

Minimally Invasive Procedures and Devices for the Management of Obesity

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SENIOR STAFF SURGEON - GENERAL, LAPAROSCOPIC, AND BARIATRIC
SURGERY

Obesity in America

Overwhelming

- Over 93million Americans with Obesity (BMI > 30)
- Obesity is linked to over 40 disease processes
 - Diabetes
 - Heart Disease
 - Stroke
 - Cancer
- Associated with a 50-100% risk of premature death
- Modest weight loss (5-15%) can dramatically decrease risks
- Median survival is reduced by eight-to-ten years for individuals with BMI 40-45 (comparable to smoking)

Growing Problem

Approximately 40% of Americans are Obese

5% are Morbidly Obese. 400% increase in the last 20 years!

No state with a rate <20% in 2010

Louisiana ranks at or near the top of this list



Weight Loss

Prevention!

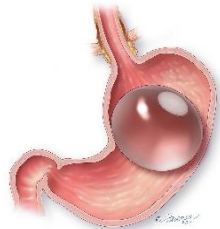


Nutrition & Exercise

An important part of weight loss, even if you pursue additional therapy

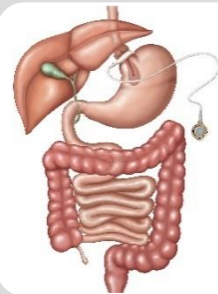


Medical Weight Loss / Pharmacotherapy



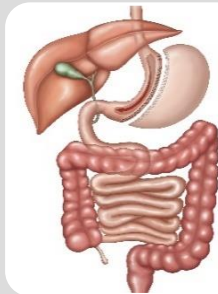
Intragastric balloon

No surgery
Two-part weight loss program
Healthy food and exercise are crucial parts of success



Laparoscopic adjustable gastric band

Least invasive of the surgical procedures
Frequent office visits



Laparoscopic/Robotic Sleeve Gastrectomy

Most common bariatric surgery in US in 2015

Not reversible



Laparoscopic Gastric Bypass

Best treatment for type 2 diabetes

Is Surgery Safe?

Overall mortality rate is about 0.1%¹ — less than gallbladder (0.7%) and hip replacement (0.93%) surgery

Risk of major complication – 4.3%

Clinical Evidence that the

- Risk of surgery < Risk of being obese

Bariatric Surgery Increases Lifespan

1. Agency for Healthcare Research and Quality (AHRQ). (2007). Statistical Brief #23. Bariatric Surgery Utilization and Outcomes in 1998 and 2004.

LABS-1 (30 day safety)

4776 patients, 3412 bypass (2975 laparoscopic and 437 open) and 1198 adjustable gastric band

30 day mortality 0.3%

4.3% had a major adverse outcome

Preop factors associated with adverse outcome= history DVT/PE, sleep apnea, BMI higher than 53, and impaired functional status

Swedish Obese Subjects Study

Primary end point was mortality.

129 deaths in control group and 101 in the surgery group during an average of 10.9 years of followup.

Myocardial infarction (25 controls and 13 surgical patients) and cancer (47 controls and 29 surgical patients) were the two most common causes of death.

Concluded that surgery was associated with long-term weight loss and decreased mortality.

Success

What is success?

- Goal is not ideal body weight
- On average patients keep off 50% of their excess weight at 5 years

Huge impact on health

- Patients may reduce risk of premature death by 30-40%
 - 60% reduction in mortality from cancer, with the largest reductions seen in breast and colon cancers
 - 56% reduction in mortality from coronary artery disease
 - 92% reduction in mortality from type 2 diabetes
 - 40% overall reduction in mortality in gastric bypass patients

Adams, T. D., et al. (2007). Long-term mortality after gastric bypass surgery. *New England Journal of Medicine*. 357 pp. 753-761



Medical Outcomes

MEDICAL OUTCOMES OF BARIATRIC SURGERY

Condition/Disease	% Resolved or Improved	% Resolved³⁰
Type 2 Diabetes	86	76.8
Hypertension	78.5	61.7
Obstructive Sleep Apnea	85.7	83.6
Hyperlipidemia	78.5	61.7

