Severe obesity: surgical and non-surgical management

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Obesity increases 1999-2016

Ogden 2017. NCHS data brief no 288. Hyattsville, MD
Prevalence of obesity: NHANES 2015-2016

Children: 2-19 y (all)  2-5 y  6-11 y  12-19 y

Adults: ≥ 20y (all)  20-39y  40-59y  ≥ 60 y

Ogden 2017. NCHS data brief no 288. Hyattsville, MD
Measurement of obesity

Body mass index

weight ÷ height²

Validity in children

– Correlates with adiposity (correlation .82-.88)¹
– Correlates with adult adiposity²
– Correlates with cardiovascular risk factors³, and long-term mortality⁴

Overweight: 
85th – 94th percentile

Obese: 
≥ 95th percentile
The charts are not big enough...

Gulati AK et al.
Pediatrics 2012
Severe obesity is not new but it is more common

Artist
Juan Carreno de Miranda, 1680
Museo del Prado, Madrid
Significant increases for obesity, severe (class 2) obesity and very severe (class 3) obesity in children

Prevalence of severe obesity 2015-2016

Class 2 = 5.2% (F), 6.7% (M)
Class 3 = 1.8% (F), 2.0% (M)

## Absolute numbers of severe obesity

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total US Population 2010 Census</th>
<th>Severe Obesity Class ≥2 BMI ≥35 or equivalent</th>
<th>Severe Obesity Class 3 BMI ≥40 or equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-13 yo</td>
<td>36 million</td>
<td>1.9 million (5%)</td>
<td>720,000 (2%)</td>
</tr>
<tr>
<td>14-17 yo</td>
<td>17 million</td>
<td>850,000 (5%)</td>
<td>340,000 (2%)</td>
</tr>
<tr>
<td>≥ 18 yo</td>
<td>235 million</td>
<td></td>
<td>14 million (6%)</td>
</tr>
</tbody>
</table>
Non-surgical Intervention
Treatment strategies

- Surgical
- Pharmaceutical
- Behavior-based

Surgical
Behavior-based
Other intensive interventions
Pharmaceutical
Orlistat for adolescent obesity

54 week double-blind RCT

539 subjects: 12 to 16 years of age, BMI 36 $\pm$ 4 kg/m$^2$

<table>
<thead>
<tr>
<th>BMI change</th>
<th>Treat</th>
<th>Control</th>
<th>Diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>kg/m2 (mean)</td>
<td>-.55</td>
<td>+ 0.31</td>
<td>-0.86</td>
</tr>
</tbody>
</table>

Fecal urgency (%)  
Flatulence (%)     
Fecal incontinence (%)  

20.7  
9.1   
8.8   
11.0  
4.4   
0.6

Chanoine et al. JAMA 2005;293:2873
Approved for **adults**: Lorcaserin (Belviq) and topiramate and phentermine (Qsymia)

Lorcaserin: 5-HT$_{2C}$ agonist
- Concerns about breast and CNS tumors, abated

Phentermine: sympathomimetic
Topiramate: anti-epileptic
- Concerns about teratogenicity and elevate resting HR

Colman *NEJM* 2012;376:1577

<table>
<thead>
<tr>
<th>Weight-Loss Efficacy of Lorcaserin (Belviq) and Phentermine plus Extended-Release Topiramate (Qsymia) at 1 Year.*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug, Study, and Treatment</strong></td>
</tr>
<tr>
<td>Belviq†</td>
</tr>
<tr>
<td>Studies 1 and 2 combined</td>
</tr>
<tr>
<td>10 mg BID</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Study 3</td>
</tr>
<tr>
<td>10 mg BID</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Qsymia‡</td>
</tr>
<tr>
<td>Study 1</td>
</tr>
<tr>
<td>15 mg/92 mg</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Study 2</td>
</tr>
<tr>
<td>7.5 mg/46 mg</td>
</tr>
<tr>
<td>15 mg/92 mg</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
</tbody>
</table>
Additional recently approved medications

**Naltrexone/Bupropion:** opioid receptor antagonist and dopamine & norepinephrine reuptake inhibitor with synergistic effect on weight
- Mean weight reduction = 6.7% (placebo = 2.4%)
- 5%-weight-$\downarrow$ = 52%, 10%-weight-$\downarrow$ = 28% (vs placebo 24% and 10%)
- Adverse events: nausea, constipation, headache. Suicidal ideation from bupropion in adolescents. Sleep disorders

**Liraglutide:** GLP-1 receptor agonist, which increases insulin secretion, decreases glucagon release, increases satiety, and slows gastric emptying.
- Mean 6.5% reduction in weight after 1 year (vs placebo 1.6%)
- 5%-weight-$\downarrow$ = 56%, 10%-weight-$\downarrow$ = 28% (vs placebo 23% and 7%)
- Adverse events: gallbladder disorders

Nuffer 2016; *Ann Pharmacotherapy*; 50:376
Combination of pharmacologic treatment and lifestyle modification is superior to drug alone

From: Benefits of Lifestyle Modification in the Pharmacologic Treatment of Obesity: A Randomized Trial

Characteristics of children presenting for weight management at 13 academic centers (n=6737)

