PCORnet Bariatric Study
pSCANNER Meeting

Andrew Odegaard, PhD MPH
University of California, Irvine
10/13/16
Overview

• Obesity
• Treatment for obesity
• Bariatric surgery
• PCORnet Bariatric Study
Obesity: A Chronic Disease

• Overweight and obesity are defined as "abnormal or excessive fat accumulation that presents a risk to health".

• There is no generally accepted definition of obesity based on total body fat. Generally, researchers have used >25% in men, and >30-35% in women, as cut-points to define obesity.
Measuring and Defining Obesity

- Body mass index (BMI) is the ratio of weight to height, calculated as weight (kg)/height (m²)

- Definition for Asian population
  Recommended to be different

The International Classification of underweight, normal weight, overweight and obesity in adults according to body mass index (BMI)

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5-24.9</td>
<td>Normal weight</td>
</tr>
<tr>
<td>25.0-29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>≥30.0</td>
<td>Obesity</td>
</tr>
<tr>
<td>≥40.0 or ≥35.0 + comorb.</td>
<td>Morbid obesity</td>
</tr>
</tbody>
</table>
The Global Obesity Epidemic
Obesity: Simple?

Energy Balance

\[ \text{IN} = \text{OUT}, \text{Weight MAINTAINED} \]
\[ \text{IN} > \text{Out} = \text{Weight GAIN} \]
\[ \text{OUT} > \text{IN} = \text{Weight LOSS} \]
Understanding Obesity

- Built Environment
- Physical Inactivity/Sedentary Activity
- Dietary Trends & Habits
- Socio Economic Status
- Genetic/Antenatal Factors

CAUSES

- Insulin Resistance & Type 2 Diabetes
- Poly cystic Ovarian Disease (PCOD)
- Cardio Vascular Disease (CVD)
- Obstructive Sleep Apnea (OSA)
- Psychosocial Problems

EFFECTS
104 Putative Causes of Obesity

- 1. agricultural policies
- 2. air conditioning
- 3. air pollution
- 4. antibiotic usage at early age
- 5. areca nut chewing
- 6. artificial sweeteners
- 7. Asian tiger mosquitos
- 8. assortative mating
- 9. being a single mother
- 10. birth by C-section
- 11. built environment
- 12. celebrity chefs
- 13. chemical toxins, (endocrine disruptors)
- 14. child maltreatment
- 15. compulsive buying
- 16. competitive food sales in schools
- 17. consuming skim milk in preschool children
- 18. consumption of pastries and chocolate (in Burkina Faso)
- 19. decline in occupational physical activity
- 20. delayed prenatal care
- 21. delayed satiety
- 22. depression
- 23. driving children to school
- 24. eating away from home
- 25. economic development (nutrition transition)
- 26. entering into a romantic relationship
- 27. epigenetic factors
- 28. eradication of Helicobacter pylori
- 29. family conflict
- 30. family divorce
- 31. first-born in family
- 32. food addiction
- 33. food deserts
- 34. food insecurity
- 35. food marketing to children
- 36. food overproduction
- 37. friends
- 38. genetics
- 39. gestational diabetes
- 40. global food system, (international trade policies)
- 41. grilled foods
- 42. gut microbiota
- 43. having children, for women
- 44. heavy alcohol consumption
- 45. home labor saving devices
- 46. hormones (insulin, glucagon, ghrelin)
- 47. hunger-response to food cues
- 48. high fructose corn syrup
- 49. interpersonal violence
- 50. lack of family meals
- 51. lack of nutritional education
- 52. lack of self-control
- 53. large portion sizes
- 54. living in crime-prone areas
- 55. low educational levels for women
- 56. low levels of physical activity
- 57. low Vitamin D levels
- 58. low socioeconomic status
- 59. market economy
- 60. marrying in later life
- 61. maternal employment
- 62. maternal obesity
- 63. maternal over-nutrition during pregnancy
- 64. maternal smoking
- 65. meat consumption
- 66. menopause
- 67. mental disabilities
- 68. no or short term breastfeeding
- 69. non-parental childcare
- 70. outdoor advertising
- 71. overeating
- 72. participation in Supplemental Nutrition Assistance Program (formerly Food Stamp Program)
- 73. perceived weight discrimination
- 74. perception of neighborhood safety
- 75. physical disabilities
- 76. prenatal maternal exposure to natural disasters
- 77. poor emotional coping
- 78. sleep deficits
- 79. skipping breakfast
- 80. snacking
- 81. smoking cessation
- 82. spanking children
- 83. stair design
- 84. stress, artificial lighting, air conditioning
- 85. sugar-sweetened beverages
- 86. taste for fat
- 87. transportation by car
- 88. television set in bedrooms
- 89. television viewing
- 90. thyroid dysfunction
- 91. vending machines
- 92. virus
- 93. weight gain inducing drugs
- 94. working long hours
- 95. NEW too much homework
- 96. NEW insufficient body heat
- 97. NEW imagining the smell of food
- 98. NEW dust components
- 99. NEW living with grandparents in China
- 100. NEW estrogens
- 101. NEW thermogenic adipocytes
- 102. NEW prenatal exposure to cigarette smoke
- 103. NEW starting college
- 104. NEW too much homework

http://www.downeyobesityreport.com/2015/10/
Consequences of Obesity
Treatment for Obesity

• 1) Losing weight via behavioral approaches

• 2) Medications

• 3) Weight loss surgery (i.e. bariatric surgery)
Candidates for Bariatric Surgery

