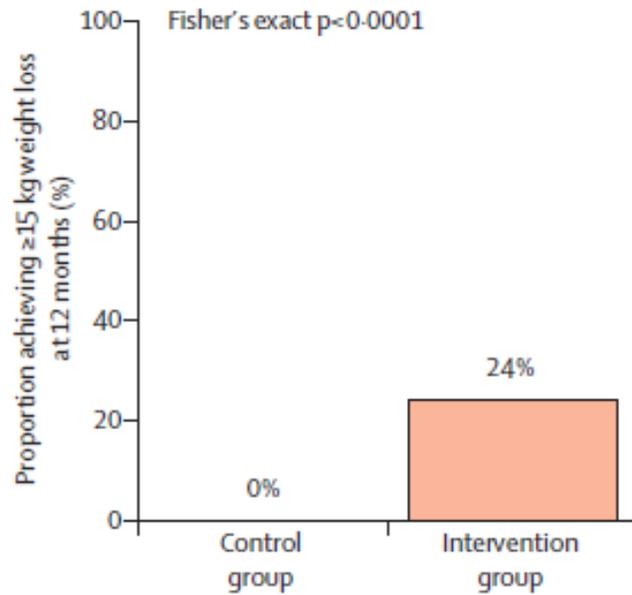
# Behavioral Therapy in Obesity/Diabetes



# Very Low Calorie Structured Diets



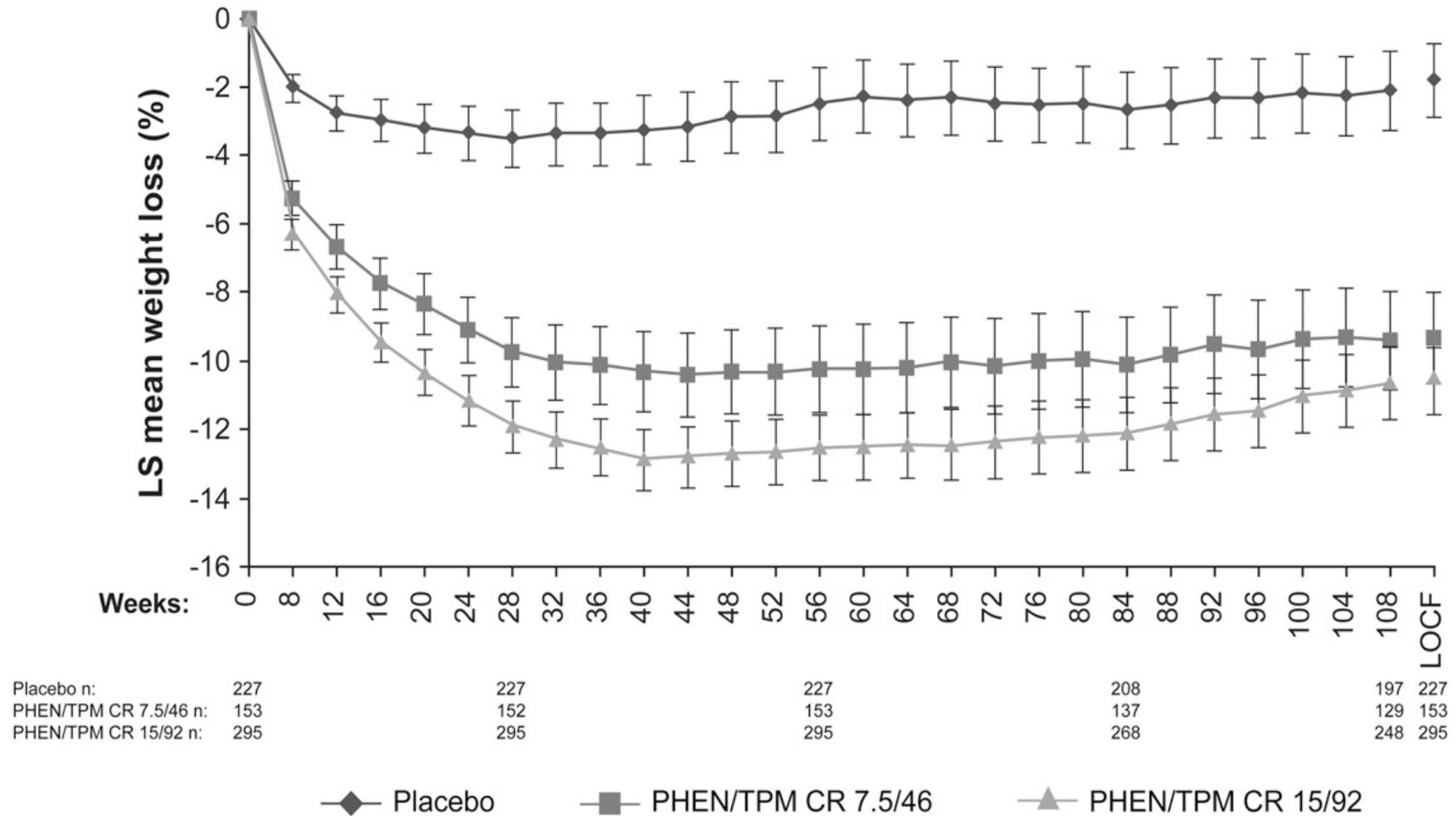
# Very Low Calorie Structured Diets in T2DM



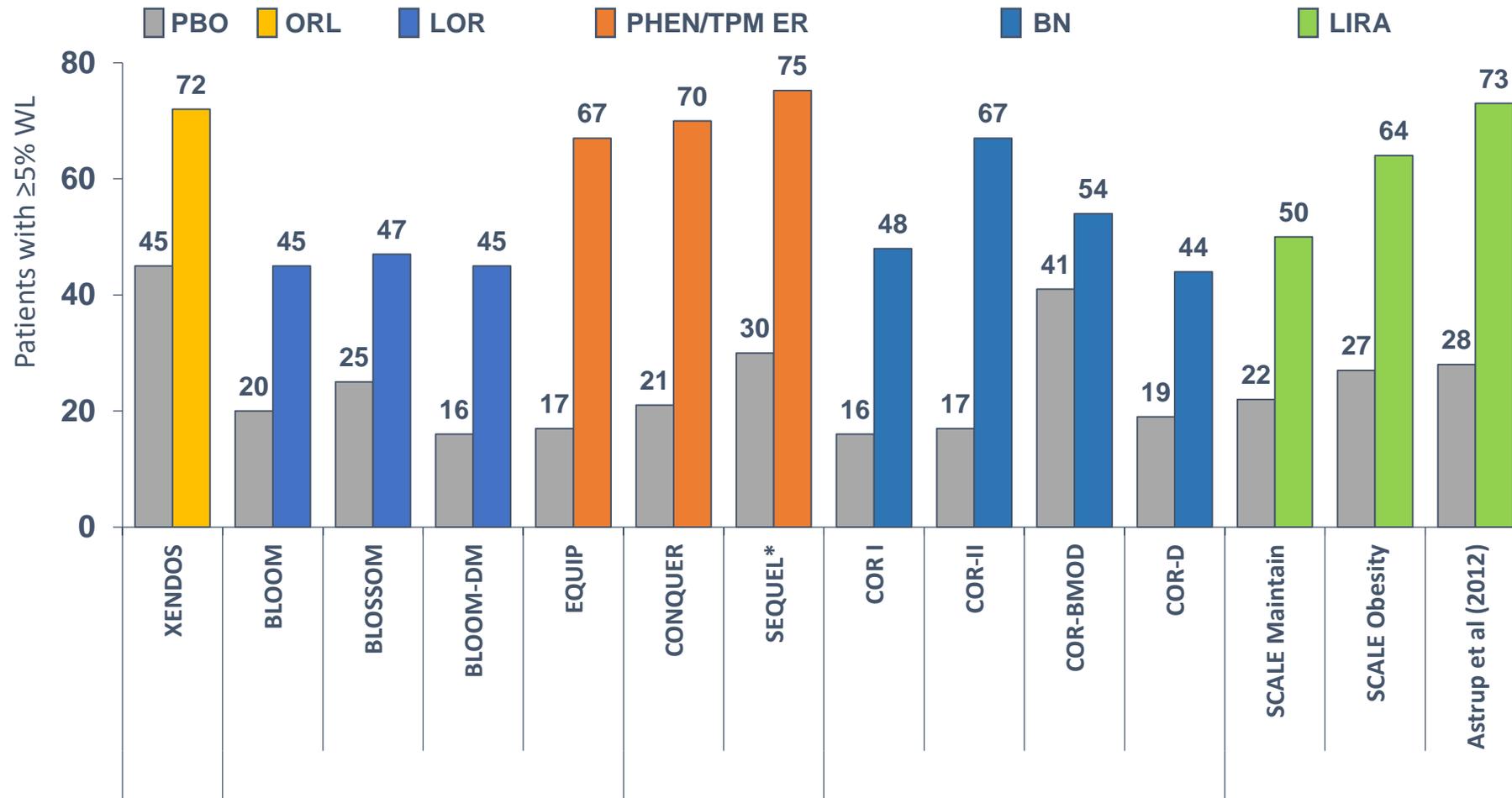
# Obesity Pharmacotherapy

- 5 FDA-approved short-term medications
  - Phentermine and noradrenergics
- 5 FDA-approved long-term medications
  - Orlistat
  - Phentermine/topiramate ER
  - Lorcaserin
  - Naltrexone/Bupropion SR
  - Liraglutide 3.0 mg

