Laparoscopic Adjustable Gastric Band – The Safest, Effective Procedure for Treating Obesity and Obesity Related Disease

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Overview

- Definition of Obesity
- Epidemiology
- Evidence supporting bariatric surgery and LAGB
  - Weight Loss
  - Safety
  - Effect on Comorbidities
- Conclusions
Definitions

- **Body Mass Index (BMI)** = weight in kg / height in m^2
- Alternative for direct measures of body fat.
- Correlates with underwater weight and dual energy x-ray absorptiometry (DXA).

<table>
<thead>
<tr>
<th>BMI</th>
<th>Weight Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5 – 24.9</td>
<td>Normal</td>
</tr>
<tr>
<td>25.0 – 29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>≥ 30.0</td>
<td>Obese</td>
</tr>
<tr>
<td>≥ 40.0</td>
<td>Morbidly Obese</td>
</tr>
<tr>
<td>≥ 50.0</td>
<td>Superobesity</td>
</tr>
</tbody>
</table>
Epidemiology

- “Globesity” WHO estimates from 2005: 1.6 billion adults were overweight; 400 million obese
- Obesity is predicted to affect 700 million by 2015.

United States: Leading Globally
- Highest percentage of overweight adults:
  - 66.3% are overweight
  - 32.2% are obese (66 million adults)
  - 5% are morbidly obese

Impact of Obesity on Health Care

- Hospital stays for obese patients increased 112% from 1996 – 2004. Increasing from 797,000 – 1.7 million hospital days / year.

- National Estimated Cost of Obesity (CDC)
  - $78.5 billion for treatment of overweight and obesity related hospitalizations in 1998 (9.1% total U.S. medical expenditures)
  - $92.6 billion in 2002

Obesity Related Disease

- Type 2 diabetes
- Hypertension
- Heart disease
- Hyperlipidemia
- Stroke
- Asthma
- Obstructive sleep apnea
- Weight-bearing degenerative problems
- Cancer (endometrial, breast, colon, prostate)
- Depression

“These comorbidities are responsible for 2.5 million deaths per year worldwide. The loss of life expectancy due to obesity is profound... a 25-year old morbidly obese man has a 22% reduction in expected remaining lifespan” (12 years of life).

Treatment for Obesity

- **Medical**
  - "Optimal and continuous application of a combination of dietary and drug therapy in association with increased exercise and behavioral modification can, at best achieve and maintain 5-10% loss of body weight."
    - Dixon et al. Diabetes Care 2002

- **Surgery**
  - "Surgery is the only treatment that has been proven to consistently achieve long-term reduction of excess weight in patients with severe clinical obesity."
    - Spivak et al. AJS 2005
“The ideal surgical operation must balance optimal weight loss with minimal morbidity and mortality.”


- Malabsorbtive Procedures

- Restrictive Procedures

Bariatric Surgery

Malabsorptive Bariatric Procedures


Bariatric Surgery

Restrictive Bariatric Procedures or combined restrictive/malabsorptive

VBG  LAGB  RYGB

Bariatric Surgery

- Efficacy and durability of weight loss
- Safety
- Improvement or resolution of comorbidities
Weight Loss Efficacy and Durability

- Systematic Review of Medium-Term Weight Loss after Bariatric Operations.
  - O’brien et al: Obesity Surgery 2006

- Of 1,703 reports identified 43 were included
  - 18 LAGB (12 Lap-Band, 5 Obtech, 1 both devices)
  - 18 RYGBP (12 standard RYGBP, 3 Banded RYGBP, 3 LL-RYGBP)
  - 7 BPD (4 standard BPD, 3 BPD – DS)

O’brien et al. Obes Surg 2006
Pooled Data

- All Procedures
  - Mean 54-67% EWL which persists through 10 years

- LAGB, RYGBP, BPD
  - BPD: Most effect on %EWL over 10 yrs.
  - RYGBP: Initial weight loss seen 1 - 2 yrs fades by 3 yr.
  - LAGB vs RYGBP
    - No difference in %EWL 3 - 10 yrs.

O’brien et al. Obes Surg 2006
Weight Loss Efficacy and Durability

- Systematic Review of Medium-Term Weight Loss after Bariatric Operations.
  - O’brien et al: Obesity Surgery 2006

- Conclusions:
  - “All bariatric operations achieve a major and durable weight loss in the medium term” (10yrs)
  - BPD: “most effect on weight” (74.4%EWL)
  - No statistical difference between RYGBP and LAGB after the second year. (RYGBP 56.6% vs LAGB 53.1%)
Bariatric Surgery

- Efficacy and durability of weight loss
- Safety
- Improvement or resolution of comorbidities

O’brien et al. Obes Surg 2006
Safety of Bariatric Procedures

- Objective Comparison of Complications Resulting from Laparoscopic Bariatric Procedures.

