Session 9 PD, Appropriate Treatment of Obesity Demonstrates Clinical & Economic Success

**Moderator:**
John D. Dawson, FSA, MAAA

**Presenters:**
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Appropriate Treatment of Obesity Demonstrates Clinical & Economic Success

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Eric S. Bour, MD, MBA, FACS, FASMBS
Anuprita D. Patkar, PhD
John Dawson, FSA, MAAA

Treating Obesity in America

The Implications to Our Health & Economy

Natalie Heidrich, MS
Field Director, Health Policy & Economics
Health Economics & Market Access
Ethicon US, LLC

Obesity is an Epidemic

OBESITY RATES AMONG US ADULTS
(BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)

INCREASES IN OBESITY IN THE USA: 2000–2010

81.5 Million Obese Americans
33.7 Million Severely Obese

225,000 Bariatric Surgery Procedures Annually
(1.5% of eligible population seeks surgery)
# Defining Obesity

## BMI Classification

<table>
<thead>
<tr>
<th>BMI</th>
<th>Clinical Classification</th>
<th>Approximate Population %</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.5 to 24.9</td>
<td>Normal Weight</td>
<td>32%*</td>
</tr>
<tr>
<td>25 to 29.9</td>
<td>Pre-obese</td>
<td>34%</td>
</tr>
<tr>
<td>30 to 34.9</td>
<td>Obesity 1</td>
<td>20%</td>
</tr>
<tr>
<td>35 to 39.9</td>
<td>Obesity 2</td>
<td>8%</td>
</tr>
<tr>
<td>40 or more</td>
<td>Obesity 3</td>
<td>6%</td>
</tr>
</tbody>
</table>

*Normal weight population percentage includes underweight persons. All data shown for United States.


The Cost of Inaction

• Currently, US spends between $147 billion\(^1\) to $190 billion\(^2\) annually on obesity-related healthcare expenses.

• Obesity-related illness is predicated will raise national health care costs by $48-$66 billion annually over the next 2 decades by adding another 7.9 million new cases of diabetes, 5 million cases of chronic heart disease and stroke, and 400,000 cancer cases.\(^3\)

• If obesity prevalence in the US stabilizes at 2010 rates and does not climb to the predicted level (42% by 2030), the US would save a combined $549.5 billion in medical expenditures.\(^4\)

\(^{1}\)Finkelstein EA et al. Annual medical spending attributable to obesity: payer- and service-specific estimates. Health Aff. 2009


\(^{3}\)Trust for America and Robert Wood Johnson Foundation. F as in Fat. 2013

Obese Patients Incur Higher Hospital Costs

Adjusted total inpatient hospital costs

3.7% HIGHER

($648 per capita cost) in obese patients compared to matched non-obese patients

Greater medical utilization compared to normal weight


Obesity Counseling is a Reimbursable Preventive Service

As part of the PPACA, preventive services are covered at no cost to patients. In that list is obesity counseling.

How do we Treat the Disease of Obesity?

Genetics
Genetic factors may account for as much as 80% of a person’s tendency to develop obesity.

“Obesity is a complex… chronic disease that… involves the integration of social, behavioral, cultural, physiological, metabolic and genetic factors.”
National Institutes of Health, 1998

Lifestyle
“More people drive long distances instead of walking, live in neighborhoods without sidewalks, tend to eat out or get ‘take out’ … Our environment often does not support healthy habits.”

Culture and Social Networks
A person’s chance of becoming obese increased by 57% if he or she had a friend who became obese; by 37% if his or her spouse was obese.

Continuum of Care

- BMI ≥35 with co-morbidities
- BMI ≥40 without co-morbidities
- BMI ≥27 with co-morbidities
- BMI ≥30 without co-morbidities
- BMI ≥25

Treating Severe Obesity

- Bariatric surgery is currently the most effective long-term treatment for obesity\(^1\)
- Some weight regain is normal\(^2\)
- Benefits of weight loss and alleviation of obesity-related conditions (even if just for short term) still result in healthier lifestyle\(^2\)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Average Weight Loss at 3 Years</th>
<th>Average Weight Loss at 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet and exercise</td>
<td>-0.1(^3)</td>
<td>-1.6(^3)</td>
</tr>
<tr>
<td>Drug therapy</td>
<td>10.7(^4),(^*)</td>
<td>Not enough data</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric Bypass</td>
<td>71.2(^5)</td>
<td>60.5(^6)</td>
</tr>
<tr>
<td>Sleeve Gastrectomy</td>
<td>66.0(^7)</td>
<td>49.0(^6)</td>
</tr>
<tr>
<td>Gastric Banding</td>
<td>55.2(^5)</td>
<td>29.5(^6)</td>
</tr>
</tbody>
</table>


This value represents follow-up of 108 weeks.
Bariatric surgery impacts obesity-associated diseases: Comorbidity reduction as found in various studies