Table 2. BMI Status at Baseline by Demographic Characteristic of Youth in POWER Study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Obesity (n=1674)</th>
<th>Class 2 (n=2337) vs. obesity OR (95% CI)</th>
<th>Class 3 (n=2726) vs. obesity OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20.8</td>
<td>33.0</td>
<td>1.3 (1.2, 1.5)</td>
</tr>
<tr>
<td>Female</td>
<td>27.9</td>
<td>34.2</td>
<td>Ref</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–5</td>
<td>16.1</td>
<td>36.4</td>
<td>1.5 (1.1, 2.0)</td>
</tr>
<tr>
<td>6–11</td>
<td>26.5</td>
<td>35.1</td>
<td>Ref</td>
</tr>
<tr>
<td>12–14</td>
<td>26.1</td>
<td>34.1</td>
<td>0.93 (0.8, 1.1)</td>
</tr>
<tr>
<td>15–17</td>
<td>22.0</td>
<td>28.9</td>
<td>0.95 (0.8, 1.1)</td>
</tr>
</tbody>
</table>

Jasik *Childhood Obesity* 2015.11:630
Evidence for comprehensive behavior-based programs for childhood obesity

36 randomized controlled studies, arranged by hours of contact.

“Comprehensive, intensive behavioral interventions (≥ 26 contact hours) in children and adolescent 6 years and older who have obesity can result in improvements in weight status for up to 12 months.”

USPSTF: Screening for obesity in children and adolescents. JAMA 2017. 317:2417
**Bright Bodies:**
12 month program for 8 to 16 year olds

**Who:** 209 ethnically diverse and low income
Mean BMI 35 kg/m²

**What:** Randomized, controlled trial
Nutrition education, behavior modification, physical activity
Twice weekly for 6 months, then twice monthly for 6 months

**Outcome:**
- 12 month
  - Intervention - 1.6 kg/m²
  - Control + 1.7 kg/m²
  \( \Delta 3.3 \text{ kg/m}², \sim 8 \text{ kg, } \sim 18 \text{ lb} \)

- 24 months (43%)
  - Intervention - 0.9 kg/m²
  - Control + 1.9 kg/m²

Savoye *JAMA* 2007;297:2697; Savoye : *Pediatr* 2011; 3: 402
Barriers to obesity intervention

Parental Underestimates of Child Weight:
A Meta-analysis

Lundahl 2014 Pediatrics

50.7% of parents under-estimate weight status of child with overweight or obesity

Low enrollment in available programs (pediatric)
• Reasons include lack of perceived health problem, time constraints, stigma


High attrition (pediatric)
• Often over 50%. Reasons include schedule, location, “not meeting needs”

Skelton Obes Rev 2011; Sallinen Gaffka Child Obes 2013 Dhaliwal Child Obes 2014
Healthcare payment systems as barrier

Medicaid: obesity consistently covered in 10 states (2008)

Commercial: 35 states allowed exclusion of obesity treatment from benefit plan

Texas: “not likely to be covered”

Texas: “state expressly allows for rate adjustments and exclusions”

Simpson L. *Pediatrics* 2009; 123:S301
Time constraints among primary care providers

Time spent on health supervision topics in 163 visits of children 2 – 10 y

- **Diet counseling** 42 seconds (interquartile [IQ] 21-85)
- **Growth** 15 seconds (IQ 7-31)
- **Physical activity** 12 seconds (IQ 5-22)

Medicare Obesity Benefit, starting 2011

“Intensive” behavior therapy when BMI $\geq 30$ kg/m$^2$:

- Month 1: visits weekly
- Months 2-6: visits every 2 weeks
- Months 7-12: monthly visit *if* 3 kg weight loss at 6 months

Visits are 15 minutes, provided by primary care provider

Low use:

50,000 seniors participated in 2013, which represents 0.38% (1 in 260) seniors with obesity.  

Kaiser Health News, 2015
Affordable Care Act policies, Medicaid, and Obesity

ACA starting Jan 2014

1. Healthcare exchanges and states with Medicaid expansion must provide USPSTF grade A and B

2. State Innovations Models are established

Report to Congress on Preventive Services and Obesity-Related Services Available to Medicaid Enrollees

Kathleen Sebelius 2014
2015: Round 2 models must include a statewide plan for population health of the state, focusing at minimum on diabetes, tobacco and obesity.

To achieve this goal, models need to integrate clinical services, public health programs, and community-based infrastructure.

JA Auerbach et al. Institute of Medicine. Nam.edu/wp-content/uploads/2015/06/SIMs Round2
Future of CMMI?

HHS Secretary Alex Azar appoints Adam Boehler as director of CMMI

Former Landmark Health CEO will likely follow through on Seema Verma’s initiative to take the innovation center in a new direction.
Summary

1. Behavior-based programs alone are inadequate for those with severe obesity
   • However, structured lifestyle modification is always part of rigorous surgical and pharmaceutical programs
   • Yet significant system barriers prevent broad implementation

2. Pharmaceutical options have improved
   • Evaluating use in children should be a priority

3. Much work needed:
   • Earlier/younger intervention
   • Novel, safe interventions to fill efficacy gap between non-surgical and surgical