A Fresh Look at Obesity and the Role of Bariatric Surgery

Enhancing Your Benefit Design Approach

National Alliance of Healthcare Purchaser Coalitions
Educational Webinar, May 2, 2019
TODAY’S SPEAKERS

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

Elliot Fegelman, MD
Therapeutic Area, Lead Metabolics
Johnson & Johnson

Neil Goldfarb
President and CEO
Greater Philadelphia Business Coalition on Health

Today’s presentation is being supported through an educational sponsorship provided by

[Logo: Ethicon, part of the Johnson & Johnson Family of Companies]
Outline for Today’s Presentation

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

Scott Kahan, MD, MPH, FTOS
Director, National Center for Weight and Wellness
Department of Health Policy & Management
Johns Hopkins School of Public Health
kahan@nationalweight.org
Disclosures


• Board of Directors/Advisors: American Board of Obesity Medicine, The Obesity Society, Obesity Action Coalition, Obesity Treatment Foundation, True Health Initiative, Playworks DC, Global Liver Institute, NASH Council

• Textbook royalties: Johns Hopkins University Press, Wolters-Kluwer, Lippincott Williams & Wilkins
Obesity Prevalence in US Adults

Obesity-Related Conditions

<table>
<thead>
<tr>
<th>Color</th>
<th>GRADE</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>4</td>
<td>Very strong</td>
</tr>
<tr>
<td>Teal</td>
<td>3</td>
<td>Strong</td>
</tr>
<tr>
<td>Green</td>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>Gray</td>
<td>1</td>
<td>Weak</td>
</tr>
</tbody>
</table>
Why Is It So Hard to Lose Weight and Keep It Off?!

Modest Weight Loss Improves Health and Risks


![Graph showing % Weight Loss and Cumulative incidence T2D (%)]
# Modest Weight Loss Improves Health and Risks

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

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

Behavioral Therapy in Obesity/Diabetes

Behavioral Therapy in Obesity/Diabetes

Very Low Calorie Structured Diets

Very Low Calorie Structured Diets in T2DM
Obesity Pharmacotherapy

• 5 FDA-approved short-term medications
  • Phentermine and noradrenergics

• 5 FDA-approved long-term medications
  • Orlistat
  • Phentermine/topiramate ER
  • Lorcaserin
  • Naltrexone/Bupropion SR
  • Liraglutide 3.0 mg
Obesity Pharmacotherapy

Obesity Pharmacotherapy

Patients with ≥5% WL

- PBO
- ORL
- LOR
- PHEN/TPM ER
- BN
- LIRA

Patients with Extreme Obesity (BMI >45)

Kahan S, et al. 2015.
Long-Term Benefits (Generally) Require Continued Management

Outcomes By Responder Status

Pharmacotherapy Improves RFs and Prevents Comorbid Conditions

<table>
<thead>
<tr>
<th></th>
<th>Orlistat</th>
<th>Lorcaserin</th>
<th>Phentermine/topiramate ER</th>
<th>Naltrexone/bupropion SR</th>
<th>Liraglutide 3.0 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>WC</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>BP</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>LDL</td>
<td>↓↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>HDL</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
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<tr>
<td>TG</td>
<td>↓↓</td>
<td>↓↓</td>
<td>↓↓</td>
<td>↓↓</td>
<td>↓↓</td>
</tr>
<tr>
<td>HR</td>
<td>↓</td>
<td>↓</td>
<td>-</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>A1C</td>
<td>↓</td>
<td>↓↓</td>
<td>↓</td>
<td>↓</td>
<td>↓↓</td>
</tr>
<tr>
<td>Diabetes</td>
<td>↓↓</td>
<td>↓↓</td>
<td>↓↓</td>
<td>↓</td>
<td>↓↓</td>
</tr>
</tbody>
</table>
Medical Devices for Obesity Treatment

- VBLOC
- Gastric Balloons
- Gastric Band
- Aspire Assist
- Plenity Hydrogel
Bariatric Surgery

- **Roux-en-Y Gastric Bypass**
- **Sleeve Gastrectomy**
Treatment Works...Only If Used

% of eligible patients

- Total eligible
- 1+ comorbidity
- 3+ comorbidity
- Bariatric surgery
- Pharmacotherapy
- IBT
Weight Loss Surgery

Gastric

Adjustable Gastric Banding
Vertical Sleeve Gastrectomy

Combination

Roux-en-Y Gastric Bypass
Defense of a Body Fat “Set Point”

Forced dietary manipulation Ad libitum fed

Body Weight (g)

Days

Overfed
Control
Food Restricted

Adapted from S. Woods
Defense of a Body Fat “Set Point”