Migraines
46% improved

Depression
47% reduced

Pseudotumor cerebri
96% resolution of headaches
95% resolution of pulsatile tinnitus

Obstructive sleep apnea
45% to 76% resolved

High cholesterol*
71% to 94% improved

Asthma
39% resolved

High blood pressure
42% to 66% resolved

Nonalcoholic fatty liver disease
37% resolution of steatosis

Metabolic syndrome
80% resolved

GERD
72% to 95% resolved

Type 2 diabetes
20% to 84% controlled

Polycystic ovarian syndrome
52% resolution of hirsutism
100% resolution of menstrual dysfunction

Urinary stress incontinence
50% resolved

Osteoarthritis/degenerative joint disease
41% resolved

Venous stasis disease
95% resolution of venous stasis ulcers

Resolution observed in the confines of studies. Ethicon has no independent data to suggest permanent resolution.

*Figure is for hyperlipidemia. Comorbidity reduction as found and relevant to females. Hyperlipidemia is a general term for high fats in blood, which may include cholesterol and/or triglycerides. See end of presentation for references.
Positive Trends in Obesity Surgical Innovation

Obesity Recognition May Increase Accessibility, Applications of Treatment

1. Economy Recovery Post-Recession
2. Research Supporting Broader Clinical Implications
3. Rising Obesity Rate & Classification of Obesity as a Disease
4. Favorable Reimbursement
5. Growing Cultural Acceptance of Bariatric Surgery

Obesity is a Disease

Recognizing obesity as a disease will help change the way the medical community tackles this complex issue that affects approximately one in three Americans.”

Patrice Harris, MD
Board Member
American Medical Association

National Coverage of Bariatric Surgery

State Mandates: NH, OK, CA, IN (HMOs only)

- Coverage Policy in Place
- No Coverage Policy in Place

Current as of 3-10-16 Coverage may have changed since this printing. 048980-160310
National Coverage of Bariatric Surgery

State Mandates: MD, NH, CA, IN Group Health Plans (HMOs only)

- Coverage Policy in Place
- No Coverage Policy in Place
- Coverage Pilot in Process

Partial Coverage: WI (<20% of population)

State Employee Coverage

Current as of 3-10-16  Coverage may have changed since this printing.
National Coverage of Bariatric Surgery

Essential Health Benefits Benchmarks

CO: Coverage begins in 2017

Coverage Policy in Place

No Coverage Policy in Place

Source: Center for Consumer Information and Insurance, Aug 2014.

Current as of 3-10-2016; Coverage may have changed since this printing. 048980-160310
National Coverage of Bariatric Coverage

US EMPLOYER SIZE, 2006-2014

Benefit Plan Designs

- Restrict to Centers of Excellence
- Create narrow networks
- Set co-insurance rates different than other surgical procedures
- Eligibility only after a defined employment period

Medical Policy

- 3, 6 or 12 month pre-surgical weight loss requirement
- Allow or limit revision or conversion procedures
- Only 1 bariatric procedure/lifetime

Other Administrative Designs:

- Employers contract directly with Hospitals or systems
- Establish a bundled payment to include complications
- Contract with bariatric providers to Include Obesity Management (medical management)

NOT ALL ARE SUPPORTIVE OF PATIENTS SEEKING TREATMENT
BARIATRIC SURGERY: INDICATIONS FOR SURGICAL INTERVENTION AND CLINICAL OUTCOMES

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President, Hillcrest Memorial Hospital and Simpsonville Medical Campus
Chair, Greenville Health System Quality and Patient Safety Council
Chair, GHS Innovative Reimbursement Model (Bundled Payment) Steering Committee
Associate Professor of Surgery, University of South Carolina School of Medicine - Greenville
Surgeon, UMG Bariatric and Minimal Access Surgery
Greenville Health System, Greenville, SC
WHY IS IT SO DIFFICULT TO LOSE WEIGHT – AND KEEP IT OFF?

The body has a complex system that manages weight and body fat levels

• Its job is to keep weight relatively steady around a “set point” or weight range

• **Set points** are determined and affected by genetic, developmental and environmental factors

• When people develop obesity, their **set points** become too high and their bodies work to maintain this higher, unhealthy weight

• Dieting to reduce weight below the **set point** causes the body to release hormones that encourage weight regain

• Without medical intervention, many patients are unsuccessful managing their weight and obesity-related conditions long-term
ADULT SURGERY GUIDELINES

• BMI > 40, or >35 with at least two medical comorbidities

• Severe obesity duration > 3-5 years

• Failure of medical management
ADOLESCENT OBESITY

• Demographics:
  • Incidence of pediatric obesity has increased from 4% in 1971 to 17% in 2012
  • South Carolina ranks 2\textsuperscript{nd} highest in US for adolescent obesity (21.5%)
  • 1 in 6 high school students are overweight

• Comorbidities:
  • Incidence of Diabetes > 30%
  • Increased incidence of cardiovascular disease
  • Obstructive sleep apnea incidence > 55%
  • NAFLD (non-alcoholic fatty liver disease) > 80%
WHAT HAPPENS TO THE OBESE ADOLESCENT?