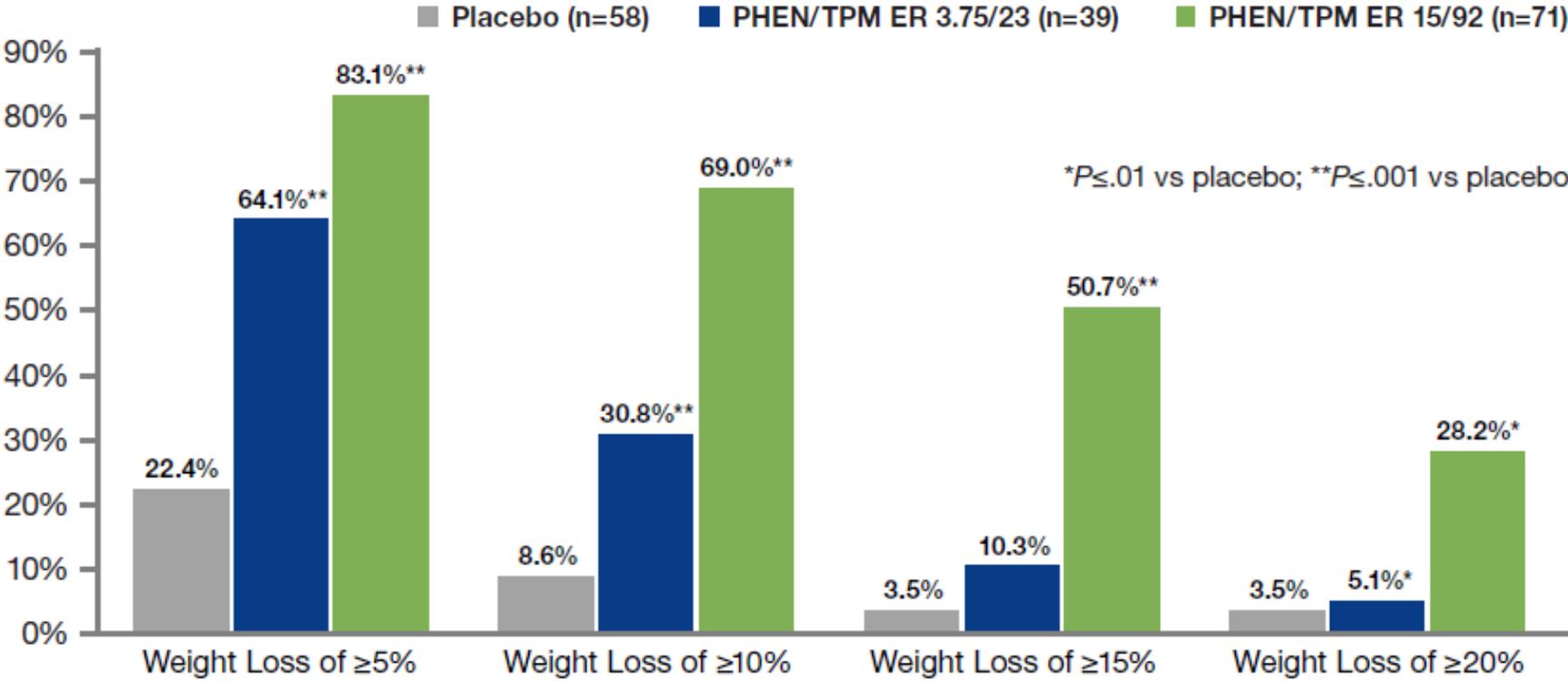
# Obesity Pharmacotherapy



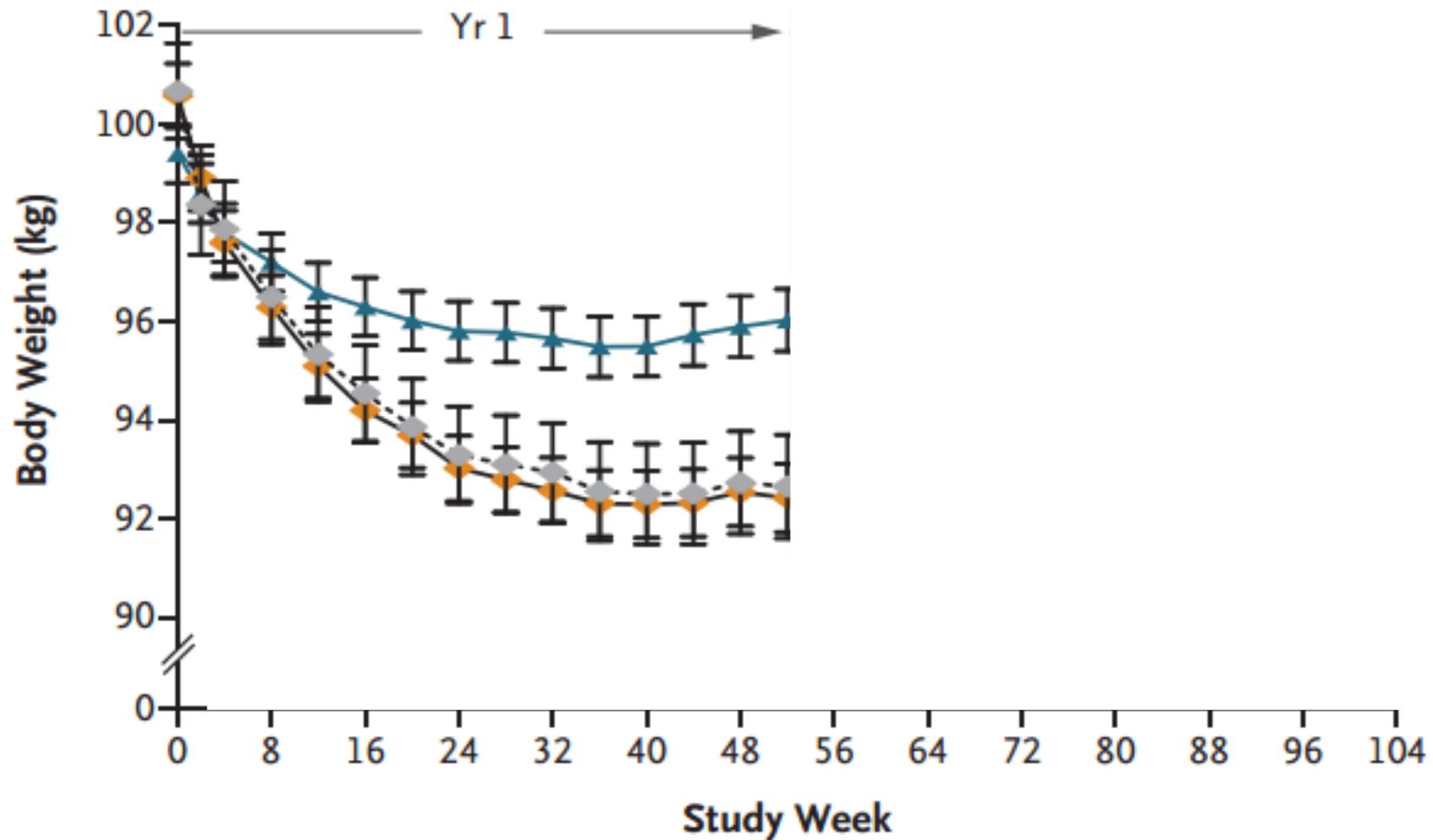
# Obesity Pharmacotherapy



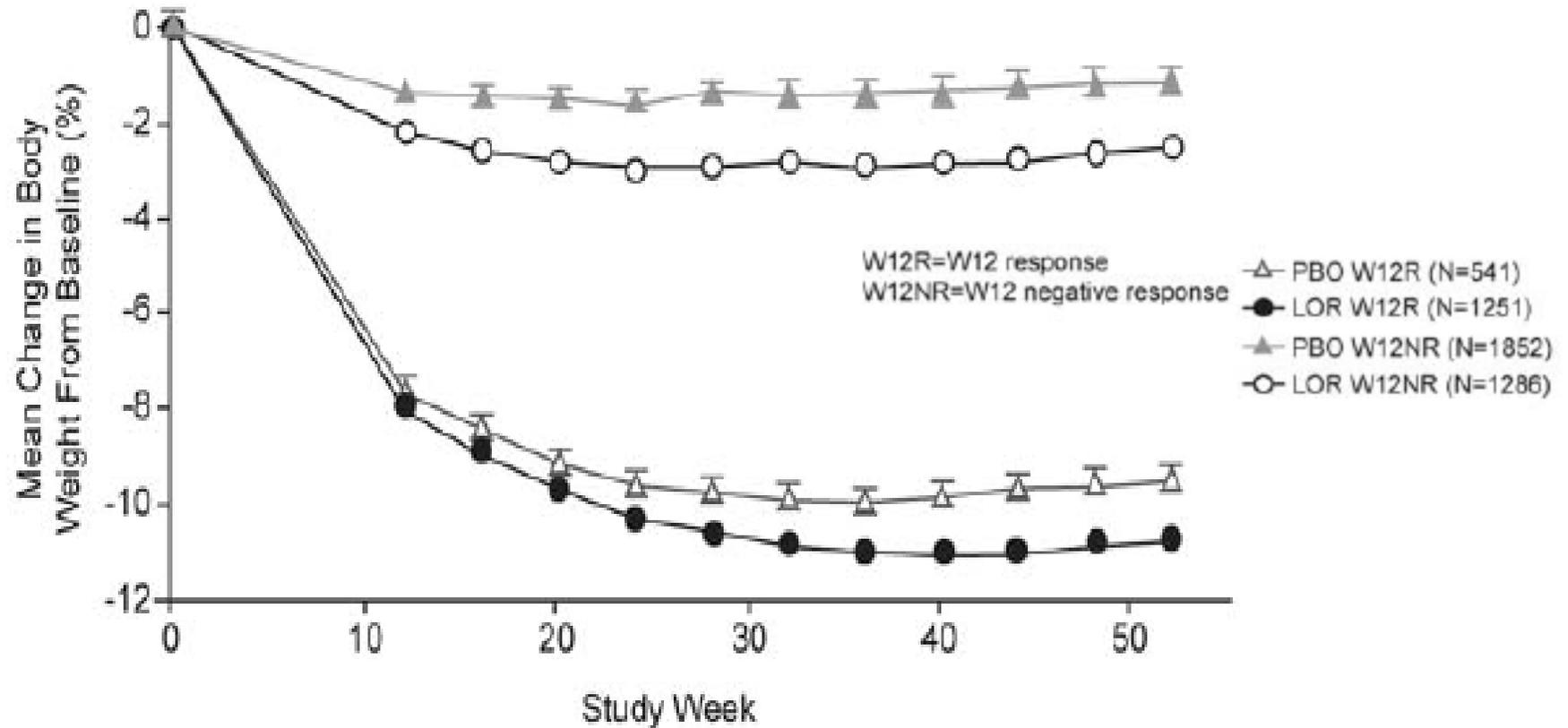
# Patients with Extreme Obesity (BMI >45)



# Long-Term Benefits (Generally) Require Continued Management



# Outcomes By Responder Status

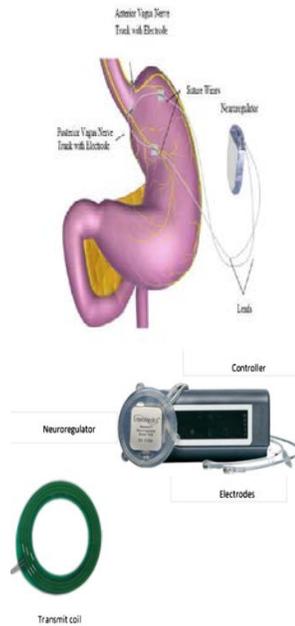


# Pharmacotherapy Improves RFs and Prevents Comorbid Conditions

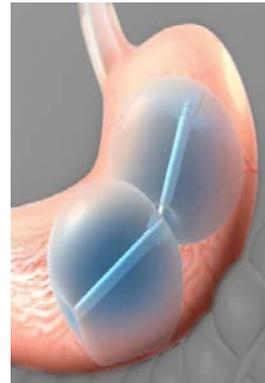
	Orlistat	Lorcaserin	Phentermine/ topiramate ER	Naltrexone/ bupropion SR	Liraglutide 3.0 mg
WC	↓	↓	↓	↓	↓
BP	↓	↓	↓	↑	↓
LDL	↓↓	↓	↓	↓	↓
HDL	↑	↑	↑	↑	↑
TG	↓↓	↓↓	↓↓	↓↓	↓↓
HR	↓	↓	-	↑	↑
A1C	↓	↓↓	↓	↓	↓↓↓
Diabetes	↓↓	↓↓	↓↓	↓	↓↓↓