Forced dietary manipulation  Ad libitum fed

Body Weight (g)

Days

0 25 50 75 100 125 150 175 200

Overfed

Control

Food Restricted

Adapted from S. Woods
Defense of a Body Fat “Set Point”

Forced dietary manipulation  Ad libitum fed

Body Weight (g)

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Adapted from S. Woods
Defense of a Body Fat “Set Point”

Forced dietary manipulation  Ad libitum fed

Body Weight (g)

Days

Overfed

Control

Food Restricted

Adapted from S. Woods
# Mechanisms of Bariatric Surgery

<table>
<thead>
<tr>
<th>Classical model</th>
<th>Current model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanical</strong></td>
<td><strong>Physiological</strong></td>
</tr>
<tr>
<td>Restricted food intake</td>
<td>Altered GI signals to brain</td>
</tr>
<tr>
<td>Malabsorption</td>
<td>• Endocrine</td>
</tr>
<tr>
<td></td>
<td>• Neuronal</td>
</tr>
<tr>
<td></td>
<td>Altered GI signals to other tissues (pancreas, liver)</td>
</tr>
</tbody>
</table>
Hormone Changes after Surgery

- Normal GI tract: Increased Ghrelin, X/A cells, GLP-1 and PYY
- PGBP: Reduced Ghrelin, Increased GLP-1 and PYY, Reduced appetite, weight loss, improved glucose tolerance
- SG: Majority of stomach and proximal intestine bypassed with enhanced delivery of nutrients to the distal gut, majority of stomach removed, nutrients pass rapidly into proximal GI tract
Changes in BMI

Edison, E Obes Surg, 2016
• Weight loss is not the only potential benefit…
• Long-term mortality reduction by comorbid disease type

Patients followed up on average for 7.1 years.
Note: in the Adams, et al. study, the rates of death not caused by disease, such as accidents and suicide, were 58% higher in the surgery group (P=0.004, 63 versus 36 deaths for 15,890 matched patients in the study).

Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis from anastomotic leak</td>
<td>0.1–5.6</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>1–4</td>
</tr>
<tr>
<td>Cardiopulmonary events</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Thromboembolic disease</td>
<td>0.34</td>
</tr>
<tr>
<td>Death</td>
<td>0.1–0.3</td>
</tr>
<tr>
<td>Late complications for LAGB</td>
<td></td>
</tr>
<tr>
<td>Band slippage</td>
<td>15</td>
</tr>
<tr>
<td>Leakage</td>
<td>2–5</td>
</tr>
<tr>
<td>Erosion</td>
<td>1–2</td>
</tr>
<tr>
<td>Late complications of bypass procedures</td>
<td></td>
</tr>
<tr>
<td>Anastomotic strictures</td>
<td>1–5</td>
</tr>
<tr>
<td>Marginal ulcers</td>
<td>1–5</td>
</tr>
<tr>
<td>Bowel obstructions</td>
<td>0.5–2</td>
</tr>
<tr>
<td>Kidney stones</td>
<td>NK</td>
</tr>
<tr>
<td>Metabolic bone disease</td>
<td>NK</td>
</tr>
<tr>
<td>Alcohol use disorder</td>
<td>NK</td>
</tr>
<tr>
<td>Micronutrient and macronutrient deficiencies from RYGB</td>
<td></td>
</tr>
<tr>
<td>2–3 years postoperative</td>
<td></td>
</tr>
<tr>
<td>Iron deficiency</td>
<td>45–52</td>
</tr>
<tr>
<td>Vitamin B&lt;sub&gt;12&lt;/sub&gt; deficiency</td>
<td>8–37</td>
</tr>
<tr>
<td>Calcium deficiency</td>
<td>10</td>
</tr>
<tr>
<td>Vitamin D deficiency</td>
<td>51</td>
</tr>
<tr>
<td>Fat-soluble vitamin deficiencies (A, D, E, and K) and protein calorie malnutrition from BPD+DS procedures</td>
<td>1–5</td>
</tr>
<tr>
<td>NK, not known.</td>
<td></td>
</tr>
</tbody>
</table>

Schauer, P, *Diabetes Care*, 2016
What is Metabolics after all?