- Overweight children become overweight adults more than 75% of the time
- There are also increases in:
  - Overall mortality
  - Heart disease
  - Malignancy
  - Joint problems
  - Infertility
ADOLESCENT SURGERY GUIDELINES

• Have failed > 6 months of organized attempts at weight loss in a multidisciplinary weight-loss program
• BMI > 95th %ile with serious comorbidities, or BMI > 99th %ile with less severe comorbidities
• Have attained skeletal and physiologic maturity
• Commit to comprehensive medical and psychological evaluations before and after surgery
• Have a supportive family environment
ADDITIONAL SURGERY GUIDELINES

• “Patients who are candidates for surgical procedures should be selected carefully after evaluation by a multidisciplinary team with medical, surgical, psychological/psychiatric, and nutritional expertise.”

• “The operation should be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of management and assessment.”

• “Lifelong medical surveillance after surgical therapy is a necessity.”

### MOST COMMON BARIATRIC PROCEDURES

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
<th>% of procedures performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROUX-EN-Y GASTRIC BYPASS</td>
<td>Bypass a portion of the small intestine and create a 15- to 30-cc stomach pouch</td>
<td>40%</td>
</tr>
<tr>
<td>SLEEVE GASTRECTOMY</td>
<td>Resect approximately three-fourths of the stomach</td>
<td>50%</td>
</tr>
<tr>
<td>LAPAROSCOPIC Adjustable GASTRIC BANDING</td>
<td>Place implantable device around the uppermost part of the stomach</td>
<td>5%</td>
</tr>
<tr>
<td>BILIOPANCREATIC DIVERSION (± DUODENAL SWITCH)</td>
<td>Remove part of the small intestine; performed with or without duodenal switch</td>
<td>5%</td>
</tr>
</tbody>
</table>
SAFETY PROFILE FOR BARIATRIC SURGERY

- Clinical evidence suggests that the risks associated with morbid obesity may outweigh the risks associated with metabolic and bariatric surgery.
- Most procedures (>90%) are performed laparoscopically due to significant advancements in laparoscopic technique.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Complications</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bariatric surgeries</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric bypass</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Gastric banding</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td><strong>Other common procedures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colectomy</td>
<td>2.4%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>0.4%</td>
<td>*</td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>0.9%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Hip replacement</td>
<td>1.0%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>
BENEFITS OF BARIATRIC SURGERY

• Resolving obesity-related diseases for many patients
• Lowering the body weight set point and changing the hormone signals in the body
• Decreasing appetite
• Increasing feeling of fullness
• Speeding metabolism
• Eliminate cravings
• Discovering life at a healthier weight
5-YEAR MORTALITY REDUCTION

Surgical Patients Had **Nine Times** Lower Risk of Dying Within the Study Period

* Includes perioperative (30-day) mortality of 0.4%
STUDY METHODS

• Data obtained from Optum Clinformatics Data Mart
• Patients ≥18 years of age
• Surgery between 2006 and 2013
• Surgical procedures included:
  • Laparoscopic adjustable gastric banding (LAGB)
  • Laparoscopic Roux-en-Y gastric bypass (LRYGB)
  • Laparoscopic sleeve gastrectomy (LSG)
• All patients were required to have a diagnosis of obesity and one or more obesity related comorbidity (T2DM, hypertension, dyslipidemia, depression, sleep apnea) during the baseline period (12-month period prior to surgery date).
STUDY METHODS

• Surgical patients were matched to medically-managed patients (controls) based on:
  • Age
  • Gender
  • Obesity category
  • Insurance type
  • Obesity-related comorbidity profile

• Preferential matching of patient cohorts was also conducted based on:
  • Average baseline monthly healthcare costs (within 15% or $150)
  • Age (within 5 years)
  • Continuous enrollment (at least 1 year after the 60-day post-surgery recovery period)
STUDY METHODS

- Management of comorbidities was evaluated every 6 months up to 5 years

- Measurements of glycosylated hemoglobin (HbA1c) and lipids were additionally evaluated annually for up to 5 years

- Incidences of the composite endpoint of death, stroke, and myocardial infarction requiring hospitalization were also assessed
TYPE OF BARIATRIC SURGERY

- LAGB: 545, 6%
- LRYGB: 4,308, 48%
- LSG: 4,208, 46%
RESULTS: DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

- Patients who underwent LAGB, LRYGB, and LSG and patients in the combined control cohort were similar in age.
- The majority of all study cohorts were female.
- Approximately 88% of all study cohorts had a baseline BMI >40 kg/m².

