Bariatric Surgery in Youth

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Disclosures:

- No relevant disclosures
- I will briefly discuss endoscopic bariatric procedures not FDA approved for youth

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Learning objectives

- **Indications** for bariatric surgery in adolescents
- **Types of bariatric surgeries** currently appropriate for adolescents
- **Short and long-term benefits and risks** of bariatric surgery in adolescents

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In October 2019, American Academy of Pediatrics issues policy statement on pediatric bariatric surgery:

PEDIATRICS®

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From the American Academy of Pediatrics Policy Statement

Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practices

Sarah C. Armstrong, Christopher F. Bolling, Marc P. Michalsky, Kirk W. Reichard and SECTION ON OBESITY, SECTION ON SURGERY

Pediatrics October 2019, e20193223; DOI: https://doi.org/10.1542/peds.2019-3223

Pediatrics 2019 Oct 27 Epub ahead of print

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Current BMI and comorbidity thresholds for youth

Severe obesity	Severe Comorbidity
Class 2: ≥ 120% of the 95th percentile for age/sex or BMI ≥ 35 kg/m^2 (whichever is lower)	•OSA (AHI ≥ 5) •Type 2 diabetes, •NASH, •orthopedic disease (Blount's, SCFE), •Idiopathic intracranial hypertension •Hypertension
Class 3: ≥ 140% of the 95th percentile for age/sex or BMI ≥ 40 kg/m^2 (whichever is lower)	Not required,but commonly present

Pratt JSA. SOARD 2018;14(7):882 - ASMBS Guidelines 2018

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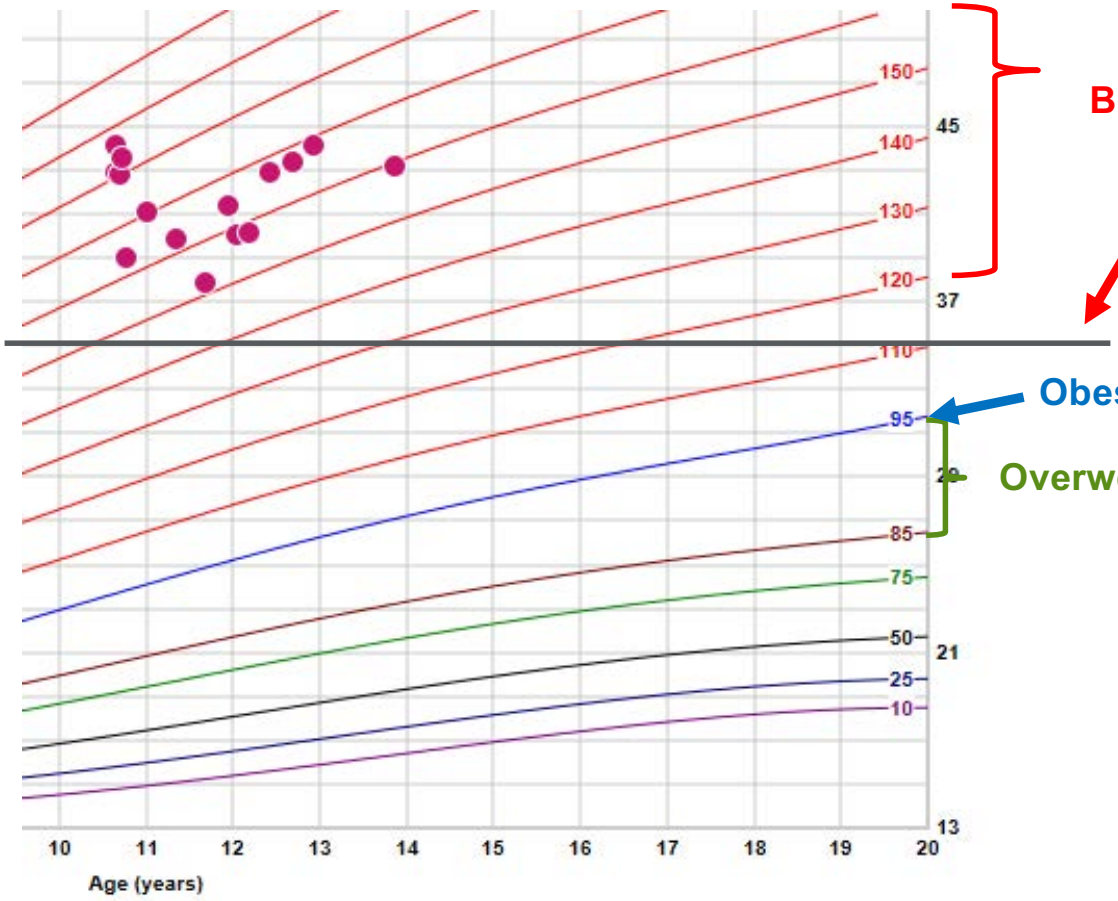
Definitions: Pediatric Obesity



Severe Obesity
BMI ≥ 120% of 95th %ile
or
BMI ≥ 35 kg/m^2,
whichever lower

Obesity BMI ≥95th %ile

Overweight BMI 85-95th%ile

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But adolescent bariatric surgery remains controversial among practitioners and public alike…

Selected public comments to NYT article by Perri Klass, 11/11/2019

THE CHECKUP

Weight-Loss Surgery for Teens Who Can't Lose Weight Any Other Way

The American Academy of Pediatrics has a new policy statement on bariatric surgery for adolescents.

"I am 57 and had gastric bypass surgery 9 years ago and **it was the best thing I have ever done for myself**. For the first time in my life I was able to keep the weight off and maintain a 120 lb weight loss. **It is no quick fix as you must change your eating habits and start exercising**. **I wish I could have had the surgery at 16…it would have changed my whole life.** No teen should have to live with being obese if there is a surgery available that can help them to not only lose the weight but keep it off as well".

"**I am interested in longer term outcomes**. How do these young people look and feel five and ten and twenty years down the road? The adults I know who have had the procedure do not do well… **I have no moral objections to these procedures. I am just not sure they work long-term**."

"This seems entirely wrong. Not addressing root cause. More of the same we get from the medical/pharma system."

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What is the rationale for bariatric surgery in youth?

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Severe Pediatric Obesity Increasing

Severe obesity in adolescents 12-19 yrs NHANES 2013-2014		
	Girls	Boys
Class II obesity	**10%**	**9%**
Class III obesity	**5%**	**4%**

Affects approximately 4.5 million US adolescents!

Skinner AC. Obesity 2016; 24:116

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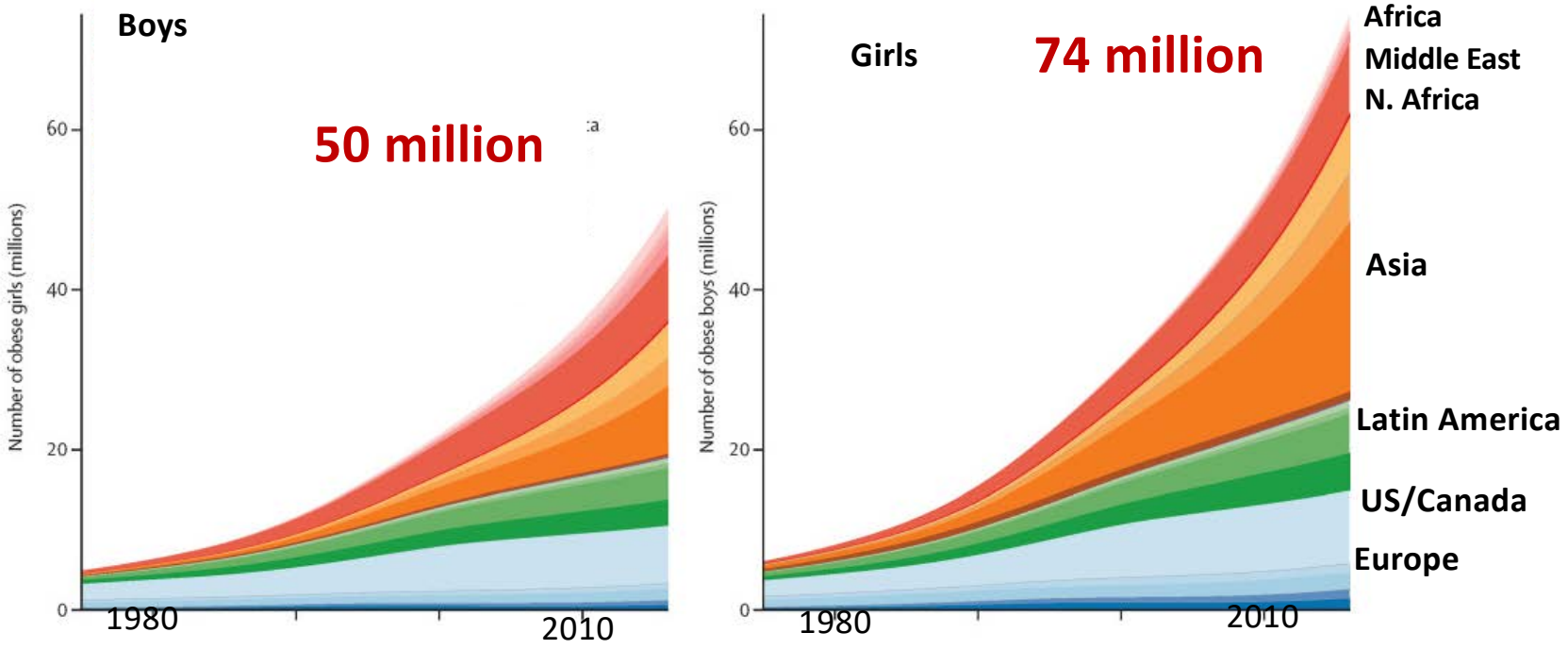
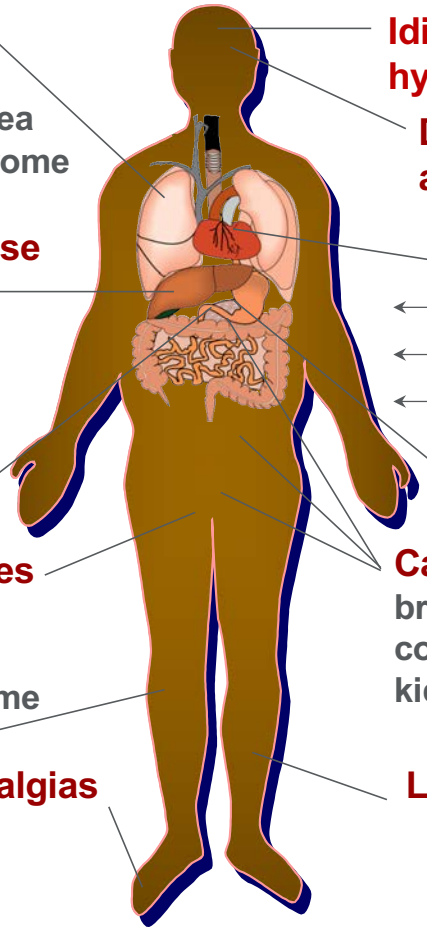
Increase in severe pediatric obesity: 1975-2016



Lancet 2017;390(10113):2627-2642

Medical Complications of Obesity



Pulmonary disease
abnormal function
obstructive sleep apnea
hypoventilation syndrome

Idiopathic intracranial hypertension

Depression, low self-esteem and QOL

Nonalcoholic fatty liver disease
steatosis
steatohepatitis
cirrhosis

Cardiovascular disease
- Diabetes
- Dyslipidemia
- Hypertension

Gallbladder disease
Pancreatitis

Gastroesophageal reflux, Constipation

Gynecologic abnormalities
abnormal menses
infertility
polycystic ovarian syndrome