# Medical Devices for Obesity Treatment

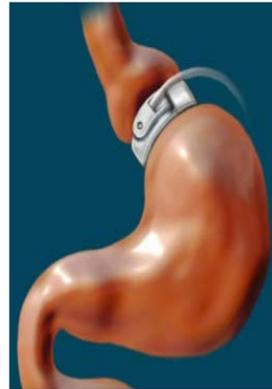
**VBLOC**



**Gastric  
Balloons**



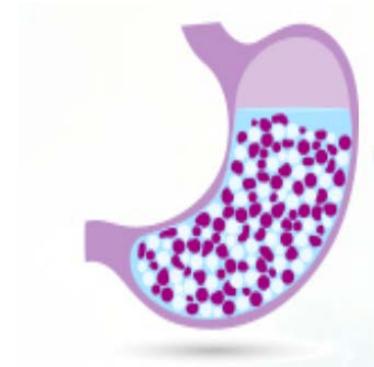
**Gastric  
Band**



**Aspire  
Assist**



**Plenity  
Hydrogel**

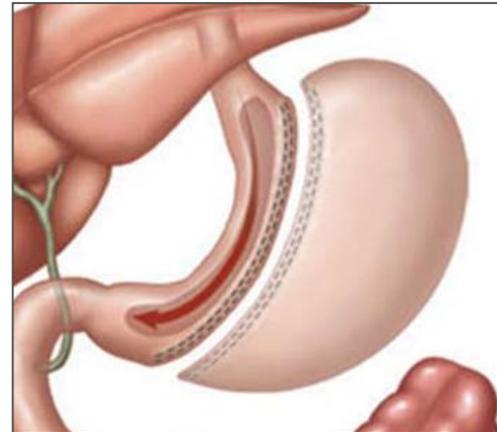


# Bariatric Surgery

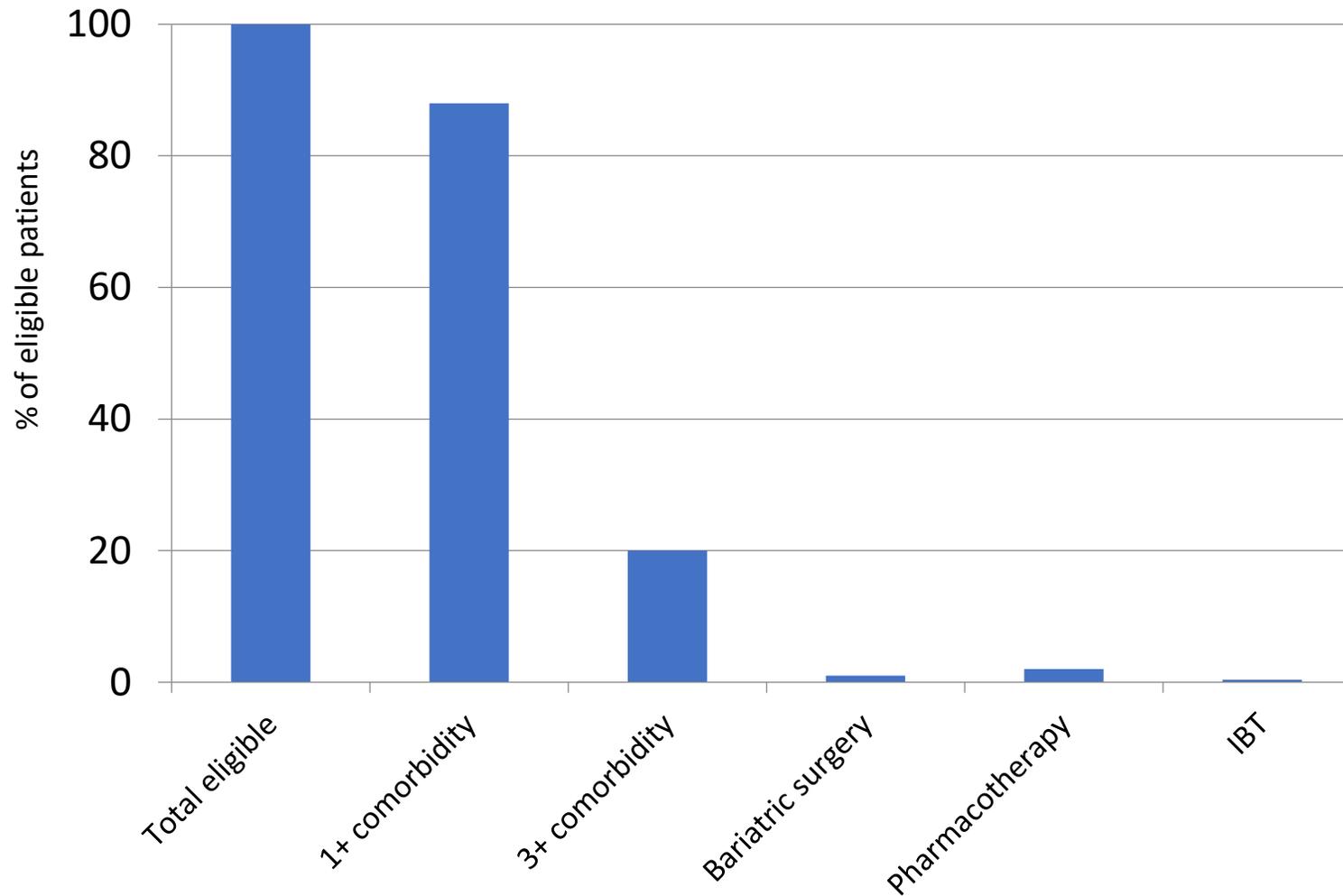
**Roux-en-Y  
Gastric Bypass**



**Sleeve  
Gastrectomy**



# Treatment Works...Only If Used



# *A Brief Overview of Obesity Treatments*

Scott Kahan, MD, MPH, FTOS

Director, National Center for Weight and Wellness

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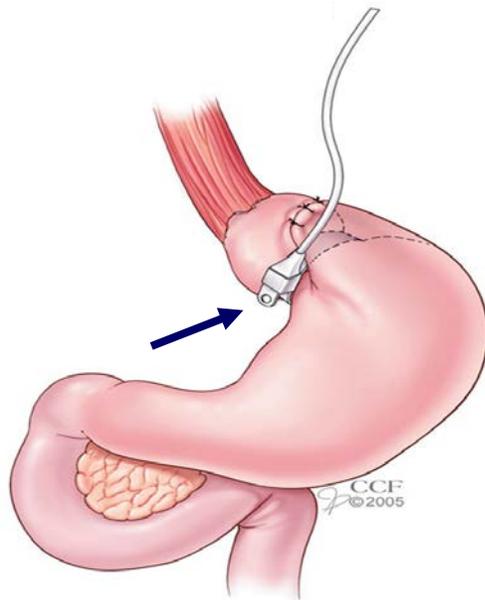
[kahan@nationalweight.org](mailto:kahan@nationalweight.org)