Although bariatric surgery cohorts were matched to controls on overall baseline monthly healthcare costs, there were differences in the attributes of the overall costs:
- The surgery cohorts had higher medication costs.
- The controls had higher medical costs.
### RESULTS: DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th></th>
<th>LAGB N=4,208</th>
<th>Control N=4,208</th>
<th>LRYGB N=4,308</th>
<th>Control N=4,308</th>
<th>LSG N=545</th>
<th>Control N=545</th>
<th>Combined Control N=9,061</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (Stdev)</td>
<td>46.3 (9.9)</td>
<td>46.4 (9.8)</td>
<td>46.4 (9.8)</td>
<td>46.5 (9.7)</td>
<td>45.1 (9.7)</td>
<td>45.1 (9.6)</td>
<td>46.4 (9.8)</td>
</tr>
<tr>
<td>Median</td>
<td>47</td>
<td>47</td>
<td>47</td>
<td>47</td>
<td>45</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td><strong>Age Group (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤30</td>
<td>260 (6.2%)</td>
<td>241 (5.7%)</td>
<td>221 (5.1%)</td>
<td>215 (5.0%)</td>
<td>35 (6.4%)</td>
<td>38 (7.0%)</td>
<td>494 (5.5%)</td>
</tr>
<tr>
<td>31-40</td>
<td>1,003 (23.8%)</td>
<td>1,003 (23.8%)</td>
<td>1,070 (24.8%)</td>
<td>1,026 (23.8%)</td>
<td>142 (26.1%)</td>
<td>137 (25.1%)</td>
<td>2,166 (23.9%)</td>
</tr>
<tr>
<td>41-50</td>
<td>1,417 (33.7%)</td>
<td>1,429 (34.0%)</td>
<td>1,432 (33.2%)</td>
<td>1,462 (33.9%)</td>
<td>198 (36.3%)</td>
<td>202 (37.1%)</td>
<td>3,093 (34.1%)</td>
</tr>
<tr>
<td>51-60</td>
<td>1,247 (29.6%)</td>
<td>1,248 (29.7%)</td>
<td>1,291 (30.0%)</td>
<td>1,321 (30.7%)</td>
<td>142 (26.1%)</td>
<td>140 (25.7%)</td>
<td>2,709 (29.9%)</td>
</tr>
<tr>
<td>≥61</td>
<td>281 (6.7%)</td>
<td>287 (6.8%)</td>
<td>294 (6.8%)</td>
<td>284 (6.6%)</td>
<td>28 (5.1%)</td>
<td>28 (5.1%)</td>
<td>599 (6.6%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3,139 (74.6%)</td>
<td>3,139 (74.6%)</td>
<td>3,265 (75.8%)</td>
<td>3,265 (75.8%)</td>
<td>378 (69.4%)</td>
<td>378 (69.4%)</td>
<td>6,782 (74.8%)</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-40 kg/m²</td>
<td>505 (12.0%)</td>
<td>505 (12.0%)</td>
<td>493 (11.4%)</td>
<td>493 (11.4%)</td>
<td>61 (11.2%)</td>
<td>61 (11.2%)</td>
<td>1,059 (11.7%)</td>
</tr>
<tr>
<td>≥40 kg/m²</td>
<td>3,703 (88.0%)</td>
<td>3,703 (88.0%)</td>
<td>3,815 (88.6%)</td>
<td>3,815 (88.6%)</td>
<td>484 (88.8%)</td>
<td>484 (88.8%)</td>
<td>8,002 (88.3%)</td>
</tr>
</tbody>
</table>

Patients who underwent LAGB, LRYGB, and LSG and patients in the combined control cohort were similar in age and the majority of all study cohorts were female. Approximately 88% of all study cohorts had a baseline BMI >40 kg/m².
### RESULTS: DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