Cancer
breast, uterus, cervix
colon, esophagus, pancreas
kidney, prostate

Joint deformities

Arthralgias

Leg deformities

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Non-operative treatment less effective in severely obese teens

Intervention	Weight Loss
Dieting	2%
Physical Activity	<1%
Drugs: Metformin	1-3%
Drugs: Orlistat	2%
Drugs: Exenatide	*3%*
Drugs: Sibutrimine	*6%*

Kelley AS. Circulation 2013;128:1689-1712

McGovern J Clin Endocrinol Metab 2008;93:4600

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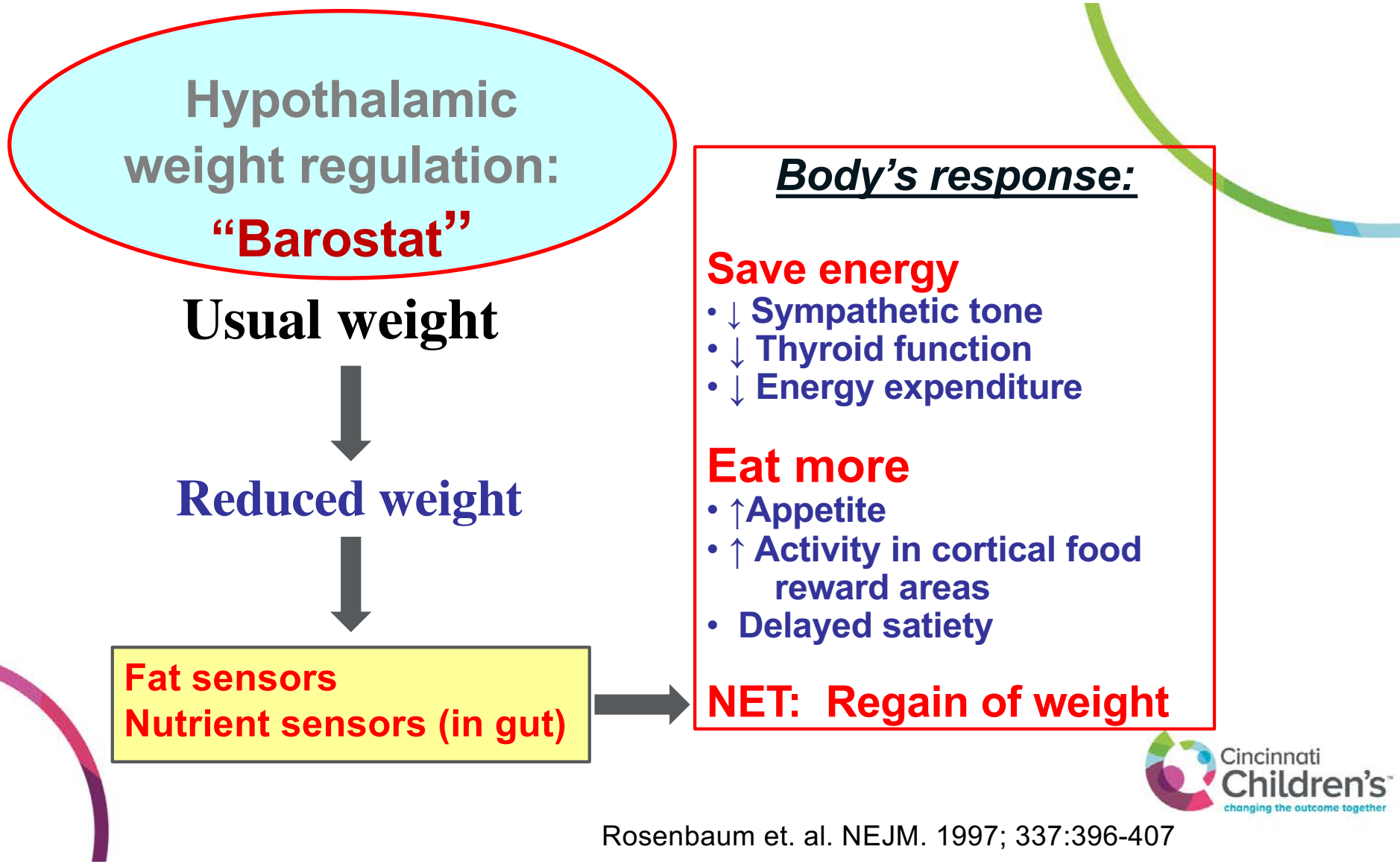

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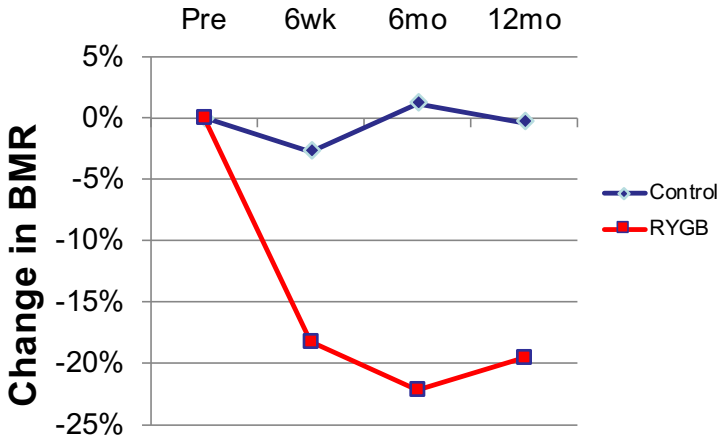
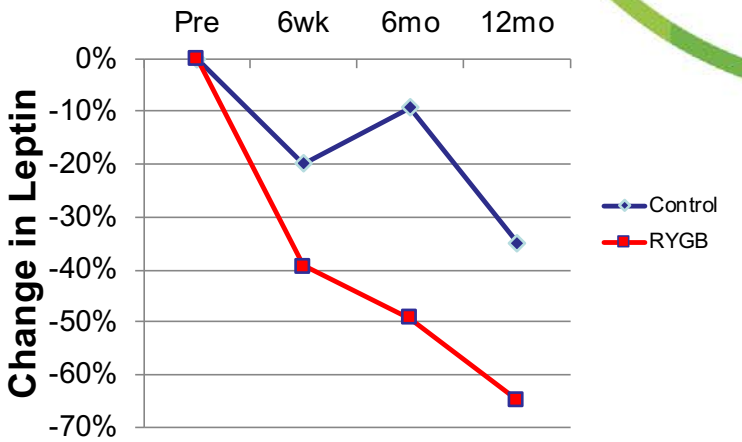
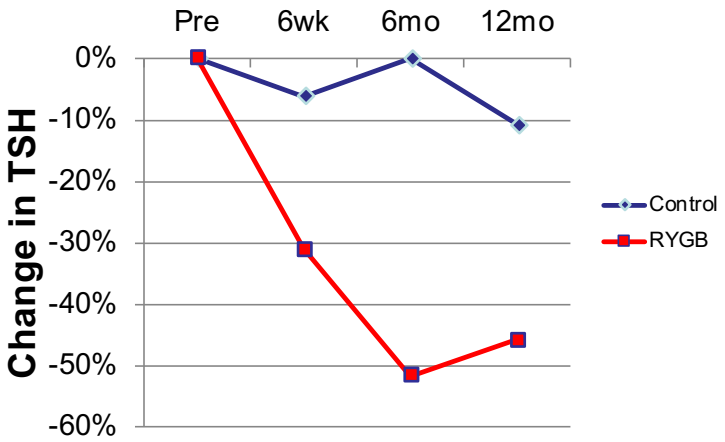
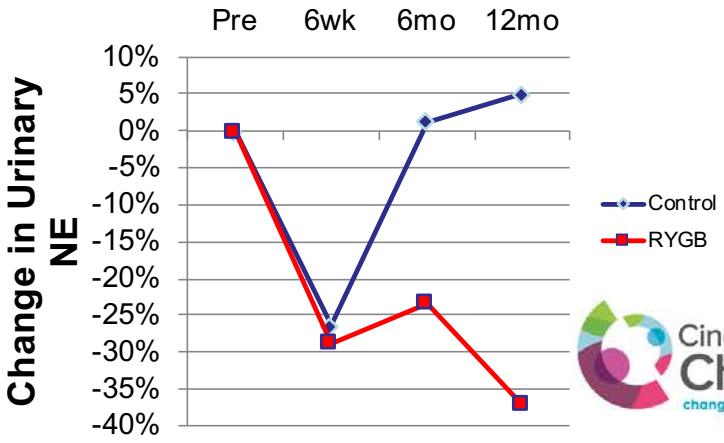
Rosenbaum et. al. NEJM. 1997; 337:396-407

RYGB generates compensatory changes to decrease energy expenditure









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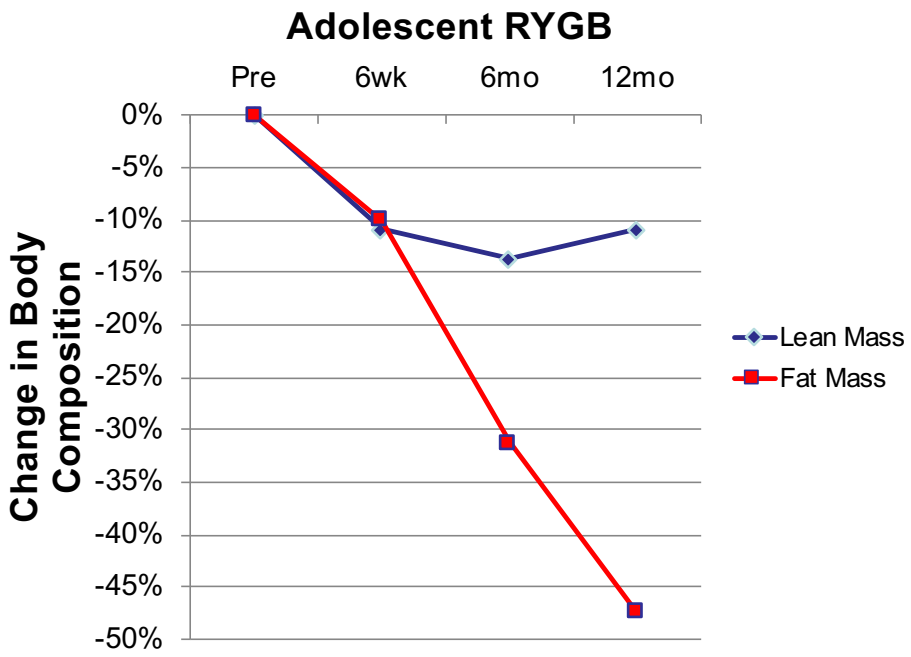
Yet RYGB still results in significant weight loss...