# Weight Loss Surgery

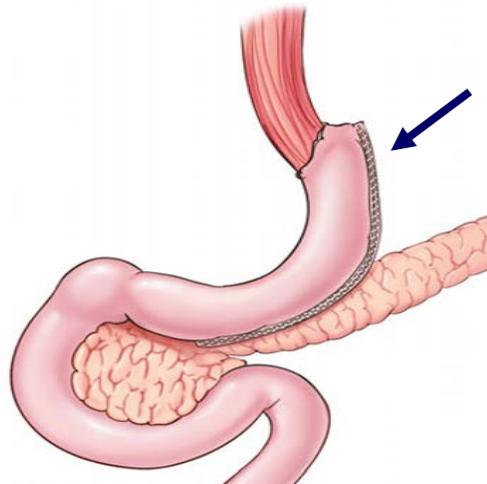
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## Gastric

Adjustable  
Gastric Banding



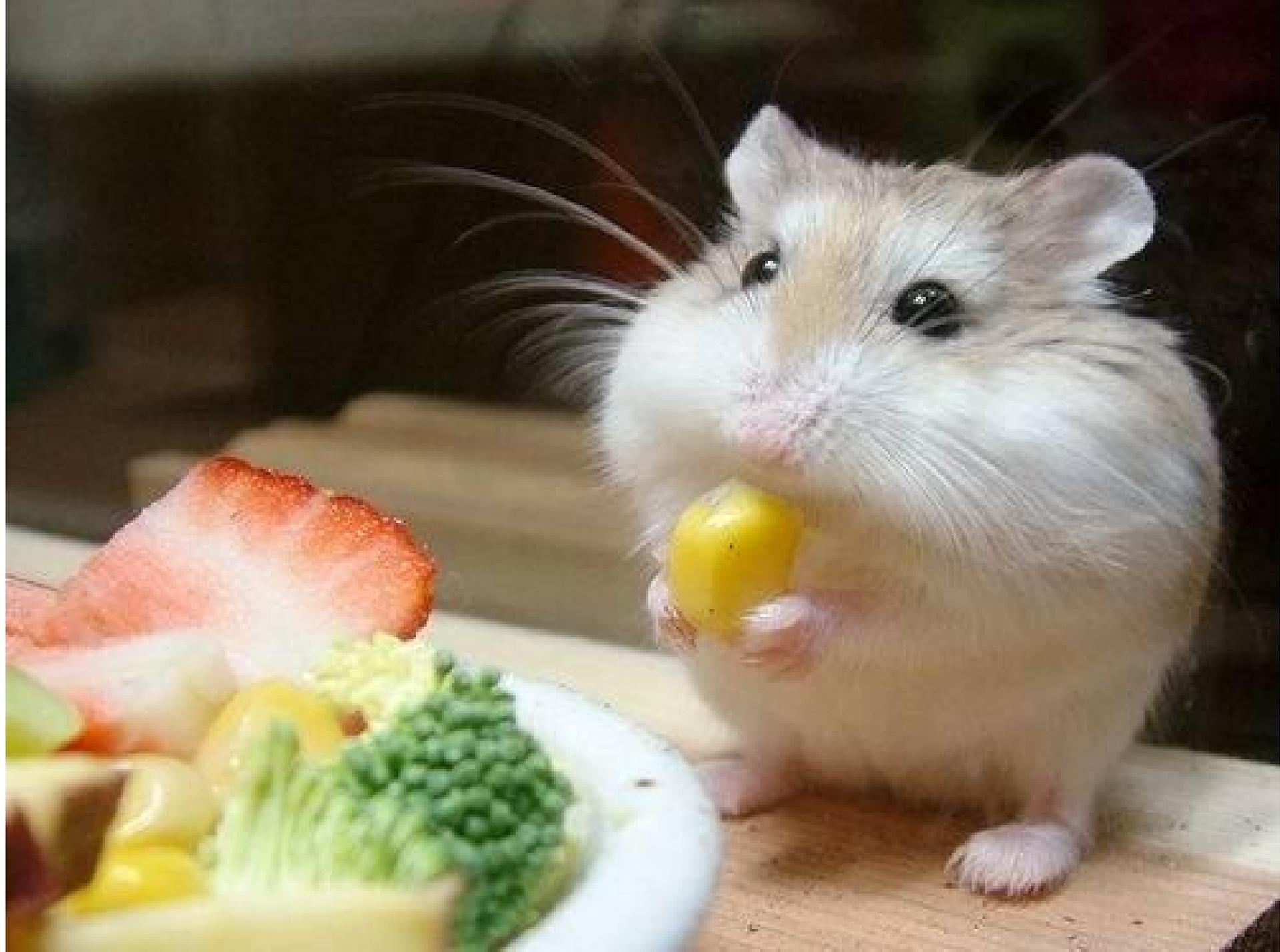
Vertical Sleeve  
Gastrectomy



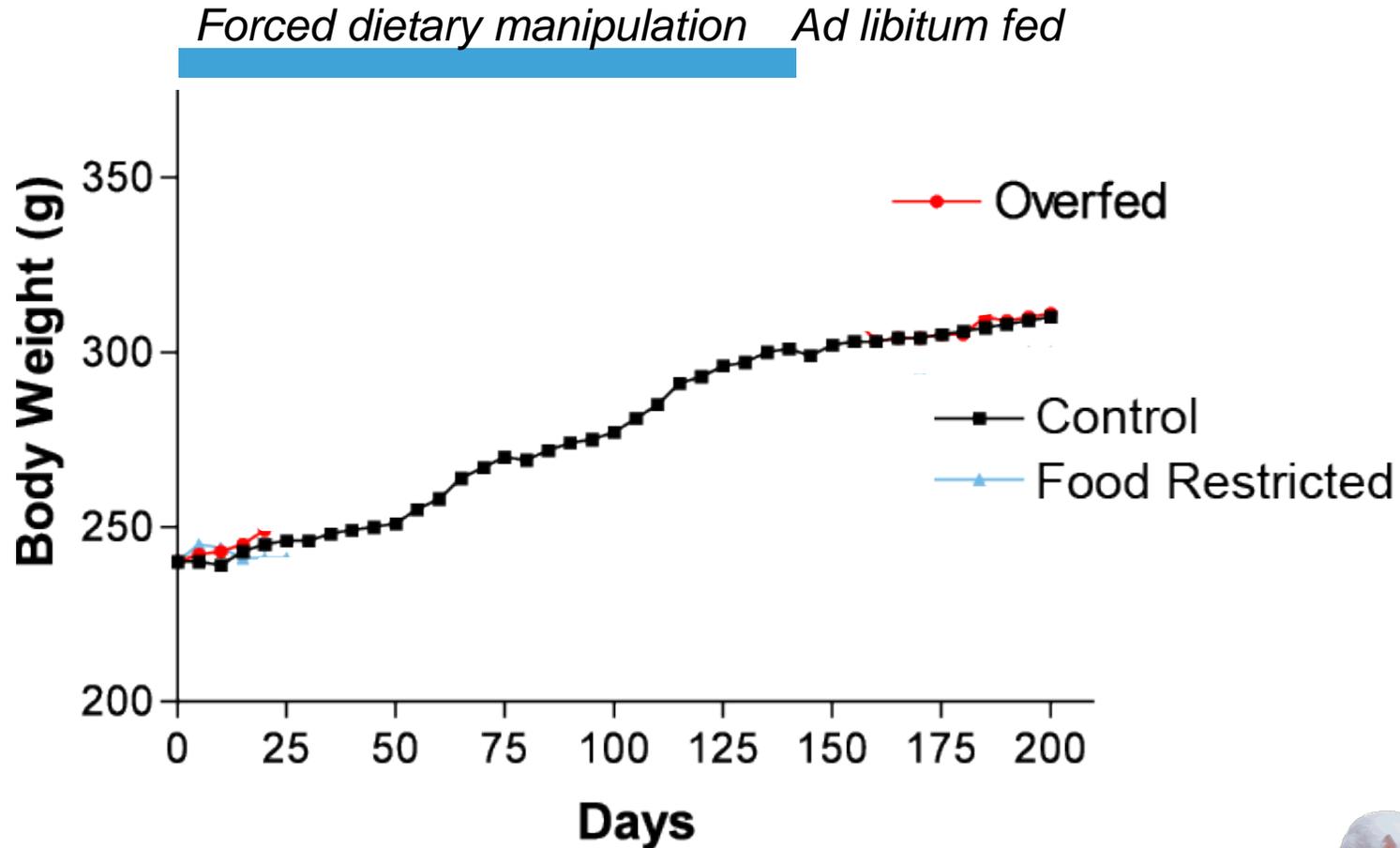
## Combination

Roux-en-Y Gastric  
Bypass





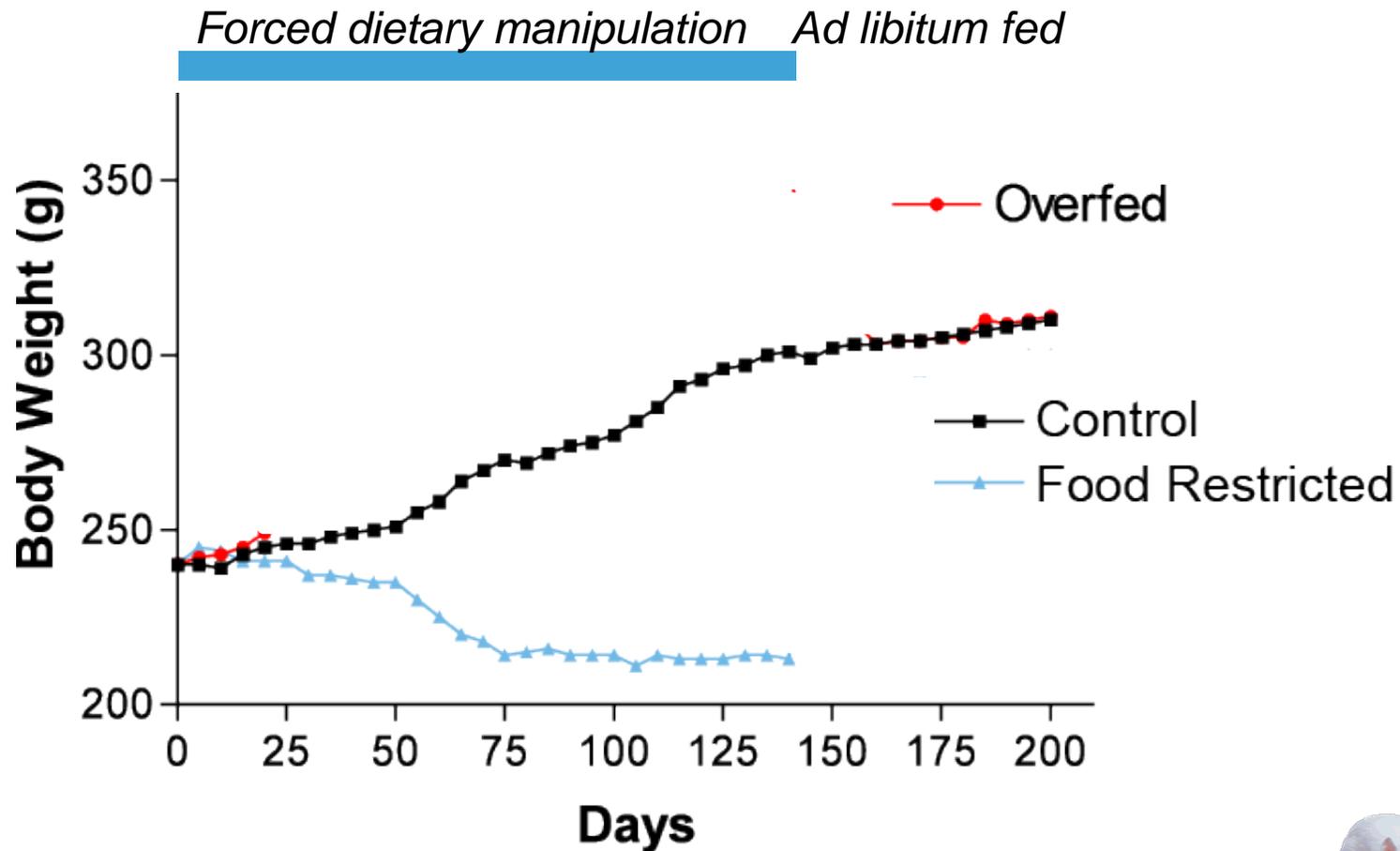
# Defense of a Body Fat “Set Point”



Adapted from S. Woods



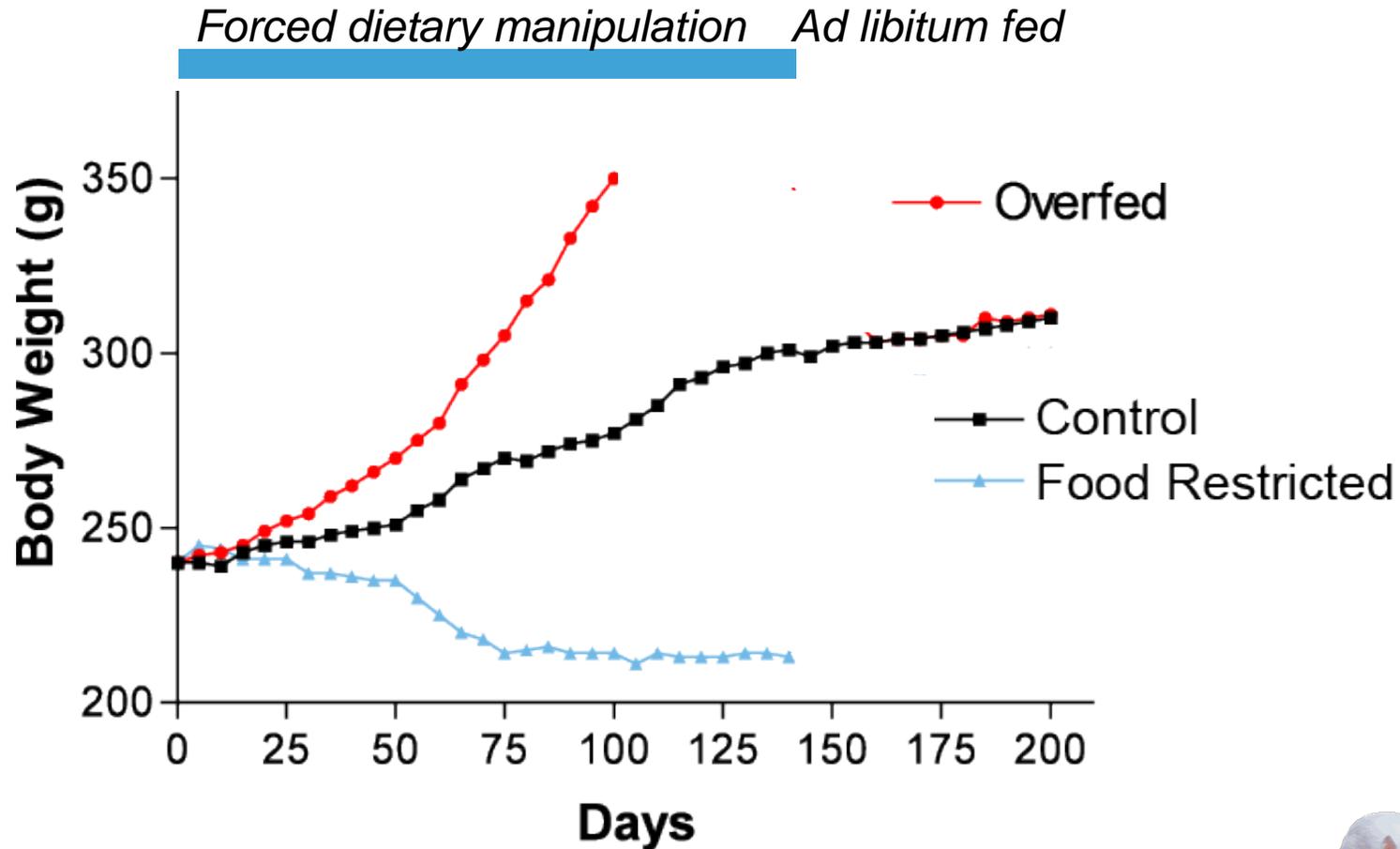
# Defense of a Body Fat “Set Point”



