The safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity.

Meagan Stephenson
Sarah Hogan

New Zealand Health Technology Assessment

Department of Public Health and General Practice
Christchurch School of Medicine and Health Sciences
Christchurch, New Zealand
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Meagan Stephenson
Sarah Hogan
CONTRIBUTIONS BY AUTHORS

This report was authored by Meagan Stephenson (Research Fellow) and Sarah Hogan. Meagan Stephenson critically appraised the literature examining the safety and effectiveness of interventions for morbid obesity, prepared the report and coordinated the project, and Sarah Hogan critically appraised the literature examining the cost effectiveness of interventions for morbid obesity.

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CONTACT DETAILS

New Zealand Health Technology Assessment (NZHTA)
Department of Public Health and General Practice
Christchurch School of Medicine and Health Sciences
PO Box 4345
Christchurch
New Zealand
Tel: +64 3 364 3696 Fax: +64 3 364 3697
Email: nzhta@chmeds.ac.nz
Website: http://nzhta.chmeds.ac.nz

LEVEL OF EVIDENCE CONSIDERED IN TECHNICAL BRIEFS

Technical Briefs are rapidly produced assessments of the best available evidence for a topic of highly limited scope. They are less rigorous than systematic reviews. Best evidence is indicated by research designs which are least susceptible to bias according to the National Health and Medical Research Council’s (NHMRC) criteria (see Appendix 1). Where methodologically acceptable and applicable, appraised evidence is limited to systematic reviews, meta-analyses, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials (RCTs). Where not available, poorer quality evidence may be considered.
CONFLICT OF INTEREST

None.
EXECUTIVE SUMMARY

**Aim**

This technical brief provides an update on the literature examining the safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity (BMI ≥ 40 or ≥ 35 with serious obesity-related comorbidities). A previous NZHTA technical brief (Day 2005) reviewed reports published up to 2004 and the current report aimed to summarise the literature published subsequent to that report. Recent primary studies were included where the secondary evidence was lacking. Of interest were studies focussing on the effectiveness, safety and cost effectiveness of surgical interventions in comparison with non-surgical (diet, exercise, psychological, pharmacological) interventions, and studies or reviews comparing the relative effectiveness and cost effectiveness of different surgical procedures. Where possible, information was included regarding the safety of different interventions, including long-term and short-term complications, and the effect of interventions on obesity-related comorbid conditions.

**Methods**

**Databases Searched:**


**Comparisons**

**Included comparisons:**

- Studies reporting on the relative effectiveness, safety and/or cost effectiveness of different bariatric surgical procedures for morbidly obese patients. Surgical procedures could be performed either as open procedures or laparoscopically, and included vertical banded gastroplasty, horizontal gastroplasty, gastric banding, gastric bypass and biliopancreatic diversion.
- Studies reporting on the effectiveness, safety and/or cost effectiveness of surgical interventions compared with non-surgical interventions (medical management or no treatment) for morbidly obese patients.

**Excluded comparisons:**

- Comparisons of variations in surgical techniques rather than different procedures
- Jejunoileal bypass procedures
- Studies which examined the effectiveness of an intervention in obese patients rather than morbidly obese patients.

**Outcomes**

Studies which included measures of weight change, fat content or fat distribution, quality of life, obesity-related comorbidities, mortality, adverse effects and short- and long-term complication rates.

**Study design**

1) Systematic reviews and health technology assessments
2) Randomised controlled trials comparing surgical interventions with other surgical interventions
3) Randomised controlled trials, controlled clinical trials and prospective cohort studies comparing surgical interventions with non-surgical treatment (medical management or no treatment)
4) For the economic analysis, studies that compare one intervention with another intervention in terms of incremental costs and benefits of those interventions.
**Key results and conclusions**

Effectiveness of bariatric surgery

Seven systematic reviews or HTAs were identified which included an examination of the evidence comparing non-surgical and surgical interventions for morbid obesity. The general consensus of the reviews included in this section was that there is adequate evidence that surgical interventions are significantly more effective than non-surgical interventions in terms of weight loss in morbidly obese patients. These findings were based on lower quality evidence with several prospective or retrospective cohort studies being commonly cited, but no randomised controlled trials being identified.

The best evidence for the relative effectiveness of surgical and non-surgical interventions comes from the Swedish Obese Subjects study, a prospective cohort study which included more than 4000 obese subjects (BMI ≥ 34 for men, BMI ≥ 38 for women) who were assigned to non-surgical or surgical intervention groups based on patient preference and eligibility for surgery. Using the most recently available follow-up data, at 10 years post-surgery the surgical group had achieved on average a 16.1% weight loss while the non-surgical group had a weight gain of 1.6%. Improvement or resolution of obesity-related comorbidities was more favourable in the surgical group. This study, which is ongoing, continues to show better weight loss and improvement of obesity-related comorbid conditions for surgical patients compared with patients who did not undergo bariatric surgery. In addition, the cumulative mortality rate, which includes data for 99.9% of the original study members, shows that patients who underwent bariatric surgery have a 29% lower risk of death compared with non-surgical intervention patients (adjusted hazard ratio = 0.71, 95% CI 0.54-0.92).

Effectiveness and safety of different surgical procedures

The evidence for the relative effectiveness and safety of different bariatric procedures for morbidly obese patients was less clear. Fourteen secondary and two primary studies were included in this part of the report, with the quality of secondary reviews varying substantially. Several high quality reviews which included only randomised controlled trials or well-controlled comparative studies were identified, however many reviews opted to include lower level evidence, such as case series data, and this limited the reliability of their findings. Amongst the studies included in secondary reviews, there was wide variation in patient populations, the length of follow-up, the reporting of loss-to-follow-up, and baseline and postoperative measures of comorbidities. The reporting of weight loss varied as well, being presented as kilograms or pounds lost compared with pre-surgery weight, pre- and post-operative BMI, percent of excess weight lost, or change in BMI. All of these factors made it very difficult for authors to provide reliable estimates of the benefits and risks associated with different procedures or to recommend one surgical treatment over another. Some conclusions were able to be drawn however.

- Many reviews suggested that excess weight loss of at least 50% could be expected following bariatric surgery
- Some studies suggested procedures with a malabsorptive component, such as gastric bypass and biliopancreatic diversion, are associated with higher weight loss compared with restrictive procedures, such as adjustable gastric banding or gastroplasty. A limitation of these studies was the length of follow-up data provided with most including data up to a maximum of 3 years post-surgery. Some data suggests that there is no difference in weight loss between gastric bypass and other procedures when long-term outcomes are considered.
- It seemed that most obesity-related comorbid conditions, in particular, diabetes, hyperuricemia, hyperlipidemia, and sleep apnoea resolved or improved with postoperative weight loss and that this was not dependent on surgical procedure. Less clear was the effect of surgery on hypertension, with some evidence being presented that this did not always resolve following surgery or that the improvement did not hold in the long-term.
- Reviews relied on inconsistently reported data when considering comorbid conditions. High loss-to-follow-up rates and a lack of baseline measures made it difficult for reviewers to ascertain the relative effectiveness of different procedures.
- Mortality rates were judged to be relatively low (<2%) for all the considered procedures but the quality of studies available for the calculation of rates was overall poor and often based on data from case series. A meta-analysis suggested a 30 day mortality rate of 0-2.1% for RYGB, AGB, and VBG based on controlled trials, and a rate of 0-0.8% using case series data for the same procedures. The mortality
rate for BPD was 0.5 – 1.3% based on case series alone. Surgeon experience was highlighted by several reviews as a possible source of variation in mortality and complication rates. In well-selected patients operated on by experienced surgeons, the perioperative mortality rate could be expected to be very low.

- The incidence and type of complications varied depending on the type of surgical procedure performed and there was wide variation in the incidence rates reported in the literature. This was partly due to inconsistency in the definition of early and late complications. While the overall mortality rate associated with bariatric surgery is low, well-controlled studies comparing the relative safety and complication rates of different procedures are still needed to aid in the selection of the most appropriate procedure.

- Very little evidence was available regarding the effect of pre- and post-operative services on the effectiveness of surgical procedures. One randomised controlled trial suggested that weight loss prior to LRYGB surgery had no effect on weight loss or resolution of comorbidities, but that shorter operating times were experienced by patients in the weight loss group.

Cost effectiveness of bariatric surgery

The search identified five primary economic research studies and five secondary research studies which met the inclusion criteria for this review. The quantity and quality of evidence was poor as has been previously suggested in other systematic reviews. The primary research studies addressed the following questions and provided some evidence toward an understanding of the cost effectiveness of bariatric surgery:

- Bariatric surgery in general was compared with no treatment in terms of the cost of the treatment and its effectiveness at reducing ongoing obesity-related medical expenses. Results suggest that bariatric surgery is more effective at reducing medical costs associated with obesity and that for patients incurring average costs pre-surgery, the surgery would take between 10.5 and 13.5 years to pay itself off. For patients who are likely to make greater productivity gains or who incur greater obesity-related medical expenses, the payback period is likely to be shorter.

- Adjustable gastric banding and gastric bypass were compared with conventional treatment in three European countries (Germany, France, and the U.K.). Both AGB and GBY were found to be cost-saving in two countries (Germany and France) and cost effective in one (the U.K). These results remained true whether effectiveness was defined in terms of QALYs gained, BMI reduction, or diabetes-free years gained.

- Vertical banded gastroplasty was compared with LapBand surgery in an economic evaluation associated with an RCT. Only twelve months follow-up data was available and this revealed no difference in quality of life and no significant difference in cost. VBG was found to result in greater weight loss over twelve months, although this was expected as LapBand surgery is thought to result in slower weight loss. The results were, therefore, inconclusive.

- Laparoscopic gastric bypass was compared with open gastric bypass in two economic evaluations which both concluded that the laparoscopic technique is the preferred treatment owing to a lower cost as well as lower rates of complications and mortality and a shorter hospital stay.

All the economic evaluations were subject to major limitations including a failure to include all relevant costs (particularly the cost of plastic surgery, which could significantly affect results) and a heavy reliance on assumptions where data were not available, mainly due to the short follow-up time for which primary data were available. The overall conclusion should be, as found by other systematic reviews, that the evidence on cost effectiveness of bariatric surgery is not sufficient to inform a decision of which treatment option should be preferred. However, the small burden of evidence is indicative of bariatric surgery being a cost effective treatment for morbid obesity.

Final comments

Overall, bariatric surgery appears to be a more clinically effective and a more cost effective treatment option for patients with morbid obesity compared with non-surgical treatments. Surgical intervention results in significantly greater weight loss and this in turn leads to the improvement and often resolution of obesity-related comorbid conditions. Less clear is the relative clinical effectiveness of different surgical procedures, mainly due to a lack of randomised controlled trials with long-term follow-up of an adequate proportion of patients. The
cost effectiveness literature is also limited and does not allow for the recommendation of one surgical procedure over another.

Many reviews suggest that the choice and success of bariatric procedures should depend largely on patient characteristics, such as baseline BMI, comorbidities, food habits and psychological differences, as well as patient and surgeon preference. Current research is focusing on the identification of the best treatment options for patients with differing risk profiles and characteristics but there is still a need for well-controlled long-term trials to ascertain which procedures may be the most appropriate and most effective for different patient groups.
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# Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>AGB</td>
<td>Adjustable gastric banding</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>AMED</td>
<td>Allied and Complementary Medicine Database</td>
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<tr>
<td>ASERNIP-S</td>
<td>Australian Safety and Efficacy Register of New Interventions- Surgical</td>
</tr>
<tr>
<td>ASGB</td>
<td>Adjustable silicon gastric banding</td>
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<tr>
<td>BAROS</td>
<td>Bariatric Analysis and Reporting Outcome System</td>
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<tr>
<td>BIOSIS</td>
<td>Biological Sciences Database</td>
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<tr>
<td>BNI</td>
<td>British Nursing Index</td>
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<tr>
<td>BPD</td>
<td>Biliopancreatic diversion</td>
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<td>BPD/DS</td>
<td>Lateral gastrectomy with duodenal switch</td>
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<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CINAHL</td>
<td>Nursing and Allied Health Database Index</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>DARE</td>
<td>Database of Abstracts of Reviews of Effects</td>
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<tr>
<td>EED</td>
<td>NHS Economic Evaluation Database</td>
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<tr>
<td>EWL</td>
<td>Excess weight loss</td>
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<tr>
<td>GB</td>
<td>Gastric banding</td>
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<tr>
<td>GBY</td>
<td>Gastric bypass</td>
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<tr>
<td>GG</td>
<td>Gastrogastrectomy (Horizontal gastroplasty)</td>
</tr>
<tr>
<td>GP</td>
<td>Gastroplasty (Gastric partitioning)</td>
</tr>
<tr>
<td>HG</td>
<td>Horizontal gastroplasty</td>
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<tr>
<td>HMIC</td>
<td>UK Department of Health Health Management Information Consortium</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
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<tr>
<td>ICSI</td>
<td>Institute for Clinical Systems Improvement</td>
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<tr>
<td>ICU</td>
<td>Intensive care unit</td>
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<tr>
<td>LAGB</td>
<td>Laparoscopic adjustable gastric banding (Lap Band® or Swedish Adjustable Gastric Band)</td>
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<td>LRYGB</td>
<td>Laparoscopic (Roux-en-Y) gastric bypass</td>
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<tr>
<td>LVBG</td>
<td>Laparoscopic vertical banded gastroplasty</td>
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<tr>
<td>JB</td>
<td>Jejunoileal bypass</td>
</tr>
<tr>
<td>MSAC</td>
<td>Medical Services Advisory Committee</td>
</tr>
<tr>
<td>MUHC</td>
<td>McGill University Health Care Centre</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council (Australia)</td>
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<tr>
<td>NICE</td>
<td>National Institute for Clinical Evidence</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>NS</td>
<td>Non-surgical</td>
</tr>
<tr>
<td>0AGB</td>
<td>Open adjustable gastric banding (Lap Band® or Swedish Adjustable Gastric Band)</td>
</tr>
<tr>
<td>ORYGB</td>
<td>Open (Roux-en-Y) gastric bypass</td>
</tr>
<tr>
<td>OVBG</td>
<td>Open vertical banded gastroplasty</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
</tr>
<tr>
<td>RYGB</td>
<td>gastric bypass (Roux-en-Y gastric bypass)</td>
</tr>
<tr>
<td>SOS</td>
<td>Swedish Obese Subjects study</td>
</tr>
<tr>
<td>SR</td>
<td>systematic review</td>
</tr>
<tr>
<td>SRGP</td>
<td>silastic ring gastroplasty</td>
</tr>
<tr>
<td>SSCI</td>
<td>Social Science Citation Index</td>
</tr>
<tr>
<td>STEER</td>
<td>Succinct Timely Evaluated Evidence Review</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 diabetes mellitus</td>
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<tr>
<td>TAU</td>
<td>Technology Assessment Unit</td>
</tr>
<tr>
<td>TRIP</td>
<td>TRIP database</td>
</tr>
<tr>
<td>QALY</td>
<td>quality-adjusted life-year</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>VLCD</td>
<td>very-low calorie diet</td>
</tr>
<tr>
<td>VBG</td>
<td>vertical banded gastroplasty</td>
</tr>
<tr>
<td>WL</td>
<td>weight loss</td>
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GLOSSARY

Surgical procedures in the published literature are often synonymous with one-another but are differentiated by name or by being performed with open or laparoscopic surgical techniques. The following procedures are described. Definitions have been adapted from a previous NZHTA report (Day, 2005) to maintain consistency with the current report.