Blunts the body's attempts to regain weight



Butte N. Obesity 2015; 23:591

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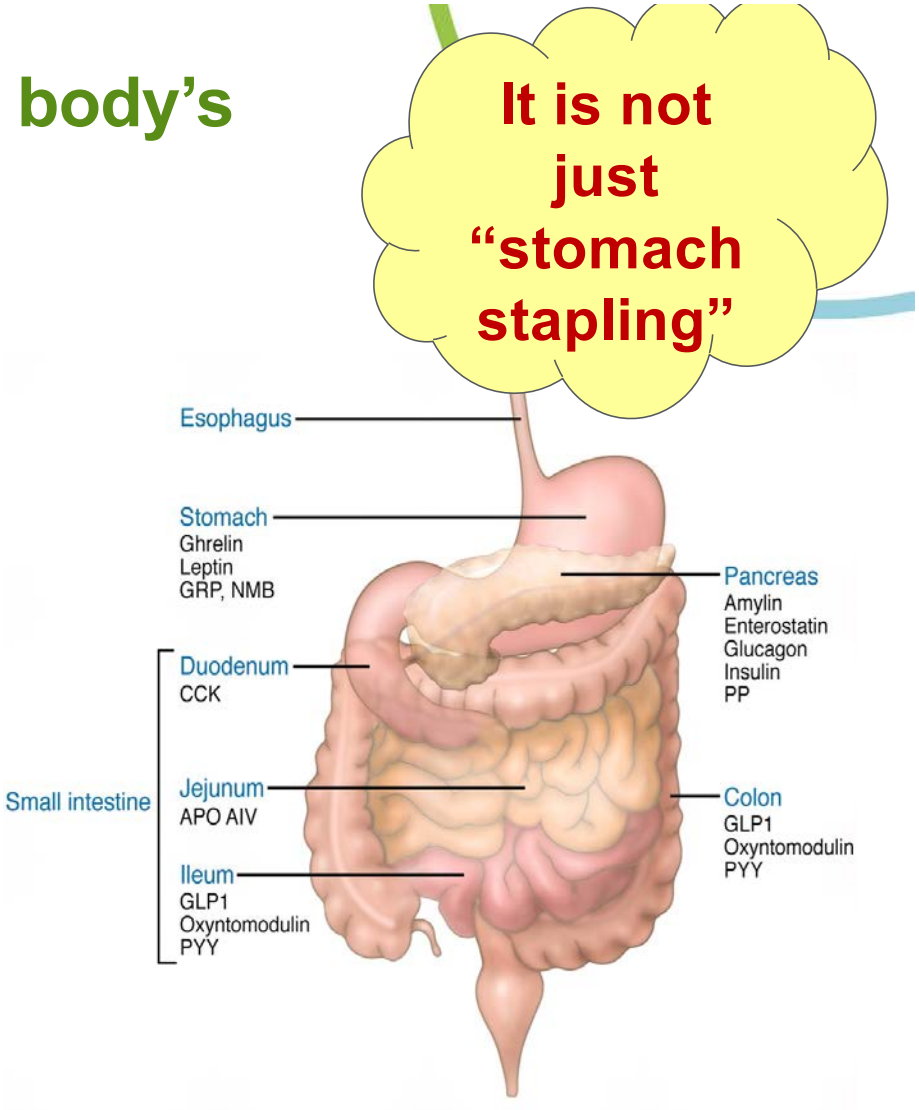
Multiple mechanisms counteract body's attempt to regain weight

Mediator	Bariatric Surgery
GLP-1	↑
Oxyntomodulin	↑
PYY	↑
CCK	↑
Bile Acids	↑
Ghrelin	↓



Bariatric Surgery in Children

Additional considerations beyond BMI and comorbidity…

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Psychosocial factors

- **Behavioral and psychological factors**:
  - Readiness to lose weight
  - Results of previous attempts
  - Adherence to medical regimens and follow-up
  - Family and social support system adequacy
  - No active psychosis or substance abuse
- **Developmental maturity and decisional capacity of adolescent**
  - Can provide informed assent (no coercion) and understand implications
  - Willing to comply with diet and behavioral modification
  - Emotional and pyschological maturity

"there is no evidence to support the application of age-based eligibility limits"

Armstrong SC et al. Pediatrics 2019 Policy Statement

Special populations

- **Pre-adolescents**
  - Preliminary studies report good BMI and comorbidity outcomes, but better outcome data needed
- **Challenging medical conditions**
  - Spina bifida, osteogenesis imperfecta
  - Hypothalamic obesity, syndromic obesity
  - Developmental delay
- **Insufficient data on safety and outcomes in these special populations**
  - Case by case evaluation with careful consideration of risk/benefit ratio
  - Need for rigorous study of outcomes

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In these more challenging cases:

- **Further evaluation may be necessary** to determine patient's ability to understand risks/benefits or impact on a medical condition
- **May require extended observation and preparation** of patient and family to ensure ability to adhere to medical and dietary regimen
- **Ethics consult** is beneficial in some cases to ensure unbiased decision

"Adolescents with cognitive disabilities, a history of mental illness or eating disorders that are treated, immature bone growth, or low Tanner stage should not be denied treatment."

ASMBS 2018

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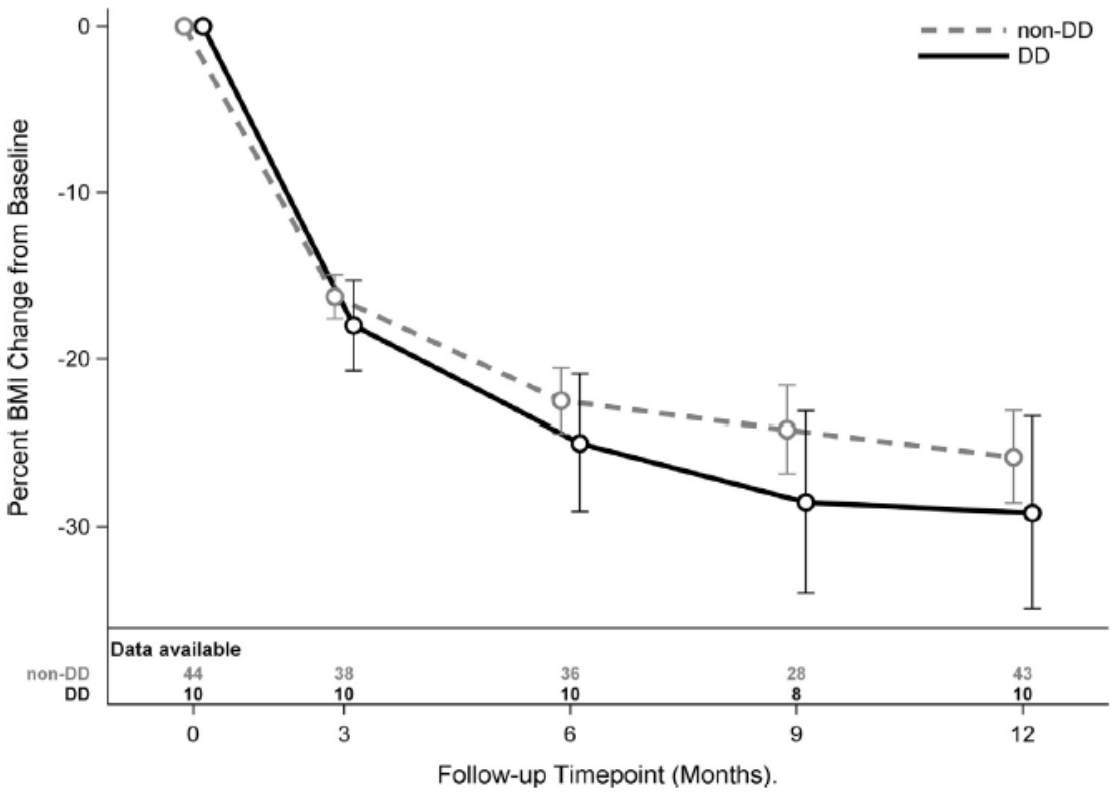
1 year outcomes similar in our program

- 10 patients with cognitive impairment
  - 60% mild
  - 30% mod
  - 10% severe
- 44 matched controls
- Similar rate of adverse events



Goddard G. SOARD 2019;15: 1662

Contraindications

- Medically correctable cause of obesity
- Ongoing substance abuse problem (within past year)
- Concurrent or planned pregnancy within 18 months of surgery
- Medical, psychiatric, psychosocial or cognitive condition that prevents adherence to postoperative dietary and medical regimen

Armstrong SC. Pediatrics 2019 Oct 27 Epub ahead of print

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Bariatric surgery in adolescents

Short and long-term outcomes

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Primary operations in adolescents:

Roux-en-Y Gastric Bypass

Vertical Sleeve Gastrectomy

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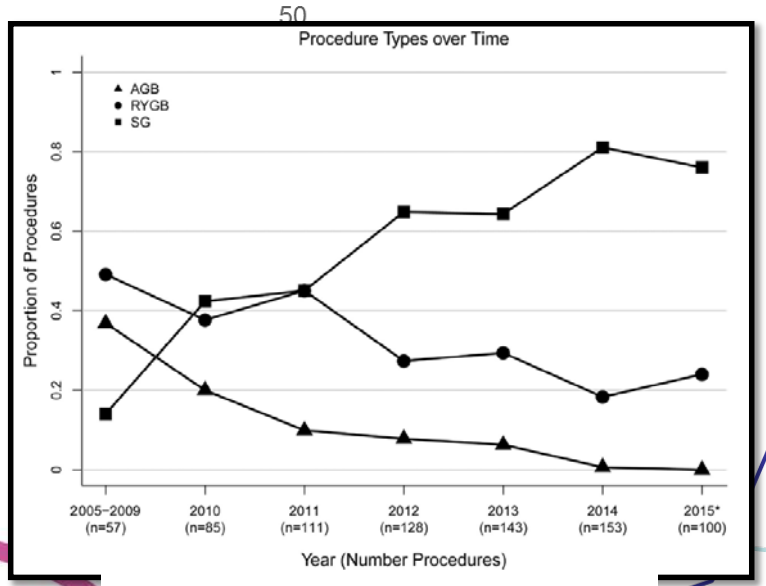
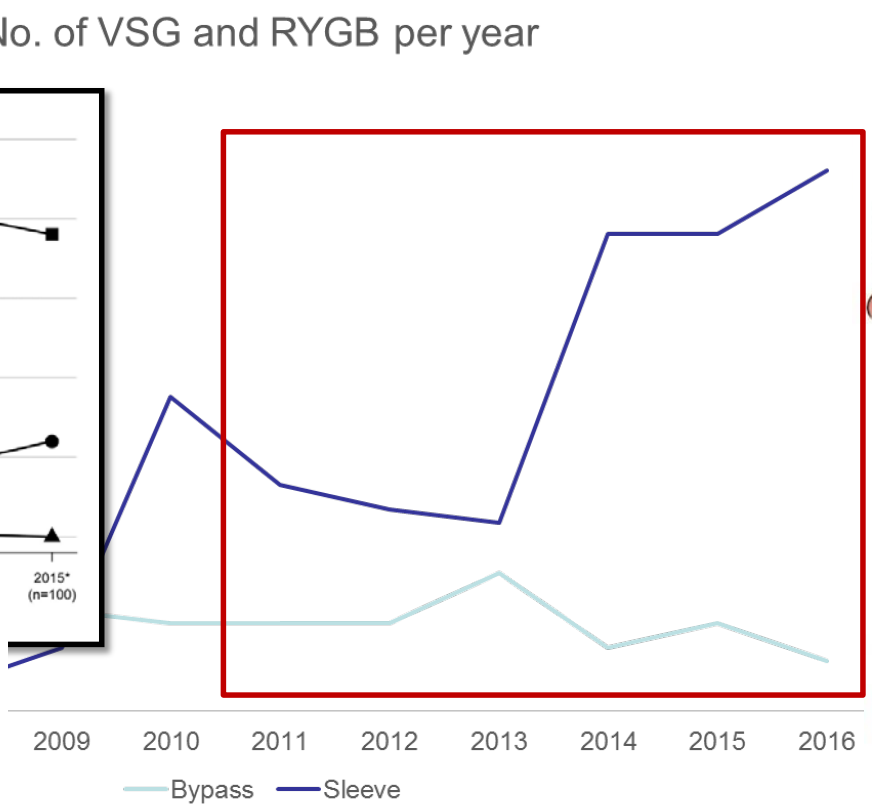
Shift to VSG among adolescent surgeries



Electronic health record data
(n=544 adolescents
Inge TH SOARD 2018



Vertical Sleeve Gastrectomy (VSG)