Adapted from S. Woods



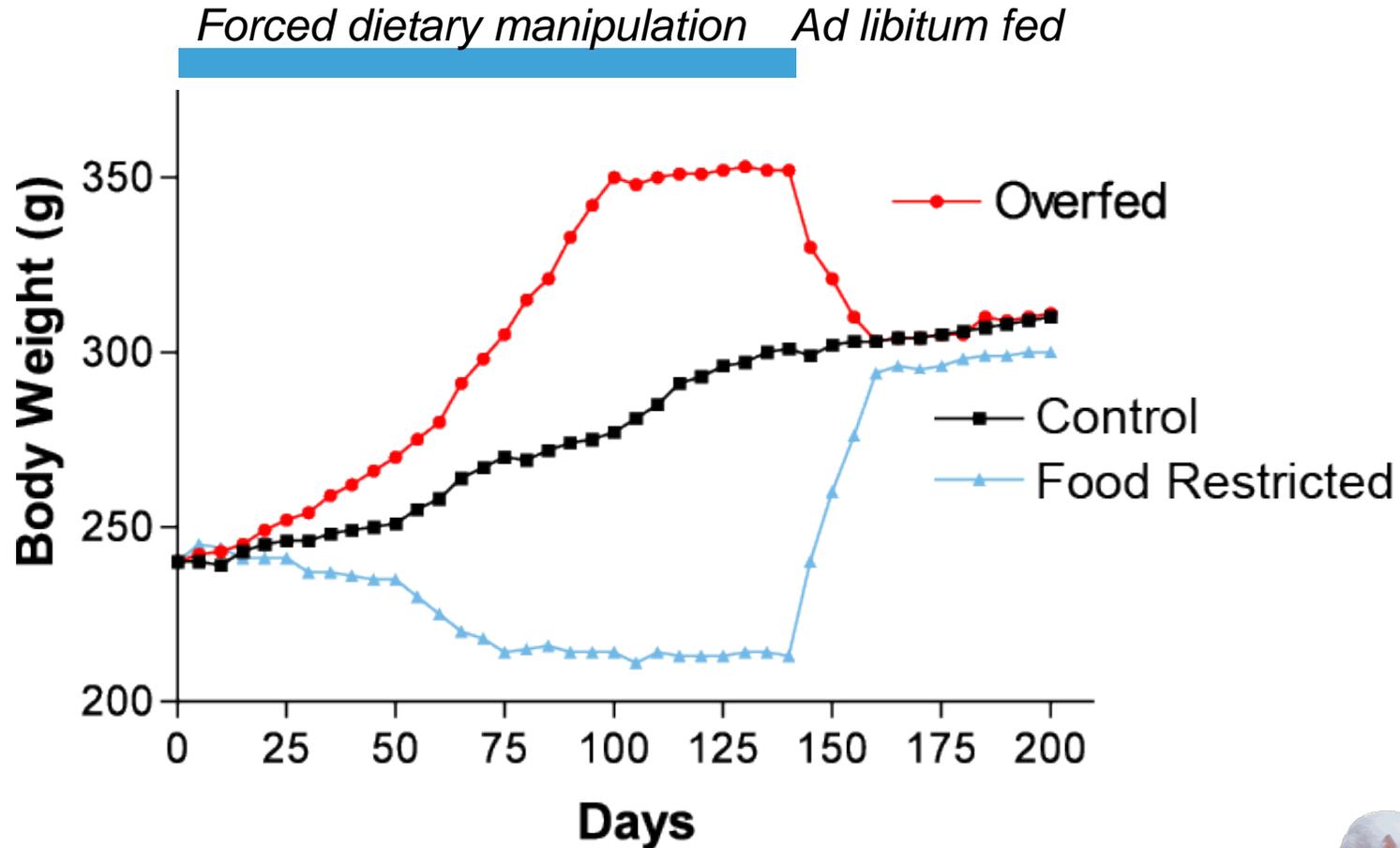
# Defense of a Body Fat “Set Point”



Adapted from S. Woods



# Defense of a Body Fat "Set Point"



Adapted from S. Woods



# Mechanisms of Bariatric Surgery

## Classical model

### Mechanical

Restricted food intake

Malabsorption

## Current model

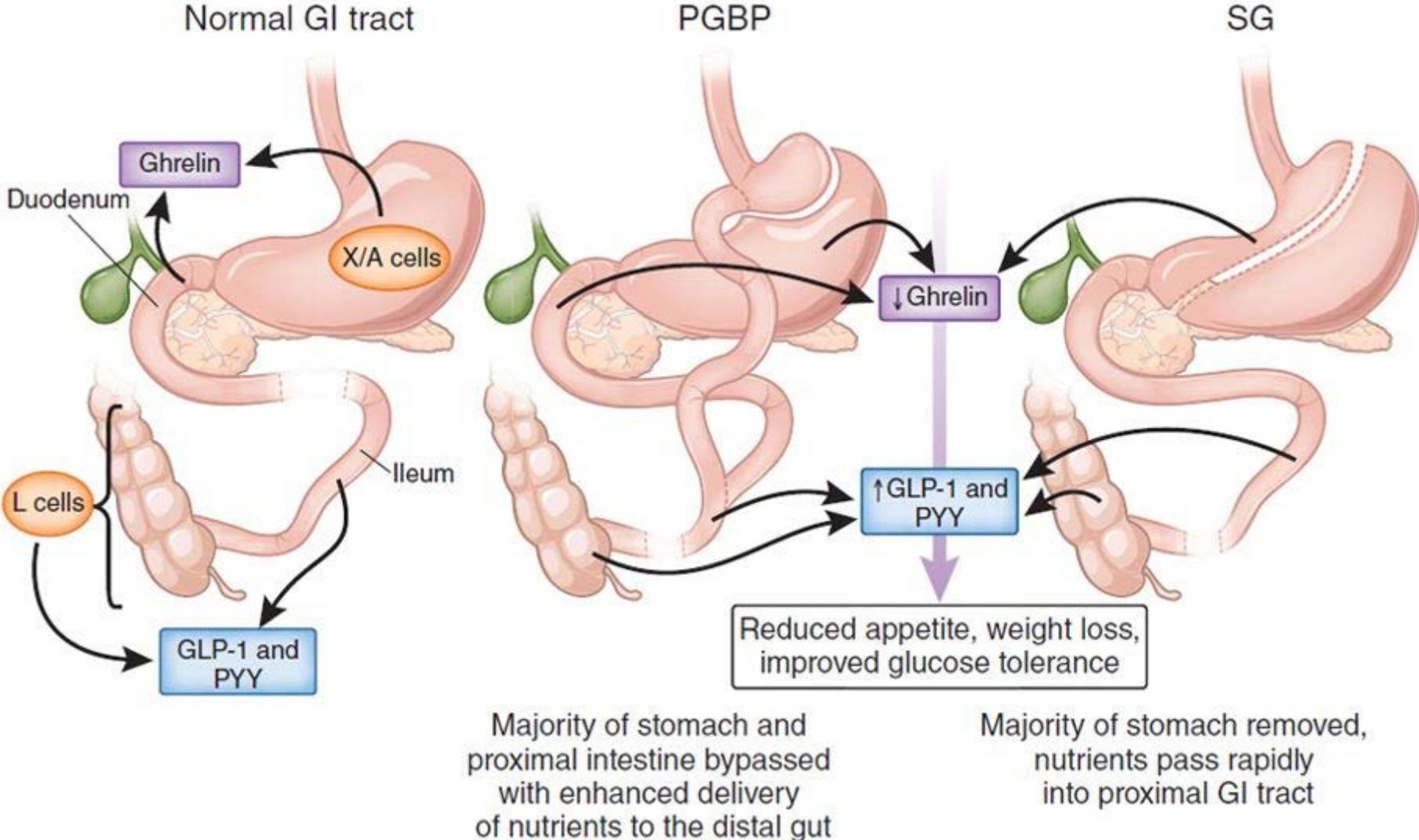
### Physiological

Altered GI signals to brain

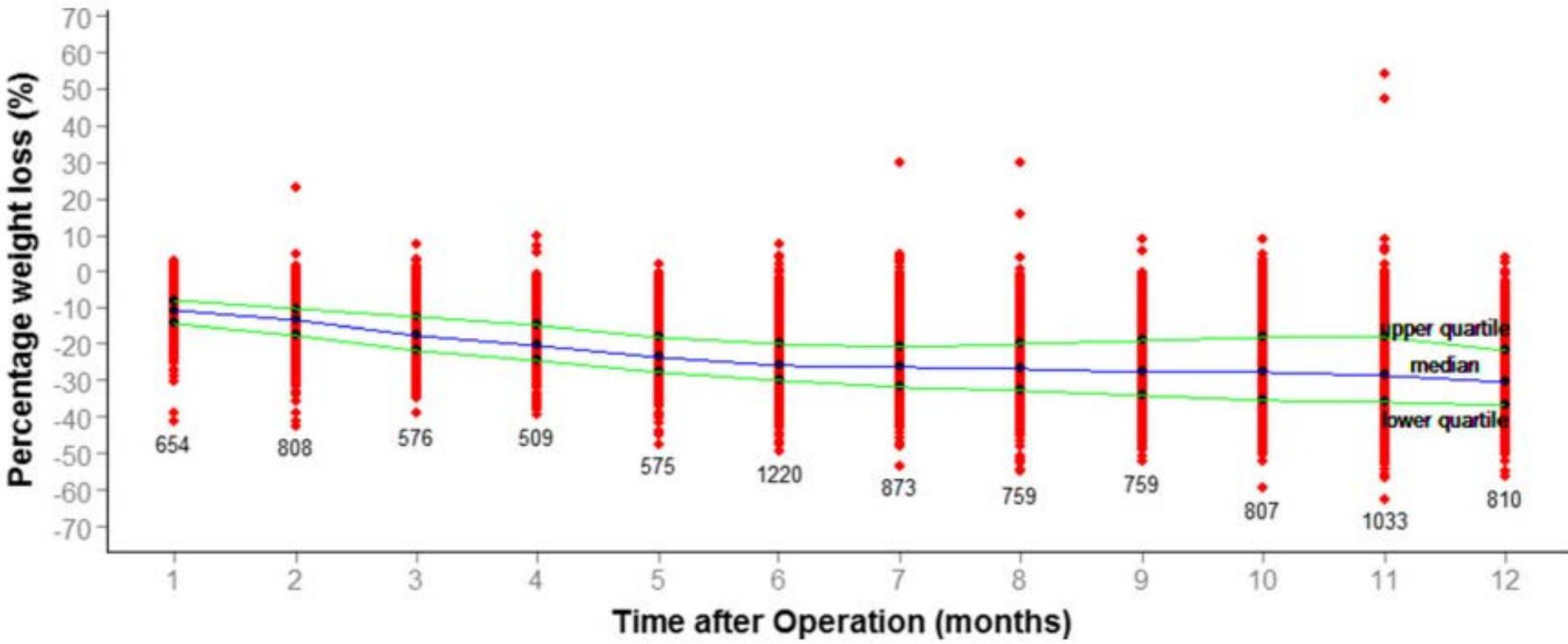
- Endocrine
- Neuronal

Altered GI signals to other tissues (pancreas, liver)