**Biliopancreatic diversion – (Scopinaro’s procedure) (BPD), lateral gastrectomy with duodenal switch (BPD/DS)**

A biliopancreatic diversion is a malabsorptive surgical procedure and involves gastric restriction in the form of removal of portions of the stomach. The resulting stomach pouch is directly connected to the end segment of the small intestine and this bypasses the duodenum and jejunum, thereby diverting bile and pancreatic juice into the distal ileum. Possible complications include malnutrition, anaemia, ulcers, hair-loss, strong body odour and loose stools. There are several variants which have been developed to overcome these problems.

**Body mass index (BMI)**

Anthropometric measure, defined as weight in kilograms divided by the square of height in metres (kg/m²). This index mathematically relates height and weight as an indicator of body fat. This measure correlates closely with body density and thickness.

**Adjustable banded gastroplasty (ABG), horizontal gastroplasty (HG) (gastrogastrostomy), gastroplasty (gastric partitioning) (GP), laparoscopic vertical banded gastroplasty (LVBG), vertical banded gastroplasty (VBG)**

Vertical or horizontal gastroplasty is a restrictive surgical procedure involving the use of staples to divide the stomach into two sections. Vertical gastroplasty involves placing the gastroplasty along the wall of the stomach with the least curvature and greatest thickness to inhibit stretching. With horizontal gastroplasty staples are placed traversely across the entire stomach and this creates a channel between the upper and lower stomach (gastrogastrostomy). Vertical banded gastroplasty is the more commonly undertaken procedure and is performed with both open and, more typically, laparoscopic techniques. This involves the creation of a small pouch in the upper section of the stomach with a small opening to allow food to pass into the rest of the stomach. The small opening is reinforced with a mesh to prevent stretching. The combined small upper stomach pouch and opening restricts food intake and slows food passage so a patient feels satiated and will therefore eat less. The small stomach pouch can stretch with overeating and if the stoma is too small this can induce vomiting (Medical Services Advisory Committee, 2003). Other complications can include leakage, stenosis, ulcer, infection and partition staple failure. This surgical procedure is not malabsorptive.

**Adjustable gastric banding (AGB), laparoscopic adjustable gastric banding (LAGB), open gastric banding (OGB), gastric banding (GB)**

Gastric banding (adjustable and non-adjustable) is a restrictive surgical procedure where a banding device is fitted around the upper stomach section, dividing the stomach into two parts which are connected by a small outlet or stoma. The upper pouch is usually 15-30 mL of capacity and combined with the small stoma restricts food intake and slows food passage so a patient feels satiated, the rationale being that the patient will eat less and lose weight. Originally gastric bands were non-adjustable and fitted via an open surgical procedure but laparoscopic adjustable gastric banding has mostly replaced this. A fitted adjustable band can be adjusted as it can be filled or aspirated with saline to adjust the rate of stomach emptying through modifying the size of the stoma. Both LapBand® and Swedish Adjustable Gastric Band are similar silicone bands connected via a silicone tube to a titanium reservoir with an access port placed under the skin of the patient’s abdomen. The access port is covered with a self-sealing silicone membrane through which saline can be administered or aspirated (Medical Services Advisory Committee, 2003).

**Gastric bypass (Roux-en-Y or resectional) (GBY), Roux-en-Y gastric bypass (RYGB), laparoscopic (Roux-en-Y) gastric bypass (LRYGB), long-limb gastric bypass (LLGBY), open (Roux-en-Y) gastric bypass (ORYGB)**
The Roux-en-Y gastric bypass is a combination surgical procedure involving both malabsorptive and restrictive methods. This procedure is widely used and has been performed with both open and laparoscopic surgical techniques. A small pouch is created in the stomach by vertical banding or stapling of the upper stomach area or by resection (removal of part of the stomach), a subtotal gastrectomy with a Roux-en-Y reconstruction. A section of the small intestine is attached to the pouch and food passes directly from the pouch into the jejunum. The small stomach pouch restricts food intake and the ingested food is not mixed with digestive enzymes produced by the stomach thereby limiting absorption with resulting weight loss. This procedure is largely irreversible, complications include partition staple failure, leaks, hernias, vomiting and dumping syndrome (Medical Services Advisory Committee, 2003). Long limb gastric (or distal) bypass is very similar to standard gastric bypass, except the length of the Roux-limb is considerably longer and this bypasses a greater proportion of the small intestine increasing the degree of malabsorption. This has similar complications to standard gastric bypass but longer term complications may include malnutrition caused by malabsorption.

Jejunoileal bypass (JB)
A malabsorptive surgical procedure. It joins the proximal jejunum to the end of the ileum where it bypasses a large section of the gastrointestinal tract. It is no longer performed and has been associated with liver failure and cirrhosis.

Morbid obesity
Commonly defined as a sub-population of obese individuals (Body Mass Index (BMI) 30 kg/m$^2$ or greater) whose BMI is in the category of 40 kg/m$^2$ or greater or a BMI of 35 kg/m$^2$ or greater where there are associated serious obesity-related comorbidities. This can be also be defined as individuals who are in excess of 200% or 45 kg over ideal weight, with ideal weight being a weight at any given age, sex and body frame associated with maximum life expectancy. Morbid obesity is a well known risk factor for other common diseases including hypertension, hypercholesterolemia, cardiomyopathy, diabetes, gallbladder disease, pancreatitis, certain kinds of cancers (colorectal, prostate, gallbladder and gynaecological), sleep apnoea, and also psychological and social dysfunction. In view of its association with many systemic illnesses, morbid obesity itself is recognised as a disease process. A sub-population of morbidly obese patients known as “super-morbidly obese” or “super-obese” patients are defined as having a BMI equal to or greater than 50 kg/m$^2$. 
BACKGROUND

This technical brief was requested by Pauline Hanna, of the Counties Manukau District Health Board.

Obesity has been recognised as a significant public health problem by the World Health Organisation (WHO, 2000) with an increasing percentage of people in developed nations being classified as obese or morbidly obese. Levels of obesity are often defined by measures of body mass index (BMI), calculated as body weight in kilograms divided by height in metres squared. A BMI greater than or equal to 30kg/m² is considered obese, while morbid obesity is defined as a BMI greater than or equal to 40kg/m², or 35kg/m² if associated with significant comorbidities (DeMaria, 2007). Obesity is associated with increased risk for a number of comorbid conditions, such as hypertension, diabetes, coronary heart disease, and several cancers, as well as increased psychosocial problems and decreased quality of life (Colquitt et al. 2005; Pannala et al. 2006). It creates a significant epidemiological and economic burden both in the direct medical costs of treating obesity-related comorbidities, and indirect costs in loss of productivity and earnings.

In New Zealand, recent research has indicated that the percentage of obese and morbidly obese people has increased consistently over the past thirty years (Tobias et al. 2004). The median BMI has shown steady increases with the prevalence of obesity rising from 9 to 20% in males, and from 11 to 22% in females between 1977 and 2003. This pattern of increase is seen in both Maori and Pakeha populations, with an increase in obesity prevalence (classified as BMI≥32) from 20 to 27% in Maori between 1989 and 2003. In addition, a large proportion of young people fall into the obese category, with 10% of school-age children being classified as obese according to a national survey in 2002, suggesting that the obesity problem will at the very least continue at its present rate and is likely to increase (Tobias et al. 2004). The prevalence of morbid obesity in New Zealand more than doubled for females and increased seven-fold for males between 1977 and 2003, with rates in 2003 being 2.1% and 3.0% for males and females respectively, corresponding to approximately 58,000 people (Tobias, 2004). Morbid obesity is higher among Maori, at 7.8% for males and 6.7% for females. The annual cost of obesity is estimated to be around $303 million dollars in New Zealand2.3

Treatment options for obese patients who wish to reduce their weight include non-surgical interventions, such as dieting, increase in physical activity, pharmacological therapy, and psychological interventions. These treatment options are described as first-line therapies for obesity, being non-invasive and involving less risk than surgical interventions (Hassen-Khodja and Lance, 2006). Pharmacological therapies include sibutramine, a noradrenaline and serotonin reuptake inhibitor, and orlistat, which prevents the absorption of fat in the intestine (Pannala et al. 2006). Pharmacological therapies have demonstrated limited success in helping people to lose weight, with the small (5-10% of initial weight) and gradual weight loss generally experienced by patients, as well as some significant side effects, contributing to high rates of non-compliance with medication (Medical Advisory Secretariat, 2005). Psychological therapies tend to involve the use of behavioural therapy techniques to motivate changes in eating behaviours. The level of weight loss achieved with these methods is comparatively small and they are not recommended as effective interventions for morbidly obese people.

Surgical procedures are a further option for morbidly obese patients and involve two main methods of action. Restrictive procedures, such as gastric banding or gastroplasty, act to restrict the capacity of the stomach and thereby the intake of food. In gastric banding procedures, a silicon band is used to separate off a small section of the stomach, the contents of which empty into the digestive system via a small outlet (stoma). In adjustable gastric banding techniques, the silicon band is lined with a balloon which can be inflated or deflated to decrease or increase the capacity of the stomach. Gastric banding procedures are entirely reversible because the band is external to the stomach and can be removed comparatively easily. In vertical or horizontal gastroplasty procedures, a surgical stapler is used to divide the stomach and create a pouch in the upper portion, which empties into the rest of the stomach via a small gap. Both of these procedures aim to limit the amount of food that can be ingested and induce faster satiety in the patient due to the reduced capacity of the stomach (DeMaria, 2007; Hassen-Khodja and Lance, 2006).

Malabsorptive procedures, such as biliopancreatic diversion, act to reduce the absorption of food once it has been ingested. These procedures limit the absorption of nutrients from ingested food by bypassing parts of the gastrointestinal tract, with gastric bypass techniques combining this with the creation of a smaller stomach. Biliopancreatic diversion (also known as Scopinaro’s procedure) involves the removal of a portion of the stomach and the attachment of a Roux limb to the small remaining portion. The Roux limb is then connected to

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1 Ministry of Health website (http://www.moh.govt.nz/moh.nsf/wpg_Index/About-Obesity)

2 Ministry of Health website (http://www.moh.govt.nz/moh.nsf/wpg_Index/About-Obesity)

3 Ministry of Health website (http://www.moh.govt.nz/moh.nsf/wpg_Index/About-Obesity)
the ileum, thus bypassing the duodenum and jejunum and diverting bile and pancreatic juice into the distal ileum. This decreases the amount of time that ingested food is digested by bile acids and pancreatic enzymes and limits the absorption of fat. Jejunolieal bypass is also a malabsorptive surgical procedure but is rarely performed any more because of unacceptably high mortality and morbidity rates. It joins the proximal jejunum to the end of the ileum where it bypasses a large section of the gastrointestinal tract. Jejunoleal bypass was excluded from the current report as it is no longer a recommended surgical option.

Gastric bypass procedures, such as Roux-en-Y and long-limb gastric bypass, have been described as hybrid or combination techniques because they involve both restrictive and malabsorptive methods. In gastric bypass procedures, the stomach is surgically divided by banding or stapling or a portion of the stomach is removed, and the remaining portion of the stomach is connected to the jejunum using a Roux limb. The length of the Roux limb can vary with long-limb gastric bypass utilising a longer limb, thus bypassing more of the jejunum and decreasing the absorption of ingested food (DeMaria 2007; Hassen-Khodja and Lance 2006).

Bariatric surgery involves intensive pre- and post-operative workup and supervision. Comprehensive assessments are required before surgery is approved and intensive follow-up monitoring by a multi-disciplinary team, including nutritional and psychological support and guidance, is needed post-surgery. Patients must be committed to this level of follow-up and to long-term if not life-long changes in their diet and eating behaviours. Pre- and post-operative services have not been examined to a great extent in the literature, but most likely play a part in determining the effectiveness of any surgical intervention.

NZHTA published a previous report examining the effectiveness, safety and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity (Day, 2005). This report concluded that bariatric surgery for morbid obesity is more effective for weight loss and resolution of comorbid conditions than non-surgical interventions, but carries with it increased risk of complications. The quality of evidence available in the literature was not high and although systematic reviews comparing different surgical procedures were identified, many of these included case series which limited the quality of their findings. Consequently, it was difficult for conclusions to be drawn regarding the relative safety and effectiveness of different surgical procedures. Short-term weight loss was generally greater after biliopancreatic diversion and gastric bypass than after restrictive procedures, but there was a lack of studies examining some newer procedures, such as laparoscopic adjustable gastric banding. There were indications this procedure could be safer initially but that long-term follow-up was needed to assess the rate of long-term complications. Surgery appeared to be cost effective compared to non-surgical treatment options or no treatment, however a lack of heterogeneity in economic analyses made it difficult to determine the relative cost effectiveness of different surgical procedures.

The current report aims to provide an update on the evidence for this topic and so focuses on systematic reviews and health technology assessments published between 2005 and 2007. Primary research studies will be examined for the period beyond which robust and relevant systematic reviews can be identified.
METHODS:

Study inclusion criteria

Publication type

Studies published in English between 2005 and October 10, 2007 inclusive, in the English language, including primary (original) research (published as full original reports) and secondary research (systematic reviews and meta-analyses) appearing in the published literature. Correspondence, editorials, and news items were excluded. Validated filters for identifying trials and economic studies were used where available for individual databases and adapted for other resources. Extended searching of internet websites, meeting abstracts, hand searching of journals, and contacting of authors for unpublished data was not undertaken.

Context

Studies reporting on the effectiveness, safety and/or cost effectiveness of surgical interventions compared with non-surgical interventions (medical management or no treatment) for morbidly obese patients. Studies reporting on the relative effectiveness, safety and/or cost effectiveness of different bariatric surgical procedures for morbidly obese patients. Where obese and morbidly obese patients are included in the sample, the results for morbidly obese patients must be reported separately.

Comparisons

Included comparisons:

1) Comparisons of surgical procedures, performed either as open procedures or laparoscopically, including vertical banded gastroplasty, horizontal gastroplasty, gastric banding, gastric bypass or biliopancreatic diversion.