Roux-en-Y Gastric Bypass (RYGB)

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Roux-en-Y Gastric Bypass (RYGB)

- **Pros**
  - Long history (40+ years)
  - Significant and durable weight loss (-30% of initial weight)
  - Significant improvement in diabetes, sleep apnea and other comorbid diseases
- **Cons**
  - More surgical risk than other options (band or sleeve)
  - **Higher risk of nutritional deficiency**

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Vertical Sleeve Gastrectomy (VSG)

Pros

- Shorter operative time
- Less change to natural anatomy
  - Fewer operative complications
  - Less malabsorption of nutrients
- Short-mid term weight loss and health outcomes comparable to RYGB

Cons

- Long staple line, risk of leak
- **Gastroesophageal reflux can occur or worsen**
  - **But can be converted to RYGB**
- **No long-term outcome data**
- Irreversible

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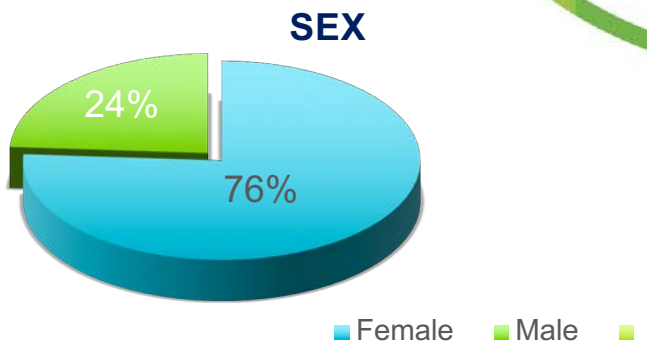
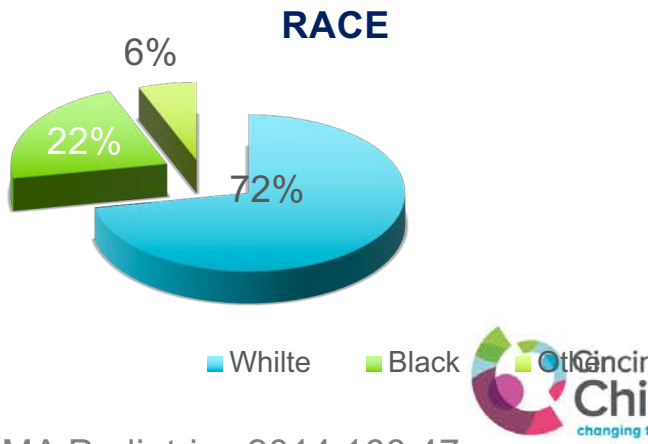
Multicenter Teen-LABS Study

- NIH-funded, Prospective Observational Study (2006-2016)
- Long term safety and efficacy study.
- 242 consecutive subjects (March 2007 – Feb 2012).
- Longitudinal assessment: Pre-op, 6mo, 12mo and annually.
- Measures: demographic, anthropometric, physical and behavioral health, physical activity
  - Standardized definitions of comorbid conditions
  - Central laboratory measures, and bio-specimens at Baseline, 6mo, 12mo and annually
  - Independent adjudication of all re-admissions/op/death

Teen-LABS: Participant Characteristics

Characteristics	N = 242
Mean Age (SD)	17 years
Age group %	
13-15 years	27%
16-17 years	38%
18-19 years	35%
Body Mass Index	
Median (Min,Max)	51 (34-88)
BMI group % (N)	
< 40 kg/m^2	3% (6)
40-49 kg/m^2	45% (109)
50-59 kg/m^2	32% (77)
≥ 60 kg/m^2	21% (50)





Inge TH. JAMA Pediatrics 2014;168:47

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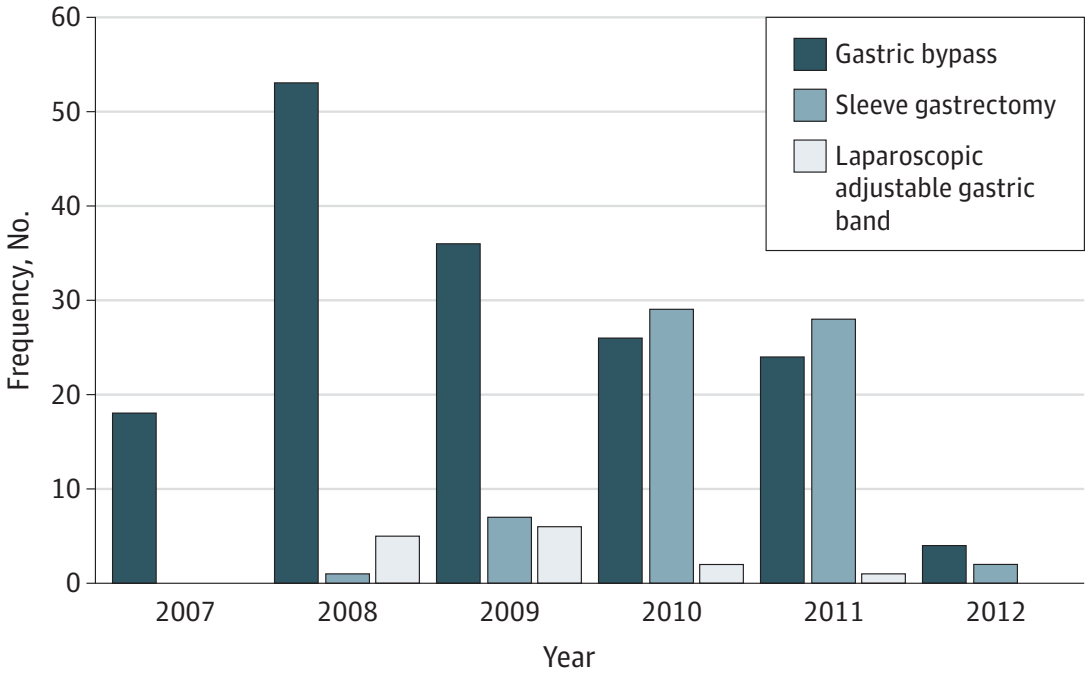
Teen-LABS: Procedure Type By Year



Inge TH. JAMA Pediatrics 2014;168:47

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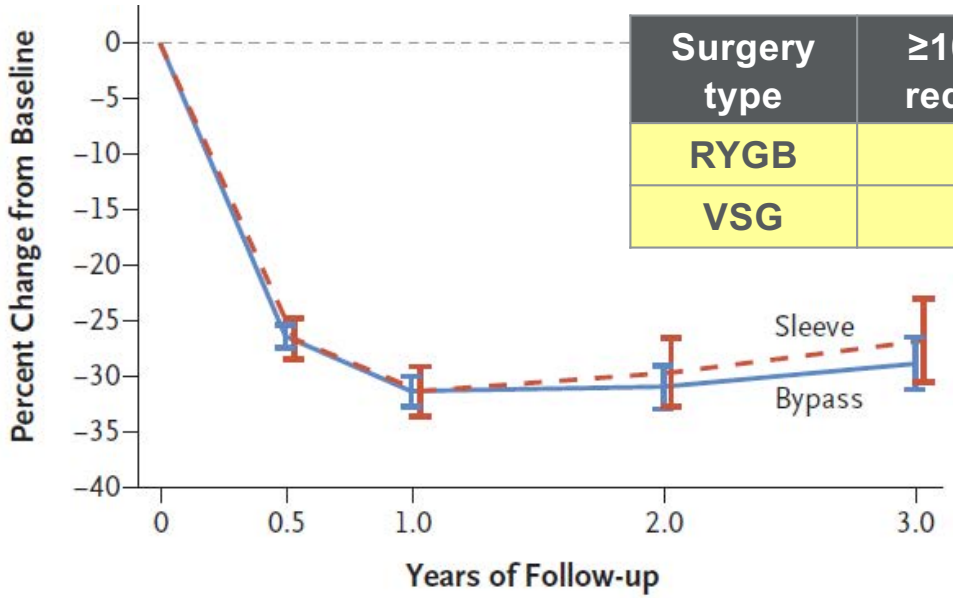
Teen-LABS: 3 Year Weight Change from Baseline



Surgery type	≥10% BMI reduction	≥ baseline weight
RYGB	89%	2%
VSG	85%	4%

SG: -27%

RYGB: -29%

No. of Participants					
Bypass	161	140	140	137	131
Sleeve	67	56	61	58	52

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Inge TH. NEJM 2016; 374:113

Teen-LABS: 3 Year Comorbidity Outcomes:

Condition	Baseline Prevalence	In Remission at 3 Years
	% Observed Prevalence (95% CI)	%Modeled Prevalence* (95% CI)
Type 2 Diabetes	13 (9-17)	**90** (65-98)
Prediabetes	10 (6-14)	**77** (48-92)
Dyslipidemia	76 (70-82)	**66** (56-74)
Elevated BP	43 (36-49)	**73** (60-83)
Abnormal kidney function	17 (12-22)	**86** (63-90)

- * Modeled prevalence used to adjust for missing data (GMM approach)

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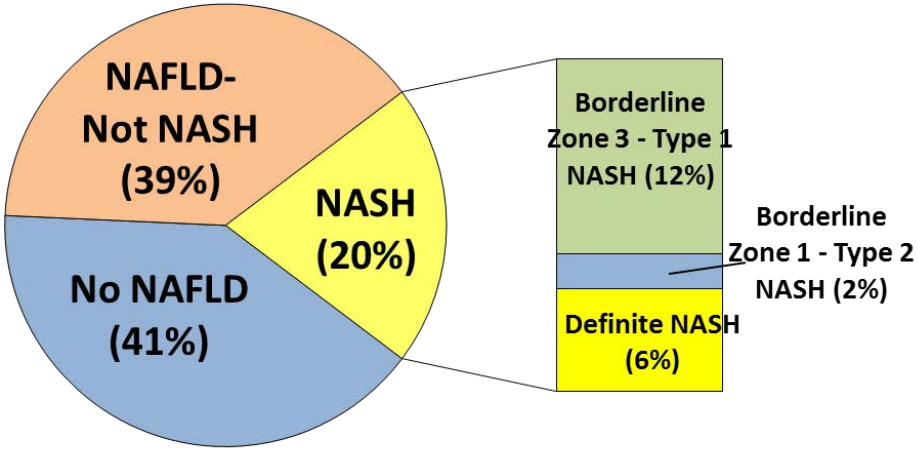
Inge TH. NEJM 2016; 374:113

Prevalence of NAFLD and NASH

157 teens with intraoperative liver biopsies (BMI 52 kg/m^2)
16 excluded due to medications (13) or insufficient tissue (3)



