The Criteria for Bariatric Surgery Should Change

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Jejunoileal Bypass: 1970’s

Gastroplasty: 1980’s

RYGB: 1980’s

1980’s - Controversy

- Very bad experience with JI bypass - Many complications
- Many technical complications
- Most insurers would not cover bariatric surgery

1991 – NIH Consensus Conference

- Patients whose BMI exceeds 40 are potential candidates for surgery if they strongly desire substantial weight loss, because obesity severely impairs the quality of their lives. They must clearly and realistically understand how their lives may change after operation.
1991 – NIH Consensus Conference

- In certain instances less severely obese patients (with BMI's between 35 and 40) also may be considered for surgery. Included in this category are patients with high-risk comorbid conditions such as life-threatening cardiopulmonary problems (e.g., severe sleep apnea, Pulmonary edema, and obesity-related cardiomyopathy) or severe diabetes mellitus.

- Other possible indications for patients with BMI's between 35 and 40 include obesity-induced physical problems interfering with lifestyle (e.g., joint disease treatable but for the obesity, or body size problems precluding or severely interfering with employment, family function, and ambulation).

Body Mass Index vs. Mortality

Exponential Increase in Risk

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Relative Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Low</td>
</tr>
<tr>
<td>19</td>
<td>Low</td>
</tr>
<tr>
<td>22</td>
<td>Medium</td>
</tr>
<tr>
<td>25</td>
<td>Medium</td>
</tr>
<tr>
<td>28</td>
<td>Low</td>
</tr>
<tr>
<td>31</td>
<td>Low</td>
</tr>
<tr>
<td>34</td>
<td>Medium</td>
</tr>
<tr>
<td>37</td>
<td>Medium</td>
</tr>
<tr>
<td>40</td>
<td>Low</td>
</tr>
<tr>
<td>45</td>
<td>Low</td>
</tr>
</tbody>
</table>


What were they worried about?

TABLE 5
Prevalence of overweight and severe overweight for persons aged 20–74 y in the United States, 1976–1980

<table>
<thead>
<tr>
<th></th>
<th>Overweight</th>
<th>Severe overweight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percent</td>
<td>Number</td>
</tr>
<tr>
<td>Male</td>
<td>24.2</td>
<td>15.6 million</td>
</tr>
<tr>
<td>Female</td>
<td>37.1</td>
<td>18.6 million</td>
</tr>
<tr>
<td>Total</td>
<td>34.0</td>
<td>34.0 million</td>
</tr>
</tbody>
</table>

* Source: National Center for Health Statistics (28) and NHANES II (29).

NHLBI Guideline for Obesity Treatment

- Evidence Inclusion:
  - Minimum of 2 years FU with comparator group for:
    - Weight loss outcome
    - CV disease
  - Minimum of 2 years FU and Direct Comparisons
    - Predictors of weight change or medical outcomes
    - Patient factors (+/- DM)
    - Surgical factors (RYGB v BPD)
  - Minimum Sample Size of 100
- Observational studies
  - Minimum Sample Size of 500
- All other observational studies (to capture infrequent complications)

Major Limitation- Did not specify Completeness of FU or data missingness

- 9% of all published bariatric studies have reasonably complete follow-up (≥75%) at 2 years.
Does Bariatric Surgery Cause Weight Loss?

- Short term (2-3 years) – high level of evidence
- Long term (>10 years) – low level of evidence

Is Bariatric Surgery Effective in Treating DM?

- Short term (2-3 years) – Yes – high level of evidence
- Long term (>10 years) – Yes – low level of evidence

Low level of evidence for bariatric surgery efficacy for:

- HTN
- Blood Lipid Control
- Mortality Reduction
- Difference in most outcomes between different operations

Moderate level of evidence for bariatric surgery efficacy for:

- QOL

Insufficient Evidence to conclude the efficacy for:

- BMI <35
- Sleeve Resection

The Very Long Term

- Very little information about very long term results and complications from bariatric surgery
Long-Term Mortality after Gastric Bypass Surgery

Ted D. Adams, Ph.D., M.P.H., Richard L. Gress, M.A., Sherman C. Smith, M.D., R. Chad Halverson, M.D., Steven C. Simper, M.D., Wayne D. Rosamond, Ph.D., Michael J. LeMorte, Ph.D., M.P.H., Antoinette M. Stroup, Ph.D., and Steven C. Hartz, Ph.D.


Surgery: 101/2010 = 5.0%
Control: 129/2037 = 6.3%

Unadjusted Hazard = 0.76 (0.56, 0.99), *p*=0.04
Adjusted Hazard = 0.73 (0.56, 0.95), *p*=0.02
Table 3. Results From Unadjusted and Adjusted Cox Proportional Hazards Models on Unmatched and Matched Cohorts of Surgical Patients and Nonsurgical Controls.

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted Hazard</th>
<th>Adjusted Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>0.60 (0.45, 0.67)</td>
<td>0.60 (0.45, 0.67)</td>
</tr>
<tr>
<td>Control</td>
<td>0.60 (0.45, 0.67)</td>
<td>0.60 (0.45, 0.67)</td>
</tr>
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</table>

RESULTS

During a mean follow-up of 7.1 years, adjusted long-term mortality from any cause in the surgery group decreased by 40%, as compared with that in the control group.

Mean FU

- Adams = 7.1 years
- SOS = 10.9 years
- VA = 6.7 years

Conclusions-Mortality

- Bariatric surgery has little to no effect on survival in multiple studies/settings
- Benefits of bariatric surgery may have been overstated
- Calls into question performing bariatric surgery for obesity alone without comorbidities
Bariatric Surgery Criteria

- Should it be BMI Based?
  - If QOL - Insufficient Evidence
  - If Longevity - Low Quality Evidence

- DM
  - Yes – Good evidence for good control at 3-5 years
  - Long-term effect not known

- HTN
  - Low quality evidence

- Lipids
  - Low quality evidence

- OSA
  - Insufficient evidence

- GERD
  - Insufficient evidence

All the above are for the RYGB

Insufficient evidence to recommend sleeve

Remember the Lap Band

- 10 years ago touted as a superior alternative to RYGB
  - Results equivalent after about 3 years
  - Safer
  - Band replacements have been done in about 5% of bariatric operations
Delivering the news about the reality of bariatric surgery: