Bariatric Surgery: Current Status

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Center for Minimally Invasive Surgery
The Ohio State University

Mortality Hazard Ratios

<table>
<thead>
<tr>
<th>BMI</th>
<th>22.5-25</th>
<th>30-35</th>
<th>35-40</th>
<th>40-45</th>
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<tbody>
<tr>
<td>White Women</td>
<td>1.0</td>
<td>1.44</td>
<td>1.88</td>
<td>2.51</td>
</tr>
<tr>
<td>White Male</td>
<td>1.0</td>
<td>1.44</td>
<td>2.06</td>
<td>2.93</td>
</tr>
</tbody>
</table>

## Medical Sequelae of Obesity

- Hypertension
- Lipid disorders
- Diabetes
- Heart disease
- Pulmonary hypertension
- Asthma
- OSA
- Gallstones
- NASH (Non-alcoholic steatohepatitis)
- Urinary incontinence
- GERD
- Arthritis/back pain
- Infertility/menstrual problems
- DVT and PE
- Depression
- Immobility
- Breast/bowel/prostate/endometrial cancer
- Venous stasis ulcers
- Accident prone

## Obesity

- Still a problem worldwide
- Still costs a lot
- Still should be considered a disease
- Still carries a societal bias
- Surgery is still the best we have to offer patients that are severely obese
Age-adjusted Percentage of U.S. Adults Who Were Obese or Who Had Diagnosed Diabetes

### Obesity (BMI ≥30 kg/m²)

<table>
<thead>
<tr>
<th>Year</th>
<th>No Data</th>
<th>&lt;14.0%</th>
<th>14.0-17.9%</th>
<th>18.0-21.9%</th>
<th>22.0-25.9%</th>
<th>&gt;26.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>No Data</td>
<td>&lt;4.5%</td>
<td>4.5-5.9%</td>
<td>6.0-7.4%</td>
<td>7.5-8.9%</td>
<td>&gt;9.0%</td>
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<td>2000</td>
<td></td>
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<tr>
<td>2008</td>
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</table>

Age-adjusted Percentage of U.S. Adults Who Were Obese or Who Had Diagnosed Diabetes

<table>
<thead>
<tr>
<th>Year</th>
<th>Obesity (BMI ≥30 kg/m²)</th>
<th>Diabetes</th>
</tr>
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<tbody>
<tr>
<td>1994</td>
<td>No Data</td>
<td>&lt;14.0%</td>
</tr>
<tr>
<td>2000</td>
<td>14.0-17.9%</td>
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<td></td>
<td>22.0-25.9%</td>
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</tr>
<tr>
<td></td>
<td>&gt;26.0%</td>
<td>&gt;9.0%</td>
</tr>
</tbody>
</table>


Projected 2012

US diabetic Population 22.7 MM
OUS diabetic Population 226.5 MM

T2DM Projected Global Incidence

1 Wild et al Diabetes Care 27:1047–1053, 2004
### A Population at Risk

- An estimated 70 percent of diabetes risk in the U.S. can be attributed to excess weight.
- The prevalence of hypertension in adults who are obese (BMI > 30) is 41.9 percent for men and 37.8 percent for women.
- The prevalence of high cholesterol for adults who are obese (BMI > 30) is 22.0 percent for men and 27.0 percent for women.

### A Population at Risk

- Overweight and obesity could account for 14 percent of cancer deaths among men and 20 percent among women in the U.S.
- In both men and women, higher BMI is associated with higher death rates from cancers of the esophagus, colon and rectum, liver, gallbladder, pancreas, and kidney.
- The same trend applies to cancers of the stomach and prostate in men and cancers of the breast, uterus, cervix, and ovaries in women.
### NIH – Candidates for Surgery

- BMI 35 - 40 in patients with co-morbidities or severe lifestyle limitations
- BMI > 40 if patient desires surgery and has failed “conventional” treatment modalities
- FDA recently approved adjustable banding for BMI 30 - 35.

### Statistics on Weight Loss Surgery

- The number of gastric bypass surgeries climbed more than 600% from 1993 to 2003.
- The average bariatric surgery patient is a woman in her late 30s who weighs approximately 300 pounds.
- The average cost of the surgery is $30,000. However, many places offer self-pay options for less than $20,000 and band <$10,000.
Center of Excellence Outcome Data

BOLD (Bariatric Outcomes Longitudinal Database)

- Procedures:
  - Gastric bypass (54.8%), gastric banding (39.8%), sleeve gastrectomy (2.3%) and biliopancreatic diversion (0.9%).

- Complications:
  - Overall, 10.77% of patients experienced one or more complications following surgery.
  - Most complications were considered relatively minor, with nausea/vomiting reported as the most frequent complication post-discharge.

- Mortality:
  - The total mortality rate across all procedures was 0.135%, approximately one death per 1,000 patients.
  - Rates for 90- and 30-day all-cause mortality were 0.112% and 0.089%, respectively.
Outcomes

- Two studies, published in the *New England Journal of Medicine* in August 2007:
  - patients who have bariatric surgery (including gastric banding, gastric bypass, and vertical banded gastroplasty) lost significant weight over the long-term and are significantly less likely to die from heart disease, diabetes and cancer seven to 10 years following the procedure than those who did not have surgery.


Bariatric Surgery
The Roux-en-Y Gastric Bypass

- Pouch of $\leq 30$ cc
- Stoma of 12 - 14 mm
- Roux limb 75-150 cm or longer
- BP limb?

Adjustable gastric banding

- Small pouch (<20cc)
- Reversible
- Adjustable
- Often can be done as 23 hr. stay or less
Sleeve Gastrectomy

Newer Procedures

• Minimally invasive procedures
• Endoscopic interventions
Greater curve plication

![Image](image1.png)

**FIGURE 3.** Final suture line with running nonabsorbable suture

*Almino C. Ramos, MD; et al. Laparoscopic Greater Curvature Plication: An Alternative Restrictive Bariatric Procedure Bariatric Times. 2010;7(5):8–10*

Greater Curve Plication

- **Advantages**
  - No transection
  - Reversible (short term)
  - No malabsorption
  - Low complication rate

- **Disadvantages**
  - Unknown long-term outcomes
  - Nausea (short-term)

*Almino C. Ramos, MD; et al. Laparoscopic Greater Curvature Plication: An Alternative Restrictive Bariatric Procedure Bariatric Times. 2010;7(5):8–10*
Weight loss after greater curve plication

![Graph showing % EWL over time](image)

**FIGURE 5.** Percent excess weight loss up to 24 months


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**Emerging Technologies**

- **Endoscopic**
  - Endoscopic restriction
    - Banding
    - Sleeves
    - Bypass
  - Endoluminal sleeves for malabsorption
  - Space occupying
TOGA- Endoscopic Restriction

TOGA Sleeve Stapler

TOGA Restrictor

TOGA- Endoscopic restriction
**Gastric Pacing**

- **VBLOC**
- Electrical impulses directed at the vagus
- Can eat normally but with reduced satiety
- Only short term data available

**Endolumenal Sleeves**

Development and testing of an attachable gastric cuff and small intestinal exclusion sleeve as a new flexible endoscopic method for treatment of obesity. Mitchell Dann, Josh Butters, Mary Lynn Wilmore, Dick Thomas, Toni Baldwin, Clay Robinson, Ray Olsen, Paul Swain  
St Mary's Hospital and Imperial College, London, ValenTx, Inc, Wilson, Wyoming USA
### Primary Endoluminal Bariatric Procedures

- Endoluminal Stents for obesity

![Stent Image](image1)

### Space Occupying Devices

*BioEnterics Intragastric Balloon (BIB)*:

![BIB Image](image2)
Metabolic Surgery: Benefits and risks, where should it fit in the care plan of the obese patient?

Dara Schuster, MD
Associate Medical Director, Evidence Based Practice
Associate Professor
Ohio State University Medical Center

Obesity Surgery and Reduction in Long-Term Mortality

- Flum&Dellinger – surgical pts. had a 59% greater chance at 5yr survival than nonsurg obese pts.
- Christou, et.al. reported mortality rate of 0.67% vs. 6.17% in surg vs. nonsurg
- MacDonald, et.al. 6-9yr mortality 1% vs. 4.5% in surg vs. nonsurg
- Large comparative series of patients showed an 89% reduction in mortality over the 5 years following surgery, compared to a non-surgically treated group of patients
Resolution of Type 2 Diabetes Mellitus

*One prospective randomized study examining Lap-Band vs. Diet & exercise
  - After 2 years, remission rates 73% vs. 13%

**Meta-analysis of 621 studies that reported remission of diabetes
  - 78% had remission of DM post-operatively
  - 62% had remission at >2 years


Resolution of Type 2 Diabetes Mellitus
Swedish Obese Subjects Study

<table>
<thead>
<tr>
<th></th>
<th>Surgical</th>
<th>Control</th>
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<tbody>
<tr>
<td>2-yr incident %</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>10-yr incident %</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>2yr remission %</td>
<td>72</td>
<td>21</td>
</tr>
<tr>
<td>10yr remission %</td>
<td>36</td>
<td>13</td>
</tr>
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</table>

Extent of remission of T2DM was influenced by extent of weight loss, duration of diabetes, presurgery hypoglycemic requirements, bariatric procedure

Resolution of Hypertension

- Weight loss results in reduction in BP
- 60- to 80% resolution/improvement of HTN
- Amount of weight loss rather than the final postoperative weight predicted improvement
- Resolution of HTN appears to be independent of the type of surgery
- Relationship between the length of pre-existing HTN preoperatively and the likelihood for resolution
- Patients with complete resolution of HTN at 1 and 12 months after SURGERY had a shorter duration of disease


Resolution of Dyslipidemia

- The changes in the lipid panel appear to be procedure-dependent, 90% improvement in cholesterol and triglyceride levels after gastric bypass/biliopancreatic diversion as compared to 50-to 70% improvement with gastric banding and gastroplasty.
- The malabsorption, in addition to the associated weight loss, plays an important role
- Swedish Obesity Study
  - 2 and 10 yrs, significant improvement in HDL and triglycerides
  - Total cholesterol was not changed

### Resolution of NASH, OSA, Pseudotumor Cerebri

- **NASH** – decrease in severity. Steatosis disappeared in 84% and fibrosis disappeared in 75% of the patients. Hepatocellular ballooning disappeared in 50% 2 years after surgery.
- **OSA** - 85.7-93% resolution, not procedure dependent but % weight loss.
- **Pseudotumor Cerebri** – success rates are higher than results of shunt placement. TOC No long term studies examining recurrence


### Definitions of Weight Loss Success

- **Weight loss**
  - >50% EBWL
- **Resolution of Co-morbidities**
  - Diabetes, HTN, OSA, Joint pains, Dyslipidemias, Venous Stasis, GERD
- **Patient Satisfaction** – discussion before the surgery occurs as to the patient’s personal goals and expectations
Anticipated Weight Loss

A meta-analysis from University of California, Los Angeles reports the following weight loss at 36 months

- Biliopancreatic diversion - 53 kg
- Roux-en-Y gastric bypass (RYGB) - 41 kg
- Adjustable gastric banding - 35 kg
- Vertical banded gastroplasty - 32 kg


Predictors of Successful Weight Loss

- Surgeon follow-up
- Attendance of postoperative support groups
- Physical activity
- Marital status
- Self-esteem
- Binge eating

Long-term, Non-Surgical Complications of Weight Loss Surgery

- Macronutrient deficiencies
- Micronutrient deficiencies
- Hypoglycemia
- Metabolic bone disease
- Psychological disease

Nutritional & Metabolic Complications

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>LAGB</th>
<th>Sleeve G</th>
<th>RYGB</th>
<th>BPD</th>
<th>BPD-DS</th>
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</thead>
<tbody>
<tr>
<td>Iron</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Thiamine</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Folate</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Calcium</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Protein</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Fat Vitamins</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+++</td>
<td>+++</td>
</tr>
</tbody>
</table>

+ standard multivitamin preparation likely to be sufficient.
++ Significant risk of deficiency or increased requirements.
+++ High risk of deficiency.