2) Surgical procedures compared with usual care (no treatment or medical management)

Excluded comparisons:

1) Comparisons of variations in surgical techniques rather than different procedures

2) Jejunoileal bypass procedures

Outcomes

Studies which included measures of weight change, fat content or fat distribution, quality of life, obesity-related comorbidities, mortality, adverse effects and short- and long-term complication rates.

Study design

1) Randomised controlled trials comparing surgical interventions with other surgical interventions

2) Randomised controlled trials, controlled clinical trials and prospective cohort studies comparing surgical interventions with non-surgical treatment (medical management or no treatment)

3) For the economic analysis, studies that compare one intervention with another intervention in terms of incremental costs and benefits of those interventions.

Sample size

For primary research, studies with samples of at least 50 participants.
**Study exclusion criteria**

Research papers were excluded if they:

- were not published in English
- were "correspondence", book chapters, conference proceedings, abstracts, news items
- were primary studies with samples of fewer than 20 participants
- reported animal studies
- did not clearly describe their methods and results, or had significant discrepancies
- did not examine, or present findings separately for, morbidly obese patients, defined as BMI $\geq 40$ or $\geq 35$ with obesity-related comorbidities
- for the question regarding the effectiveness and safety of surgical compared with non-surgical interventions, studies were excluded if they were not randomised controlled trials, controlled clinical trials or prospective cohort studies
- for the question regarding the relative effectiveness and safety of different surgical procedures, studies were excluded if they were not randomised controlled trials
- for the question regarding cost effectiveness of bariatric surgery, studies were excluded if they did not include costs and benefits of comparative interventions

**MAIN SEARCH TERMS**

Details of the search strategy are presented in Appendix 2.

MESH headings (Medline subject headings): obesity-morbid, gastroplasty, exp economics, quality of life, value of life, quality adjusted life years, models-economic, markov chains, monte carlo method, decision tree, exp “costs and cost analysis”, clinical trials

Medline subheadings and publication types: economics[as a floated subheading], randomized controlled trial[publication type], clinical trial[publication type]

Embase subject headings (where different from Medline): morbid obesity, exp health care economics, exp health care cost, clinical trial, randomized controlled trial

Additional free text (used in all databases): obesity, weight loss, weight reduction, gastric surgery, bariatric surgery, gastric band$, gastric bypass, lap band$, restrictive surgery, malabsorptive surgery, “roux en y”, bilipancreatic diversion, bilipancreatic bypass, jejunooideal bypass, jejeuno-ideal bypass, jejunooideal bypass, jejeuno-ideal bypass, gastro?gastrostomy, gastroplasty, economic$, cost?, costing?, costly, costed, price?, pricing, pharmacoeconomic, pharmaco-economic, budget$, (value adj1 (money or monetary)), fee, fees, quality of life, QoL, hrQoL, quality adjusted life year$, qaly$, cba, cea, cua, utilit$, markov$, mone carol, (decision adj2 (tree$ or analy$ or model$)), (expenditure not energy)

**SEARCH SOURCES**

**Principal sources of information**

**Bibilographic databases:**
- Medline
- PubMed (last 90 days)
- Embase
- Cochrane Central Register of Trials
- Current Contents

**Review databases:**
- Cochrane Database of Systematic Reviews
- DARE database
- BMJ Clinical Evidence
- NHS Economic Evaluation Database
- Health Technology Assessment Database
Guidelines compilations:
US Guidelines Clearing House
UK National Library of Guidelines
Scottish Intercollegiate Guidelines Network
New Zealand Guidelines Group

APPRAISAL METHODOLOGY

The evidence presented in the selected secondary research studies was classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC, 2000). The designations of the levels of evidence are shown in Table 1 below.

Table 1. Designations of levels of evidence*

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly-designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from descriptive studies – e.g., case series, either post-test or pre-test/post-test designs</td>
</tr>
</tbody>
</table>

*Modified from NHMRC (2000)

Appraisal consisted of a two stage process. Initially, titles and abstracts (where available) identified from the search strategies, including references cited in retrieved papers and review articles, were scanned and excluded as appropriate. The remaining studies were retrieved as full text and the predetermined selection criteria were applied to identify articles eligible for appraisal.

Summaries of appraisal results are shown in tabular form (known as Evidence Tables) which detail study design, study setting, sample, methods, results, reported conclusions and NZHTA reviewer conclusions/comments based on the limitations and validity of the study.

RESULTS

Using the above search strategy, two searches were conducted: one of the effectiveness and safety literature and one of the cost effectiveness literature. These searches identified 286 and 452 potentially relevant articles/abstracts, respectively, of which 51 were retrieved in total. Of these retrieved articles, 28 were excluded.

Twenty-three retrieved articles were appraised (listed in Appendix 4). Included papers are presented in the evidence tables below. Included studies were all level III-3 and above according to NHMRC’s hierarchy of evidence, including systematic reviews of randomised controlled trials (Level II), systematic reviews which included well-designed pseudo-randomised controlled trials (Level III-1), and lower level systematic reviews which included a large proportion of case series.

The results are presented in two sections. The first section examines the effectiveness and safety of bariatric surgery compared with non-surgical interventions and the relative effectiveness and safety of different bariatric procedures. The results for this section present first, the findings and evidence tables (pages 9-15) for studies examining the performance of surgical compared with non-surgical interventions. Secondly, the findings of secondary and primary research studies investigating the relative effectiveness and safety of different bariatric procedures are presented. The evidence tables for these studies appear on pages 23-44. The second section addresses the cost effectiveness of bariatric surgery and different bariatric procedures, and the relevant evidence tables for these findings are presented on pages 59-63. Overall conclusions summarising effectiveness and cost effectiveness findings follow this section and appear on pages 64-66.
SECTION 1: EFFECTIVENESS AND SAFETY OF BARIATRIC SURGERY

Fourteen systematic reviews or technology assessments were identified as eligible for inclusion in this part of the report. Seven reviews included findings regarding the effectiveness and safety of non-surgical treatments compared with surgical interventions for morbidly obese patients. All fourteen reviews included comparisons of the performance of different surgical procedures with regards to weight loss and most provided some information regarding mortality and complications.

While nine reports commented on the change in comorbidities following surgical or non-surgical interventions, there was some variation in the way this was reported. This is reflective of the quality of studies included in these reviews. Much of the comorbidity and complications data came from case series, with inconsistency in the included comorbidities being common. Baseline comorbidity rates and post-operative or long-term follow-up of comorbidities was lacking in the literature. One meta-analysis (Maggard et al. 2005) provided pooled estimates of comorbidity incidence and resolution.

Effectiveness and safety of surgical versus non-surgical interventions

Colquitt et al. (2005) Cochrane Collaboration systematic review

A systematic review published by the Cochrane Collaboration (Colquitt et al. 2005) compared the effectiveness and safety of bariatric surgery with no treatment or medical management in morbidly obese adults. A search utilising a wide range of databases and with stringent inclusion and exclusion criteria yielded five eligible studies. Two were randomised controlled trials, one comparing gastroplasty with a very low calorie diet and one BPD with a prescribed diet, and three were prospective cohort studies comparing different types of surgical procedures (AGB, GBY, VBG) with no surgery, diet or conventional treatment.

The review concluded that gastric surgery resulted in very good weight loss and improved quality of life in morbidly obese adults when compared with non-surgical interventions, such as low calorie diets. The weight loss was maintained for up to eight years and was associated with reductions in comorbidities, such as diabetes and hypertension, and a reduction in the number of patients requiring medication for these illnesses. Bariatric procedures however, were associated with some side effects, and the risk of mild to severe complications or death. The authors acknowledged that the follow-up period required for studies to be included in the review (at least 12 months) was not long enough to fully determine the effectiveness of surgical procedures on outcomes. They also noted that the majority of studies included women aged 30-50 years, and so might not be representative of the effect of bariatric surgery in men or patients in other age groups. In other respects though, this was a sound review.

The Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (2005)

A large and high quality systematic review of the effectiveness and safety of bariatric surgery for morbidly obese patients was completed by the Medical Advisory Secretariat (2005). The search of a number of relevant databases (to December 2004) identified 15 relevant systematic reviews or health technology assessments, five of which compared surgical and non-surgical interventions. One of the strengths of this report was the thoroughness of the search and the exclusion of case series from analyses.

The authors concluded that bariatric surgery is effective for sustained weight loss of about 16% for morbidly obese patients and is also effective in the reduction or resolution of comorbid conditions. A systematic review included in the report suggested that commercial and organised weight loss programmes were overall not effective and calorie controlled diets may result in a small weight loss (2-5kg).

NZHTA Technical Brief (2005)

A technical brief produced by New Zealand Health Technology Assessment compared the effectiveness and safety of surgical and non-surgical interventions for morbid obesity. Two health technology assessments were identified from a thorough search of relevant databases (search date 2000 - 2004). The report concluded that surgical interventions resulted in significantly greater and more sustained weight loss and resolution of comorbidities than non-surgical interventions. Pharmacological treatment and controlled calorie diets resulted in small weight reductions which were maintained for 12 months. Studies were overall not of a high quality, with the best evidence comparing surgical and non-surgical interventions coming from the Swedish Obese
Subjects prospective cohort study. One of the important potential limitations of studies comparing surgical and non-surgical weight loss interventions mentioned in the report, is that non-surgical treatment options are more commonly offered to obese patients (BMI 30 - 35) whereas surgical options are more often presented to morbidly obese patients (BMI \( \geq 40 \) or \( \geq 35 \) with comorbidities). Consequently, the overall baseline weight of surgical patients was heavier than that of non-surgical patients. This could also mean that there were differences in the incidence of obesity-related comorbidities between the groups. Surgery was associated with a risk of serious complications.


Hassen-Khodja and Lance (2006) examined the surgical treatment of morbid obesity and included comparisons of the clinical effectiveness and safety of surgical and non-surgical interventions. Again, the major studies identified by the search were the SOS prospective cohort study and a retrospective cohort study (Christou et al. 2004). This review included 10-year follow-up data from the SOS study and reported an overall 16.1% weight loss in the surgery group compared with a 1.6% gain for the non-surgical group. It was pointed out that the treatment received by the non-surgical group varied as did the type of surgical procedure selected by patients in the surgical group. The retrospective study included in this report (Christou et al. 2004) included a large sample of surgical (n=1035) and non-surgical (n=5746) patients and found a 67.1% EWL (SD= 23.7%) in the surgical group. Weight loss data was not available for the control group.

In the SOS study the incidence of comorbidities for both groups of patients were also reported. The incidence of diabetes, hypertriglyceridemia, and hypertension were all lower in the surgical group with diabetes being 4 times lower at the 10 year follow-up. Overall, the AETMIS report concluded that surgical treatment is a more effective treatment option than non-surgical interventions for morbidly obese adults, but that it carries with it some potentially serious complications. The diversity of patient characteristics and a lack of well-designed studies prevented the authors from recommending one surgical treatment over another.

Maggard et al. (2005) American College of Physicians Clinical Guidelines Meta-analysis

Maggard et al. (2005) conducted a meta-analysis of effectiveness and adverse events associated with the surgical treatment of obesity. The search (to July 2003) included randomised controlled trials, comparative studies and case series with more than ten patients; however the case series were used mainly to examine adverse events. Weight loss, mortality, complication rates, control of comorbidities and changes in quality of life measures were reported. The SOS study was again a major source of data regarding weight loss and resolution of comorbidities. Hypertension, diabetes and lipid abnormalities were all lower in the surgical group at 24 months follow-up, however hypertension improvements were not significantly different between the two groups at the eight year follow-up. A retrospective cohort study (Christou et al. 2004) reported mortality rates of 6.17% in the non-surgical control group and 0.68% in the surgical group at two years follow-up. When comorbidities were examined using the large number of case series identified by the search (n=114), diabetes showed improvement in 64-100% of patients, hypertension improved in 25-100% of patients and dyslipidemia improved in 60-100% of patients.

The overall conclusions of the meta-analysis were that surgery results in sustained and greater weight loss than non-surgical treatment options and that this is accompanied by significant improvements in comorbid conditions. Direct comparisons between pharmacological, diet and surgical treatments could not be made because of a lack of heterogeneity in baseline patient characteristics and follow-up. However, findings suggested that surgical procedures result in a 20-40kg weight loss compared with 2-5kg from conventional treatments. Controlled trials or well-matched observational studies are needed to address the effectiveness and safety of different procedures and selection of procedure will depend on patient characteristics (age, gender, BMI, comorbidity profile). The lack of studies researching the effectiveness and safety of bariatric surgery in children and adolescents was also highlighted.


The British Medical Journal (Arterburn et al. 2006) produced a set of clinical guidelines examining the effects of bariatric surgery in morbidly obese adults and the effects of drug treatments in obese adults. The review included systematic reviews and randomised controlled trials but some search and eligibility criteria, for example the databases utilised, were not reported. The search identified two relevant systematic reviews
(Colquitt et al. 2005; Maggard et al. 2005) comparing bariatric surgery with usual care or other non-surgical intervention and weight loss and safety outcomes were reported. The findings of these systematic reviews relied heavily on the SOS prospective cohort and two retrospective cohort studies. Conclusions of the report were that bariatric surgery results in greater weight loss than non-surgical interventions in morbidly obese adults and that this is maintained for up to 10 years. The SOS study reported a 0.25% mortality rate and 13% post-operative complication rate in a cohort of patients who underwent a variety of surgical procedures (VBG 70%, GBY 6%, GB 23%). Usual care varied for the non-surgical group and did not often include pharmacotherapy. Mortality rates in the retrospective cohort studies ranged from 0.4% - 1.9% at 30 days follow-up.