- 480 LA GB, 235 RYGB, 65 BPD ± DS over 36 months
  - Surgical techniques were standardized and performed by a fellowship trained bariatric surgeon
  - Post-operative complications were graded for analysis

## Classification of Complications from Bariatric Operations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
</table>
| I     | 1. Not life threatening  
2. Not requiring drugs other than: analgesics, antireflux, antipyretics, antiemetics, antidiarrheals, Rx for UTI  
3. Interventions only at bedside  
4. Hospital stay ≤ 2x median stay |
| IIa   | 1. Drug therapy, TPN or Blood transfusion  
2. Hospital stay ≥ 2x median stay |
| IIb   | 1. Therapeutic imaging, endoscopy  
2. Reoperation not requiring organ resection or anastamotic revision |
| III   | 1. Events with residual lasting disability  
2. Reoperation requiring anastamotic revision, organ resection |
| IV    | 1. Death as a result of any complication |

Safety of Bariatric Procedures

- Objective Comparison of Complications Resulting from Laparoscopic Bariatric Procedures.

Results

Table 5. Distribution of Complications by Grade and Time (Early Versus Late)

<table>
<thead>
<tr>
<th>Grade*</th>
<th>LAGB (n = 480)</th>
<th>RYGB (n = 235)</th>
<th>BPD±DS (n = 65)</th>
<th>Total (n = 780)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/IIa/IIb</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>III/IV</td>
<td>1</td>
<td>0.2</td>
<td>5</td>
<td>2.1</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>54</td>
<td>16</td>
<td>112</td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time‡</th>
<th>LAGB (n = 480)</th>
<th>RYGB (n = 235)</th>
<th>BPD±DS (n = 65)</th>
<th>Total (n = 780)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early</td>
<td>16</td>
<td>3.3</td>
<td>22</td>
<td>9.4</td>
<td>22</td>
</tr>
<tr>
<td>Late</td>
<td>26</td>
<td>5.4</td>
<td>32</td>
<td>13.6</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>54</td>
<td>54</td>
<td>112</td>
<td>—</td>
</tr>
</tbody>
</table>

*LAGB had a lower grade III/IV complication rate versus RYGB and BPD±DS (chi-square).
†Fisher’s exact test used.
‡LAGB had lower early and late complication rates versus RYGB and BPD±DS (chi-square).
BPD, biliopancreatic diversion; BPD±DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.
Safety of Bariatric Procedures

- Objective Comparison of Complications Resulting from Laparoscopic Bariatric Procedures.

- Conclusions:
  - “All three procedures are safe”
    - Early (0%), Late (0.1%) mortality rates.
    - Over-all complication rate 14.4% (Published complication rate for major foregut operations for non-malignant disease is 24%)

  - “LAGB is the safest bariatric operation in terms of both complication rate and severity”

Bariatric Surgery

- Efficacy and durability of weight loss
- Safety
- Improvement or resolution of comorbidities

O’brien et al. Obes Surg 2006
Effect on Comorbidities

- Laparoscopic Adjustable Gastric Band Versus Laparoscopic Roux-en-Y Gastric Bypass

  - Procedures by 2 fellowship trained bariatric surgeons
  - LAGB = 120 patients (20%)
    - 24% had BMI > 50, 6% had BMI > 60
  - RYGB = 470 patients (80%)
    - 16% had BMI > 50

Effect on Comorbidities

Results:

- Weight Loss: In favor of RYGB through 36 months. (p<0.001)

- Resolution/improvement of comorbidities
  - No statistically significant difference observed through 36 month follow-up

**Effect on Comorbidities**

**Table 2.** Early and late complications after LAGB and RYGB

<table>
<thead>
<tr>
<th>Complication</th>
<th>LAGB (n = 470)</th>
<th>Reoperation</th>
<th>RYGB (n = 120)</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric perforation</td>
<td>1 (0.2%)</td>
<td>—</td>
<td>—</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>PE</td>
<td>1 (0.2%)</td>
<td>—</td>
<td>1</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Acute obstruction</td>
<td>15 (3.1%)</td>
<td>—</td>
<td>—</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Death</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Subtotal Early</td>
<td>17 (3.6%)</td>
<td>—</td>
<td>3 (2%)</td>
<td>8 (7%)</td>
</tr>
<tr>
<td>Late complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pouch enlargement</td>
<td>56 (12%)</td>
<td>11</td>
<td>—</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Band slippage</td>
<td>12 (2%)</td>
<td>12</td>
<td>1</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Band erosion</td>
<td>1 (0.2%)</td>
<td>2</td>
<td>4</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Port/tubing comp.</td>
<td>13 (2.7%)</td>
<td>* 13</td>
<td>1</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Subtotal Late</td>
<td>82 (17%)</td>
<td>38 (8%)</td>
<td>7 (6%)</td>
<td>17 (14%)</td>
</tr>
<tr>
<td>Total</td>
<td>99 (21%)</td>
<td>38 (8%)</td>
<td>10 (8%)</td>
<td>25 (21%)</td>
</tr>
</tbody>
</table>

SBO, small bowel obstruction
PE, Pulmonary embolism

Effect on Comorbidities

- Laparoscopic Adjustable Gastric Band Versus Laparoscopic Roux-en-Y Gastric Bypass

- Conclusions:
  - “LAGB is a simpler, less invasive, and safer procedure compared to RYGB. Despite the fact that the mean %EWL in RYGB patients was higher than that in LAGB patients at all times, both procedures were equally effective at controlling comorbidities.”