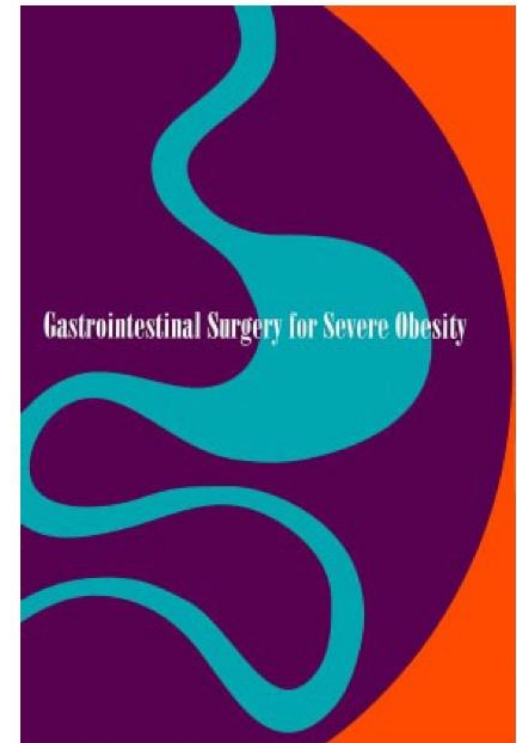
Buchwald, H., et al. (2004). Bariatric surgery: a systematic review and meta-analysis. Journal of the American Medical Association. 292(12) pp. 1724-1737

(2013, November) ASMBS Resources Fact Sheet, Metabolic and Bariatric Surgery.
<https://asmbs.org/resources/metabolic-and-bariatric-surgery>

Surgical Candidates

NIH Consensus Statement

- Surgery is an accepted and effective approach that provides consistent, permanent weight loss for morbidly obese patients
- Previous Attempts at Weight Loss without success
- BMI ≥ 35 with related co-morbid conditions
- BMI ≥ 40



Consensus Statement

NIH Consensus Development Conference
March 25–27, 1991

Volume 9, Number 1

Pre Operative Workup

ASMBS Guidelines

- Complete H & P (obesity-related co-morbidities)
- Routine Labs
- CXR
- Nutrient screening with iron studies, B₁₂ and folic acid, and 25-vitamin D
- GI Eval?
 - H. Pylori, Gallbladder, Elevated LFTs
- Informed Consent
- Financial Information

<https://asmbs.org/resources/clinical-practice-guidelines-for-the-perioperative-nutritional-metabolic-and-nonsurgical-support-of-the-bariatric-surgery-patient>

Pre Operative Workup

- Psychological Evaluation
 - Evaluation for barriers to success
 - Assesses environmental, familial, and behavioral factors
 - Evaluation of ability to incorporate nutritional and behavioral changes
- Nutritional Assessment
 - “Cleared” by dietician
 - Evidence of ability to make diet changes

Pre Operative Workup

Glycemic Control

- Ideally
 - HgA1C: 6.5-7%
 - Fasting Glucose \leq 110
- Reality
 - HgA1C: \leq 8

Lipids

- Tested and treated by National Cholesterol Education Program Adult Treatment Panel III guidelines

Cardiac

- EKG
- Echo if suspected Cardiac disease or Pulmonary HTN
- Cardiology consult for pts with Cardiac Disease
- B Blockers?

Pre Operative Goals

Tobacco

- Avoidance in all patients
 - 6 weeks before surgery
 - Forever after secondary to healing and ulcer risks

Pregnancy

- Avoid 12-18 months after surgery
- For pt with malabsorptive procedures
 - Discuss non-oral therapy
- Pregnancy after surgery should include nutrition labs every trimester
- Estrogen therapy should be discontinued prior to surgery
- Women should be informed that fertility may improve (esp PCOS)

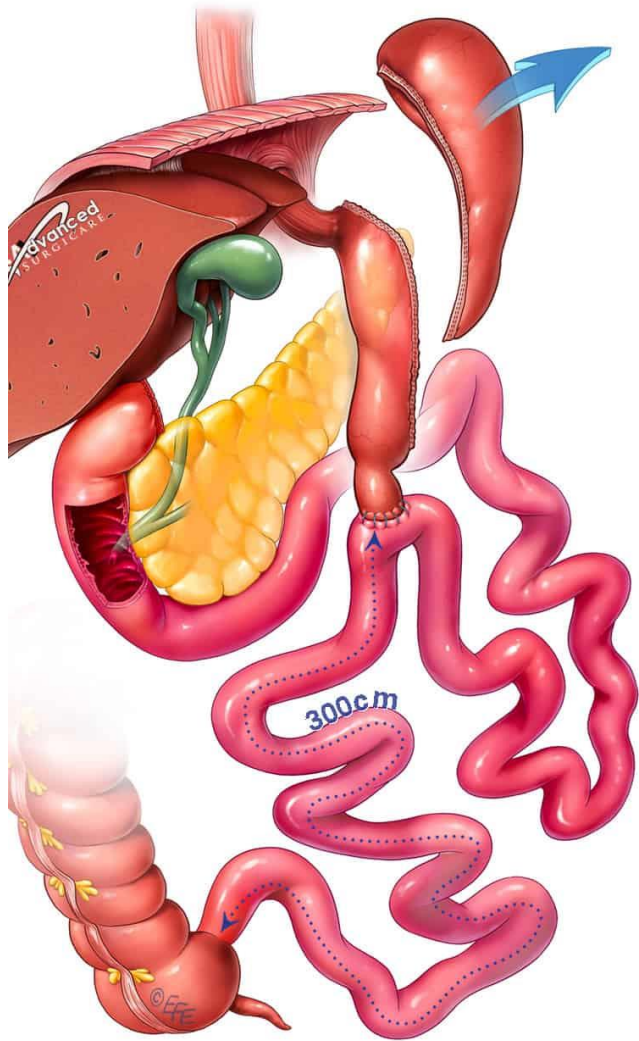
Anything New?



- We've had great success with current procedures
- Why look for new options?
 - Safer
 - More weight loss
 - Less side effects
 - Less Invasive
 - Less Weight Re-Gain

Surgical Therapies





SADI-S

- Becoming common as a second stage procedure after Sleeve Gastrectomy
- This is a modification of the duodenal switch
- Addresses some concerns associated with the traditional duodenal switch
 - Technically easier
 - Less malnutrition
 - Lower OR times
- Short term weight loss outcomes are comparable to traditional DS
- Decreased Vitamin deficiencies
- Comparable resolution of co-morbid conditions

SADI-S

- Retrospective Evaluation of 91 patients
- Recent 2 year FU
 - Decreased BMI by an average of 17.2 kg/m²
 - Noted 0% long term complications
 - OSA resolution – 94%
 - Type 2 Diabetes resolution – 94%
 - Hyperlipidemia resolution – 75%
 - Hypertension resolution – 68%
 - GERD resolution – 13%

Surve, A., Rao, R., Cottam, D. *et al.* Early Outcomes of Primary SADI-S: an Australian Experience. *OBES SURG* **30**, 1429–1436 (2020). <https://doi.org/10.1007/s11695-019-04312-6>

Endoscopic Therapies

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Gastric Balloon (Available in the US)

Orbera

- Fluid Filled
- Removed after 6 months



Obalon

- Air Filled
- No EGD for placement
- 3 smaller balloons placed over a 6-9 week period



Gastric Balloon (Non FDA Approved)

Elipse

- No EGD needed
- Fluid Filled
- Valve opens after 16 weeks

Spatz Adjustable Balloon

- Balloon size is adjustable (Can decrease volume for intolerance, can increase volume for more restriction)
- 12 month Removal Time



Orbera Outcomes

-
- Weight loss at 52 weeks (6 months after balloon removal)
 - 45.9% of the Orbera group achieved $\geq 25\%$ excess weight loss (up from 71.8% at balloon removal)
 - 32.6% of the diet alone group achieved $\geq 25\%$ EWL
 - Moderate difference in weight loss in Balloon group, but significant
- Recent Adverse Event Warning from FDA regarding Pancreatitis with the fluid filled balloons

A Randomized, Multi-Center Study to Evaluate the Safety and Effectiveness of an Intra-gastric Balloon As an Adjunct to a Behavioral Modification Program, in Comparison With a Behavioral Modification Program Alone in the Weight Management of Obese Subjects

Barham K. Abu Dayyeh, Laura L. Eaton, George Woodman, Anita Courcoulas, Daniel J. Pambianco, Christopher J. Gostout, et al.

Endoscopic Sleeve Gastroplasty

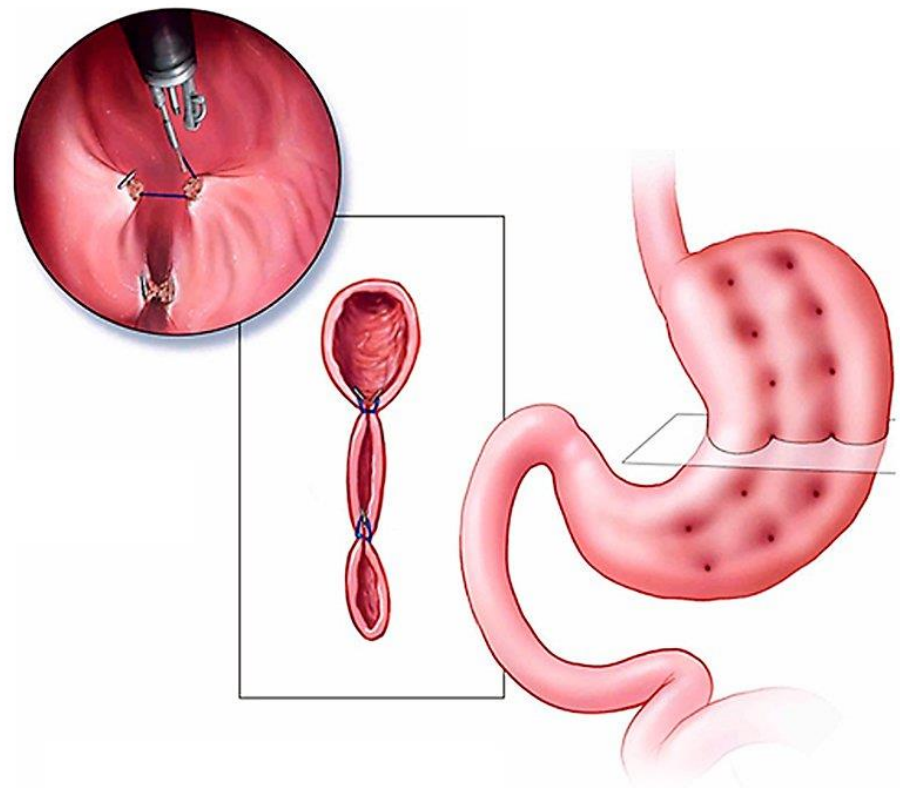
Decreases size of stomach endoscopically

Less weight loss than a gastric sleeve (45% EWL at one year)