• *Qualifications for bariatric surgery in most areas include:*

• BMI ≥ 40, or more than 100 pounds overweight

• BMI ≥35 and at least two obesity-related co-morbidities such as type II diabetes, hypertension, sleep apnea and other respiratory disorders, non-alcoholic fatty liver disease, osteoarthritis, lipid abnormalities, gastrointestinal disorders, or heart disease

• Inability to achieve a healthy weight loss sustained for a period of time with prior weight loss efforts
Types of Bariatric Surgery: The Roux-en-Y Gastric Bypass

Overview
The Roux–en–Y gastric bypass procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum. Not only is the stomach pouch too small to hold large amounts of food, but by skipping the duodenum, fat absorption is substantially reduced.

https://medlineplus.gov/ency/imagepages/19268.htm
Types of Bariatric Surgery: **Sleeve Gastrectomy**

The Laparoscopic Sleeve Gastrectomy – often called the sleeve – is performed by removing approximately 80 percent of the stomach. The remaining stomach is a tubular pouch that resembles a banana.
Types of Bariatric Surgery: **Adjustable Gastric Band**

The Adjustable Gastric Band – often called *the band* – involves an inflatable band that is placed around the upper portion of the stomach, creating a small stomach pouch above the band, and the rest of the stomach below the band.

http://asmbs.org/patients/bariatric-surgery-procedures
PCORnet Bariatric Study: Overview of Scientific Aims

The main goal is to provide accurate estimates of the 1-, 3-, and 5-year benefits and risks of the three main surgical treatment options for severe obesity:

- Roux-en-y gastric bypass (RYGB)
- Adjustable gastric banding (AGB)
- Sleeve gastrectomy (SG)

Focus on the outcomes that have been shown to be most important to adults and adolescents with severe obesity:

- Weight loss,
- Improvement in diabetes,
- Risk of adverse events
- (Also weight loss and diabetes were specifically named in the PFA)
Three Specific Aims

Aim 1: To what extent does weight loss and weight regain differ across the three bariatric surgical procedures (RYGB, AGB, and SG) at 1, 3, and 5 years?
   - Sub Aim: explore heterogeneity by race/ethnicity, pre-op BMI, age

Aim 2: To what extent does bariatric surgery lead to improvements in diabetes risk at 1, 3, and 5 years?
   - Rate of remission from diabetes (A1C <6.5%, off DM medications)
   - Rate of incident diabetes among those without it at baseline

Aim 3: What is the frequency of adverse events following different bariatric surgical procedures at 1, 3, and 5 years?
   - Severe adverse events, including hospitalization, re-operations
   - Mortality
**PBS Timeline - Data Collection from CDM**

<table>
<thead>
<tr>
<th>Date</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPLETE</td>
<td>Wave 1 SSDC Distribution (DRN OC Group 1 DMs only) and output returned</td>
</tr>
<tr>
<td>9/28/16</td>
<td>Aim 1 Individual Level Query distribution (DRN OC Group “Research Ready”; have usable study data per SSDC)</td>
</tr>
<tr>
<td>11/1/16</td>
<td>Wave 2 SSDC distribution</td>
</tr>
<tr>
<td>November/December 2016</td>
<td>Decisions on DataMarts to participate in PBS Year 2</td>
</tr>
<tr>
<td>January 2017</td>
<td>Aim 1 Aggregate Level Query Distribution</td>
</tr>
<tr>
<td>Feb 2017 – Dec 2017</td>
<td>Aims 2 and 3: Individual level and aggregate level Query distribution</td>
</tr>
</tbody>
</table>
pSCANNER DataMarts Participating

- Budgeted: UC Irvine, UCLA, UCSD, VA VINCI
- DataMarts sent SSDC Wave 1 and PBS Aim 1 Individual-level query: UC Irvine, UCLA
Very Preliminary Results

Number of unique patients with a valid bariatric code in an IP setting who meet all inclusion criteria
UCI: 510
UCLA: 1393

Number of adults with a BMI in the year before surgery
UCI: 298 (59%)
UCLA: 244 (18%)

Number of adults with a BMI >=35 in year before surgery
UCI: 227 (76% of those with a BMI); 189 SG; 22 RYGB; 16 AGB
UCLA: 211 (86% of those with a BMI); 169 SG; 41 RYGB; 0 AGB
Very Preliminary Results

Among those with a BMI >=35 in year before surgery, number with any diabetes diagnosis code in the year before surgery:
UCI: 62
UCLA: 56

Among those with a BMI >=35 in year before surgery, what number have BMI at 6-18 months after surgery
UCI: 130 (57%)
UCLA: 166 (79%)

Among those with a BMI >=35 in year before surgery, what number have BMI at 30-42 months after surgery
UCI: 43
UCLA: 0
Acknowledgements: Study Principal Investigators

• David Arterburn, clinical investigator, PORTAL [lead site]
  • Bariatric surgery researcher
  • Leader of several multisite bariatric studies
  • Group Health Site-PI for PORTAL

• Kathleen McTigue, clinical investigator, PaTH
  • Obesity researcher
  • Lead, PaTH Weight Cohort
  • Co-chair of the Bariatric Topic Brief Team

• Neely Williams, patient partner, Mid-South
  • Community engagement leader
  • Patient co-investigator, Mid-South
  • Bariatric surgery patient
Acknowledgements

• UCI team
• Roni Bracha and Robynn Zen