**Institute for Clinical Systems Improvement (ICSI) Technology Assessment Report (2005)**

Metfessel et al. (2005) examined the use of gastric restrictive surgery in severely obese adults. Information regarding some aspects of the search strategy, for instance, the search date and databases searched, were not reported so the quality of this review is difficult to judge. However, the report did identify similar studies to those identified by other reviews. The SOS study and Christou et al. (2004) were identified as major sources of findings. Larger weight loss and resolution of comorbidities was identified from these studies and the report concluded that gastric surgery was an option for morbidly obese patients.
Table 2. Evidence table of secondary research studies comparing non-surgical interventions with surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
<th>Authors, study design, country, evidence grading</th>
<th>Interventions and methods</th>
<th>Results - comparative studies including RCTs of surgical vs non-surgical interventions</th>
</tr>
</thead>
</table>
| Arterburn et al. (2006) British Medical Journal Clinical Evidence Clinical Guidelines Evidence grade II | Effects of drug treatments in obese adults Effects of bariatric surgery in morbidly obese adults Search: July 2005 Included Systematic reviews and RCTs comparing drug treatments and surgical interventions for obesity Excluded: RCTs comparing drug treatments with less than 4 months follow-up RCTs comparing surgical interventions with less than 12 months follow-up RCTs with greater than 30% loss to follow-up unless intention to treat analysis completed Outcomes: Reduction in mortality Adverse effects of treatment Mean weight loss (kg) Proportion of people losing 5% or more of baseline body weight Proportion of people maintaining weight loss Inclusion criteria for measures of morbid obesity: Not specified Method of review of search and studies: Not specified | Bariatric surgery findings:  
- Two systematic reviews (Colquitt et al. 2005; Maggard et al. 2005) identified no RCTs which were judged to be of sufficient quality to include in the Clinical Evidence review  
- Both systematic reviews identified 1 prospective cohort study with matched controls (Swedish Obese Subjects study) and two retrospective studies which compared surgical and non-surgical interventions (Christou et al. 2004; Flum and Dellinger 2004)  
Bariatric surgery vs usual care:  
- SOS study: participants self-selected surgery or usual care, each surgery intervention person matched on 18 variables with non-surgery person. Surgical procedures varied (VBG 70%, GBY 6%, GB 23%). Usual care varied and usually did not include pharmacotherapy.  
- Surgery significantly increased weight loss compared with usual care at 1 year (change in body weight -23.4% with surgery, +0.1% without, p< 0.001). Long term follow-up showed that differences in weight loss remained significant at 10 years (16.1% with surgery, +1.6% without, p<0.001)  
- Mean percent weight loss at 10 years was 16.5% with VBG (n=451), 25% with GBY (n=34) and 13.2% with GB (n=156), follow-up rates were not reported in the Clinical Evidence review  
Bariatric surgery vs non-surgical intervention  
- Two retrospective cohort studies in morbidly obese adults  
- Surgery significantly decreased mortality at 5 year follow-up when compared with non-surgical treatment (1 study) and 15 year follow-up (1 study)  
- The form of the non-surgical interventions were not described in the Clinical Evidence review  
Complications and mortality rates  
- SOS: 5 deaths in 2010 people (0.25%), 13% post-operative complications, 2.2% re-operation  
- Retrospective studies: 1) mortality 0.4%, digestive disorders at 5 year follow-up 36.4% with surgery and 24.7% without; 2) mortality 1.9% with GBY surgery [30 day rate]  
- A further retrospective study published after the search date for this review (Flum et al. 2004) found 4.6% mortality rate at 1 year follow-up  
- Surgeon inexperience strongly associated with surgical mortality |
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<th>Clinical efficacy and safety</th>
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<tbody>
<tr>
<td>Hassen-Khodja and Lance (2006) AETMIS report Evidence grade III-3</td>
<td>Surgical treatment of morbid obesity Search date: 1998 – April 2005 Databases: Medline, Cochrane Library, Healthstar, HTA database, INAHTA Included: RCTs, non-randomised controlled trials and case series, a grid was developed to select studies based on study design publications date, number of patients treated, length of follow-up, relevance of clinical and economic outcome measures</td>
<td>Surgical vs non-surgical interventions: SOS intervention study – (Agren et al. 2002b, Sjostrom et al. 2004) open surgery (VBG, GB, GBY) compared with a medical therapy control subjects matched on 18 variables BMI &gt;34 for men and BMI &gt; 38 for women Variation in the conventional treatment offered to non-surgical group Weight loss at 1 year 25.1 ± 10.1% for surgery and 0.7% ± 6.5% for non-surgical Weight loss at 6 years 16.7 % ± 11.8% for surgery and 0.9% gain ± 10.1% for NS Drop out rate – 10% surgery and 19% NS Weight loss at 10 years 16.1% surgery and 1.6% gain NS Lost to follow-up 24.7% surgery and 26.4% for NS Surgery post-operative mortality was 0.25%</td>
<td>Comorbidities: SOS study: 2 year follow-up: incidence of diabetes 30 times lower in surgical patients than non-surgical patients Hypertiglyceridemia 10 times lower Hypertension 2.5 times lower 10 year follow-up: diabetes 4 times lower Overall discussion: Surgical treatment is a more effective therapeutic option than non-surgical interventions for morbidly obese people but has some potentially serious complications. Diversity of characteristics of patients with morbid obesity and the inadequate number of well-designed comparative studies do not allow one technique to be systematically favoured over another</td>
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<tr>
<td>Christou et al. (2004) Retrospective comparative study Patients matched by age and sex 1035 surgical and 5746 non-surgical patients with mean initial BMI 50 (range 36 – 98) Data extracted from provincial health-insurance databases 16 study years, 126 VBG, 68 VBG then RYGB, 841 RYGB 5 year follow-up EWL surgery = 67.1% (SD 23.7%), EWL non-surgery not reported</td>
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</tbody>
</table>
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</tr>
</thead>
<tbody>
<tr>
<td>Colquitt et al. (2005)</td>
<td>Interventions: 1) comparisons of surgical procedures, including VBG, horizontal gastroplasty, gastric banding, GBY, BPD 2) surgical procedure vs usual care (no treatment or medical management)</td>
<td>Surgical vs non-surgical interventions:</td>
</tr>
<tr>
<td>Cochrane Collaboration Systematic review</td>
<td></td>
<td>- Gastroplasty vs VLCD – 1 RCT</td>
</tr>
<tr>
<td>Evidence grade III-2</td>
<td>Search dates: Most recent searches – December 2009</td>
<td>- BPD vs diet – 1 RCT</td>
</tr>
<tr>
<td>Databases:</td>
<td></td>
<td>- Adjustable silicone gastric banding vs GBY vs diet consult – prospective cohort</td>
</tr>
<tr>
<td>Inclusion criteria:</td>
<td></td>
<td>- LAGB vs open GBY vs no surgery – prospective cohort</td>
</tr>
<tr>
<td>Hand searching of relevant journals, reference lists of relevant trials, experts contacted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCTs comparing different surgical procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCTs and prospective cohort studies comparing surgical and non-surgical interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants: adults aged 18 years and over with morbid obesity, in whom previous non-surgical interventions have failed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes: weight change, fat content [e.g. BMI] or fat distribution [e.g. waist-hip ratio] after 12 months follow-up Quality of life Change in comorbidities Mortality Adverse effects Revision rates</td>
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</tbody>
</table>

Limitations of the review (acknowledged by authors): Included studies with 12 months or longer follow-up. Expert opinion suggests follow-up should consider outcomes beyond five years. Majority of included patients were women in late 30s to early 50s who were morbidly obese. Potential benefits of weight loss may be greater among morbidly obese men of a similar age (CVD risk higher) or younger adults who have a great time to accrue benefit of maintained weight loss.

Implications for practice: The limited evidence suggests surgical interventions result in greater weight loss than non-surgical interventions, and that the results are maintained for at least 8 years. The weight loss is associated with reductions in comorbidities, such as diabetes and hypertension, and medication use. However surgery is associated with adverse effects and the possibility of post-operative mortality. There are a number of different operative procedures but the lack of quality evidence means that the comparative safety and effectiveness of these procedures is uncertain.
### Table 2. Evidence table of secondary research studies comparing non-surgical interventions with surgical interventions for patients with morbid obesity

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<th>Clinical efficacy and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Day (2005)</em>&lt;br&gt;New Zealand Health Technology Assessment Technical Brief&lt;br&gt;New Zealand Evidence grade III-2</td>
<td>What is the safety and effectiveness of surgical and non-surgical interventions for morbidly obese patients?&lt;br&gt;BMI 40+ or 35+ with significant comorbidities&lt;br&gt; Included: HTAs and systematic or non-systematic reviews or meta-analyses RCTs, controlled clinical trials Comparative studies e.g. cohort and case control designs&lt;br&gt;Outcomes: BMI change, EWL, morbidity, mortality, psychosocial outcomes e.g. QoL&lt;br&gt;Search date: 2000 - September 2004&lt;br&gt;Databases: Medline, Cochrane controlled trials register, Cinahl, Embase, review databases (5), guidelines (3)</td>
<td>Surgical vs non-surgical interventions:&lt;br&gt;Non-surgical interventions:&lt;br&gt;2 HTAs&lt;br&gt;Lefevre and Aronson (2003b) Blue Cross and Blue Shield&lt;br&gt;Good evidence that surgical interventions improve outcomes for morbidly obese patients compared to non-surgical interventions&lt;br&gt;Best evidence from SOS, comorbidities improved for surgical patients&lt;br&gt;STEER (Allgood, 2001)&lt;br&gt;Data suggested improved quality of life outcomes for surgical patients but serious adverse effects associated with surgery&lt;br&gt;Overall conclusions:&lt;br&gt;Surgical interventions resulted in significantly greater and more sustained weight loss and resolution of comorbidities but risked more serious complications.&lt;br&gt;Baseline weight of surgical patients was heavier than that of conventional treatment patients because conventional treatment is not usually offered to morbidly obese patients.&lt;br&gt;Pharmacological interventions resulted in a small weight loss sustained for 12 months&lt;br&gt;Low Fat Diets and Low Calorie Diets resulted in small weight reductions when combined with exercise and/or behavioural therapy but studies were not of high quality</td>
<td></td>
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</tbody>
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Table 2. Evidence table of secondary research studies comparing non-surgical interventions with surgical interventions for patients with morbid obesity

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</tr>
</thead>
<tbody>
<tr>
<td>Medical Advisory Secretariat (2005)</td>
<td>Evidence-based analysis of the effectiveness, safety and cost effectiveness of bariatric surgery to treat morbid obesity</td>
<td>15 systematic reviews or HTAs identified (some described in section comparing different surgical procedures):</td>
</tr>
<tr>
<td>Health Technology Assessment systematic review</td>
<td>Bariatric surgery compared with optimal conventional management or another type of bariatric procedure</td>
<td>ECI (2004) – systematic review of bariatric surgery to 2004– graded evidence as strong, moderate or weak based on quality, quantity, consistency and magnitude of effect. Inclusion criteria included control group who did not receive surgery. Results [weight loss, safety and comorbidities] reported separately for different surgical procedures – AGB, VBG, and RYGB. Also compared different bariatric procedures for effectiveness, safety and comorbidities (RCTs, controlled trials). Also reviewed studies of surgery in nonmorbidly obese adults (1 RCT), and morbidly obese adolescents (5 studies)</td>
</tr>
<tr>
<td>Ontario, Canada</td>
<td>Search date: April 2004 Subsequent search of Medline and Embase in December 2004</td>
<td>AHRQ (2004) – literature search of controlled studies of surgical treatments for obesity (2002 – 2003, RCTs, non RCTs, case series). Overall conclusions were that surgery results in greater sustained weight loss than non-surgical interventions in very obese (BMI 40+) individuals. This results in improved comorbidity outcomes but AHRQ review team did not comment on poor quality of the evidence on comorbid conditions. RYGB results in greater weight loss than VBG, post-operative mortality rates of less than 1% have been achieved by a number of surgeons.</td>
</tr>
<tr>
<td>Evidence grade II-2</td>
<td>Included: Systematic reviews, RCTs, non-RCTs or cohort studies with ≥ 100 patients Cost effectiveness studies</td>
<td>Blue Cross Blue Shield Association Technology Evaluation Centre (2003): surgery vs non surgery treatment in morbidly obese patients. Found that surgery improved health outcomes for morbidly obese patients, best evidence from SOS study (16% decrease in total body weight at 6 years vs 0.8% increase for usual care). Also concluded that some comorbid conditions and QOL improve after surgery</td>
</tr>
<tr>
<td></td>
<td>Excluded: Case reports Animal studies Non-systematic reviews</td>
<td>United States Centers for Medicare and Medicaid Services (Nov, 2004). Evidence for bariatric surgery in beneficiaries with comorbid conditions, and in beneficiaries who are obese without comorbid conditions</td>
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<tr>
<td></td>
<td>Databases: Cochrane library, ACP journal club, DARE, INHTA, EMBASE, MEDLINE, reference sections from reviews and articles</td>
<td>United Kingdom NHS HTA (2002): systematic review of the clinical effectiveness of surgery to manage morbid obesity (search October 2001, RCTs, prospective cohort studies). Overall, surgery resulted in greater weight loss than nonsurgical interventions and QOL and comorbidities improved. Gastric bypass seemed to produce greater weight loss and improvements in comorbidity conditions than gastroplasty or jejunoileal bypass.</td>
</tr>
<tr>
<td></td>
<td>Outcomes: Improvement in comorbid conditions Short and long-term weight loss Quality of life Adverse effects Economic analysis data</td>
<td>Primary Literature reviewed. Detailed summary of the Swedish Obese Subjects study.</td>
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<td></td>
<td>Conclusions: Bariatric surgery is effective for sustained weight loss of about 16% for morbidly obese people (BMI 40+ or 35+ with comorbid conditions). Also effective at resolving comorbid conditions. This is largely based on evidence from the SOS study (10 year outcomes). There is evidence that malabsorptive procedures are better than other banding techniques for weight loss and comorbid conditions. However there are no long-term prospective published comparisons available for these comparisons. A recent RCT systematic review suggested that major commercial and organised self-help weight loss programmes were in general not effective (Tsau, 2005). A recent RCT reported 1 year outcomes in people assigned to either low-carbohydrate or conventional weight loss diet. At the end of 1 year weight loss was similar for both groups (mean 2-5 kg).</td>
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<td></td>
<td>Comments: Robust and thorough review. High quality.</td>
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</table>
Table 2. Evidence table of secondary research studies comparing non-surgical interventions with surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
<th>Authors, study design, country, evidence grading</th>
<th>Interventions and methods</th>
<th>Results - comparative studies including RCTs of surgical vs non-surgical interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maggard et al. (2005) Meta-analysis United States Evidence grade III-3</td>
<td>Meta-analysis of effectiveness and adverse events associated with surgical treatment of obesity Search date: To July 2003 Databases: Medline, Embase, CCTR, systematic reviews Assessors: 3 reviewers independently reviewed the studies, abstracted data Consensus reached for disagreements (2 reviewers) Included: Initially, RCTs, controlled clinical trials and cohort studies After scan of the literature, case series with 10+ patients included to augment efficacy data and look at adverse events Outcomes: Weight loss, mortality, complication rates, control of comorbidities, QoL</td>
<td>Surgical vs non-surgical interventions: 2 RCTs (1979 – 1988) both showing greater weight loss with surgery at 24 months HG v diet Jejunoleal bypass v medical treatment • SOS study – voluntary bariatric surgery v conventional treatment Average age = 47, 2/3 women, average baseline BMI =41 10 year follow-up surgery 16.1% decrease and NS 1.6% increase in weight • O’Brien et al. (2006) LAGB v medical treatment (VLCD, pharmacotherapy and exercise) Weight loss 71% for surgery and 21% for non-surgery group Comorbidities: • SOS: hypertension, diabetes and lipid abnormalities lower in surgery group at 24 month follow-up (OR 0.02 – 0.38) Diabetes (OR=0.16) but not hypertension improvements still present at 8 year follow-up Improvements (hypertension) persisted in small proportion of GBY patients (greater weight loss) 10 year follow-up showed diabetes, hyperuricemia, and some lipid abnormalities continued to show improvement Improvement in QoL surgery group but not non-surgery • Christou (2005): matched cohort study (age, gender, first dx of morbid obesity) 2 year follow-up – mortality 6.17% of controls and 0.66% of surgery patients • Case series (N=114): Diabetes (21 studies): 64-100% improvement (initial range 3-100% with condition) Hypertension (19 studies): 25 – 100% improvement from initial range 16-83% with condition. Dyslipidemia (11 studies): 60-100% improvement from initial range 3-65% with condition Conclusions: Surgery results in greater weight loss in severely obese individuals than does medical treatment (20-30kgs maintained for 10 years+) This is accompanied by significant improvements in comorbid conditions. Direct comparisons of surgery and pharmaceutical or diet treatments cannot be made because the samples are different (Initial BMI) and follow-up is different. However, findings suggest 20-40kg for surgery and 2-5kg for conventional treatment. Very little information re adolescents or children. Controlled trials or well matched observational studies are needed to address different procedures effectiveness and safety. Selection of procedure depends on patient type (age, sex, BMI, comorbidity profile).</td>
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<tr>
<td></td>
<td></td>
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</tr>
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<tbody>
<tr>
<td>Metfessel et al. (2005) ICSI report Evidence grade III-2 but lack of information about inclusion criteria</td>
<td>Gastric restrictive surgery for clinically severe obesity in adults</td>
<td>Overall efficacy of surgery:</td>
</tr>
<tr>
<td></td>
<td>Search date: Not reported</td>
<td>- Christou et al. (2004) Observational cohort study</td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: Not reported</td>
<td>- Database used to extract 1035 surgery and 5746 control subjects consisting of severely obese subjects who did not have surgery</td>
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<tr>
<td></td>
<td>Exclusion Criteria: Not reported</td>
<td>- Excluded those with active medical conditions other than morbid obesity</td>
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<tr>
<td></td>
<td>Outcomes: Not reported</td>
<td>- BMI surgery 38-98</td>
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<tr>
<td></td>
<td>Databases: Medline and bibliographies</td>
<td>- 79% RYGB, VBG 18.7%, LRYGB 2.2%</td>
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<td></td>
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<td>- 35% of VBG converted to open RYGB</td>
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<td>- 5 year follow-up, mean follow-up 2.5-2.6 years</td>
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<td></td>
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<td>- RYGB &gt; VBG (68.7 vs 57.3% EWL)</td>
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<td></td>
<td></td>
<td>Surgery group – significantly lower incidence of cancer, CV conditions, endocrinological diseases, other comorbidities</td>
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<td></td>
<td>- Significantly higher rate of digestive conditions</td>
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<td></td>
<td></td>
<td>- Mortality rate over 5 years was 0.68% surgery and 6.17% non-surgery</td>
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<td></td>
<td></td>
<td>- Mean number hospitalisations, days in hospital and physician visits all lower for surgery group</td>
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<td></td>
<td></td>
<td>Strengths: exclusion of comorbidities at patient selection stage</td>
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<tr>
<td></td>
<td></td>
<td>- Weakness: lack of info about weight loss in controls, short mean follow-up and lack of BMI matching between cohorts</td>
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<td>- SOS (2004) 1845 surgically treated and 1640 conventional therapy obese patients</td>
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<td></td>
<td></td>
<td>- 641 surgical and 427 non-surgical patients followed up at 10 years</td>
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<td></td>
<td></td>
<td>- Inclusion: BMI 34+ men and 38+ women, age 37-60 years</td>
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<td></td>
<td></td>
<td>- Intention to treat analysis used, data adjusted for age, gender, energy/activity level, baseline BMI</td>
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<td></td>
<td></td>
<td>- Surgical patients were slightly younger, heavier and slightly higher insulin level than controls</td>
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<td></td>
<td></td>
<td>- Mean total weight decrease 1% after 6 months in control group (maximum)</td>
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<td></td>
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<td>- Surgery 1 year follow-up: 38% WL for RYGB, 26% VBG, 21% GB, additional 23.4% weight loss in second year, gradual weight gain after 2 years</td>
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<tr>
<td></td>
<td></td>
<td>- 10 year follow-up: 25% RYGB, 16.5% VBG and 13.2% GB, 1.6% gain non-surgical</td>
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<td></td>
<td></td>
<td>Incidence and recovery rates of diabetes, hypertriglyceridemia and hyperuricemia improved in surgery group, recovery rate of hypertension improved</td>
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<tr>
<td></td>
<td></td>
<td>Strengths: long follow-up and sample size</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Weakness: total weight loss rather than EWL, lack of inclusion of some comorbidities, lack of statistical testing of different surgical procedures</td>
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<td>- Suggests not all comorbidities improve and long-term follow-up needed because 2 year follow-up not always indicative of course of weight change.</td>
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<tr>
<td></td>
<td></td>
<td>Conclusions:</td>
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<td>- Gastric surgery an option for BMI 40+ or 35+ with comorbidities</td>
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</table>
Effectiveness and safety of different surgical procedures: Secondary research