Mean BMI 52

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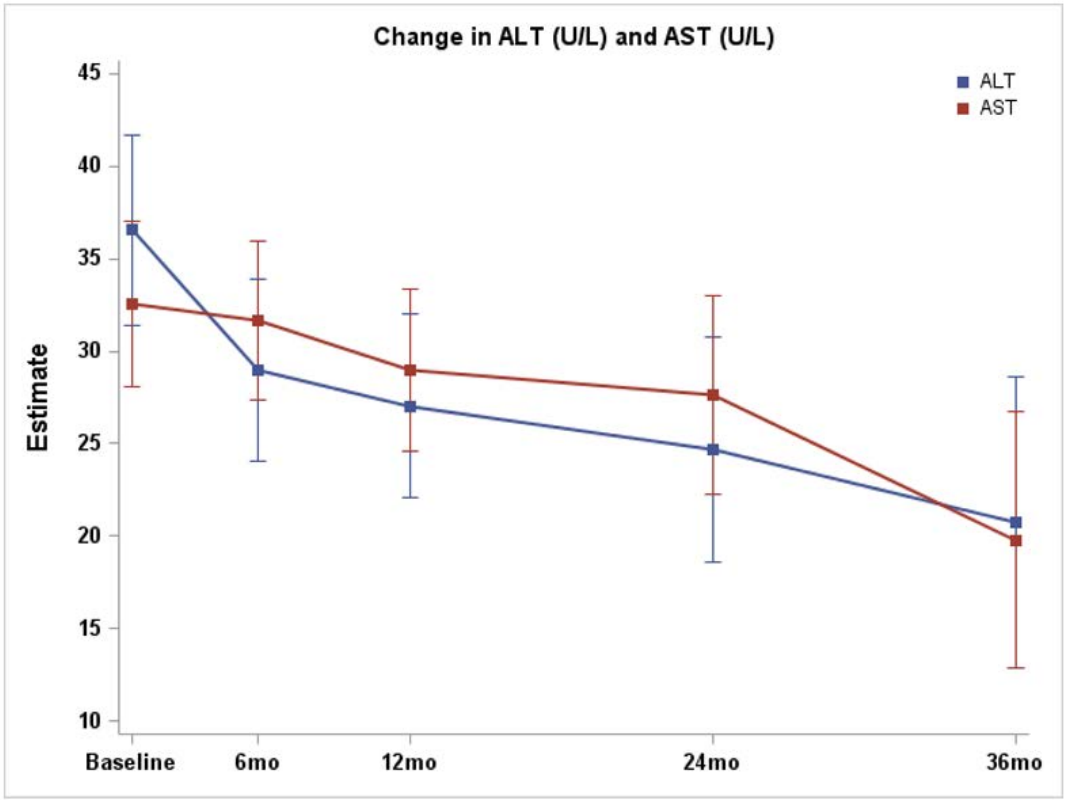
Xanthakos et al.. Gastroenterology 2015

ALT outcomes at 3 years



Xanthakos et al. Manuscript in preparation

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Quality of life improves, but long-term outcomes unknown

Teen-LABS : Impact of Weight on Quality of Life-Kids (IWQOL)			
IWQOL-KIDS Mean total scores	Overall	RYGB	VSG
Baseline	**62.9**	**61.9**	**63.9**
3 years	**83.1**	**84.0**	**82.0**

Inge TH. NEJM 2016; 374:113

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What about adverse events?

- **Early post-operative period (≤ 30 days)**
  - Major and minor complications

- **Long-term (31 days – 3 years)**
  - Re-operations and other procedures
  - Nutritional deficiencies

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Early Postoperative Complications (≤ 30 days) in Teen-LABS

- 19 subjects (7.9%) ➡ 20 Major Complications
- 36 subjects (14.9%) ➡ 47 Minor Complications

- **Major:** Life threatening/permanent harm (**no deaths**), organ loss, **reoperation (2.7%),** blood transfusion, major deviation in anesthetic/operative management
- **Minor:** Unplanned perioperative events (liver/spleen lac), mesenteric hematoma, injury to adjacent organs, deviation from routine care (initiate non-oral enteric feeding, TPN administration, etc.)

	Major	Minor
RYGB	9.3%	16.8%
VSG	4.5%	11.9%
LAGB	7.1%	7.1%

Inge TH. JAMA Pediatrics 2014;168:47

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Staple line leak (2%-2.5% in adults):

- Fever, tachypnea, tachycardia, pain
- Consider endoscopic options if stable and contained leak
  - Endolumenal stents
  - Fibrin glue/clips
  - Endoluminal wound-vac
- NPO → NJ feeds/TPN
- Surgical re-exploration if unstabl or leak not contained
- High morbidity/mortality in adults

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Teen-LABS Procedural Complications (≤ 31 days – 3 years)

		All (N=228)		Bypass (N=161)		Sleeve (N=67)	
	Procedure	Events (n)	Per 300 person-yrs	Events (n)	Per 300 person-yrs	Events (n)	Per 300 person-yrs
13%	Intrabdominal operation	47	22	38	25	9	15
13%	Endoscopic procedures	48	23	41	27	7	12

Top 5 operations or procedures overall (events per 300 person years):

1. Upper endoscopies: 17.6 (RYGB: 20, VSG: 10)
2. Cholecystectomy 8.6 (RYGB: 10, VSG: 5)
3. Stricture dilation 5.2 (RYGB: 7, VSG: 2)
4. Lysis of adhesions 2.9 (RYGB: 4, VSG: 0)
5. Repair of internal hernia 2.4 (RYGB: 3, VSG: 0)

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Inge TH. NEJM 2016; 374:113

Potential endoscopic indications post bariatric surgery

- **Persistent nausea and vomiting after intake**
  - Anastomotic stricture: RYGB
  - Partial gastric volvulus: VSG
- **Worsening or new onset GERD: VSG > RYGB**
  - Pyloric dilation/botox may help?
  - Bile reflux?
- **Epigastric pain**
  - Anastomotic ulcers: RYGB
  - Gastritis: bile reflux (VSG)
  - Cholelithiasis

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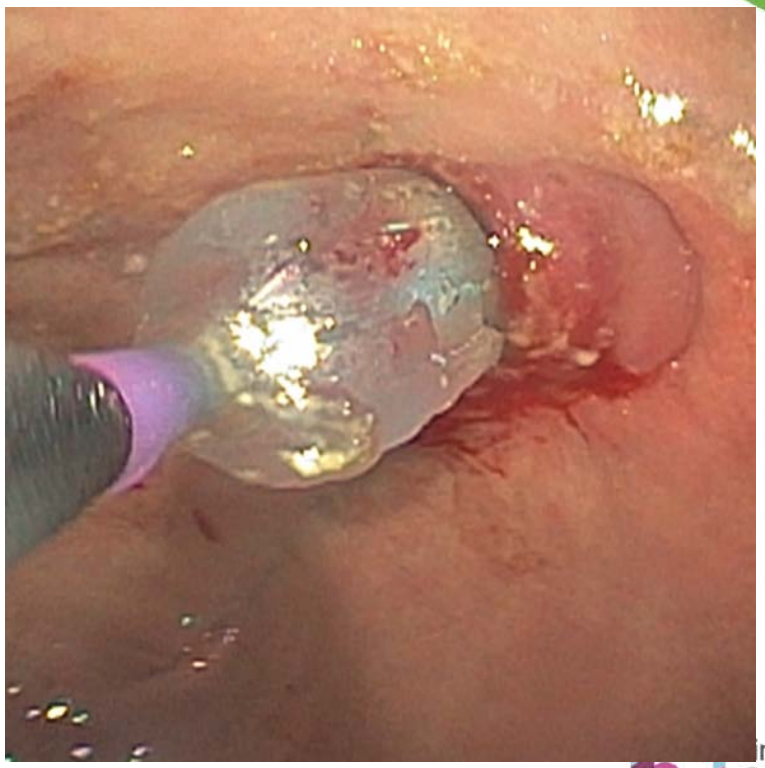
Anastomic Stricture: balloon dilation



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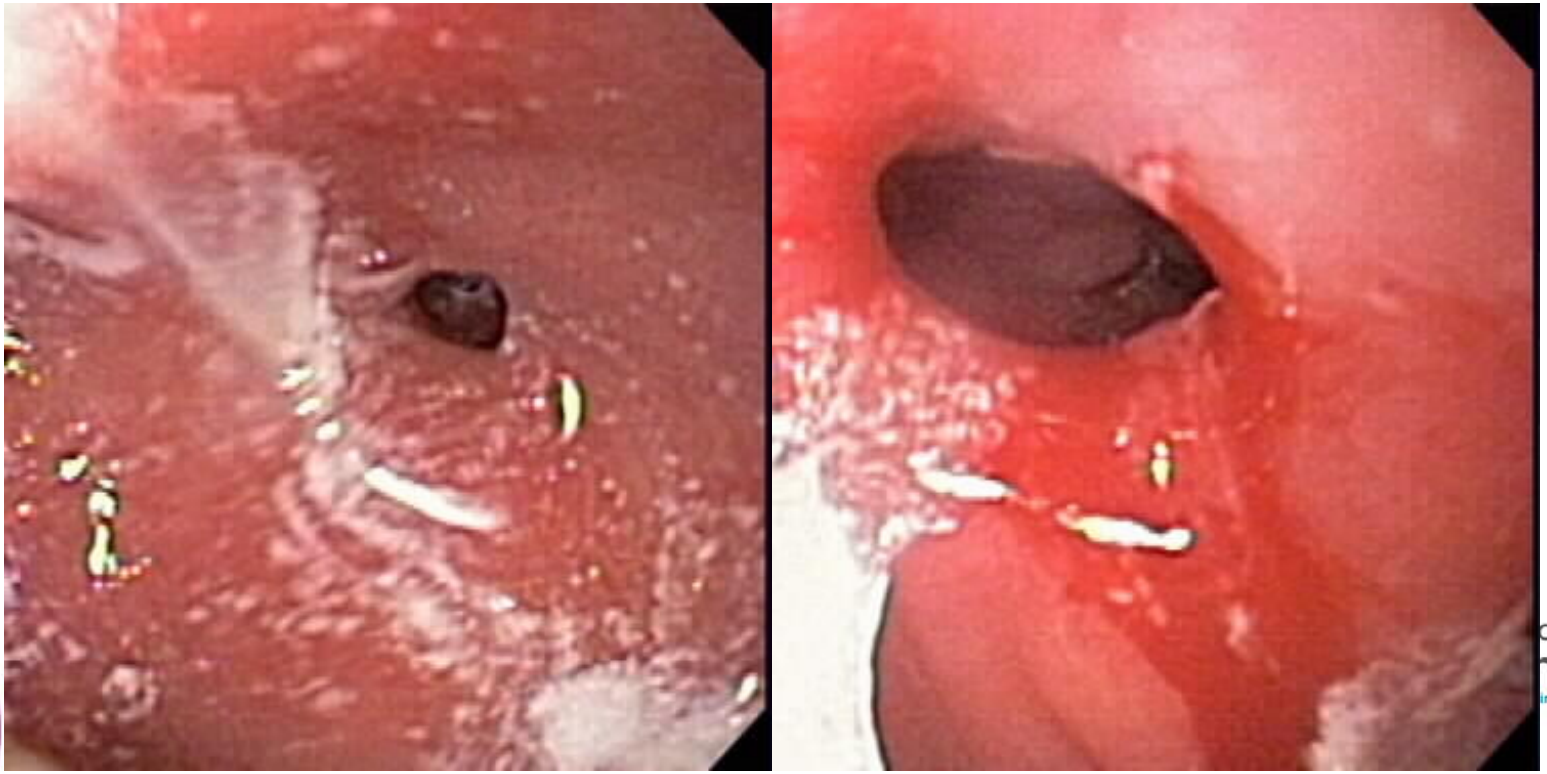
Stricture pre and post-dilation