# Hormone Changes after Surgery



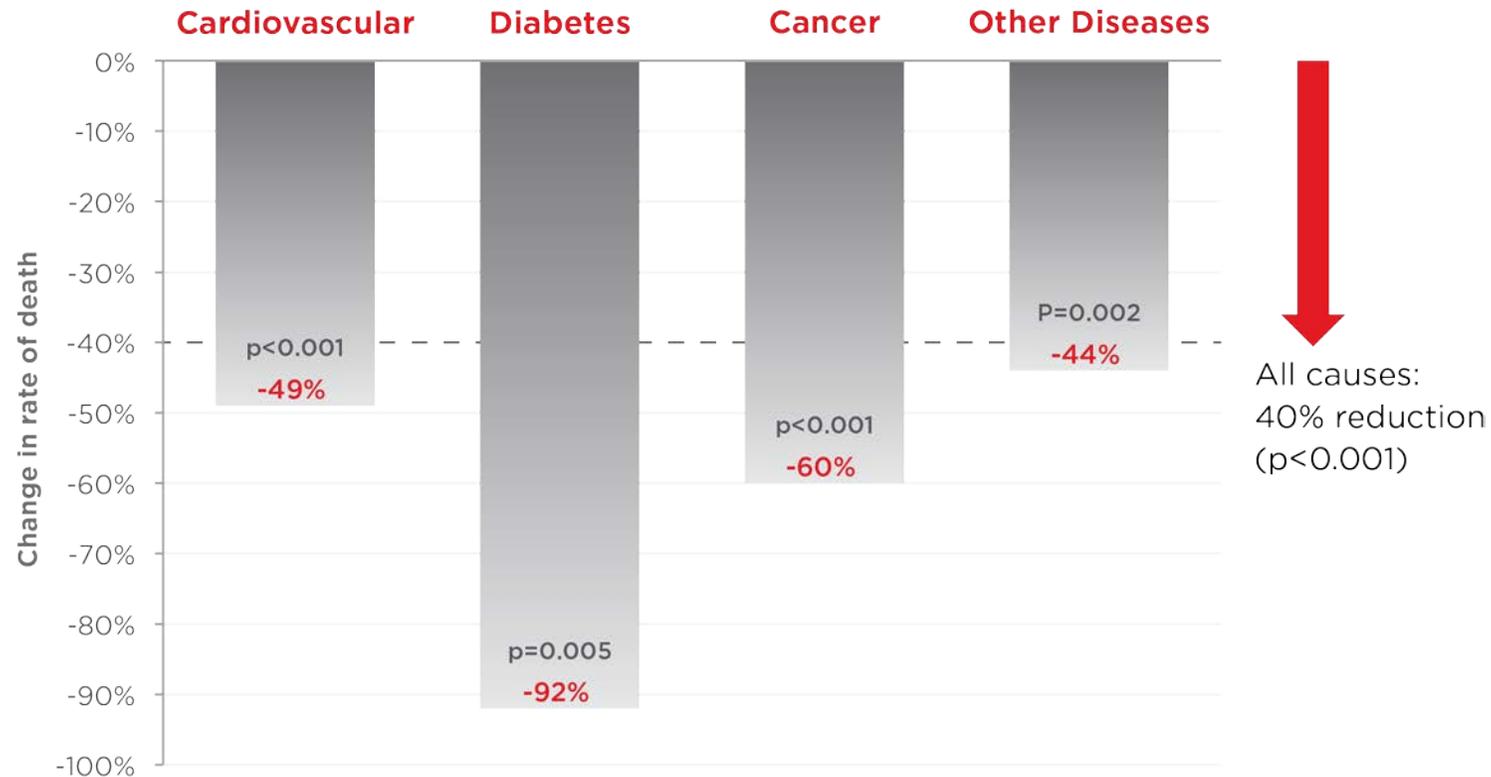
# Changes in BMI



Edison, E *Obes Surg*, 2016

# •Weight loss is not the only potential benefit...

- Long-term mortality reduction by comorbid disease type



Patients followed up on average for 7.1 years.

Note: in the Adams, et al. study, the rates of death not caused by disease, such as accidents and suicide, were 58% higher in the surgery group (P=0.004, 63 versus 36 deaths for 15,850 matched patients in the study).

Adams TD, Gress RE, Smith SC et al. Long-term mortality after gastric bypass surgery. N Engl J Med 2007; 357(8):753-61.

# Complications

**Table 2—Complications of metabolic surgery**

Complications	Frequency (%)
Sepsis from anastomotic leak	0.1–5.6
Hemorrhage	1–4
Cardiopulmonary events	<1
Thromboembolic disease	0.34
Death	0.1–0.3
Late complications for LAGB	
Band slippage	15
Leakage	2–5
Erosion	1–2
Late complications of bypass procedures	
Anastomotic strictures	1–5
Marginal ulcers	1–5
Bowel obstructions	0.5–2
Kidney stones	NK
Metabolic bone disease	NK
Alcohol use disorder	NK
Micronutrient and macronutrient deficiencies from RYGB	
2–3 years postoperative	
Iron deficiency	45–52
Vitamin B <sub>12</sub> deficiency	8–37
Calcium deficiency	10
Vitamin D deficiency	51
Fat-soluble vitamin deficiencies (A, D, E, and K) and protein calorie malnutrition from BPD+DS procedures	1–5

NK, not known.

Schauer, P, *Diabetes Care*, 2016

# What *is* Metabolics after all?

- The idea that biologic changes occur through distant signals that are released following traditional weight-loss surgery
- These distant signals turn on, and off, complex cell-to-cell and intracellular events that change the cells' behavior
- These cellular changes influence the organs they make up to behave differently, and alter organ-to-organ communications
- *In toto*, these changes result in health improvements that proceed, and are unrelated to, the weight loss ultimately experienced by the patient.

# Type II Diabetes Mellitus



# The *complete* list of Randomized & Controlled trials for impact on Diabetes

**Table 1—Metabolic surgery RCTs for T2D (n = 794)**

Study	BMI (kg/m <sup>2</sup> ), % of patients	Design	No. of patients randomized	Follow-up (months)	Remission criteria*	Outcome (remission or change in HbA <sub>1c</sub> )
Dixon (8)	<35, 22%	LAGB vs. control	60	24	HbA <sub>1c</sub> <6.2%	73% vs. 13%, <i>P</i> < 0.001
Schauer (30,31)	<35, 36%	RYGB vs. SG vs. control	150	36	HbA <sub>1c</sub> ≤6.0%	35% vs. 20% vs. 0, <i>P</i> = 0.002
Mingrone (32,33)	>35, 100%	RYGB vs. BPD vs. control	60	60	HbA <sub>1c</sub> ≤6.5%	42% vs. 68% vs. 0, <i>P</i> = 0.003
Ikramuddin (34,35)	<35, 59%	RYGB vs. control	120	24	HbA <sub>1c</sub> <6%	44% vs. 9%, <i>P</i> < 0.001
Liang (36)	<35, 100%	RYGB vs. control	101	12	HbA <sub>1c</sub> <6.5%**	90% vs. 0 vs. 0, <i>P</i> < 0.0001
Halperin (37)	<35, 34%	RYGB vs. control	38	12	HbA <sub>1c</sub> <6.5%	58% vs. 16%, <i>P</i> = 0.03
Courcoulas (38,39)	<35, 43%	RYGB vs. LAGB vs. control	69	36	HbA <sub>1c</sub> <6.5%	40% vs. 29% vs. 0, <i>P</i> = 0.004
Wentworth (40)	≤30, 100%	LAGB vs. control	51	24	Fasting blood glucose <7.0 mmol/L	52% vs. 8%, <i>P</i> = 0.001
Parikh (41)	<35, 100%	Bariatric surgery (RYGB, LAGB, SG) vs. control	57	6	HbA <sub>1c</sub> <6.5%	65% vs. 0, <i>P</i> = 0.0001
Ding (42)	<35, 34%	LAGB vs. control	45	12	HbA <sub>1c</sub> <6.5%***	33% vs. 23%, <i>P</i> = 0.46
Cummings (43)	<35, 25%	RYGB vs. control	43	12	HbA <sub>1c</sub> <6.0%	60% vs. 5.9%, <i>P</i> = 0.002

\*Remission was a primary or secondary end point. Reaching HbA<sub>1c</sub> value without diabetes medication, unless otherwise specified. \*\*Remission not precisely defined, HbA<sub>1c</sub> <6.5% by extrapolation. \*\*\*On or off diabetes medications.

