Metabolic and Bariatric Surgery

James Ellsmere, MD MSc FRCSC FACS

Bariatric Surgery Program
QE II Health Sciences Centre
Dalhousie University, Halifax NS
Metabolic and Bariatric Surgery

• Rationale for Bariatric surgery
• Impact on metabolic outcomes
• Risk of adverse events
• Evolving diabetes guidelines
• Increasing role for improving reconstructive surgery outcomes
Obesity

• Obesity is a chronic, life-threatening disease
• Excessive body fat that often results in serious health problems
• Independent risk factor or aggravating agent for approximately 30 health conditions
• Leads to significant medical, psychological, social, physical and economic impacts
Degrees of Obesity

NORMAL
BMI 18.5 — 24.9

OVERWEIGHT
BMI 25 — 29.9

OBESE
BMI 30 — 34.9

SEVERE OBESE
BMI 35 — 39.9

MORBIDLY OBESE
BMI ≥ 40
Goals of Bariatric Surgery

• Improve or resolve obesity associated comorbidities (i.e. diabetes)

• Discontinue or decrease medications

• Improve quality of life

• Enhance mobility
Bariatric Surgery
A Systematic Review and Meta-analysis

Henry Buchwald, MD, PhD
Yoav Avidor, MD
Eugene Braunwald, MD
Michael D. Jensen, MD
Walter Pories, MD
Kyle Fahrbach, PhD
Karen Schoelles, MD

The world epidemic of overweight (body mass index [BMI], calculated as weight in kilograms divided by the square of the height in meters, ≥25) and obesity (BMI ≥30) is estimated to encompass about 1.7 billion individuals, and the percentage of overweight adults is highest in the United States. Approximately two thirds of individuals living in the United States are overweight, and of those, almost half are obese. The BMI subgroups experiencing the most rapid growth are 35 or higher (23 million) and 40 or higher (8 million). The rise in the prevalence of obesity is associated with increases in the prevalence of obesity comorbidities (e.g., type 2 diabetes, hyperlipidemia, hypertension, obstructive sleep apnea, heart disease, stroke, asthma, back and lower extremity weight-bearing degenerative problems, several forms of cancer, depression, etc.). These comorbidities are responsible for more than 2.5 million deaths per year worldwide. The loss of life expectancy due to obesity is profound—in comparison with a normal-weight individual, a 25-year-old morbidly obese man has a 22% reduction in expected remaining lifespan, representing an approximate loss of 12 years of life.

Unfortunately, diet therapy, with and without support organizations, is relatively ineffective in treating obesity in the long term. There are currently no truly effective pharmaceutical agents to treat obesity, especially morbid obesity. In 1991, the National Institutes of Health established guidelines for the surgical therapy of morbid obesity (BMI ≥40 or BMI ≥35 in the presence of significant comorbidities), now referred to as bariatric surgery.

Context About 5% of the US population is morbidly obese. This disease remains largely refractory to diet and drug therapy, but generally responds well to bariatric surgery.

Objective To determine the impact of bariatric surgery on weight loss, operative mortality outcome, and 4 obesity comorbidities (diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea).

Data Sources and Study Selection Electronic literature search of MEDLINE, Current Contents, and the Cochrane Library databases plus manual reference checks of all articles on bariatric surgery published in the English language between 1990 and 2003. Two levels of screening were used on 2738 citations.

Data Extraction A total of 136 fully extracted studies, which included 11 overlapping patient populations (5% studies), were included for a total of 22094 patients. Nineteen percent of the patients were men and 72.6% were women, with a mean age of 39 years (range, 16-64 years). Sex was not reported for 1537 patients (8%). The baseline mean body mass index for 16 944 patients was 46.9 (range, 32.3-68.8).

Data Synthesis A random effects model was used in the meta-analysis. The mean (95% confidence interval) percentage of excess weight loss was 61.2% (58.1%-64.4%) for all patients; 57.5% (40.7%-54.2%) for patients who underwent gastric banding; 61.6% (56.7%-66.5%), gastric bypass; 68.2% (61.5%-74.8%), gastroplasty; and 70.1% (66.3%-73.9%), biliopancreatic diversion or duodenal switch. Operative mortality (≥30 days) in the extracted studies was 0.1% for the purely restrictive procedures, 0.5% for gastric bypass, and 1.1% for biliopancreatic diversion or duodenal switch. Diabetes was completely resolved in 76.8% of patients and resolved or improved in 86.0%. Hyperlipidemia improved in 70% or more of patients. Hypertension was resolved in 61.7% of patients and resolved or improved in 78.5%. Obstructive sleep apnea was resolved in 89.7% of patients and was resolved or improved in 83.6% of patients.