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<th>Control N=545</th>
<th>Combined Control N=9,061</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Obesity Related Comorbidities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T2DM</td>
<td>1,321 (31.4%)</td>
<td>1,321 (31.4%)</td>
<td>1,664 (38.6%)</td>
<td>1,664 (38.6%)</td>
<td>172 (31.6%)</td>
<td>172 (31.6%)</td>
<td>3,157 (34.8%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>2,157 (51.3%)</td>
<td>2,157 (51.3%)</td>
<td>2,241 (52.0%)</td>
<td>2,241 (52.0%)</td>
<td>262 (48.1%)</td>
<td>262 (48.1%)</td>
<td>6,555 (72.3%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3,006 (71.4%)</td>
<td>3,006 (71.4%)</td>
<td>3,152 (73.2%)</td>
<td>3,152 (73.2%)</td>
<td>397 (72.8%)</td>
<td>397 (72.8%)</td>
<td>4,660 (51.4%)</td>
</tr>
<tr>
<td>Depression</td>
<td>1,145 (27.2%)</td>
<td>1,145 (27.2%)</td>
<td>1,383 (32.1%)</td>
<td>1,38 (32.1%)</td>
<td>138 (25.3%)</td>
<td>138 (25.3%)</td>
<td>2,664 (29.4%)</td>
</tr>
<tr>
<td>Sleep Apnea</td>
<td>1,654 (39.3%)</td>
<td>1,654 (39.3%)</td>
<td>2,055 (47.7%)</td>
<td>2,05 (47.7%)</td>
<td>248 (45.5%)</td>
<td>248 (45.5%)</td>
<td>3,951 (43.6%)</td>
</tr>
<tr>
<td><strong>Pre-surgery Cost per Month</strong></td>
<td>$925 ($1,189)</td>
<td>$925 ($1,188)</td>
<td>$995 ($1,151)</td>
<td>$995 ($1,150)</td>
<td>$906 ($1,050)</td>
<td>$905 ($1,078)</td>
<td>$957 ($1,164)</td>
</tr>
<tr>
<td>Mean (Stdev)</td>
<td>$925 ($1,189)</td>
<td>$925 ($1,188)</td>
<td>$995 ($1,151)</td>
<td>$995 ($1,150)</td>
<td>$906 ($1,050)</td>
<td>$905 ($1,078)</td>
<td>$957 ($1,164)</td>
</tr>
<tr>
<td>Median</td>
<td>$925</td>
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<td>$995</td>
<td>$995</td>
<td>$906</td>
<td>$905</td>
<td>$957</td>
</tr>
</tbody>
</table>

Although, all 3 laparoscopic bariatric surgery cohorts were matched to controls on overall baseline monthly healthcare costs, there were differences in the attributes of the overall costs in that the surgery cohorts had higher medication costs and controls had offsetting higher medical costs.
The increase in the percentage of patients medication-free for the treatment of T2DM was consistent for up to 5 years among T2DM patients in cohorts with LAGB and LRYGB (50.6% and 74.9%, respectively).
One year post-index, use of insulin among patients with T2DM declined from the baseline period among study cohorts with LAGB (20.8% to 14.2%), LRYGB (27.8% to 8.7%), and LSG (19.8% to 5.2%), but increased among the combined control group (17.0% to 18.7%).
For the subset of T2DM patients with HbA1c measurements (36%), mean HbA1c levels were lower among patients who had LAGB (6.5%), LRYGB (5.9%), and LSG (6.2%) than among the combined control group (7.2%).
The increase in the percentages of patients medication free for the treatment of dyslipidemia was consistent up to 4 years for the study cohort with LSG (75.0%) and up to 5 years among study cohorts with LAGB and LRYGB (51.2% and 73.7%, respectively).
The increase in the percentage of patients medication-free for the treatment of hypertension was consistent up to 5 years among study cohorts with LAGB and LRYGB (35.3% and 56.4%, respectively).
### INCIDENCE OF THE COMPOSITE ENDPOINT OF DEATH, MYOCARDIAL INFARCTION & STROKE WITH HOSPITALIZATION AMONG THE STUDY COHORTS

<table>
<thead>
<tr>
<th></th>
<th>LAGB</th>
<th>P-value LAGB vs. Control</th>
<th>LRYGB</th>
<th>P-value LRYGB vs. Control</th>
<th>LSG</th>
<th>P-value LSG vs. Control</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>4,208</td>
<td></td>
<td>4,308</td>
<td></td>
<td>545</td>
<td></td>
<td>9,061</td>
</tr>
<tr>
<td>Baseline</td>
<td>0.31%</td>
<td>&lt;0.01</td>
<td>0.26%</td>
<td>&lt;0.01</td>
<td>0%</td>
<td>1.0</td>
<td>0.68%</td>
</tr>
<tr>
<td>Recovery Period (60 days Post-index)</td>
<td>0.12%</td>
<td>0.53</td>
<td>0.49%</td>
<td>&lt;0.001</td>
<td>0%</td>
<td>1.0</td>
<td>0.09%</td>
</tr>
<tr>
<td>Up to 2 Year Post-recovery Period</td>
<td>0.93%</td>
<td>0.20</td>
<td>0.72%</td>
<td>0.01</td>
<td>0.55%</td>
<td>0.21</td>
<td>1.15%</td>
</tr>
<tr>
<td>N for 2-5 Year Post-recovery Period</td>
<td>3,137</td>
<td></td>
<td>3,051</td>
<td></td>
<td>371</td>
<td></td>
<td>8,006</td>
</tr>
<tr>
<td>2-5 Year Post-recovery Period</td>
<td>1.34%</td>
<td>0.03</td>
<td>1.21%</td>
<td>&lt;0.01</td>
<td>0.81%</td>
<td>0.16</td>
<td>1.80%</td>
</tr>
</tbody>
</table>

- In the 2 years post-recovery, patients with LRYGB had a lower incidence of the composite endpoint than the combined control group.
- In the 2-5 years post-recovery patients with LRYGB and LAGB had lower incidences of the composite endpoint than the combined control group.
Patients who underwent surgery had substantial risk reductions for death/MI/stroke, chronic kidney disease, and NAFLD 0-2 years post-surgery.
SUMMARY