**Canadian Agency for Drug and Technologies in Health (CADTH), Technology Report (2007)**

A very recent systematic review produced by the Canadian Agency for Drugs and Technologies in Health (CADTH) (Boudreau and Hodgson, 2007) examined the clinical and cost effectiveness of LAGB compared with other open or laparoscopic surgical procedures or non-surgical interventions. This high quality review included seven health technology assessments and systematic reviews as well as several primary trials retrieved as part of a search completed in April 2007. Two reviewers critically appraised the studies and a quality score was assigned to each report. Case series were excluded from the search.

While many of the included reviews received low quality scores, this was mainly due to the inclusion of case series and thus inadequate minimisation of selection bias. Two reviews received good to excellent quality scores, both of which are included in the current report (Colquitt et al. 2005; Lefevre 2007). The report concluded that there was a lack of high quality studies in the LAGB literature, with case series, a lack of long-term follow-up data and low or non-reporting of follow-up rates being common. Varying definitions of early and late complications and inconsistent reporting of complications made it difficult to provide any conclusions regarding the safety of one procedure compared with another. All the considered procedures (LAGB, VBG, LVBG, RYGB and LRYGB) had very low mortality rates. LAGB consistently had lower short-term complication rates but there may be long-term complications, for example, band erosion or slippage, which require re-operation. A lack of long-term follow-up data made it difficult to assess the long-term safety profile of LAGB in comparison with other procedures.

With regards to weight loss, the authors suggested that RYGB leads to greater weight loss than LAGB and VBG in early years post-surgery but it is less clear whether this difference persists in the long-term. Patient selection criteria, such as baseline BMI, comorbidities, psychological differences and food habits, such as sweet eating, may affect success but have not been examined yet.

**Blue Cross Blue Shield Association Technical Evaluation Centre, Technology Assessments (2005, 2007)**

Two technology assessments published by the Blue Cross Blue Shield Technology Evaluation Centre (Lefevre, 2005; Lefevre, 2007) examined the effectiveness and safety of different bariatric surgical procedures for morbidly obese patients. In the first (Lefevre, 2005), the effectiveness and safety of LAGB, BPD and long-limb GBY were each compared with GBY. Comparative studies as well as case series or single-arm studies with at least 100 patients and at least 12 months follow-up were eligible for inclusion. Overall, there was little high quality evidence identified by the literature search and the authors concluded that there was insufficient evidence to be able to draw conclusions about the relative effectiveness of gastric bypass and BPD or long-limb GBY.

The second report (Lefevre, 2007) reexamined the evidence comparing the effectiveness of LAGB and GBY procedures. Comparative studies with at least 25 patients per treatment arm and single-arm studies with at least 100 patients were eligible for inclusion. Seven comparative trials and 57 single-arm studies were identified and appraised with an additional 9 single-arm studies providing some long-term follow-up data for LAGB. In the comparative trials LAGB and LGBY patients were generally matched for age, gender and BMI with follow-up varying from 1 to 3 years. All found greater weight loss or greater excess weight loss following LGBY; however for two of these studies data were only available for 1-year follow-up. In terms of safety, there were no deaths in patients undergoing LAGB, two deaths in LGBY patients (0.3%) and some variation in short-term and long-term complications between the different procedures. Much of the information regarding complications came from case series and because these studies did not provide direct comparisons of the procedures and varied in length, follow-up rates and reporting of complications, the author could not draw any conclusions about the relative safety of each procedure. The most common adverse event reported in the comparative studies was wound infection (LAGB 1%, LGBY 2.5%) and in the case series wound infection, cardiopulmonary complications and conversion to open procedure occurred for between two and six percent of patients. Reoperations were more common following LAGB (23.8% versus LGBY 16.4%) but these rates were only reported in three studies.

The review concluded that LAGB resulted in less weight loss at 1-year follow-up than GBY, and that short-term complications and deaths as a result of either procedure were rare, occurring less often with LAGB. There was a lack of long-term follow-up in case series and it was difficult to directly compare LAGB and GBY based on
the evidence base. They did however recommend that either procedure was effective and safe enough to allow for patient choice between LAGB and GBY.

**Agence D’Evaluation des Technologies et Modes D’Intervention en Sante (AETMIS) (2006)**

Hassen-Khodja et al. (2006) authored a report for AETMIS which examined the surgical treatment of morbid obesity and included randomised controlled trials, comparative studies and case series published between 1998 and 2005. Studies were selected based on a set of criteria developed by the authors, which included the number of patients treated, length of follow-up and the relevance of clinical measures; however the details of these criteria were not reported. The quality of included studies was not high and for many comparisons a single retrospective cohort study was analysed. Two meta-analyses (Buchwald et al. 2004; Maggard et al. 2005) provided some data regarding the performance of four surgery types, namely gastroplasty, GBY, GB and BPD. Buchwald (2004) reported a lower weight loss following gastric banding compared with GBY, gastroplasty and BPD and a lower post-operative mortality rate for restrictive procedures (0.1%) compared with GBY (0.5%) and BPD (1.1%). Maggard et al. (2005) reported lower weight loss with AGB and VBG than RYGB and BPD at 3 years follow-up. Overall, surgical procedures resulted in 50-70% excess weight loss with some variation between procedures, although this was not consistent.

The authors of this report concluded that surgical treatment was a more effective intervention than non-surgical treatment options for morbidly obese people but carries the risk of some potentially serious complications. The diversity of patient characteristics and the lack of well-designed long-term studies made it very difficult to recommend one technique over another. Outcomes following surgery depended to a great extent on the exclusion of patients at high risk of post-operative complications and adequate preparation of patients prior to surgery, including counseling regarding the life-long commitment to follow-up post-surgery. Patient characteristics, such as age, comorbidities, BMI, food patterns and level of commitment to follow-up, and surgeon experience were all said to affect the effectiveness and safety of surgery.


The British Medical Journal (Arterburn et al. 2006) produced a set of clinical guidelines examining the effects of bariatric surgery in morbidly obese adults and the effects of drug treatments in obese adults. The review included systematic reviews and randomised controlled trials but some search and eligibility criteria, for example the databases utilised, were not reported. Comparisons of the effectiveness of different bariatric procedures yielded the following results:

**Gastric banding compared with gastric bypass**

One small trial suggested gastric banding was less effective in reducing weight than gastric bypass at 18 months follow-up. The authors concluded that there was insufficient evidence to draw conclusions about the relative effectiveness and safety of GB compared with GBY.

**Gastric banding compared with VBG**

The authors based their findings largely on the systematic review by Colquitt et al. (2005) and so shared the same inconclusive findings. The authors concluded that there was insufficient evidence to draw conclusions about the relative effectiveness and safety of GB compared with VBG. Postoperative complications were described as ‘common’ and laparoscopic GB was associated with shorter hospital stays and fewer readmissions than open GB.

**Gastric bypass compared with VBG**

The authors based their findings largely on the systematic review by Colquitt et al. (2005) and reported that there was some evidence that GBY was associated with increased weight loss at 1-3 years follow-up than VBG, but also some studies which found no difference between the procedures. Again a small risk of perioperative mortality but higher risk of postoperative complications was highlighted. The authors concluded that there was insufficient evidence to draw conclusions about the relative effectiveness and safety of GBY compared with VBG.

Overall recommendations were that bariatric surgery is effective in reducing potentially over 20% of body weight, and that this may be maintained for 10 years. Operative and postoperative complications were described as common and up to 2% of people die within 10 days of surgery. However, surgery may reduce long-
term mortality compared with no surgery. GBY, GB and VBG were all recommended as effective procedures while BPD and sleeve gastrectomy were rated as being of unknown effectiveness due to a lack of high quality evidence.


The United States Department of Veterans Affairs and Department of Defense produced a systematic review as part of the development of their clinical guidelines for the assessment and treatment of overweight and obesity. While many of their recommendations for diet, exercise, pharmacotherapy and behavioral interventions were based on studies of obese patients, the bariatric surgery evidence was generated from studies of morbidly obese patients, and so was included in the current report. The recommendations of the review were that there is good evidence that surgery is the only effective therapy for clinically significant and sustained weight loss in morbidly obese patients but only fair evidence regarding the effectiveness of different procedures.

Mortality rates in the included studies were less than 2% and the authors suggested that this would be less than 1% for experienced surgeons operating on well-selected patients. Age, male gender, severe obesity and the presence of comorbid conditions were all associated with higher mortality. Serious complications, such as anastomotic leaks, peritonitis, abscesses and pulmonary emboli were rare (1% incidence) but other complications were more common. Gastrointestinal symptoms were more common following restrictive procedures while malabsorptive procedures were associated with nutritional deficiencies. The safety and efficacy for special populations, for instance, people with psychiatric disorders, addictions or disabilities, remains unclear because the selection criteria used to recommend bariatric surgery often excludes them.

Centre for Obesity Research and Education (CORE) systematic review (2006)

The Centre for Obesity Research and Education (CORE) published a systematic review of the medium- to long-term weight loss effects (3-10 years post-surgery) of different bariatric surgical procedures (O’Brien et al. 2006). A range of databases were utilised and randomised controlled trials, comparative studies and case series with greater than 100 patients were considered eligible for inclusion. Tests of heterogeneity were completed where possible and mean %EWL at different follow-up periods was reported. Forty-three reports were included (18 LAGB, 18 RYGB, 7 BPD) with pooled estimates suggesting that there was a 54-67%EWL between 1 and 10 years after bariatric surgery with no diminishing effect at 10 years follow-up. Follow-up rates were not reported and the authors acknowledged that this occurred because of a lack of information in included studies. Overall, the authors concluded that bariatric surgery achieves a major reduction in weight (> 50%EWL) which is sustainable for at least 10 years. All procedures were effective, however, there appeared to be a fading of effectiveness over time for RYGB and this was not apparent in other procedures (AGB or BPD). The authors acknowledged some limitations to the review, including a lack of loss-to-follow-up data, and a general lack of high quality long-term data, which make it difficult to determine which procedure is more effective. For some long-term (8-10 years) time points, data were only available from one or two studies.