Conclusions Effective weight loss was achieved in morbidly obese patients after undergoing bariatric surgery. A substantial majority of patients with diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea experienced complete resolution or improvement.

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Author Affiliations: Department of Surgery, University of Minnesota, Minneapolis (Dru Buchwald); Ethicon Endo-Surgery Inc, a Johnson & Johnson company, Cincinnati, Ohio (Dru Avidor); Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, Mass (Dru Braunwald); Department of Medicine, Mayo Clinic College of Medicine, Rochester, Minn (Dru Jensen); Department of Surgery, East Carolina University School of Medicine, Greenville, NC (Dr Pories); and MedStorWorks Inc, Medford, Mass (Dr Fahrbach and Schoelles).

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Corresponding Author: Henry Buchwald, MD, PhD, University of Minnesota, 420 Delaware St SE, MMC 290, Minneapolis, MN 55455 (buchwa001@umn.edu).
Meta-analysis - 136 Primary Studies

5 Randomized Controlled Trials
   (9 Study Groups; 621 Patients)

28 Nonrandomized Controlled Trials or Series
   (48 Study Groups; 4613 Patients)

101 Uncontrolled Case Series
   (122 Study Groups; 16 860 Patients)
<table>
<thead>
<tr>
<th>Category</th>
<th>Count/Total (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex†</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3769/19388 (19.4)</td>
</tr>
<tr>
<td>Female</td>
<td>14082/19388 (72.6)</td>
</tr>
<tr>
<td><strong>Current or former smoker</strong></td>
<td>455/1881 (24.2)</td>
</tr>
<tr>
<td><strong>Non-smoker</strong></td>
<td>397/571 (69.5)</td>
</tr>
<tr>
<td><strong>Prior bariatric surgery</strong></td>
<td>255/5799 (4.4)</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td></td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>2507/16342 (15.3)</td>
</tr>
<tr>
<td>Glucose tolerance impairment‡</td>
<td>1118/4331 (25.8)</td>
</tr>
<tr>
<td>Sleep disordered breathing</td>
<td>2399/12266 (19.6)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>5808/16421 (35.4)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>1021/2868 (35.6)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>2568/6391 (40.2)</td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>1092/4488 (24.3)</td>
</tr>
<tr>
<td>Asthma</td>
<td>279/2601 (10.7)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>132/1887 (7.0)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>8/348 (2.3)</td>
</tr>
<tr>
<td>Degenerative joint disease</td>
<td>4160/8277 (50.3)</td>
</tr>
<tr>
<td>Depression</td>
<td>402/2306 (17.4)</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>1983/4583 (43.3)</td>
</tr>
</tbody>
</table>
Decrease Morbidity

• Buchwald (2004)- meta-analysis looking at over 22,000 patients who had received bariatric surgery noted:
  – 76.8% resolution of Type 2 DM
  – 61.7% resolved HTN
  – 83.6% resolved or improved sleep apnea
  – 70% had an improvement in dyslipidemia
Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery

Lars Sjöström, M.D., Ph.D., Anna-Karin Lindroos, Ph.D., Markku Peltonen, Ph.D., Jari Torgerson, M.D., Ph.D., Claude Beuchard, Ph.D., Björn Carlsson, M.D., Ph.D., Sven Dahlgren, M.D., Ph.D., Bo Larsson, M.D., Ph.D., Kristina Nabie, Ph.D., Carl David Sjöström, M.D., Ph.D., Marianne Sullivan, Ph.D., and Hans Wedel, Ph.D., for the Swedish Obese Subjects Study Scientific Group

ABSTRACT

BACKGROUND

Weight loss is associated with short-term amelioration and prevention of metabolic and cardiovascular risk, but whether these benefits persist over time is unknown.

METHODS

The prospective, controlled Swedish Obese Subjects study involved obese subjects who underwent gastric surgery and contemporaneously matched, conventionally treated obese control subjects. We now report follow-up data for subjects (mean age, 48 years; mean body-mass index, 41) who had been enrolled for at least 2 years (4,047 subjects) or 10 years (1,703 subjects) before the analysis (January 1, 2004). The follow-up rate for laboratory examinations was 86.6 percent at 2 years and 74.5 percent at 10 years.