- Bariatric surgery is safe – especially as compared to many other complex procedures
- Bariatric surgery is effective in reducing medication burden for T2DM, dyslipidemia, and hypertension
- Bariatric surgery reduces medical sequelae of morbid obesity including stroke, MI, and NAFLD
- Bariatric surgery reduces the composite endpoint of stroke, MI and death within 2 years following the index procedure
ECONOMIC SECTION
US Payer Panel Appropriate Treatment of Obesity Demonstrates Clinical & Economic Success
Anuprita D. Patkar, PhD
Global Director, Health Economics & Market Access
ETHICON | Johnson & Johnson
Economics of Obesity
Recap of the Big Picture

Direct and Indirect costs of morbid obesity high

In the US, the annual cost of obesity-related expenditures ranges $147-$190 billion

Medical costs can be ~30% higher when treating an obese patient

Only 20% of patients on dietary treatment maintain a weight loss

About 25% of patients considering surgery are denied approval at least 3x before obtaining approval, by then, 60% will report worsening health problems

Most of the costs of obesity are related to the chronic comorbidities of diabetes, hypertension, and cardiovascular disease

Versus Normal weight, Obese:
- 42% higher Annual costs
- 77% higher prescription costs
- 37% higher primary care costs
Examining the Economic Benefits of Bariatric Surgery
Recent Economic Evidence Insurance Claims Assessment

- Second aim of the retrospective Optum Insurance Claims assessment was to estimate the economic impact of the clinical benefits of bariatric surgery on medical costs and return on investment (RoI) of the surgery in morbidly obese patients with comorbidities: Type 2 Diabetes (T2DM), Dyslipidemia, Hypertension (HTN)

- Data Source: de-identified claims of an administrative claims database Optum Clininformatics Datamart (claims of privately insured enrollees from throughout the United States)

- Data Timeframe: Data from 2006-2013 were accessed
Examining the Economic Benefits of Bariatric Surgery
Methods: Study Design Recap

Each surgery cohort was matched to a non-surgical control on their socio-demographic and comorbid characteristics

<table>
<thead>
<tr>
<th>6 Cohorts in the Study</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic BM Surgery Cohorts</td>
<td>Matched Control Cohort (non-surgery)</td>
</tr>
<tr>
<td>Banding (LAGB)</td>
<td>Banding Control</td>
</tr>
<tr>
<td>Bypass (LRYGB)</td>
<td>Bypass Control</td>
</tr>
<tr>
<td>Sleeve (LSG)</td>
<td>Sleeve Control</td>
</tr>
</tbody>
</table>
Examining the Economic Benefits of Bariatric Surgery

Methods: Economic Outcome Measures

- The economic outcome measures were compared between surgery and control patients, at baseline and every 6 months up to 5 years among all patients in study cohorts.

- For each obese comorbidity cohort (T2DM/ HTN/ Hyperlipidemia), the following economic outcomes captured:
  - **Total Direct Healthcare costs** *(Mean monthly costs per patient)*
    1. Total prescription costs: frequency and pattern of use of medications
    2. Total medical costs: inpatient and outpatient

- All costs were inflation adjusted to 2013 U.S. dollars.

- All measurements were analyzed using mixed models for repeated measurements and adjusted for respective baseline values.
Examining the Economic Benefits of Bariatric Surgery
Results: Impact on Total Monthly Prescription Costs

- Total mean monthly Rx costs showed statistically significant decline for all 3 surgical cohorts vs their medically managed controls during the study periods up to 5 years post-surgery (p<0.05)
- Findings consistent across the different comorbid groups (T2DM/HTN/dyslipidemia relative to their respective matched control groups)

Patients w/ T2DM, dyslipidemia, and hypertension
Examining the Economic Benefits of Bariatric Surgery: Results: Impact on Total Monthly Medical Costs

- Total mean monthly medical costs generally increased during study periods except for patients who underwent LRYGB.

- Patients with T2DM, dyslipidemia, and hypertension.
Over time, the total healthcare costs generally increased for patients with one or more obesity related comorbidities in all study cohorts with laparoscopic bariatric surgery and in the combined control group.

Patients who underwent gastric bypass had the greatest reductions in total healthcare costs vs control at 5 years (p<0.05).

LSG also showed favorable trend vs control up to 2.5 years with data available for this group.
Examining the Economic Benefits of Bariatric Surgery

Methods: ROI Calculation

- The ROI is the ratio of cost savings to the initial surgery investment cost

  ✓ The cost associated with bariatric surgery ("investment") is estimated from the incremental costs incurred during the surgery hospital stay, and, typically, in the month prior to the surgery, and the two months after surgery.

  ✓ Cost savings from bariatric surgery were calculated as the difference in direct costs between bariatric surgery patients and controls.