Colquitt et al. (2005) Cochrane Collaboration systematic review

A systematic review published by the Cochrane Collaboration (Colquitt et al. 2005) compared the effectiveness and safety of different bariatric surgical procedures, including VBG, HGP, GB, GBY and BPD in morbidly obese adults. A search utilising a wide range of databases and with stringent inclusion and exclusion criteria yielded 21 eligible randomised controlled trials.

Gastric bypass compared with gastroplasty

Twelve trials suggested GBY leads to a greater loss of weight than VBG or HGP up to 5 years after surgery. Patients lost on average 18-25% more excess weight by one year following gastric bypass compared with VBG, however two trials showed no difference. Gastric bypass patients lost on average 35-42% of their initial weight while HGP patients lost 16-29% of their initial weight. Comorbidities were reduced after surgery with 60% of patients free of medication at 3 years follow-up. Side effects, for example dumping syndrome, and post-operative deaths were more common following gastric bypass. Revisions, conversions and re-operations were more common following gastroplasty procedures.
**Vertical banded gastroplasty compared with adjustable gastric banding**

One trial suggested there was greater weight loss, fewer side effects and greater patient satisfaction with AGB (43kg) than VBG (35kg) over five years (statistical significance not provided). A second trial, which compared laparoscopic procedures, showed a significantly lower BMI with VBG (30.1 versus 35.5, p<0.05) at 1 year follow-up but no difference after 2 years and 3 years. Laparoscopic AGB was associated with shorter operative time and hospital stays than VBG but more late complications and re-operations.

**Laparoscopic compared with open surgery techniques**

Seven trials suggested that laparoscopic and open surgery techniques for GBY, VBG and AGB resulted in the same weight loss. There was little difference in the rate of complications but some difference in the type of complications and laparoscopic procedures took longer to perform on average.

**Conclusions**

Overall the limited evidence suggested that surgical interventions result in greater weight loss than non-surgical interventions and that this is maintained for at least eight years. The weight loss is associated with a reduction in comorbidities, such as diabetes, hypertension, and in medication use. There was not enough high quality evidence to ascertain the comparative safety and effectiveness of different surgical procedures. There was a lack of long-term follow-up data and one of the limitations of this review, acknowledged by the authors, was the inclusion of studies with only relatively short-term follow-up data (minimum 12 months). The patients included in studies were also most often women aged 30-50 years and the authors suggested the effectiveness of procedures may be different in men or younger or older populations.

**NZHTA Technical Brief (2005)**

A technical brief produced by New Zealand Health Technology Assessment compared the effectiveness and safety of surgical and non-surgical interventions for morbid obesity. Ten health technology assessments and 13 primary studies were identified comparing different surgical procedures, with more evidence available for GBY than other procedures. There was a lack of information regarding LAGB and BPD compared with RYGB and overall the available evidence was limited to lower quality studies. The report concluded that, while there was evidence that surgical interventions were on the whole effective, the relative safety and effectiveness of different procedures was more difficult to assess. It appeared that GBY and BPD may result in greater short-term weight loss but there was little long-term follow-up data available for LAGB procedures and it may be that these differences do not persist.

**Alberta Heritage Foundation for Medical Research (AHFMR) Technology Assessment (2005)**

A technology assessment was completed for the Alberta Heritage Foundation for Medical Research (Guo et al. 2005) investigating the effectiveness of LAGB for the treatment of morbid obesity in comparison with RYGB (open or laparoscopic) and LVBG. The search utilised a wide range of databases and included systematic reviews, randomised controlled trials, comparative studies and case series with long-term follow-up (≥5 years) and at least 500 patients. Three reviews and 18 primary studies were included in the report.

The three reviews identified by the search were all relatively high quality and suggested that LAGB was as effective as VBG but less effective than RYGB. Long-term follow-up data comparing these procedures was lacking however. All procedures seemed to result in improvements in obesity-related comorbid conditions, such as, diabetes, hypertension, hyperlipidemia, and sleep apnoea, and in overall quality of life (MSAC, 2003). The average mortality rates for the three reviews suggested that LAGB was at least as safe as RYGB or VBG.

The primary studies identified by this report included one randomised controlled trial, two comparative studies and 14 large case series. Post-operative mortality rates were similar for LAGB and LRYGB (both <1.0%) as were conversion rates (0-3.6%) and reported early complications (2-20%). Late complication rates and re-operations were higher for LAGB (9-44%, LRYGB 8-15%, LVBG 14%) but definitions of early and late complications varied between studies. Reoperations were more common following LAGB compared with LRYGB.

The authors of this review concluded that there was a lack of high quality long-term data regarding the effectiveness of LAGB, and that randomised controlled trials were needed to ascertain which procedures are most appropriate for which patient groups. The authors did suggest that LAGB appeared to be less effective
than LRYGB and LVBG, but given previous comments about the quality of the evidence base, this does not seem a valid conclusion. LAGB appeared to be as safe as LVBG and RYGB in terms of mortality and short-term complications, but may be associated with higher long-term complications. The choice of procedure should be tailored to the patient’s characteristics and situation and long-term studies with systematic surveillance and minimal loss-to-follow-up are needed.

The Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (2005)

A large and high quality systematic review of the effectiveness and safety of bariatric surgery for morbidly obese patients was completed by the Medical Advisory Secretariat (2005). The search of a number of relevant databases (to December 2004) identified 15 relevant systematic reviews or health technology assessments, five of which compared surgical and non-surgical interventions. One of the strengths of this report was the thoroughness of the search and the exclusion of case series from analyses.

The authors of the report concluded that bariatric surgery is more effective than non-surgical interventions, based largely on data from the SOS study. It was also concluded that there is evidence that procedures with a malabsorptive component (GBY and BPD) are better than banding techniques but that there are no long-term prospective studies available for these comparisons.

Maggard et al. (2005) American College of Physicians Clinical Guidelines Meta-analysis

Maggard et al. (2005) conducted a meta-analysis of effectiveness and adverse events associated with the surgical treatment of obesity. The search (to July 2003) included randomised controlled trials, comparative studies and case series with more than ten patients; however the case series were used mainly to examine adverse events. Weight loss, mortality, complication rates, control of comorbidities and changes in quality of life measures were reported. Studies which did not report weight loss in kilograms were excluded from pooled data estimates.

Five randomised controlled trials comparing different surgical procedures provided sufficient data for pooled weight loss estimates. Two trials compared the effectiveness of RYGB and VBG and found a higher weight loss for RYGB at 12 and 36 months (9kg more than VBG). These data were supported by many case series as well as the five controlled trials excluded because they did not report weight loss in kilograms. Two trials compared VBG with LAGB and found little difference in weight loss at 36 months follow-up. Combined controlled trials and case series supported this finding. One trial compared open and laparoscopic RYGB and found no significant difference in weight loss.

Pooled estimates of early death mortality (<30 days) were calculated separately for the controlled trials and case series. Mortality rates based on controlled trials were 1.0% for RYGB, 0.4% for AGB and 0.2% for VBG while for case series they were 0.3% for RYGB, 0.02% for AGB, 0.3% for VBG and 0.9% for BPD. No significant differences between procedures were reported. One study reported a learning curve effect on mortality rates with a 6% mortality rate for less than 20 procedures compared with a 0% mortality rate for more than 250 procedures. No strong conclusions could be drawn regarding other adverse events which varied between procedures and were inconsistently reported. Wounds, wound infection and incisional hernia were all lower for laparoscopic procedures, but re-operations were more common.

Case series (n=114) were used to examine the incidence and resolution of comorbidities following bariatric surgery. There was wide variation in the baseline incidence of comorbidities, for example, the incidence of diabetes was reported in 21 studies with between 3% and 100% of patients having the illness prior to surgery and 64-100% of patients experiencing post-surgical resolution of the illness. Similar patterns were reported for hypertension and dyslipidemia but the wide variation in pre-surgery incidence and post-surgery resolution made it difficult for the authors to draw any conclusions regarding the effectiveness of surgery on comorbid conditions.

Maggard et al. concluded that controlled trials or well-matched comparative trials were needed before the relative effectiveness and safety of different surgical procedures could be addressed.
Institute for Clinical Systems Improvement (ICSI) Technology Assessment Report (2005)

A report for the ICSI (Metfessel et al. 2005) examined the use of gastric restrictive surgery in severely obese adults. Information regarding some aspects of the search strategy, for instance, the search date and databases searched, were not reported so the quality of this review is difficult to judge. Two systematic reviews (Buchwald et al. 2004; Chapman et al. 2004) were identified as well as several randomised controlled trials and comparative studies. There was no conclusive evidence for more weight loss following different procedures in the reviews or randomised trials, and there was very little long-term follow-up data (> 2 years). There was also wide variation in the reporting and definition of complications and conclusive information about short- and long-term complications was not available. Comorbidities (diabetes, hyperlipidemia, hypertension and sleep apnoea) were reported as resolving in 70-86% of cases (Buchwald et al. 2004).

The report concluded that gastric restrictive surgery is an option for morbidly obese patients and that RYGB, VBG and LAGB are all relatively safe procedures (< 1.0% perioperative mortality). Comorbidities were improved and often resolved following surgery. Long-term follow-up data for LAGB was lacking.

Manterola et al. (2005)

Manterola et al. (2005) conducted a systematic review of the comparative effectiveness of different surgical procedures for morbid obesity. Randomised controlled trials, comparative studies and case series were included in the search strategy which utilised a limited number of databases. A quarter of the articles identified as eligible for inclusion (24%) were unobtainable and the final review included 6 comparative studies and 25 case series, thus limiting the reliability of the findings. Wide variation in the number and quality of studies available for different surgical procedures makes it very difficult to come to any conclusions regarding their relative effectiveness based on this review.

Primary research

Two very recent primary studies were identified which were not included in any of the selected reviews. One study (Angrisani et al. 2007) compared the effectiveness of two surgical procedures (LAGB and LRYGB). It was included in one review but retrieved after peer review, and so was included in full in this report to allow for a more detailed appraisal. The other (Alami et al. 2007) compared the effectiveness of LRYGB in patients who were requested to lose weight prior to surgery and patients who were not. This study was included as part of the sub-question regarding wrap-around services.

Angrisani et al. conducted a randomised controlled trial comparing the long-term (5 year follow-up) effectiveness of LAGB and LRYGB. The sample included 27 LAGB patients and 24 LRYGB patients with no significant differences between the groups in age, weight or BMI prior to surgery. No deaths occurred for either group and complication rates were similar. The operative time was significantly shorter for LAGB (60 ± 20 mins) compared with LRYGB (220 ± 100 mins) as was the length of hospital stay (2 ± 1 days LAGB, 4 ± 2 days LRYGB, p<0.05). Two LRYGB and no LAGB patients experienced early complications, with one LRYGB patient requiring a long intensive care unit stay (jejunal perforation followed by an acute abdomen and sepsis). One LRYGB (internal hernia) and 2 LAGB (gastric pouch dilatation) patients experienced late complications, with both LAGB patients having their gastric bands removed as a consequence.

The LRYGB group demonstrated greater weight loss in kilograms, %EWL and decrease in BMI than the LAGB group at 5 years follow-up. At 60 months post-surgery the average weight in kilograms was 97.9kg for LRYGB patients and 84.0kg for LAGB patients, with excess weight loss of 47.5% (LAGB) and 66.6% (LRYGB) (p<0.001) and average BMI of 34.9 (LAGB) and 29.8 (LRYGB). Follow-up rates were not reported so it is unclear whether these results represent all patients, those who were available at all time points, or whether intention-to-treat analyses were carried out. The authors reported that the sleep apnoea, diabetes, and hyperlipidemia present in patients before bariatric surgery had all resolved by the 5 year follow-up, but that low baseline rates meant it was not possible to comment on the effectiveness or relative effectiveness of the surgical procedures. Three patients had hypertension prior to surgery and no mention was made of their resolution or improvement at follow-up.

The follow-up period of five years is longer than many other studies of these surgical procedures, however even longer-term data is needed before the relative effectiveness of the two techniques can be judged. A recent meta-analysis by O’Brien et al. (2006) suggests that there may be a reduction in weight loss over time following
LRYGB with little difference between RYGB and AGB at 5-10 years follow-up. These results were based on a small number of studies with lengthy follow-up and included case series, so the findings need to be investigated further. The authors also acknowledged that this study occurred at the beginning of their experience with the LRYGB technique and so rates of complications may have been subject to a surgical learning curve effect.

Alami et al. conducted a randomised controlled trial comparing patients who were instructed to lose weight prior to LRYGB surgery with a group who were not. One hundred patients were randomly allocated to either group following contact with a bariatric surgery clinic, however 39 of those patients did not undergo LRYGB surgery, mostly due to either moving, deciding not to undergo surgery or opting for LAGB surgery instead. In those who did undergo LRYGB surgery, there was no significant difference in the age, gender or initial BMI between the groups. The weight loss group did demonstrate a significantly lower average BMI prior to surgery though (WL 44.5 kg/m², NWL 50.7 kg/m²). There were no intra- or post-operative deaths in either group and complication rates were similar. Total operating time was significantly lower in the weight loss group (220 mins) compared with the no weight loss group (257 mins) but the length of hospital stay was similar.

There was an initial significant difference in weight loss at the two week, six week and three month follow-up checks, but this difference had disappeared by six months and both groups had achieved similar weight loss by this time (WL group = 53.9%EWL, NWL group = 50.9%EWL). There was similar resolution of comorbidities in both groups by 3 months follow-up with the average number of comorbidities decreasing from 4.5 to 0.7 for the weight loss group and 0.6 for the no weight loss group.