RESULTS

After two years, the weight had increased by 0.1 percent in the control group and had decreased by 23.4 percent in the surgery group (P < 0.001). After 10 years, the weight had increased by 1.6 percent and decreased by 16.1 percent, respectively (P < 0.001). Energy intake was lower and the proportion of physically active subjects higher in the surgery group than in the control group throughout the observation period. Two- and 10-year rates of recovery from diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, and hyperuricemia were more favorable in the surgery group than in the control group, whereas recovery from hypercholesterolemia did not differ between the groups. The surgery group had lower 2- and 10-year incidence rates of diabetes, hypertriglyceridemia, and hyperuricemia than the control group; differences between the groups in the incidence of hypercholesterolemia and hypertension were undetectable.

CONCLUSIONS

As compared with conventional therapy, bariatric surgery appears to be a viable option for the treatment of severe obesity, resulting in long-term weight loss, improved lifestyle, and, except for hypercholesterolemia, amelioration in risk factors that were elevated at baseline.
Weight Change (%)
Energy Intake (kcal/day)
Proportion Active at Work (%)
Proportion Active During Leisure Time (%)
Incidence
Hypertriglyceridemia, Low HDL Cholesterol, Hypercholesterolemia
Incidence
Diabetes, Hypertension, Hyperuricemia

![Graph showing incidence of Diabetes, Hypertension, and Hyperuricemia over 2 and 10 years for Control and Surgery groups.](image-url)
Cumulative Mortality (%)
Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium

ABSTRACT

BACKGROUND
To improve decision making in the treatment of extreme obesity, the risks of bariatric surgical procedures require further characterization.

METHODS
We performed a prospective, multicenter, observational study of 30-day outcomes in consecutive patients undergoing bariatric surgical procedures at 10 clinical sites in the United States from 2005 through 2007. A composite end point of 30-day major adverse outcomes (including death; venous thromboembolism; percutaneous, endoscopic, or operative reintervention; and failure to be discharged from the hospital) was evaluated among patients undergoing first-time bariatric surgery.

RESULTS
There were 4776 patients who had a first-time bariatric procedure (mean age, 44.5 years; 21.1% men; 10.9% nonwhite; median body-mass index [the weight in kilograms divided by the square of the height in meters], 46.5). More than half had at least two coexisting conditions. A Roux-en-Y gastric bypass was performed in 3412 patients (with 87.2% of the procedures performed laparoscopically), and laparoscopic adjustable gastric banding was performed in 1198 patients; 166 patients underwent other procedures and were not included in the analysis. The 30-day rate of death among patients who underwent a Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding was 0.3%; a total of 4.3% of patients had at least one major adverse outcome. A history of deep-vein thrombosis or pulmonary embolus, a diagnosis of obstructive sleep apnea, and impaired functional status were each independently associated with an increased risk of the composite end point. Extreme values of body-mass index were significantly associated with an increased risk of the composite end point, whereas age, sex, race, ethnic group, and other coexisting conditions were not.

CONCLUSIONS
The overall risk of death and other adverse outcomes after bariatric surgery was low and varied considerably according to patient characteristics. In helping patients make appropriate choices, short-term safety should be considered in conjunction with both the long-term effects of bariatric surgery and the risks associated with being extremely obese. (ClinicalTrials.gov number, NCT00433810.)
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total (N=4610)*</th>
<th>Laparoscopic Adjustable Gastric Banding (N=1198)</th>
<th>Laparoscopic Roux-en-Y Gastric Bypass (N=2975)</th>
<th>Open Roux-en-Y Gastric Bypass (N=437)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>15 (0.3)</td>
<td>0</td>
<td>6 (0.2)</td>
<td>9 (2.1)</td>
<td>&lt;0.001</td>
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<tr>
<td>Deep-vein thrombosis or venous thromboembolism</td>
<td>20 (0.4)</td>
<td>3 (0.3)</td>
<td>12 (0.4)</td>
<td>5 (1.1)</td>
<td>0.05</td>
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<tr>
<td>Tracheal reintubation</td>
<td>20 (0.4)</td>
<td>2 (0.2)</td>
<td>12 (0.4)</td>
<td>6 (1.4)</td>
<td>0.004</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>51 (1.1)</td>
<td>1 (0.1)</td>
<td>45 (1.5)</td>
<td>5 (1.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Operation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>11 (0.2)</td>
<td>0</td>
<td>6 (0.2)</td>
<td>5 (1.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Placement of percutaneous drain</td>
<td>16 (0.3)</td>
<td>0</td>
<td>13 (0.4)</td>
<td>3 (0.7)</td>
<td>0.48</td>
</tr>
<tr>
<td>Abdominal operation</td>
<td>118 (2.6)</td>
<td>9 (0.8)</td>
<td>94 (3.2)</td>
<td>15 (3.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Failure to be discharged by day 30</td>
<td>17 (0.4)</td>
<td>0</td>
<td>13 (0.4)</td>
<td>4 (0.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>Composite end point‡</td>
<td>189 (4.1)</td>
<td>12 (1.0)</td>
<td>143 (4.8)</td>
<td>34 (7.8)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Sleeve Gastrectomy (SG)