  ✓ Monthly medical costs were normalized to December 2008 dollar value.
Examining the Economic Benefits of Bariatric Surgery:
Results: ROI for Obese-Diabetics with LRYGB Scenario

- ROI for T2DM Patients who Underwent LRYGB

- ROI for T2DM Patients Using Insulin who Underwent LRYGB

Similar trends in the Obese-HTN and Obese-Dyslipidemia Scenarios
# Examining the Economic Benefits of Bariatric Surgery: Results: ROI in Obese-Diabetics LRYGB Scenario

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Difference Between T2DM Patients who Underwent LRYGB and Controls</th>
<th>Difference Between T2DM Patients Using Insulin who Underwent LRYGB and Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3 Months Prior to Surgery</td>
<td>$355</td>
<td>-$2,529</td>
</tr>
<tr>
<td>Surgery to 1 Month After (Surgery Recovery Period)</td>
<td>$24,162</td>
<td>$22,256</td>
</tr>
<tr>
<td>1-2 Months After (Surgery Recovery Period)</td>
<td>$24,316</td>
<td>$22,083</td>
</tr>
<tr>
<td>6 Months After Surgery Recovery Period (ASRP)</td>
<td>$20,804</td>
<td>$17,757</td>
</tr>
<tr>
<td>1 Year ASRP</td>
<td>$18,148</td>
<td>$14,625</td>
</tr>
<tr>
<td>1.5 Year ASRP</td>
<td>$16,137</td>
<td>$10,131</td>
</tr>
<tr>
<td>2 Years ASRP</td>
<td>$13,166</td>
<td>$6,441</td>
</tr>
<tr>
<td>2.5 Years ASRP</td>
<td>$10,741</td>
<td>$2,877</td>
</tr>
<tr>
<td>3 Years ASRP</td>
<td>$7,764</td>
<td>-$1,905</td>
</tr>
<tr>
<td>3.5 Years ASRP</td>
<td>$5,026</td>
<td>-$8,097</td>
</tr>
<tr>
<td>4 Years ASRP</td>
<td>$915</td>
<td>-$13,803</td>
</tr>
<tr>
<td>4.5 Years ASRP</td>
<td>-$2,448</td>
<td>-$18,603</td>
</tr>
<tr>
<td>5.0 Years ASRP</td>
<td>-$5,118</td>
<td>-$23,409</td>
</tr>
</tbody>
</table>
Examining the Economic Benefits of Bariatric Surgery

Results: ROI Consistent Across the Globe

- Consistent ROI showing the savings and break-even point for a bariatric surgery benefit within 2 to 4 years
  - Several studies show increased short-term medical costs at an acceptable cost-effectiveness

NOTE: In the United Kingdom, bariatric surgery was considered cost-effective compared to conventional treatment. (Ackroyd, et al., Clegg, et al.)
Summary
Surgery is a Sound Economic Decision

- Patients who had laparoscopic bariatric surgery had sustained lower costs for medications for the treatment of T2DM, dyslipidemia, and hypertension compared to medically-managed controls.

- Of the 3 types of laparoscopic bariatric surgeries among all patients in study cohorts, LRYGB was associated with the greatest reductions in medication costs and was the only surgery type also associated with sustained lower total healthcare costs in comparison to medically-managed controls up to 5 years post-surgery.
  - LSG appeared to provide an economic benefit early-on, finding is limited due to shorter (2.5 years) follow-up data availability.

- These data indicate that surgical therapy is clinically more effective and ultimately less expensive than standard therapy for morbidly obese patients with the metabolic comorbid conditions.
Key Takeaways...

John D. Dawson, FSA, MAAA
Senior Vice President and Actuary
Willis Towers Watson

262/780-3270
What have we learned?

- Obesity is a disease that drives significant health care expenditures…$147 to $190 billion annually

- Obesity rates are growing…The most rapid growth is occurring among the highest BMI classes

- Losing weight and keeping it off is really hard

- Treatments for obesity include Lifestyle/Behavior Modification, Pharmacology, and Surgery

- Bariatric Surgery is indicated for patients with a BMI >40 or BMI >35 with comorbidities

- Bariatric Surgery impacts obesity-related diseases

- The surgery conversion rate is roughly 1.5% among those who would qualify for surgery
What have we learned?

Bariatric Surgery is the Most Effective Long Term Treatment for Obesity

Average Weight Loss at 3 Years
- Diet and Exercise: -0.1%
- Drug Therapy: 10.7%
- Gastric Bypass: 71.2%
- Sleeve Gastrectomy: 66.0%
- Gastric Banding: 55.2%

Average Weight Loss at 5 Years
- Diet and Exercise: -1.6%
- Drug Therapy: 10.7%
- Gastric Bypass: 60.5%
- Sleeve Gastrectomy: 49.0%
- Gastric Banding: 29.5%
What have we learned?