The numbers of patients contributing data at the six and twelve month follow-up time points was low but this may have been because the operations were carried out between May 2004 and October 2005 and many patients had their surgery less than six or twelve months ago. Nevertheless, this does lessen the reliability of the findings. In addition, longer follow-up is needed before conclusions can be drawn about long-term differences between the two groups. Early data would suggest that there was no benefit in terms of weight loss but possible benefit in length of operating time for patients who lose weight prior to bariatric surgery.
### Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
<th>Authors, study design, country, evidence grading</th>
<th>Interventions and methods</th>
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<tbody>
<tr>
<td>Boudreau and Hodgson (2007)</td>
<td>Clinical and cost effectiveness of LAGB compared to RYGB (open and lap), VBG (open and lap), lifestyle modification or control groups (e.g. intensive diet regime)</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td>Canadian Agency for Drugs and Technologies in Health (CADTH)</td>
<td>Included studies: RCTs or cohort or case-control studies</td>
<td>• HTAs included: AETMIS (1988 – 2005) – included SRs but also retrospective non-comparative studies. LAGB, RYGB, BPD. Sample size at follow-up periods not reported, possible bias in that it may be the most successful cases or most committed patients who were successfully followed-up. Quality of HTA = 2 (major flaws) because of uncertainties regarding the literature search and selection bias.</td>
</tr>
<tr>
<td>Systematic review Canada</td>
<td>Excluded: case series, comparisons of different techniques within the same surgical procedure, reports containing information about operations outside the focus of this report e.g. BPD</td>
<td>• AHFMR HTA (Guo, 2005) – LAGB, RYGB, VBG, emphasis on longer-term follow-up. Included 3 HTAs, 1 RCT, 3 comparative non-randomised trials and 10 case series. Quality score = 2 (major flaws) – inadequate minimisation of selection bias.</td>
</tr>
<tr>
<td>Evidence grade III-2</td>
<td>Participants: Obese patients</td>
<td>• ICSI (2005) – bariatric surgery (LAGB, RYGB, VBG. Baseline differences between groups missing, 12mth and 24mth %EWL rates, quality score =1( extensive flaws) because of missing information regarding search, eligibility and selection criteria.</td>
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<td>Search: PubMed, BIOSIS Previews, EMBASE, MEDLINE, PreMEDLINE, information via alerts until April 9, 2007. Cochrane databases searched 2007. Search and retrieval limited from 2005 to 2007 for SRs and HTAs and 2004 to 2007 for primary clinical and economic studies. Websites of relevant agencies Hand searching of journals Critical appraisal, 2 reviewers, 3rd reviewer used where consensus could not be reached</td>
<td>• Systematic reviews included: Blue Cross TEC – LAGB, GB (1980 – 2006). 8 comparative (3 matched controls) and 57 case series. Quality score = 4, (between minor and major flaws), possible selection bias, difficulty in interpreting results because of the case series and most of the comparative studies were between facilities.</td>
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<tr>
<td></td>
<td>Critical appraisal, 2 reviewers, 3rd reviewer used where consensus could not be reached</td>
<td>• O’Brien et al (2006) – LAGB, RYGB. No follow-up rates reported, no information re total patient populations. Quality score = 2 (major flaws) – inadequate minimisation of bias in selecting and including studies</td>
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<tr>
<td></td>
<td>Outcomes: %EWL, change in BMI or BMI reduction, change in obesity-related comorbidities</td>
<td>• MAS HTA (2005), included HTAs 2004 and primary studies 1990 – 2004 (LAGB, RYGB, GB, BPD, lack of long-term evidence. Quality score = 2 , possible selection bias.</td>
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<td>• Cochrane Collaboration review (Calkiell et al. 2005) – surgery for morbid obesity, 23 RCTS, 3 non-randomised studies. GB, VBG, LAGB, RYGB. Quality score = 7 (minimal flaws)</td>
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<td>• Primary trials:</td>
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<td>• O’Brien et al (2006) 40 LAGB v 40 non-surgical, 30-35 BMI + comorbidity, 24 mth follow-up, significantly greater %EWL for LAGB group (87.2%) compared with non-surgical (21.8%). Follow-up rates differed between groups.</td>
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<td>• Van Diielen (2005) 50 LAGB v 50 VBG RCT</td>
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<td>• Miller et al (2007) – LAGB v VBG prospective comparative trial based on patient preference</td>
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<td>• Jan et al (2007)LAGB v LRYGB prospective comparative trial – 5 year follow-up</td>
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<td></td>
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<td>• Quebbemann (2003) retrospective comparative trial, LRYGB v LAGB, &gt;65 years old</td>
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<td></td>
<td></td>
<td>• Pontorolli (2006) retrospective trial LAGB v control patients who refused surgery, change in BMI, comorbidities, possible difference between groups before intervention, 4 year follow-up</td>
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<td>Conclusions:</td>
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<td>• Much of the literature regarding LAGB is case series, lack of long-term follow-up (i.e. ≥ 5 years), and low participation at follow-up. Case series may be the best source of this information until better quality studies are followed up, variation and inconsistency of reporting complications, varying definition of early and late complications.</td>
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<td>• Very low mortality rates are associated with LAGB, VBG, LVGB, RYGB, LRYGB. LAGB consistently has fewer short-term complications, however there may be long-term complications that require re-operation, diminishing its safety profile and affecting its economic profile</td>
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<td>• RYGB leads to greater EWL in early years post surgery, VBG patients may also lose more weight than LAGB, it is less clear whether this difference persists over the long term.</td>
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<td>• Patient selection criteria such as baseline BMI, comorbidities, psychological differences, food habits may affect success but are unaddressed at this stage</td>
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<td></td>
<td></td>
<td>• Cost of LAGB is reasonable</td>
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<td></td>
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<td>• Angrisani (2007) was retrieved after peer review – RCT LRYGB v LAGB, 5 year follow-up,</td>
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<td>• One caution with LAGB is whether the low complication rate persists past 3 years (erosion, slippage, surgery)</td>
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<tr>
<td>Lefevre (2007) Blue Cross Blue Shield Association Technology Evaluation Centre Technology Assessment</td>
<td>Effectiveness and safety of LAGB in comparison with open or lap gastric bypass for morbidly obese patients.</td>
<td>7 comparative trials and 57 single arm studies.</td>
</tr>
<tr>
<td>Search strategy: 1980 – September 2006 Databases: MEDLINE, PubMed, Manual search of bibliographies and Cochrane reviews</td>
<td>Include: Comparative studies with at least 25 patients per treatment arm - LAGB vs GBY. Single-arm studies with at least 100 patients investigating LAGB. Most complete or recent article from studies with multiple publications. At least 1 year follow-up Morbidly obese patients - BMI 40+ or 35+ with serious comorbidities.</td>
<td>Additional 9 single-arm studies met criteria of at least 50% patients followed-up at 2 years and provide information on long-term weight loss and adverse events for LAGB.</td>
</tr>
<tr>
<td>O’Brien et al (2006) excluded: BMI 30 - 35, n=80, LAGB vs non-surgical treatment.</td>
<td>7 comparative trials; - LAGB vs LGBY - 3 trials, matched patients. Cottam et al (2006) n=181 each tmt arm, 3 year follow-up, patients matched on BMI and surgery date. Weight loss: LGBY(76% EWL) &gt; LAGB (48% EWL) at 1 year, LGBY (80%) &gt; LAGB (55%) at 2 years, LGBY (74%) &gt; LAGB (51%) at 3 years. Hell et al (2000) n=30/tmt arm, 3 procedures (GBY, VBG, LAGB), patients matched on age, gender, BMI. Weight loss - patients with &gt;50% EWL at 1 year GBY (93%) &gt; LAGB (54%). Weber et al (2004) n = 103/tmt arm, patients matched on age, gender, BMI. Weight loss: LGBY (55%) &gt; LAGB (35%) at 1 year, decrease in BMI LGBY (14.8) &gt; LAGB (9.0)</td>
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</tr>
<tr>
<td>O’Brien et al (2006) excluded: BMI 30 - 35, n=80, LAGB vs non-surgical treatment.</td>
<td>7 comparative trials; - LAGB vs LGBY - 4 trials with comparisons of outcomes from separate case series. Weight loss 19.4 - 34.0% EWL, all studies showed greater weight loss for LGBY groups.</td>
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<tr>
<td>Adverse events: - Short-term Rates low for LAGB and lower than LGBY. No deaths in 1658 patients undergoing LAGB. Most common short-term event was wound infection (1% of patients) [LGBY 2.5%]. Remainder of short-term events was &lt;1% [LGBY 2.5%].</td>
<td>Rates low for LAGB and lower than LGBY. No deaths in 1658 patients undergoing LAGB. Most common short-term event was wound infection (1% of patients) [LGBY 2.5%]. Remainder of short-term events was &lt;1% [LGBY 2.5%].</td>
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<td>- Long-term Reoperations (3 studies, 344 patients) LAGB 23.8% [LGBY 16.4%]. Slippage/dilatation LAGB 5% [LGBY NA]. Other [band erosion, obstruction, port problems, hernia] LGBY &lt;5% [LGBY obstruction 5.2%].</td>
<td>Long-term complications data was less well reported. Lack of long term follow-up in case series. Difficulty to directly compare LAGB and GBY as risks and benefits differ. LAGB fewer complications, decreased hospital stay but less weight loss. Sufficient evidence to allow for patient choice between LAGB and GBY.</td>
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</tr>
<tr>
<td>Parikh et al (2005) adverse events by severity and timing. Total complication rate 8.7% LAGB and 23.0% LGBY.</td>
<td>Discussion: Reinforces 2005 TEC assessment that LAGB results in less weight loss at 1 year than GBY. Suter et al (2006) investigated attrition bias and effect on EWL, compared intention to treat analyses by treatment received analyses. Two weight loss curves differed by years 3-5. Serious short-term adverse events very uncommon and occurred less with LAGB than LGBY. Death extremely uncommon. Long-term complications data was less well reported. Lack of long term follow-up in case series. Difficulty to directly compare LAGB and GBY as risks and benefits differ. LAGB fewer complications, decreased hospital stay but less weight loss. Sufficient evidence to allow for patient choice between LAGB and GBY.</td>
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<td>Update of previous TEC assessments 2003a, 2003b</td>
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<tr>
<td>Blue Cross Blue Shield Association Technology Evaluation Centre, Evidence grade III-3</td>
<td>• Are outcomes of LAGB as good as outcomes of open GBY for patients with morbid obesity&lt;br&gt;• Are outcomes of BPD as good as outcomes of open GBY for patients with super obesity&lt;br&gt;• Are outcomes of long-limb GBY as good as outcomes of open GBY for patients with super obesity</td>
<td>Surgical procedure comparisons:&lt;br&gt;• LAGB vs GBY&lt;br&gt;4 comparative studies (see Lefevre, 2007)&lt;br&gt;4 single-arm&lt;br&gt;• BPD vs GBY&lt;br&gt;1 comparative study, 7 single-arm&lt;br&gt;Deveney et al (2004) comparative study, n=237 GBY and n=113 BPD&lt;br&gt;Non-random allocation, %EWL same for both groups (63%) at 1 year&lt;br&gt;Similar mortality rate (0.8% vs 0.9%)&lt;br&gt;Similar wound infection rate (20% vs 22%)&lt;br&gt;Anastomotic leaks more common following BPD (6%)&lt;br&gt;7 single-arm trials: average %EWL = 68% at 1 year&lt;br&gt;Adverse events poorly reported&lt;br&gt;Slater et al (2004) reported vitamin deficiencies after BPD, over a 4 year period 48% of patients low in calcium and 63% low in vitamin D, 69% low in vitamin A, 68% low in vitamin K and 50% low in zinc&lt;br&gt;Conclusions:&lt;br&gt;Lack of high quality evidence, comparative trials&lt;br&gt;Not sufficient to draw conclusions but suggest BPD is not more effective than GBY&lt;br&gt;• LLGBY vs GBY&lt;br&gt;6 comparative studies&lt;br&gt;1 single-arm&lt;br&gt;No significant differences in weight loss&lt;br&gt;Comparison of two versions of same procedure&lt;br&gt;Insufficient evidence to draw conclusions about the efficacy and safety relative to GBY</td>
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</table>

Search date: 1985 - July 2005<br>MEDLINE, PubMed, Manual search of bibliographies and Cochrane reviews<br>Included:<br>Comparative studies with one or more comparisons of interest and at least 25 patients per treatment arm<br>Single-arm studies with at least 100 patients investigating LAGB or BPD or LLGBY<br>Most complete or recent article from studies with multiple publications<br>At least 1 year follow-up<br>Morbidly obese patients - BMI 40+ or 35+ with serious comorbidities<br>Studies were not limited to super obese patients for BPD or LLGBY procedures<br>Outcomes:<br>Weight loss<br>Adverse effects of surgery<br>Long term adverse effects<br>Quality assessment:<br>Based on USPSTF with 5 quality indicators:<br>Randomisation, allocation to groups<br>Maintenance of groups<br>Definition of intervention<br>Comparable measurements<br>Appropriate analysis
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<tr>
<td>Hassen-Khodja and Lance (2006) AETMIS report Systematic review Evidence grade III-3</td>
<td>Surgical treatment of morbid obesity Search date: 1998 – April 2005 Databases: Medline, Cochrane Library, Healthstar, HTA database, INAMTA Included: RCTs, non-randomised controlled trials and case series. A grid was developed to select studies based on study design, publication date, number of patients treated, length of follow-up, relevance of clinical and economic outcome measures</td>
<td>Comparative studies of surgical procedures:  - BPD vs RYGB 1 retrospective cohort study  - BPD vs VBG 1 retrospective comparative study BPD 60% EWL and VBG 48% EWL at 2 years, significance not reported  - VBG vs VBG-RYGB 1 retrospective non-comparative study, n= 328 VBG and 560 VBG-RYGB VBG-RYGB 62±17% and VBG 47 ± 23% at 5 years (sig diff) Staple line disruption most common complication, late-complication rate was 22% for first 272 VBG-RYGB cases but 1% for next 351  - VBG vs RYGB vs LSAGB 1 prospective study RYGB (60± 8.2%) more effective for EWL than VBG (40.1±8.3%) or LSAGB (39.7±7.6%) No difference in rating of QoL  - LRYGB vs LAGB Two institutions, n=1200 LRYGB and n=805 LAGB Data retrospective for LRYGB group and prospective for LAGB group Initial BMIs significantly different for the two groups LRYGB lost significantly more weight (74.6% EWL) than LAGB (40.4% EWL) at 18 months LRYGB led to more complications than LAGB – early, intra-operative and deaths Follow-up rates differed substantially (37% LRYGB and 97% LAGB)  - AGB vs NAGB Four centres, n=1812 NAGB, n=1968 AGB patients EWL and early complication rates same in both groups at 2 years Significant differences in late complications and re-operations</td>
</tr>
<tr>
<td>Authors, study design, country, evidence grading</td>
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<tr>
<td>Hassen-Khodja and Lance (2006) continued AETMS report Systematic review Evidence grade III-3</td>
<td>Comparison of four main surgery types: 2 meta-analyses Buchwald (2004) Gastroplasty, GBY, AGB and NAGB and BPD 5 RCTs and 28 non-randomised controlled studies, 101 case series and 2 health-economic studies Surgery EWL 95% CI 58 – 64% Gastric banding 47%, GBY 62%, gastroplasty 68% and BPD 70% Post-operative mortality 0.1% for restrictive procedures, 0.5% GBY and 1.1% BPD</td>
<td><strong>Clinical efficacy and safety</strong></td>
</tr>
</tbody>
</table>
|                                                 | Maggard (2005) RYGB, VBG, AGB, BPD At 36 months WL RYGB = 41.5kg, VBG = 32.0kg, AGB=34.8kg, BPD = 53.1kg | **Comorbidities:**  \* SOS study:2 year follow-up: incidence of diabetes 30 times lower in surgical patients than non-surgical patients Hypertriglyceridemia 10 times lower Hypertension 2.5 times lower 10 year follow-up: diabetes 4 times lower **Overall discussion:** Surgical treatment is a more effective therapeutic option than non-surgical interventions for morbidly obese people but has some potentially serious complications. Diversity of characteristics of patients with morbid obesity and the inadequate number of well-designed comparative studies do not allow one technique to be systematically favoured over another. Outcomes depend to a great extent on: Exclusion of patients at risk of post-operative complications Psychological preparation Clinical preparation Acceptance of long-term if not lifelong follow-up Patient characteristics – age, personality, BMI, food patterns, understanding and commitment, comorbidities, contra-indications **Other factors are also important to success of intervention:** Learning curve of surgeons Appropriate clinical setting Mgmt by a multidisciplinary team Long-term medical follow-up Reconstructive plastic surgery may be necessary