• The idea that biologic changes occur through distant signals that are released following traditional weight-loss surgery
• These distant signals turn on, and off, complex cell-to-cell and intracellular events that change the cells’ behavior
• These cellular changes influence the organs they make up to behave differently, and alter organ-to-organ communications
• *In toto*, these changes result in health improvements that proceed, and are unrelated to, the weight loss ultimately experienced by the patient.
Type II Diabetes Mellitus
The *complete* list of Randomized & Controlled trials for impact on Diabetes

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

<table>
<thead>
<tr>
<th>Study</th>
<th>BMI (kg/m²), % of patients</th>
<th>Design</th>
<th>No. of patients randomized</th>
<th>Follow-up (months)</th>
<th>Remission criteria*</th>
<th>Outcome (remission or change in HbA₁c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dixon [8]</td>
<td>&lt;35, 22%</td>
<td>LAGB vs. control</td>
<td>60</td>
<td>24</td>
<td>HbA₁c &lt;6.2%</td>
<td>73% vs. 13%, ( P &lt; 0.001 )</td>
</tr>
<tr>
<td>Schauer (30,31)</td>
<td>&lt;35, 36%</td>
<td>RYGB vs. SG vs. control</td>
<td>150</td>
<td>36</td>
<td>HbA₁c ≤6.0%</td>
<td>35% vs. 20% vs. 0, ( P = 0.002 )</td>
</tr>
<tr>
<td>Mingrone (32,33)</td>
<td>&gt;35, 100%</td>
<td>RYGB vs. BPD vs. control</td>
<td>60</td>
<td>60</td>
<td>HbA₁c ≤6.5%</td>
<td>42% vs. 68% vs. 0, ( P = 0.003 )</td>
</tr>
<tr>
<td>Ikramuddin (34,35)</td>
<td>&lt;35, 59%</td>
<td>RYGB vs. control</td>
<td>120</td>
<td>24</td>
<td>HbA₁c &lt;6%</td>
<td>44% vs. 9%, ( P &lt; 0.001 )</td>
</tr>
<tr>
<td>Liang (36)</td>
<td>&lt;35, 100%</td>
<td>RYGB vs. control</td>
<td>101</td>
<td>12</td>
<td>HbA₁c &lt;6.5%**</td>
<td>90% vs. 0 vs. 0, ( P &lt; 0.0001 )</td>
</tr>
<tr>
<td>Halperin (37)</td>
<td>&lt;35, 34%</td>
<td>RYGB vs. control</td>
<td>38</td>
<td>12</td>
<td>HbA₁c &lt;6.5%</td>
<td>58% vs. 16%, ( P = 0.03 )</td>
</tr>
<tr>
<td>Courcoulas (38,39)</td>
<td>&lt;35, 43%</td>
<td>RYGB vs. LAGB vs. control</td>
<td>69</td>
<td>36</td>
<td>HbA₁c &lt;6.5%</td>
<td>40% vs. 29% vs. 0, ( P = 0.004 )</td>
</tr>
<tr>
<td>Wentworth (40)</td>
<td>≤30, 100%</td>
<td>LAGB vs. control</td>
<td>51</td>
<td>24</td>
<td>Fasting blood glucose &lt;7.0 mmol/L</td>
<td>52% vs. 8%, ( P = 0.001 )</td>
</tr>
<tr>
<td>Parikh (41)</td>
<td>&lt;35, 100%</td>
<td>Bariatric surgery (RYGB, LAGB, SG) vs. control</td>
<td>57</td>
<td>6</td>
<td>HbA₁c &lt;6.5%</td>
<td>65% vs. 0, ( P = 0.0001 )</td>
</tr>
<tr>
<td>Ding (42)</td>
<td>&lt;35, 24%</td>
<td>LAGB vs. control</td>
<td>45</td>
<td>12</td>
<td>HbA₁c &lt;6.5%***</td>
<td>33% vs. 23%, ( P = 0.46 )</td>
</tr>
<tr>
<td>Cummings (43)</td>
<td>&lt;35, 25%</td>
<td>RYGB vs. control</td>
<td>43</td>
<td>12</td>
<td>HbA₁c &lt;6.0%</td>
<td>60% vs. 5.9%, ( P = 0.002 )</td>
</tr>
</tbody>
</table>

*Remission was a primary or secondary end point. Reaching HbA₁c value without diabetes medication, unless otherwise specified. **Remission not precisely defined, HbA₁c <6.5% by extrapolation. ***On or off diabetes medications.

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Schauer, P, *Diabetes Care*, 2016
Durability of Affect on Diabetes

Schauer, P, *Diabetes Care*, 2016
Bone and Joint Disease
Obesity and Joint Replacement

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

![BMI in TKA Graph](image)

Emerging Evidence Suggests Metabolic Role

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

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

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

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

• Implement a bariatric surgery benefit (if not already available)

• Review current benefit:
  • Eligibility criteria
  • Waiting periods
  • Prior authorization procedures
  • Procedures covered and clinical guidelines
  • Pre- and post-surgical lifestyle modification and support
  • Out-of-pocket payments and financial barriers

• Ensure appropriate placement of bariatric surgery in the overall obesity strategy
Provider Network Considerations

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