National Coverage of Bariatric Surgery

- Bariatric surgery is a covered benefit under most state Medicaid programs

- State employees have access to bariatric surgery in most states
  - Bariatric surgery is covered: 41 States (Wisconsin coverage is limited to one plan)
  - Coverage Pilot is in progress: 5 States
  - No Coverage Offered: 4 States

- Bariatric surgery is a covered benefit under Medicare

- More than 50% of employers with 1000 or more employees offer bariatric surgery coverage

- Bariatric surgery is coverage is available in nearly half of the states through public insurance exchanges
What did we learn about the clinical and economic efficacy of bariatric surgery?
What did we learn about the impact of bariatric surgery on the treatment of obesity and related comorbid conditions?

- **Related to treating type 2 diabetes, bariatric surgery was shown to**
  - Reduce the use of insulin and other medications used to treat diabetes
  - Help patients achieve lower HBA1c measurements…gastric bypass patients averaged between 6.0%-6.5%

- **Related to treating dyslipidemia, bariatric surgery was shown to**
  - Reduce the use of medications generally required to treat hyperlipidemia
  - Reduce triglyceride levels…below 100 mg/dl for gastric bypass and gastric sleeve patients
  - Offer a more modest impact on total cholesterol compared to the control group, but
  - HDL levels were notably higher for bariatric surgery patients
  - The decline in LDL levels was significant for gastric bypass patients

- **Related to treating hypertension, bariatric surgery was shown to**
  - Reduce the use of medications generally required to treat hypertension

- **In each of these cases, gastric bypass and gastric sleeve patients performed better than adjustable gastric band patients**
What did we learn about the economic impact of bariatric surgery?

- **Among all bariatric surgery patients…**
  - Initially, the average monthly medical cost relating to gastric bypass patients exceeded the control group, but by the middle of the third year gastric bypass patients average cost dropped and stayed below the control.
  - Prescription drug costs for all three bariatric surgery types dropped below the control group in the very first year.

- **Among bariatric surgery patients diagnosed with related comorbid conditions…**
  - The average monthly medical cost for all surgery patients was below the control group for the first five years.
  - At year 5, the average monthly medical cost for adjustable gastric band increased above the control group cost.
  - Medication costs for surgery patients was less than the control in all years following surgery.

- **When considering medical and prescription drug costs combined for patients diagnosed with type 2 diabetes before surgery**
  - Gastric bypass had lower medical and prescription drug cost than the control in all years.
  - Gastric sleeve patients seemed to perform well, subject to data limitations.
  - Adjustable gastric band patients’ cost was similar to the control group.
What did we learn about the economic impact of bariatric surgery?

ROI for T2DM Patients Using Insulin who Underwent LRYGB
- $30,000
- $20,000
- $10,000
- $0
- $10,000
- $20,000
- $30,000

ROI for T2DM Patients who Underwent LRYGB
- $0
- $10,000
- $20,000
- $30,000

Cost Difference vs. Control Cohort

Time From Index Date (Year)

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How can we apply these findings?
Current Trends in Covering Bariatric Surgery

Benefit Plan Designs

- Restrict to Centers of Excellence
- Create narrow networks
- Set co-insurance rates different than other surgical procedures
- Eligibility only after a defined employment period

Medical Policy

- 3, 6 or 12 month pre-surgical weight loss requirement
- Allow or limit revision or conversion procedures
- Only 1 bariatric procedure/lifetime

Other Administrative Designs:

- Employers contract directly with Hospitals or systems
- Establish a bundled payment to include complications
- Contract with bariatric providers to Include Obesity Management (medical management)
Health plan payers and sponsors that cover bariatric surgery…

➢ The study findings affirm the clinical and economic efficacy of your current coverage policy

➢ Review your coverage policy to ensure that it remains current

   □ Coordinate bariatric surgery coverage as a component of an overall strategy to manage obesity
   □ Emphasize on centers of excellence and narrow networks based on cost and quality
   □ Negotiate bundled payments with select providers / steer patients to these providers
   □ Consider continued efficacy of adjustable gastric band in light of emerging data
   □ Incorporate benefit design incentives to promote patient compliance with post-surgery treatment plan
      ✓ Reimburse out of pocket costs in exchange for adherence to medical follow-up plan
      ✓ Contribute to plastic surgery treatment following successfully achieving recovery milestones
Health plan payers and sponsors that exclude bariatric surgery…

- Evaluate the cost of your decision to exclude bariatric surgery coverage in light of the study findings
  - Lack of coverage effectively precludes most covered persons from pursuing surgery treatment
    - Continuation of adverse medical and prescription drug claim costs
    - Unresolved workforce productivity impediment

- Consider adding bariatric surgery coverage as a component of an overall strategy to manage obesity

- Design your coverage program using leading-edge coverage concepts
  - Centers of excellence and narrow networks based on cost and quality
  - Bundled payments with select providers / steer patients to these providers
  - Benefit design incentives to promote patient compliance with post-surgery treatment plan