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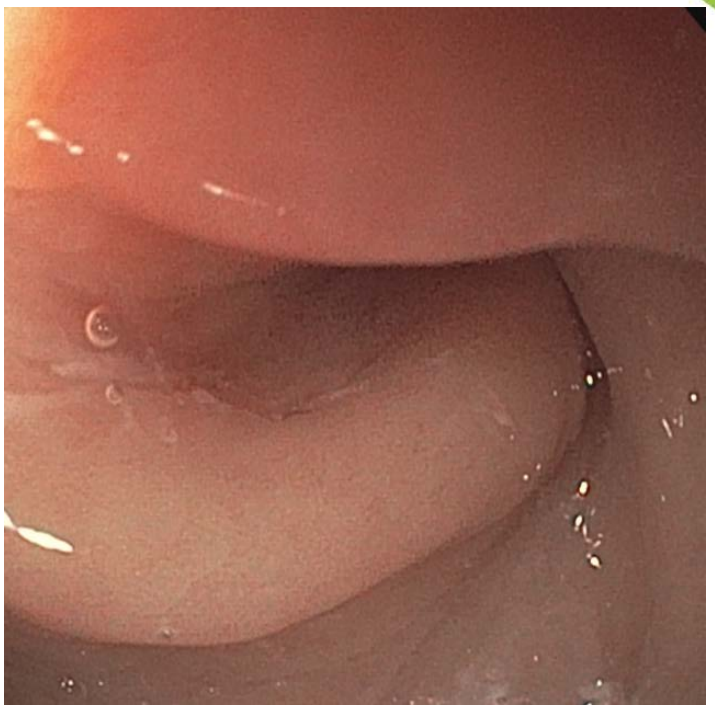
Partial gastric volvulus: VSG



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VSG and increased long-term risk of esophagitis/ Barrett's esophagus in adults

Surgeries done 2007-2010, Follow-up EGD ≥ 3 years

	Preoperative	Postoperative	P-value
GERD symptoms	34%	68%	<.0001
VAS score	1.8	3	.02
Daily PPI	19%	57%	<.0001
Esophagitis			
Class A	13	46	<.0001
Class B	8	33	<.0001
Class C	4	12	.04
Class D	0	9%	.002
Barrett's Esophagus	0	17%	<.0001

Genco A. SOARD 2017;13:568

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Erosive Esophagitis

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Anastomotic ulcers: risks include NSAIDs, smoking, ? H. pylori

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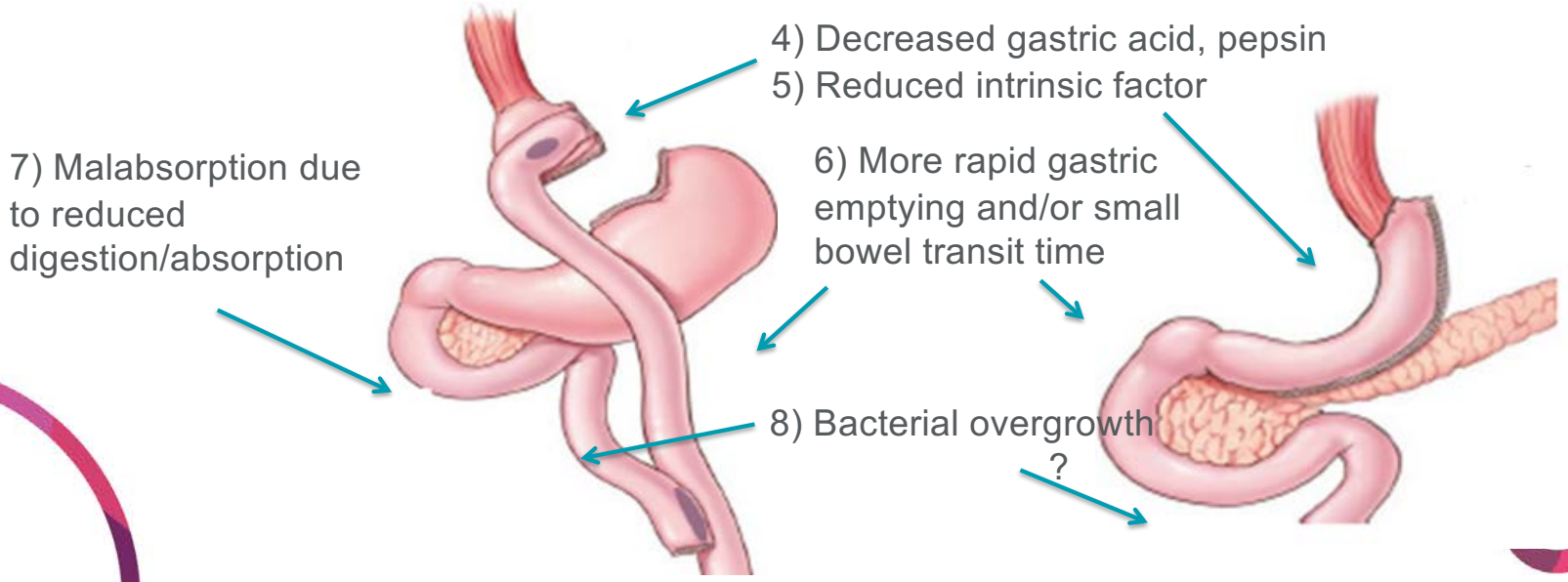
Nutritional deficiencies after bariatric surgery: multiple risk factors

1) Preoperative obesity- associated malnutrition (vitamin D, iron, B12, folate)

2) Decreased post-operative intake (reduced hunger, food intolerance, N/V)

3) Inadequate nutrient supplementation (non-adherence, insufficient amounts)



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Teen-LABS: 5 Year Nutritional Abnormalities

Abnormality		Baseline %	5Years %	P Value
Low Ferritin				
	RYGB	2.5	71	<0.0001
	SG	11	45	0.002
High transferrin				
	RYGB	0.6	15.6	0.02
	SG	0	4.8	Not estimable
Low vitamin B12				
	RYGB	0.6	11.5	0.06
	SG	0	7.1	Not estimable
Low Vitamin A				
	RYGB	6	16	0.09
	SG	5	7	ns

Xanthakos S. Clinical Gastroenterol Hepatol Oct 2019 epub

Stable Nutritional Measures

Abnormality	Procedure	Baseline	5 Years	P value
		% Prevalence	% Prevalence	
Low 25-OH D	RYGB	45	51	ns
	VSG	19	33	ns
Elevated PTH	RYGB	11	16	n/a
	VSG	1.6	0	Not estimable
Low Vitamin B1	RYGB	1.3	0.9	Not estimable
	VSG	0	0	Not estimable
Low Folate	RYGB	3	1	ns
	VSG	1.6	4.8	ns
Albumin	RYGB	4.4	2.5	Not estimable
	VSG	0	2.3	Not estimable

- No data collected on zinc, selenium, copper, C, E, K, no MMA, homocysteine

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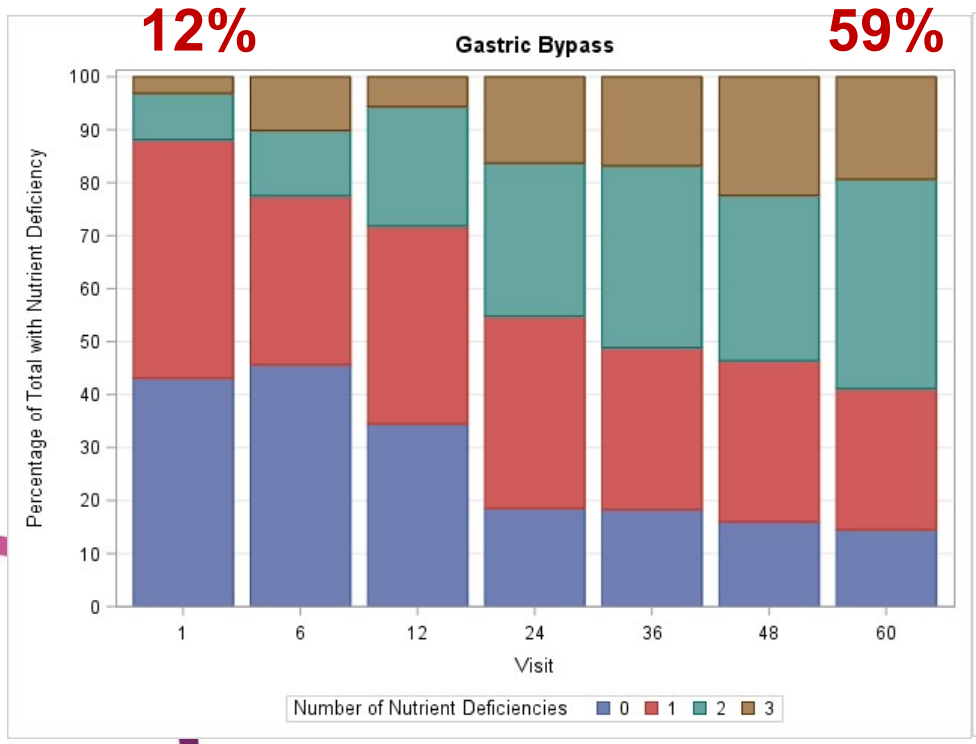
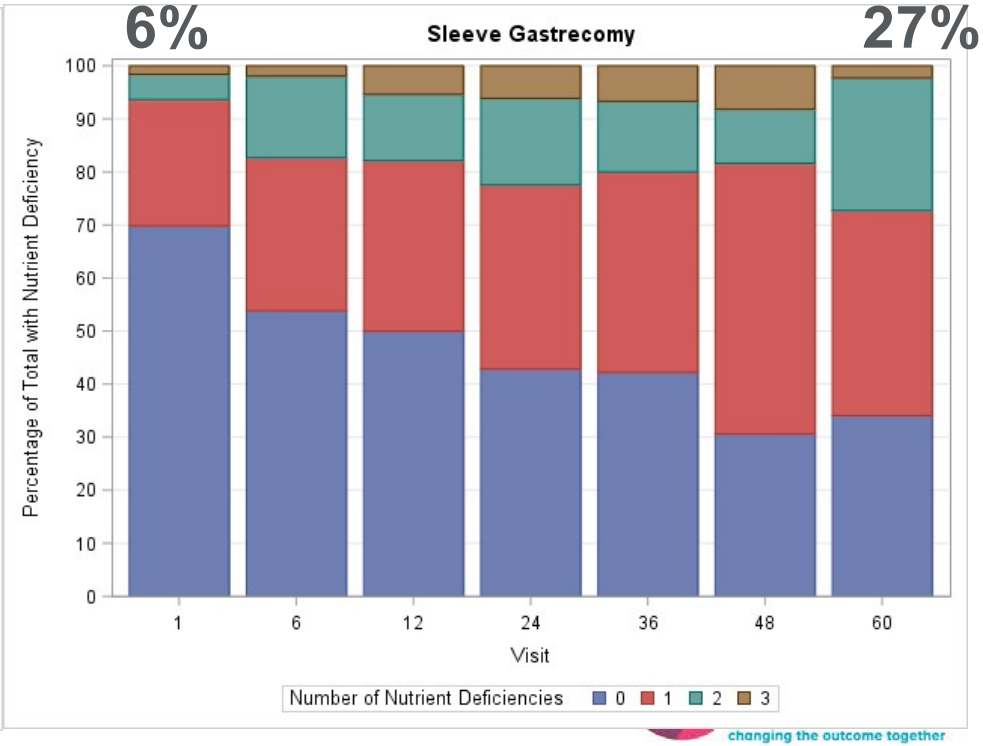
Xanthakos S. Clinical Gastroenterol Hepatol Oct 2019 epub

RYGB → increasing prevalence of 2 or more nutritional deficiencies





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Xanthakos S. Clinical Gastroenterol Hepatol Oct 2019 epub

Higher intake of MVI, vitamin B12 and D supplements was associated with better nutritional measures

- Prescribe appropriate supplementation
- Monitor status annually or more frequently if symptomatic

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Potential symptoms of nutritional deficiencies

Signs and Symptoms	Potential Nutritional Deficiencies
Anemia, fatigue, exercise intolerance	Iron, vitamin B12, folate, copper, B6
Neurological signs Ataxia, opthalmoplegia Peripheral weakness, parasthesia	Thiamine (B1), vitamin B12, copper
Osteopenia, osteomalacia	Vitamin D, calcium
Night blindness, visual impairment	Vitamin A (s/p BPD)
Hemorrhage (fetal)	Vitamin K in mother (s/p BPD)
Alopecia, edema	Protein – calorie malnutrition