Schauer, P, *Diabetes Care*, 2016



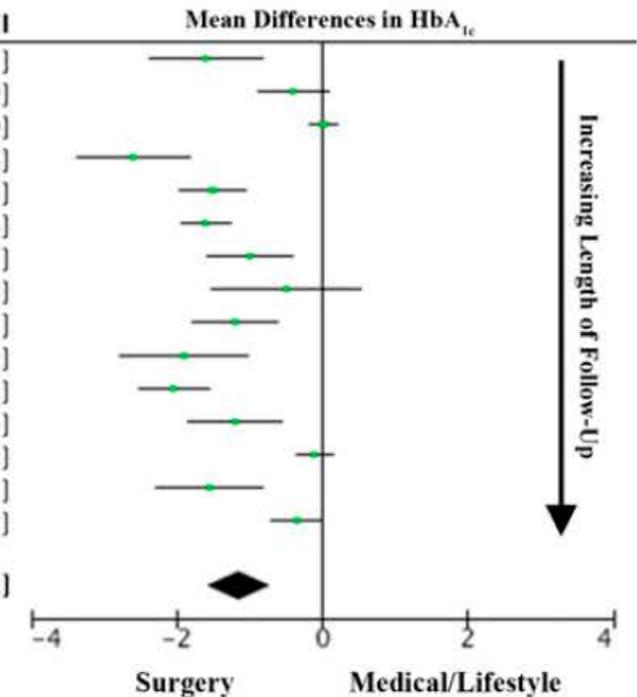
# Durability of Affect on Diabetes

Study (Operation) [Follow-up; HbA <sub>1c</sub> end point]	Surgery			Medical/ Lifestyle			Weight	IV, Random, 95% CI
	Mean	SD	N	Mean	SD	N		
Parikh 2014 (RYGB/LAGB/SG) [6 mo; ≤6.5% off meds] (41)	6.2	0.9	20	7.8	1.7	24	6.1%	-1.60 [-2.39, -0.81]
Courcoulas 2014 (RYGB/LAGB) [12 mo; ≤6.5% off meds](38)	6.6	0.8	41	7	0.9	17	6.9%	-0.40 [-0.89, 0.09]
Ding 2015 (LAGB) [12 mo; ≤6.5%] (42)	7.17	0.3	18	7.15	0.28	22	7.5%	0.02 [-0.16, 0.20]
Halperin 2014 (RYGB) [12 mo; ≤6.5% off meds] (37)	6.2	1.4	19	8.8	1	19	6.1%	-2.60 [-3.37, -1.83]
Ikramuddin 2013 (RYGB) [12 mo; ≤7.0%] (34)	6.3	0.9	57	7.8	1.5	57	7.0%	-1.50 [-1.95, -1.05]
Liang 2013 (RYGB) [12 mo; ≤7.0% off meds] (36)	6	0.3	31	7.6	1.4	70	7.3%	-1.60 [-1.94, -1.26]
Schauer 2012 (RYGB/SG) [12 mo; ≤6.0%] (30)	6.5	0.95	99	7.5	1.8	41	6.7%	-1.00 [-1.58, -0.42]
Cummings 2016 (RYGB) [12 mo; ≤6.5% off meds] (43)	6.4	1.6	15	6.9	1.3	17	5.3%	-0.50 [-1.52, 0.52]
Dixon 2008 (LAGB) [24 mo; ≤6.2% off meds] (8)	6	0.8	30	7.2	1.4	30	6.7%	-1.20 [-1.78, -0.62]
Ikramuddin 2015 (RYGB) [24 mo; ≤7.0%] (35)	6.5	1.6	56	8.4	2.9	54	5.8%	-1.90 [-2.78, -1.02]
Mingrone 2012 (RYGB/BPD) [24 mo; ≤6.5% off meds] (32)	5.65	0.95	20	7.69	0.57	20	7.0%	-2.04 [-2.53, -1.55]
Wentworth 2014 (LAGB) [24 mo; ≤7.0%] (40)	6.1	0.8	23	7.3	1.4	25	6.5%	-1.20 [-1.84, -0.56]
Courcoulas 2015 (RYGB/LAGB) [36 mo; ≤6.5% off meds] (39)	7.1	0.4	38	7.2	0.4	14	7.5%	-0.10 [-0.35, 0.15]
Schauer 2014 (RYGB/SG) [36 mo; ≤6.0%] (31)	6.85	1.3	97	8.4	2.2	40	6.3%	-1.55 [-2.28, -0.82]
Mingrone 2015 (RYGB/BPD) [60 mo; ≤6.5% off meds] (33)	6.55	0.5	38	6.9	0.6	15	7.3%	-0.35 [-0.69, -0.01]

Random-Effect Model  
 Heterogeneity: Tau<sup>2</sup> = 0.63; Chi<sup>2</sup> = 200.88, df = 14 (P < 0.00001); I<sup>2</sup> = 93%  
 Test for overall effect: Z = 5.20 (P < 0.00001)

602

465 100.0% -1.14 [-1.57, -0.71]



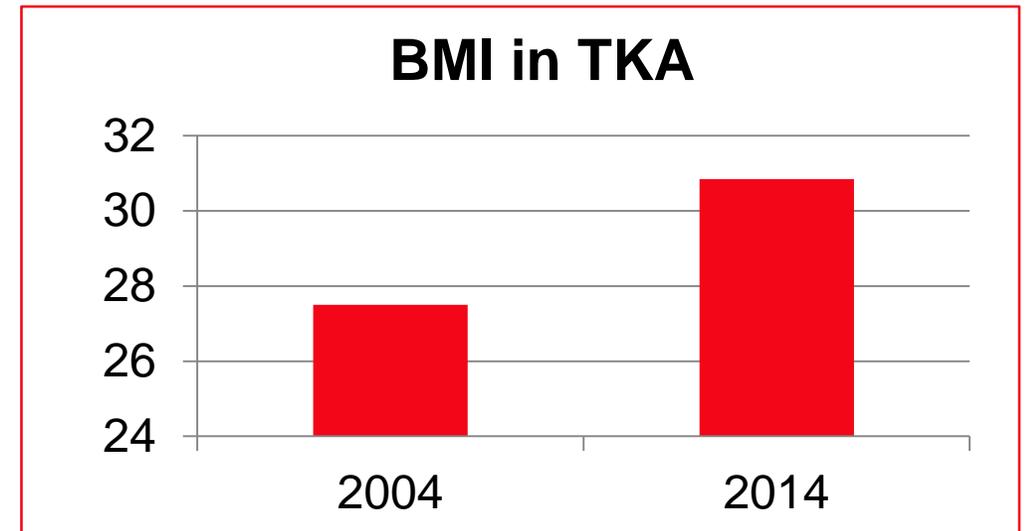
Schauer, P, *Diabetes Care*, 2016

# Bone and Joint Disease



# Obesity and Joint Replacement

- OA responsible for 91% of Hips (THA) and 98% of Knee (TKA)
- 90% of patients undergoing TKA are overweight or obese
- A rise of 5 BMI results in the doubling of risk for TKA
- OA develops as cartilage breaks down faster than replaced
  - Mechanical
  - Humeral
  - Metabolic
  - Genetic



Kulkarni, K, M, *Maturitas*, 2016

# Emerging Evidence Suggests Metabolic Role

- Non-Alcoholic Steato-hepatitis (NASH)
- Female Cancers
- Sleep Apnea
- Inflammatory Diseases

# BENEFIT DESIGN CONSIDERATIONS

- Know Your Data
- Review Your Benefits
- Review Your Provider Network and Payment Mechanisms

Content is based on a panel discussion at the National Alliance's November 2018 Fall Forum. Participants included: Dr. Janine Kyrillos, director of the Comprehensive Weight Management Program at Thomas Jefferson University; Dr. Samuel Wasser, bariatric surgeon at Virtua; and, John Dawson, Chief Actuary at Healthstat.

# Data

- Obesity rates: overall, demographic subgroups, geographic location
- Bariatric surgery rates (if benefit already offered)
  - Overall and by procedure type
  - By provider
  - As proportion of candidate population
  - Waiting times from referral to surgery
- Surgical outcomes
  - Short term
  - Longer term

# Benefits

- Implement a bariatric surgery benefit (if not already available)
- Review current benefit:
  - Eligibility criteria
  - Waiting periods
  - Prior authorization procedures
  - Procedures covered and clinical guidelines
  - Pre- and post-surgical lifestyle modification and support
  - Out-of-pocket payments and financial barriers
- Ensure appropriate placement of bariatric surgery in the overall obesity strategy

# Provider Network Considerations

- Review the current network. Consider narrowing the network.
  - Accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)
  - Health plan criteria for selecting and monitoring centers of excellence
    - Volume
    - Quality metrics including infection and other complication rates, repeat surgery rates, short and long-term outcomes
- Review payment mechanisms with health plans