Effect on Comorbidities

- Early U.S. Outcomes of RYGB versus LA SGB for morbid obesity
  - 232 RYGB, 160 LA SGB. No significant pre-op difference in comorbidities
  - Results:
    - %EWL was greater with RYGB
      - P < 0.05 at 3, 6, 12, 18 months
      - 24 months: No significant difference (RYGB 68% vs LAGB 47.5%)

Effect on Comorbidities

- Early U.S. Outcomes of RYGB versus LAS GSB for morbid obesity

- Results:

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>LGBP (%)</th>
<th>LASGB (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>65.8</td>
<td>56.0</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>72.1</td>
<td>77.1</td>
<td>NS</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>47.8</td>
<td>37.4</td>
<td>NS</td>
</tr>
<tr>
<td>Arthritis</td>
<td>75.3</td>
<td>83.9</td>
<td>NS</td>
</tr>
<tr>
<td>GERD</td>
<td>84.4</td>
<td>88.2</td>
<td>NS</td>
</tr>
<tr>
<td>Stress urinary incontinence</td>
<td>69.8</td>
<td>79.6</td>
<td>NS</td>
</tr>
</tbody>
</table>

Effect on Diabetes

Comparison of Rates of Resolution of Diabetes Mellitus after Gastric Banding, Gastric Bypass and Biliopancreatic Diversion


- Review of prospectively collected data
- 218 LAGB, 53 RYGB, 11 BPD/DS
- 3 year follow-up period

Effect on Diabetes

- **Results:**
  - **Weight Loss**
    - At each time point there was significant disparity in %EWL
      - BPD/DS > RYGB > LAGB

### Table 3. Weight Loss in Diabetic Population

<table>
<thead>
<tr>
<th>Year of followup</th>
<th>LAGB</th>
<th>RYGB</th>
<th>BPD/DS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%EWL</td>
<td>% Followup</td>
<td>%EWL</td>
</tr>
<tr>
<td>1</td>
<td>43</td>
<td>87</td>
<td>66</td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td>87</td>
<td>68</td>
</tr>
<tr>
<td>3</td>
<td>45</td>
<td>65</td>
<td>66</td>
</tr>
</tbody>
</table>

*LAGB versus RYGB and LAGB versus BPD/DS.
BPD/DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric banding; %EWL, percent excess weight loss; RYGB, Roux-en-Y gastric bypass.

Effect on Diabetes

- **Results:**
  - **Diabetes Resolution:**
    - No statistical difference in post-op resolution based on oral agents or insulin use.
  - **Malabsorptive vs Restrictive**
    - No statistical difference (p = 0.12 for oral agents, p = 0.72 for insulin).

<table>
<thead>
<tr>
<th>Postoperative year</th>
<th>LAGB (%)</th>
<th>RYGB (%)</th>
<th>BPD/DS (%)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>39</td>
<td>22</td>
<td>11</td>
<td>0.10</td>
</tr>
<tr>
<td>2</td>
<td>34</td>
<td>13</td>
<td>13</td>
<td>0.33</td>
</tr>
</tbody>
</table>

BPD/DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric banding; RYGB, Roux-en-Y gastric bypass.

<table>
<thead>
<tr>
<th>Postoperative year</th>
<th>LAGB (%)</th>
<th>RYGB (%)</th>
<th>BPD/DS (%)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14</td>
<td>7</td>
<td>11</td>
<td>0.80</td>
</tr>
<tr>
<td>2</td>
<td>18</td>
<td>13</td>
<td>13</td>
<td>0.99</td>
</tr>
</tbody>
</table>

BPD/DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric banding; RYGB, Roux-en-Y gastric bypass.

Effect on Diabetes

Comparison of Rates of Resolution of Diabetes Mellitus after Gastric Banding, Gastric Bypass and Biliopancreatic Diversion


Conclusions:

- Laparoscopic bariatric surgery is highly effective in delivering diabetes resolution

- Despite disparity in %EWL between LAGB, RYGB, BPD/ DS the rates of resolution of diabetes are equivalent.

Diabetes Resolution With LAGB

- Treating Diabetes in the morbidly obese by LAGB
  - Dolan K et al: Obesity Surgery 2003
  - 88 diabetics undergoing LAGB, follow-up 48 months
    - 32/49 medication dependent diabetics off all meds
      - 65.3% resolution at 48 months

- Early U.S. Outcomes of RYGB versus LASGB for morbid obesity
    - 77% resolution of DM at 24 months
Conclusions

■ %EWL:
  ■ BPD produces the greatest excess weight loss

■ Safety:
  ■ LAGB is the safest procedure in terms complication rate and severity

■ Impact on Comorbidities
  ■ No difference between the 3 procedures
Conclusions

- Laparoscopic adjustable gastric banding produces > 50% EWL which is sustained through 10 years of follow-up. It is the safest bariatric procedure, and compared to the more invasive options provides equivalent reduction in comorbidities.