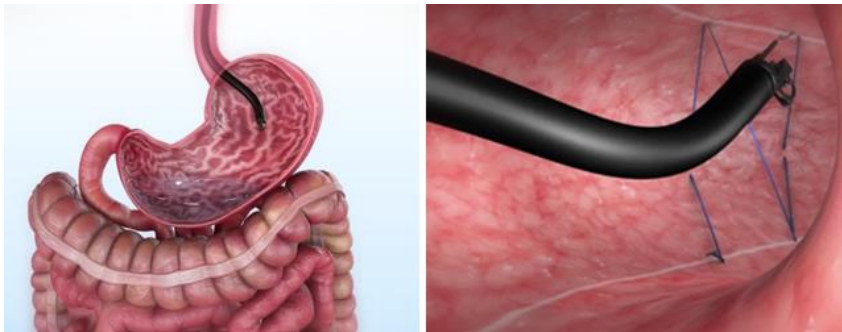
Not covered by insurance

Tend towards higher rates of weight gain

Used for patients with BMIs 30-40



Endoscopic Sleeve Gastroplasty



○ 5 year FU

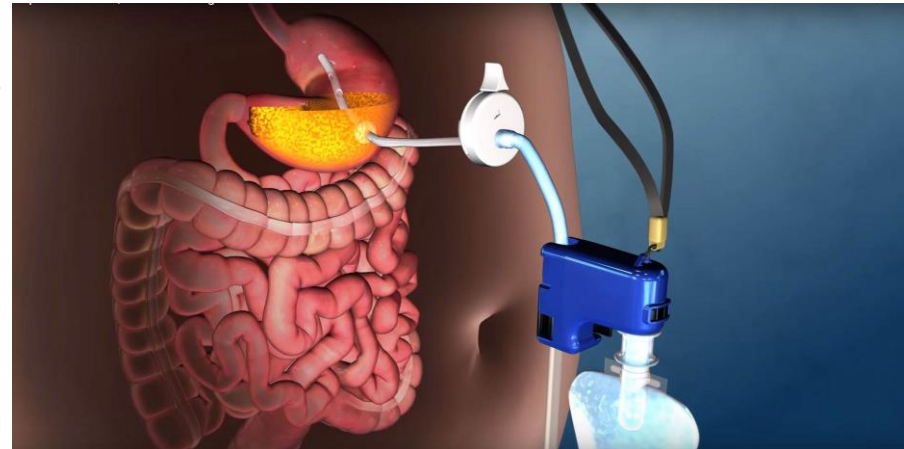
- One year weight loss 15.2% TBWL
 - TWL for sleeve at 12 months is approximately 30.5%
- At 5 years 15.5% TBWL
- At 5 years 10% achieved 10% TBWL
- Maximum weight loss at 24 months

- Meta Analysis shows
 - EWL for Lap Sleeve at 12 months – 69.3%
 - EWL for Endo Sleeve at 12 months – 63%

Aspiration Therapy

AspireAssist

- 37%-54% EWL at one year
- On average 3x more than lifestyle changes alone
- Placed like a PEG tube
- Aspirate 3x /day
- Removes approximately 30% of your meal



EndoBarrier

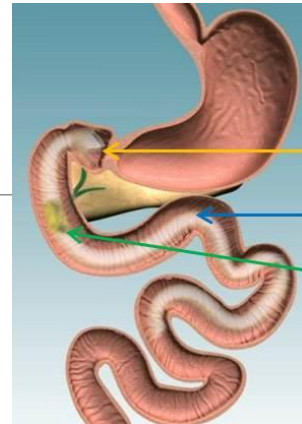
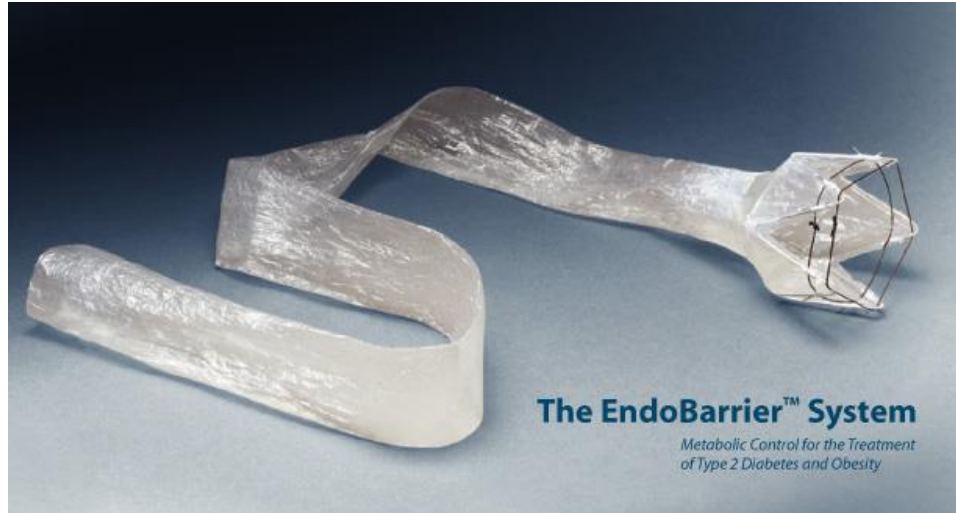


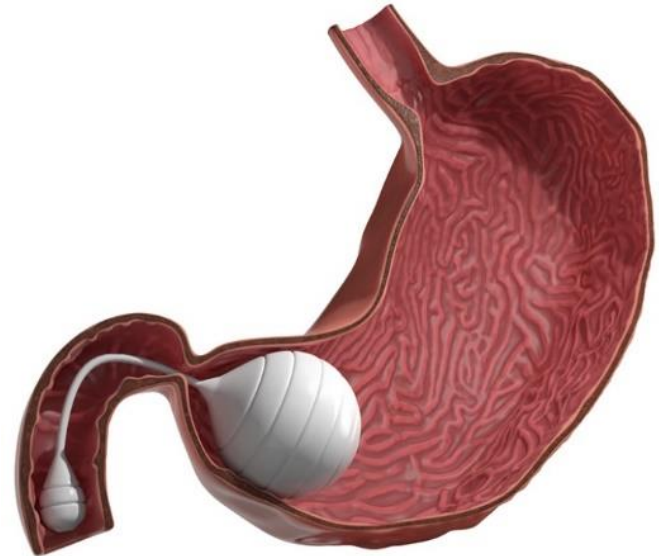
Figure demonstrating concept of the Endobarrier:

- ANCHOR** attaches to duodenum
- LINER** extends 60cm along duodenum and jejunum
- FOOD** passing through endobarrier without touching intestinal wall



Transpyloric Shuttle

- Two Bulbs Joined by a Flexible Catheter
- Facilitates Partial Gastric Outlet Obstruction



Incisionless Anastomosis

GI Windows

- Anastomosis created by compression
- 40% weight loss at one year
- Need for more safety and efficacy studies



The devices are connected to create a compression anastomosis



When the anastomosis is fully formed, the devices are passed



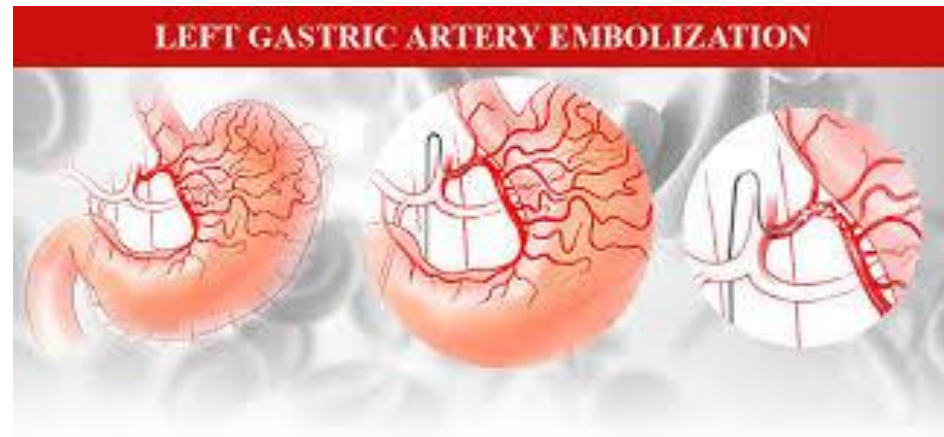
A treatment path is created, bypassing a portion of the small bowel

Interventional Radiology Therapies

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Left Gastric Artery Embolization

- Felt to decrease hunger by decreasing Ghrelin levels
- Very early data
- Not felt to be an adequate standalone weight loss procedure
- Initial study with about 14kg at 9 months but no fu data available



Summary

Overall weight loss surgery is extremely safe

Patient's live longer after weight loss surgery than without

Choice of surgery is multi factorial and often is patient choice

There are new procedures on the horizon

Pre operative optimization and preparation is essential to success