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Other factors associated with worsening nutritional status after first year

- **RYGB** (iron, B12, vitamin A, and PTH)
- **Female sex** (iron)
- **Pregnancy** (iron and B12)
- **Black race** (vitamin A and D, PTH)
- **Interval weight regain** (iron, vitamin D, PTH)
- **Not associated**
  - Income or education level of guardian
  - Acid suppression

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Pregnancy Caveats

- **Avoid in first 18-24 months** post surgery
  - Transient drop in folate in first 12 months in Teen-LABS cohort
  - Decline in dietary calcium, iron, folate, zinc, vitamin A and D intake in 1st year in Teen-LABS
- **Baseline and more frequent monitoring**
- **Additional supplements may be needed**
  - Calcium
  - Iron: parenteral iron if needed
- **Infants can develop deficiencies if a mother is breast-feeding and nutritionally deficient** (more often after BPD)

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Additional GI complications:

- **Diarrhea**
  - Lactose intolerance
  - C.difficile screening
  - Bacterial overgrowth (consider empiric Flagyl or trial of probiotic)
  - If it persists, EGD ± colonscopy to r/o celiac or other causes
- **Dumping syndrome/post-prandial hypoglycemia**
  - First try dietary management
- **RUQ pain/gallstones**
  - Consider ursodiol prophylactically x first 6 months (evidence mixed)

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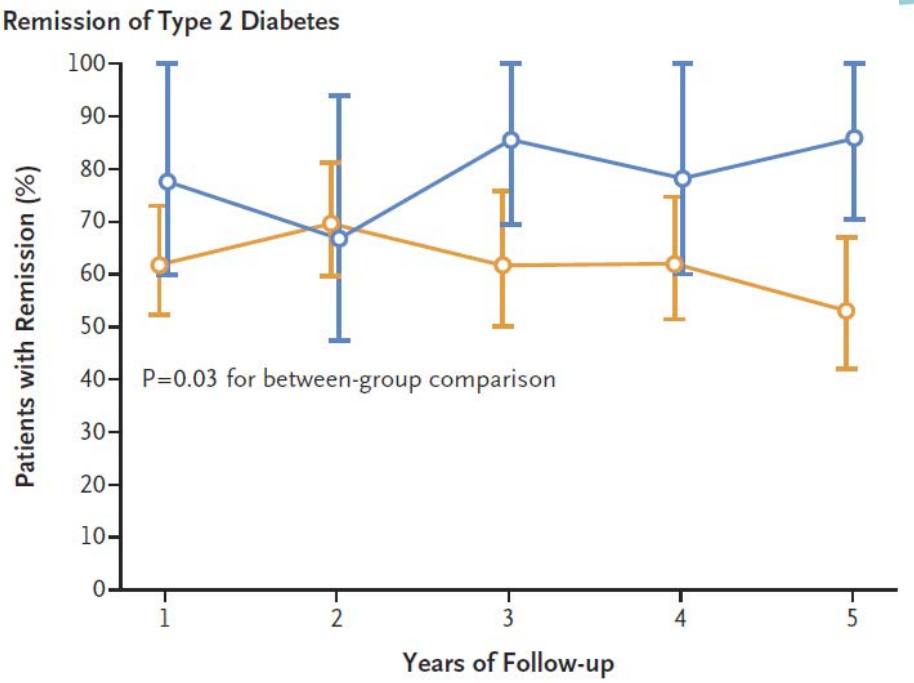
Long-term risks/benefits pending

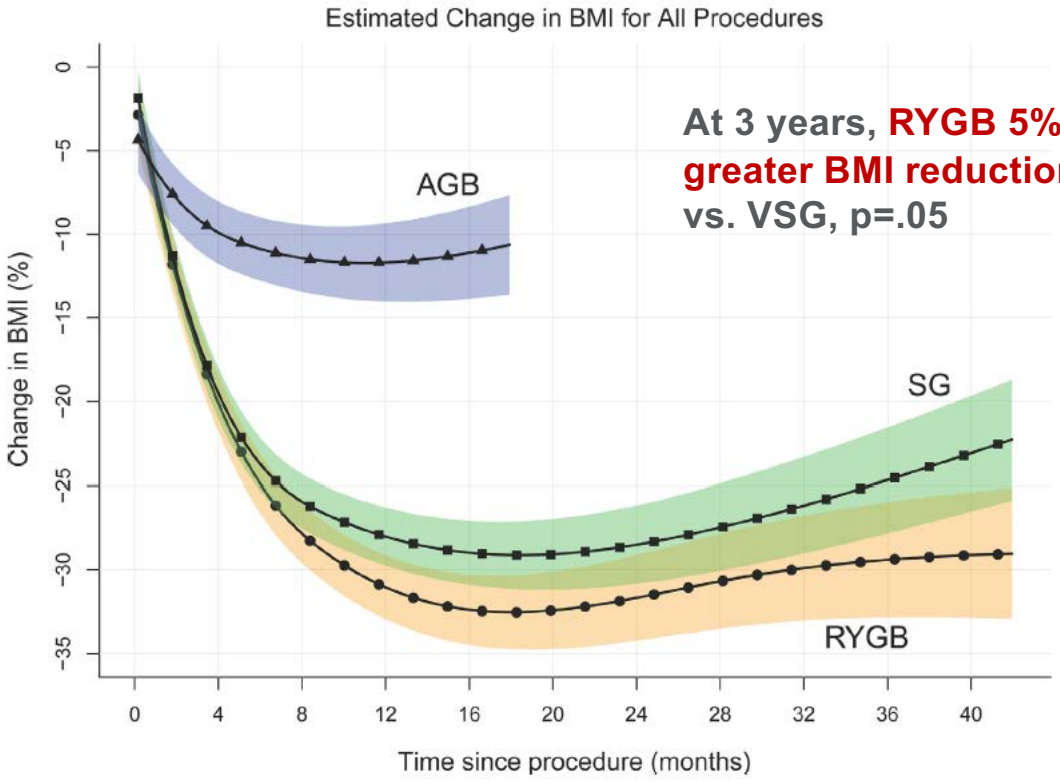
- **Teen LABS 10 year data collection in process**
- **5 year RGYB outcomes adolescents vs. adults**
  - Weight -26% in adolescents vs. -29% in adults
  - Remission of T2 diabetes and hypertension significantly higher in youth
  - higher rate of intrabdominal operations in 5 years in youth vs. adults



Inge TH. NEJM 2019; 380(22):2136

Long-term comparisons of RYGB and VSG needed for comparative effectiveness

Retrospective analysis from electronic health records in a national research network: 544 (306 SG, 177 RYGB, 61 AGB) adolescents (age 12–19 yr)



At 3 years, RYGB 5% greater BMI reduction vs. VSG, p=.05

At 5 years, insufficient N for statistical comparison, but trend toward stabilization

- RYGB **- 24%** (95%CI: -17%,-31%)
- VSG **-21%** (95%CI:-12,-29%)

Inget TH. SOARD 2018;14:1374

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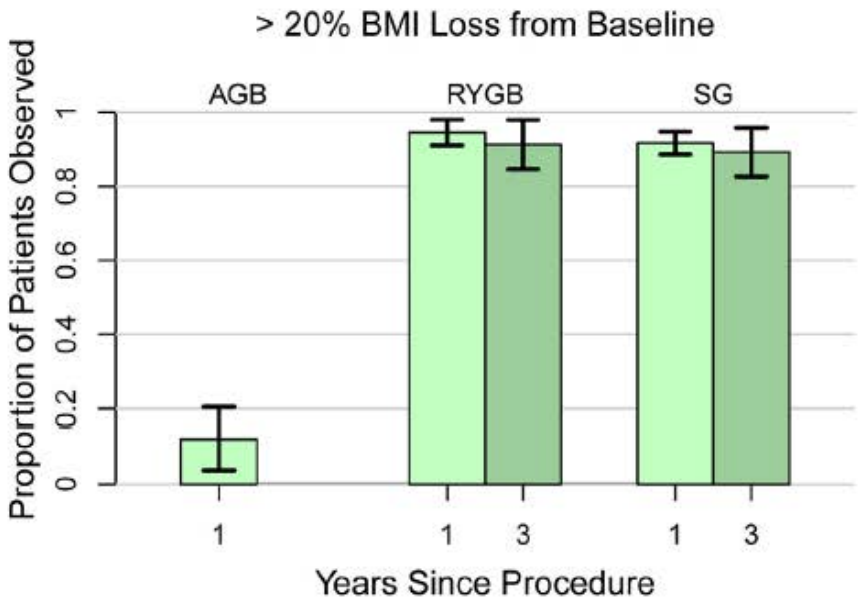
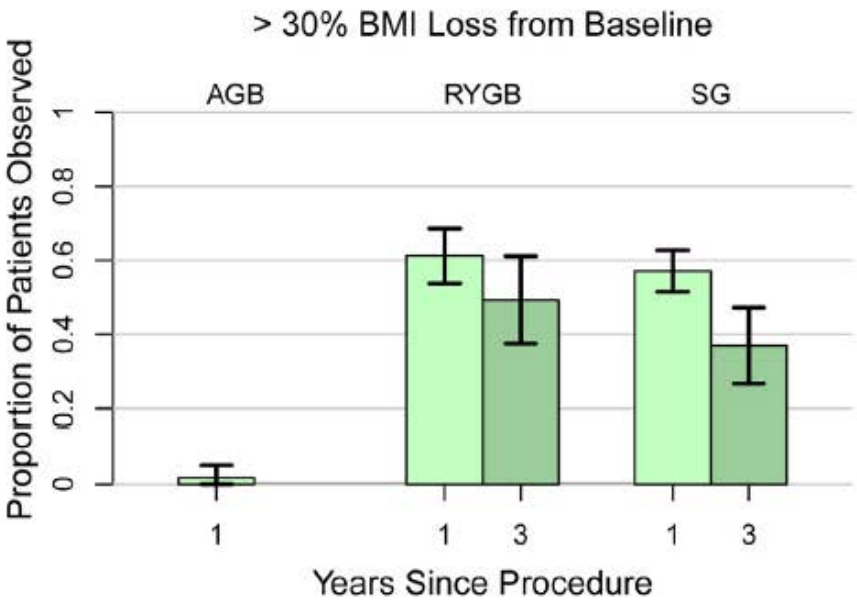
Comparable maintenance of significant weight loss at 1 and 3 years: RYGB and VSG





Inget TH. SOARD 2018;14:1374

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Follow up of Adolescent Bariatric Surgery 5+ (FABS-5): Single center outcomes

RYGB surgery

- n=58 (81% of eligible)
- Baseline age 17 yrs
- Baseline BMI, 58 kg/m^2
- Mean f/u, 8 years

HealthWorks! (Non-Op)