Roux-en-Y Gastric Bypass (RYGB)
Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes

METHODS
We assessed outcomes 5 years after 150 patients who had type 2 diabetes and a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 27 to 43 were randomly assigned to receive intensive medical therapy alone or intensive medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy. The primary outcome was a glycated hemoglobin level of 6.0% or less with or without the use of diabetes medications.
* P<0.05 for comparison with medical-therapy group at 60 mo

▲ P<0.05 for comparison between surgical groups at 60 mo

Patients Taking Diabetes Medications (%)
Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes

CONCLUSIONS
Five-year outcome data showed that, among patients with type 2 diabetes and a BMI of 27 to 43, bariatric surgery plus intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia. (Funded by Ethicon Endo-Surgery and others; STAMPEDE ClinicalTrials.gov number, NCT00432809.)
Weight and Metabolic Outcomes 12 Years after Gastric Bypass

METHODS
A total of 1156 patients with severe obesity comprised three groups: 418 patients who sought and underwent Roux-en-Y gastric bypass (surgery group), 417 patients who sought but did not undergo surgery (primarily for insurance reasons) (non-surgery group 1), and 321 patients who did not seek surgery (nonsurgery group 2). We performed clinical examinations at baseline and at 2 years, 6 years, and 12 years to ascertain the presence of type 2 diabetes, hypertension, and dyslipidemia.
The scatter plot illustrates the mean percent change from baseline across different follow-up dates. The data points are color-coded as follows:

- **Baseline**: Black dots.
- **2-Yr follow-up**: Orange diamonds.
- **6-Yr follow-up**: Green squares.
- **12-Yr follow-up**: Blue triangles.
- **Underwent surgery later**: White diamonds.

The x-axis represents the follow-up dates ranging from 2001 to 2017, while the y-axis shows the mean percent change from baseline, ranging from -70 to 70 percent.
Weight and Metabolic Outcomes 12 Years after Gastric Bypass

CONCLUSIONS
This study showed long-term durability of weight loss and effective remission and prevention of type 2 diabetes, hypertension, and dyslipidemia after Roux-en-Y gastric bypass. (Funded by the National Institute of Diabetes and Digestive and Kidney Diseases and others.)
• Evidence supports gastrointestinal operations as effective treatments for overweight T2DM patients.

• Randomized controlled trials with postoperative follow-up ranging from 1 to 5 years have documented sustained diabetes remission in 30–63% of patients, though erosion of remission occurs in 35-50% or more.

• With or without diabetes relapse, the majority of patients who undergo surgery maintain substantial improvement of glycemic control for at least 5 to 15 years.
Metabolic surgery should be recommended to treat T2DM for all appropriate surgical candidates with BMIs > 40 (37.5*) and those with BMIs 35.0-39.9 (32.5-37.4*) when hyperglycemia is inadequately controlled despite lifestyle & optimal medical therapy.

Metabolic surgery should be considered for the treatment of T2DM in adults with BMIs 30-34.9 (27.5-32.4*) when hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin).
Reconstructive Surgical Morbidity
Exponential Increase in Risk

BMI (kg/m[^2])

Relative Morbidity Rate

- High risk
- Medium risk
- Low risk
Metabolic and Bariatric Surgery

• Surgery is the best option for most morbidly obese individuals
• Requires life long commitment
• Most obesity related co-morbidities improve or resolve with weight loss surgery resulting in less medication requirements, enhanced mobility, optimized quality of life and improved overall survival