Hypoglycemia

- Rare occurrence
- Etiology unknown
- Considered a late complication
- Hyperinsulinemic hypoglycemia
  - Adaptive beta cell hypertrophy due to the obese insulin resistant state
  - Nesidioblastosis after surgery

Metabolic Bone Disease

- Multifactorial – related to calcium deficiency, vitamin D deficiency and weight loss itself
- At 10yrs. post RYGB, increased alkphos, low Ca, low vit D.
- At 4yrs., hypocalcemia increased from 15 to 48%
- As early as 3-9mon, patients have demonstrated increased bone markers
Prevention of Bone Disease

- Supplementation is recommended for all RYGB patients
- 1200-1500mg elemental calcium
- Calcium citrate plus vitamin D preferred
- Consider DEXA scan if evidence of calcium deficiency

Weight Regain- Failure

- Weight regain at 10 years post-op
  - There was a significant ($P < 0.0001$) increase in BMI in both morbidly obese (BMI < 50 kg/m²) and super obese patients (BMI > 50 kg/m²) from the nadir to 5 years and from 5 to 10 years.
  - There was a significant increase in failures and decrease in excellent results at 10 years when compared with 5 years.
  - The failure rate when all patients are followed for at least 10 years was 20.4% for morbidly obese patients and 34.9% for super obese patients.

Steps to Weight Loss Success After Bariatric Surgery

<table>
<thead>
<tr>
<th>Steps to Weight Loss Success After Bariatric Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Control food portions for calorie reduction – forever!</td>
</tr>
<tr>
<td>• Eat healthy foods (high in nutrition, low in calories)</td>
</tr>
<tr>
<td>• Engage in physical activities <em>daily</em></td>
</tr>
<tr>
<td>• Nutritional counseling and “refresher courses”</td>
</tr>
<tr>
<td>• Participate in counseling to deal with the emotional and mental aspects of obesity and weight loss surgery</td>
</tr>
<tr>
<td>• Participate in bariatric support groups, have an accountability group</td>
</tr>
<tr>
<td>• Set Goals - Monitor success of weight loss</td>
</tr>
</tbody>
</table>

Long-Term Follow-Up Care for the Weight Loss Surgery Patient

<table>
<thead>
<tr>
<th>Long-Term Follow-Up Care for the Weight Loss Surgery Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifelong monitoring, Nutritional deficiencies can occur at any time over the years</td>
</tr>
<tr>
<td>Tests performed 3-6month intervals for first 2 years, yearly thereafter</td>
</tr>
<tr>
<td>• Complete blood count</td>
</tr>
<tr>
<td>• Chem 10</td>
</tr>
<tr>
<td>• Albumin/pre-albumin</td>
</tr>
<tr>
<td>• B&lt;sub&gt;12&lt;/sub&gt;, folate</td>
</tr>
<tr>
<td>• Fat soluble vitamins*</td>
</tr>
<tr>
<td>• Uric Acid</td>
</tr>
<tr>
<td>• PTH</td>
</tr>
<tr>
<td>• Iron</td>
</tr>
<tr>
<td>• Social and Emotional issues</td>
</tr>
<tr>
<td>• Presence of maladaptive behavior - addictions</td>
</tr>
</tbody>
</table>
What We Don’t Know About Weight Loss Surgery

- How to define success?
- What is the best age for surgery?
- What is the correction procedure for a given patient scenario?
- Patient selection – need for revisional surgery
- What is the best titration plan for medications?

Position Statements

- IDF – “Bariatric surgery is an appropriate treatment for people with type 2 diabetes and obesity (BMI equal to or greater than 35) not achieving recommended treatment targets with medical therapies, especially where there are other obesity related co-morbidities”.
- ADA – “Bariatric surgery should be considered for adults with BMI 35 kg/m2 and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy”. (B)