- n=30
- Baseline age 15 years
- Baseline BMI, 51kg/m^2
- Mean f/u, 7.3 years

Inge TH et al. Lancet Diabetes Endocrinol 2017;5:165

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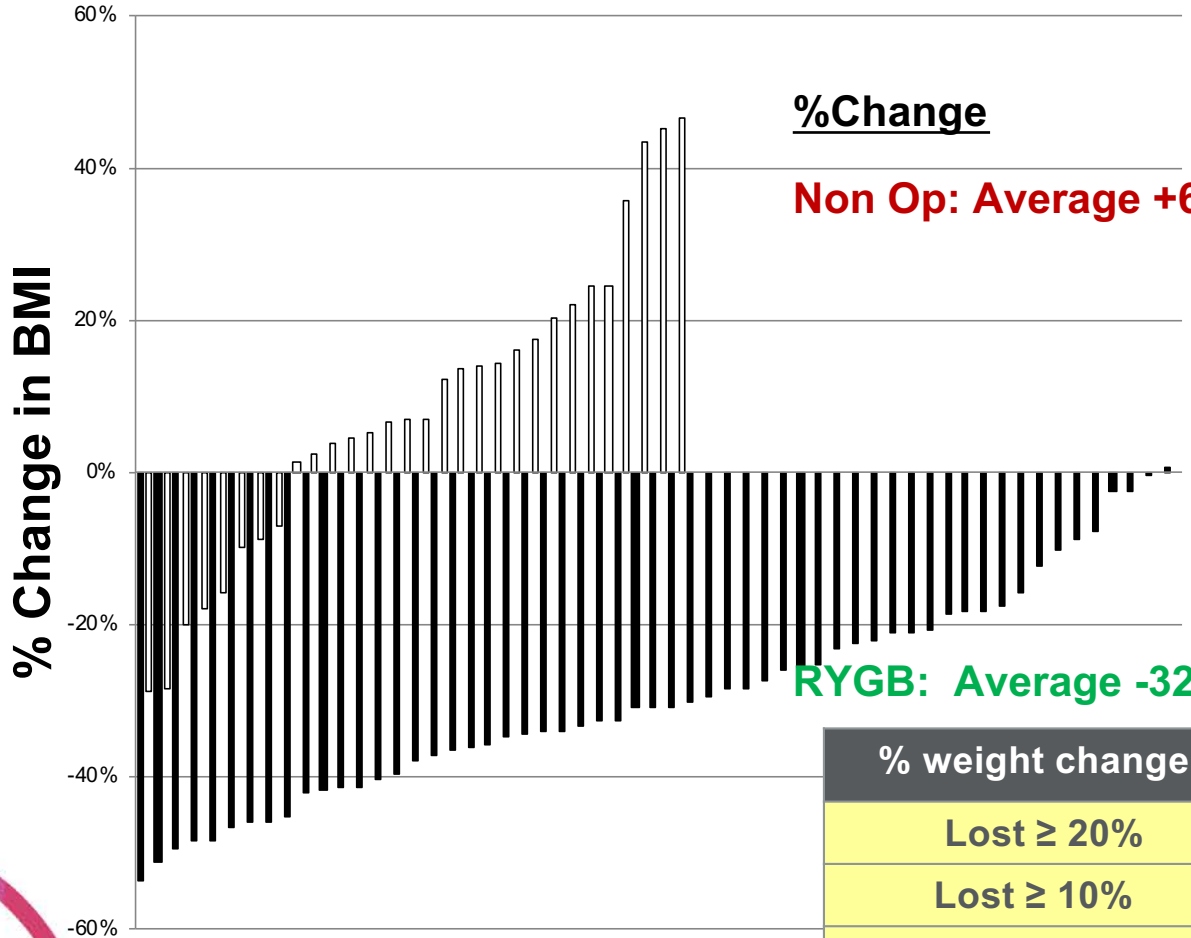
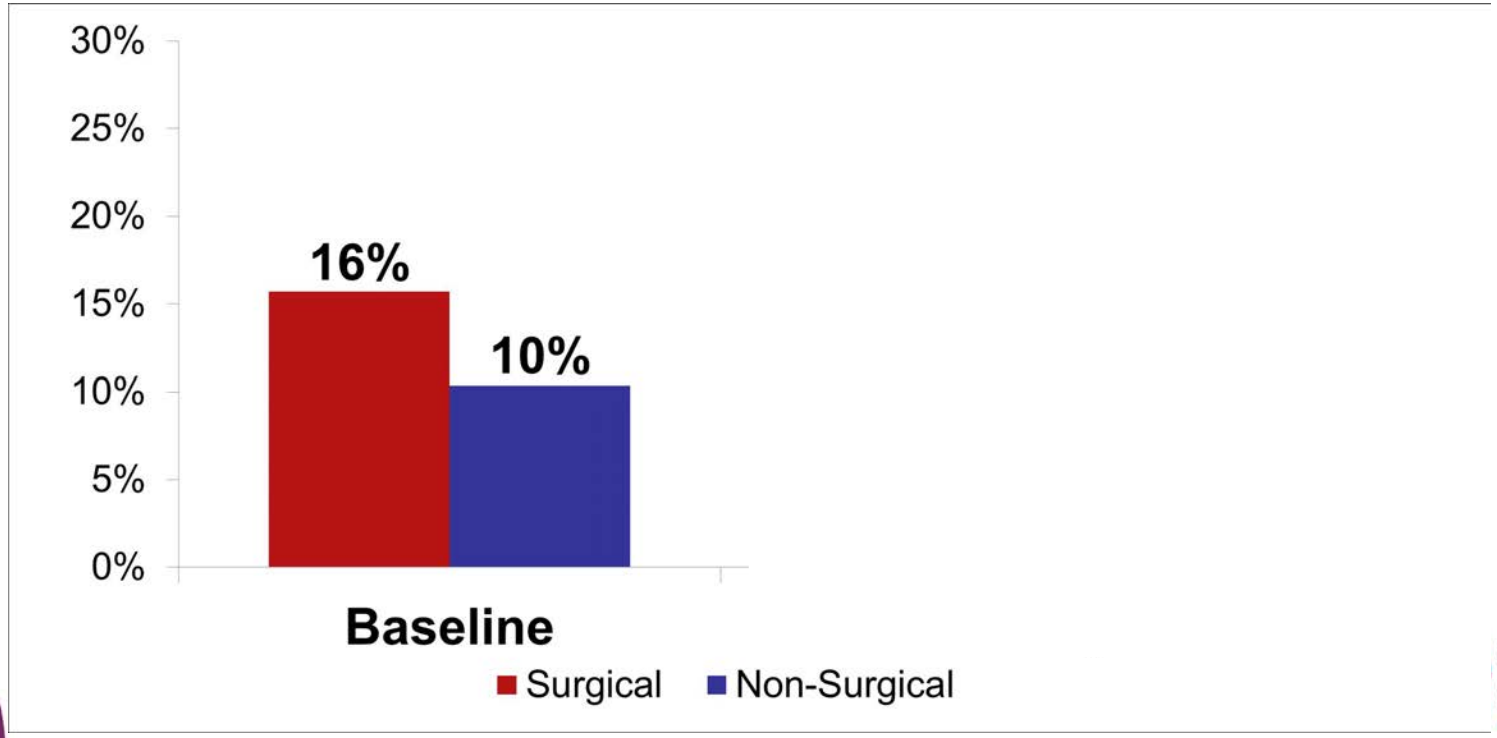


% weight change	RYGB	Lifestyle alone
Lost ≥ 20%	77%	10%
Lost ≥ 10%	89%	20%
Lost ≥ 5%	93%	27%
> baseline weight	2%	73%

Type 2 diabetes cases



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Barriers: surgery not likely to be widely scalable

- Nearly 4.5 million US adolescents are severe obese
- But only 1000-1600 estimated bariatric cases per year
- Why?
  - Insurance barriers (47% of medically qualified teens approved)
  - Minority adolescents less likely to undergo surgery
  - Cultural factors? Health disparities?
  - Provider discomfort with referral?
  - Patient preference – “don’t want surgery”

Armstrong SC. Pediatrics 2019
Oct 27 Epub ahead of print

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Endoscopic bariatric treatments: a new “less-invasive” frontier?

- Intragastric balloons
  - Endoscopically placed (3 FDA approved for adults)
  - Swallowed
- Aspiration therapy
- Endoscopic sleeve gastroplasty
- Endoscopic duodenal resurfacing/sleeves

5-20% average weight loss reported
Long-term and nutritional outcomes unclear
Not all patients respond or contine treatment

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3 studies in youth: intragastric balloons

- **Nobili et al Pediatric Obesity 2015**
  - 10 children/adolescents, positive short term 3 month outcomes comparable to adults
- **Pezzo et al. Nutrire 2017**
  - 10 adolescent females, mean BMI 41
  - Nausea/vomiting transient in 50%, no serious complications
  - Removed post 6 months, no long-term outcomes
  - 4.29 ± 1.04 kg/m reduction in BMI
- **Reece E et al. Int J Obesity 2017**
  - 12 adolescents in comprehensive lifestyle program + intragastric balloon x 6 months
  - Weight loss at 6 months 7.05 kg±7.13
  - Not sustained at 24 months – weight regain

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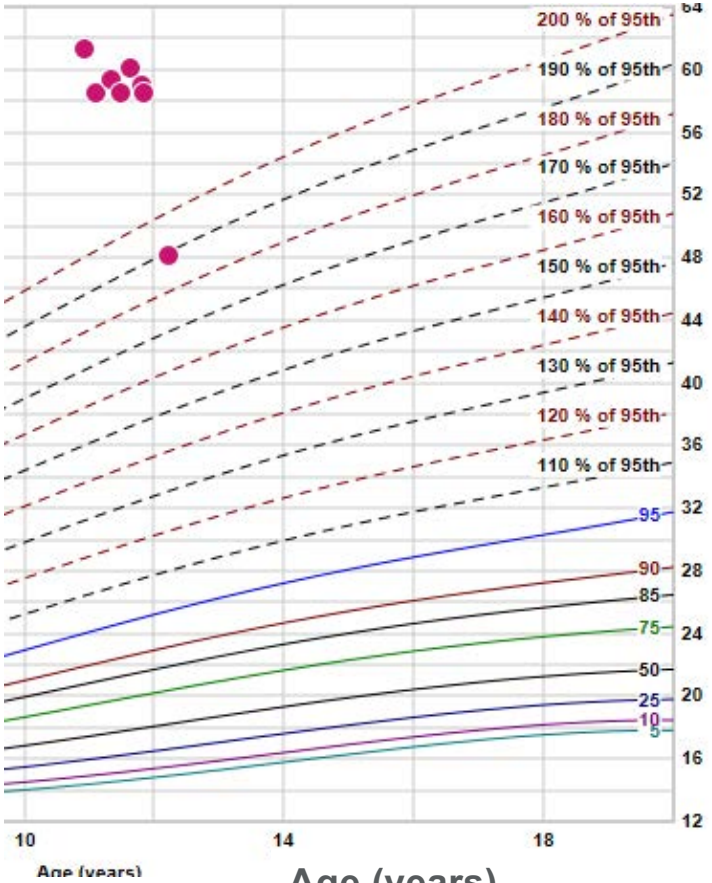
What weight management intervention did this patient have?



BMI (kg/m2)

Age (years)

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Summary #1

- **Bariatric surgery results in durable weight loss in majority of severely obese adolescents**
  - **Substantial and sustained decrease in BMI for majority**
  - **Corrects comorbidities & improves health**
  - **Reduces/prevents incident comorbidities**
  - **Enhances quality of life**
  - **RYGB more durable than VSG?**

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Summary #2

- Surgery has risks
  - Early complications
  - Later adverse nutritional effects (RYGB > VSG)
- A “window” of opportunity to reverse severe pediatric obesity?
  - Surgery at lower BMI= ↓residual severe obesity
- Objective, prospectively collected data to inform clinical care and decision-making in the future
  - Long-term weight, nutrition and clinical, psychosocial and quality of life outcomes

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Team Care & Team Science

- **Clinical Team**
  - Michael Helmrath, Stavra Xanthakos, Susan Sewell, Linda Kollar, Cassandra McDaniel, Penni Taylor, Sanita Ley
- **NIH/NIDDK and Teen-LABS collaborators**

NIH National Institute of Diabetes and Digestive and Kidney Diseases

Teen Longitudinal Assessment of Bariatric Surgery

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