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**Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity**
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Clinical efficacy and safety |
|------------------------------------------------|--------------------------|---------------------------------------------------------------------------------|
| Arterburn et al. (2006) British Medical Journal Clinical Evidence Clinical Guidelines Evidence grade II | Effects of drug treatments in obese adults Effects of bariatric surgery in morbidly obese adults Search: July 2005 Included Systematic reviews and RCTs comparing drug treatments and surgical interventions for obesity Excluded: RCTs comparing drug treatments with less than 4 months follow-up RCTs comparing surgical interventions with less than 12 months follow-up RCTs with greater than 30% loss to follow-up unless intention to treat analysis completed | Complications and mortality rates:
SOS: 5 deaths in 2010 people (0.25%), 13% post-operative complications, 2.2% re-operation
- Retrospective studies: 1) mortality 0.4%, digestive disorders at 5 year follow-up 36.4% with surgery and 24.7% without; 2) mortality 1.9% with GB surgery (30 day rate)
- A further retrospective study published after the search date for this review (Flum et al. 2005) found 4.6% mortality rate at 1 year follow-up
- Surgeon inexperience strongly associated with surgical mortality

Gastric Banding vs GBY:
- 1 small RCT: gastric banding less effective than GBY in reducing weight at 18 months

Gastric Banding vs VBG
- 1 systematic review (Colquitt et al. 2005): 1 RCT found gastric banding resulted in smaller weight loss at 1 year compared with VBG but greater loss at 5 years (43kg gastric banding, 33kg VBG). 1 RCT found gastric banding resulted in greater EWL at 18 months (62.5%) compared with VBG (60%, sig not assessed). 1 RCT found fewer people had an excellent or good result (residual excess weight <50%) at 2 years compared with VBG (35% gastric banding, 74% VBG, p<0.001)
- open vs lap gastric banding: 1 RCT. No sig difference [34.5kg v 33kg]
- mortality: 1 sys review showing 0.4% 30 day mortality in comparative studies, surgical complications 13.2%, reoperations 7.7%, gastrointestinal symptoms 7.0%

GBY vs VBG
- 1 systematic review: 4 RCTs found that GBY significantly increased %WL at 1-3 years compared with VBG, 2 RCTs found no sig difference between procedures
- Two subsequent RCTs: LGBY increased weight loss compared with lap VBG at 1 and 2 years
- Mortality: 3 RCTs no deaths, 1 RCT reported no deaths with VBG but 2 deaths (10%) with GBY, 1 RCT reported more early postoperative complications with GBY than VBG. 1 RCT no deaths in either group and no sig diff in reoperation rates or perioperative complications

Key recommendations:
- Bariatric surgery (VBG, GBY, or GB) may increase weight loss compared with no surgery in morbidly obese people.
- Bariatric surgery may result in loss of over 20% of body weight, which may be largely maintained for 10 years.
- Operative and postoperative complications are common and up to 2% of people die within 10 days of surgery. However, surgery may reduce long term mortality compared with no surgery.
- BPD and sleeve gastrectomy both rated as having unknown effectiveness due to a lack of RCT evidence
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<th>Authors, study design, country, evidence grading</th>
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<th>Results - comparative studies including RCTs comparing different surgical interventions Clinical efficacy and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Veterans Affairs and Defense (2006)</td>
<td>Databases: Medline, PubMed, DARE, CCTR, hand searching of bibliographies</td>
<td>Bariatric surgery recommendations: For adults with BMI $\geq 40$ there is good evidence from numerous high quality systematic reviews that bariatric surgery is the only effective therapy for promoting clinically significant weight loss (ECRI, 2004; Maggard et al. 2005; Shekelle et al. 2004) (\text{ECRI (2004)}) – weight loss was maintained for at least 3 years for all procedures examined, although the average patient remained obese following surgery. Safety and efficacy of surgery in patients with uncontrolled psychiatric disorders, substance abuse, oxygen dependence, severe CVD, or status post MI, or wheelchair-bound remains unknown (generally excluded from studies). Patients with BMI between 35 and 40 who have obesity-related comorbidity should also be considered for weight loss surgery. Evidence is not as robust as for patients with BMI &gt; 40 (Shekelle, 2004).</td>
</tr>
<tr>
<td>Systematic review which contributed to the development of clinical guidelines</td>
<td>Search date: 1995 – 2004</td>
<td>Comorbidity: There is fair evidence that surgery-induced weight loss improves obesity-associated comorbidities (Maggard et al. 2005; Shekelle et al. 2004). Diabetes, hypertension, dyslipidemia, sleep apnoea all improved or resolved following bariatric surgery. Relatively few studies report these outcomes and most of the studies that do are case series and/or have incomplete follow-up of patients. Quality of Life: Fair evidence for substantial improvement in QoL.</td>
</tr>
<tr>
<td>Evidence grade United States</td>
<td>Inclusion criteria: RCTs, systematic reviews, meta-analyses</td>
<td>Type of surgery: There is fair evidence from RCTs and observational studies that RYGB results in greater weight loss than VBG and AGB (ECRI, 2004). Data regarding the efficacy of AGB includes only a minority of studies reporting long-term (&gt; 3 years) weight loss outcomes. Evidence is fair to support LLRYGB as a means of substantial weight loss. A small number of BPD and BPD-DS studies meet criteria for inclusion in evidence-based review</td>
</tr>
<tr>
<td></td>
<td>Adults &gt;18 years</td>
<td>Consistent evidence from several RCTs that laparoscopic procedures result in equivalent weight loss and fewer wound complications than open surgical procedures. Less consistent evidence suggests shorter hospital stays for Lap procedures. Insufficient evidence with regards to other major complications.</td>
</tr>
<tr>
<td></td>
<td>Minimum 6 months follow-up</td>
<td>Adverse effects of surgery: Adverse events occur in about 10-20% of cases (Flum and Dellinger, 2004). Rates of mortality and adverse events vary depending on the procedure used. 30 day risk of mortality varies from 0 to 1.9% (Maggard et al. 2005; Shekelle et al. 2004). Advanced age, male gender and super-obesity have consistently been associated with higher mortality. Flum (2005) 30 day, 90 day and 1 year mortality rates were 2%, 2.8%, and 4.6% respectively. Greater for $\geq 65$ years of age.</td>
</tr>
<tr>
<td></td>
<td>Baseline BMI or body weight reported</td>
<td>Operative and postoperative complications are common – pulmonary emboli, anastomotic leaks, periitonitis, and absceses each have about a 1% incidence. Other less severe complications include incisional hernias, wound infections and anastomatic strictures. Reoperations are required in 1.3 – 11.3% of cases depending on the procedure (Shekelle, 2004).</td>
</tr>
<tr>
<td></td>
<td>Key outcomes cited</td>
<td>Gastrointestinal symptoms common after surgery (7.7 – 37.7% of cases)</td>
</tr>
<tr>
<td></td>
<td>Treatment strategies for weight loss including diet, exercise, behavioural modification, drug therapy, bariatric surgery</td>
<td>Nutritional deficiencies may develop, particularly after procedures with a malabsorptive component [iron, calcium, folate, Vitamins A, D, E, K, B12]. Nutritional supplementation advice and follow-up is especially important for women who have undergone bariatric surgery and subsequently become pregnant.</td>
</tr>
<tr>
<td></td>
<td>Acceptable trial sample size varied depending on the research question</td>
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</tr>
</tbody>
</table>
### Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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<tbody>
<tr>
<td>O’Brien et al. (2006)</td>
<td>Reported weight loss effects of bariatric surgical procedures &gt; 3 years and up to 10 years after operation.</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td>Centre for Obesity Research and Education (CORE)</td>
<td>Search date: up to Sept 2005</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td>Systematic review</td>
<td>Databases: Medline, Embase, Current Contents, ScienceDirect, PubMed and Cochrane relevant obesity research journals</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td>Australia</td>
<td>Procedures included: LAGB, RYGB, BPD/BPD-DS, Banded RYGB, Long-limb RYGB</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td>Evidence grade III-2</td>
<td>Gastropasty excluded because the use of this group has diminished following RCT evidence of inferior outcome in comparison to RYGB.</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Included: RCTs, comparative studies, case series &gt;100 patients at entry</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Weight loss data of ≥ 3 years from operation</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Data Extraction: 1 reviewer</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Assessment of heterogeneity: Separation of different procedures and groups.</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Could not assess heterogeneity of loss-to-follow-up and method of measuring weight.</td>
<td>Clinical efficacy and safety</td>
</tr>
<tr>
<td></td>
<td>Data synthesis and analysis: Mean %EWL number of patients and time of follow-up</td>
<td>Clinical efficacy and safety</td>
</tr>
</tbody>
</table>

Results: 43 reports included - 18 LAGB, 18 RYGB (12 standard, 3 banded RYGB, 3 LL-RYGB) and 7 BPD or DS variants. Pooled data: Overall 54-67% EWL between 1 and 10 years after surgery with no diminishing of effect at 10 years. Report weight loss effects of bariatric surgical procedures > 3 years and up to 10 years after operation. Weighted mean weight loss for each surgical procedure: RYGB: 52.5 – 67.5% EWL at 1-10 years follow-up. Decrease in %EWL over time (67.3% at 1 year, 52.5% at 10 years) LL-RYGB: 53.3 – 60.3% EWL at 1-10 years follow-up. Decrease in %EWL over time (58.5% at 2 years, 55.5% at 10 years) Banded RYGB: 61.5 – 78.8% EWL at 1-10 years follow-up. Decrease in %EWL over time (78.8% at 2 years, 61.5% at 10 years) AGB (Lap-Band and Obtech SAGB): 42.0 – 59.3% EWL at 1-8 years follow-up. Initial increase followed by stabilisation of %EWL over time (42.0% at 1 year, 55.2% at 5 years, 59.3% at 10 years – 1 study). No fading of effectiveness evident. Banded RYGB: 61.5 – 78.8% EWL at 1-10 years follow-up. Decrease in %EWL over time (58.5% at 2 years, 55.5% at 10 years) No differences between BPD and BPD-DS at any time point. No significant differences in initial BMI or subsequent BMI between 3 RYGB, LAGB or BPD. No operation has achieved a sustained reduction below 30 kg/m² BMI

Conclusions: Bariatric surgery can achieve a major reduction in weight (>50%EWL) which is sustained for at least 10 years. BPD appears to have the most effect on weight [Mean %EWL = 74.4%] for 3-10 years follow-up RYGB mean = 56.6% for 3-10 years LAGB mean = 53.1% for 3 - 8 years Banded RYGB shows a fading pattern in %EWL from years 2 onwards. Banded RYGB may be more effective. Limitations acknowledged by authors: General lack of information on patients lost to follow-up. Number of reports available for inclusion low, especially lack of medium – long term data. Ratio of change in fat mass to muscle mass should become a standard part of reporting weight loss. Because of these limitations it is difficult to conclusively determine which procedure is more effective.
Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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<tr>
<td>Colquitt et al. (2005) Cochrane Collaboration Systematic review Evidence grade III-2</td>
<td>Interventions: 1) comparisons of surgical procedures, including VBG, horizontal gastroplasty, gastric banding, GBY, BPD 2) surgical procedure vs usual care (no treatment or medical management)</td>
<td>• Comparisons of surgical procedures: GBY vs VBG – 4 RCTs GBY vs VBG vs gastric banding – 1 RCT LGBY vs L VBG – 1 RCT GBY vs horizontal gastroplasty – 5 RCTs GBY vs gastrosplasty vs gastrogastrotomy – 1 RCT VBG vs horizontal gastroplasty – 1 RCT VBG vs AGB – 1 RCT LVBG vs LAGB – 1 RCT Open vs lap AGB – 1 RCT Open vs lap VBG – 1 RCT</td>
</tr>
<tr>
<td>Search dates: Most recent searches – December 2004</td>
<td></td>
<td>GBY versus gastroplasty 12 RCTs suggested that gastric bypass surgery leads to a greater loss of weight than from VBG or HG (18-25% more after 1 year, 33% by 5 years). Two RCTs found no significant difference. Gastric bypass patients lost 35-42% of initial weight, HG patients lost 16-29% of initial weight. Comorbidities reduced following surgery with 60% of surgical patients free of medication at 3 years. Side-effects of procedures, e.g. heartburn, dumping syndrome, were more evident following gastric bypass than gastroplasty. There were 5 post-operative deaths following gastric bypass and 1 following gastroplasty. Revisions, re-operations and conversions were more common following gastroplasty than gastric bypass. Gastric banding had a higher reoperation rate (44%) than VBG (4%). Additional procedures following weight loss, e.g. trimming, were more common following gastric bypass than gastroplasty. In laparoscopic procedures, early postoperative complications were more common following gastric bypass than VBG and analgesic use was higher.</td>
</tr>
<tr>
<td>Databases: Cochrane Library, MEDLINE, PubMed, Embase, PsychINFO, CINAHL, SSC, British Nursing Index, Journal of Obesity Surgery website Web of Science Proceedings, BIOSIS, AMED National Research Register Hand searching of relevant journals, reference lists of relevant trials, experts contacted</td>
<td>Inclusion criteria: RCTs comparing different surgical procedures RCTs and prospective cohort studies comparing surgical and non-surgical interventions</td>
<td>VBG vs HG One RCT in patients who were able to lose a lot of weight before surgery, suggested that the VBG group lost more weight (10kg) following surgery than the HG group (weight gain). More vomiting in the VBG group.</td>
</tr>
<tr>
<td>Participants: adults aged 18 years and over with morbid obesity, in whom previous non-surgical interventions have failed</td>
<td>Outcomes: weight change, fat content (e.g. BMI) or fat distribution (e.g. waist-hip ratio) after 12 months follow-up Quality of life Change in comorbidities Mortality Adverse effects Revision rates</td>
<td>VBG vs AGB 1 RCT (VBG vs AGB) and 1 RCT (lap VBG vs lap AGB) suggested there was greater weight loss with AGB over 5 years (43kg) than VBG (36 kg). No sig diff between laparoscopic procedures at 2 and 3 years follow-up although BMI was slightly lower following VBG. Fewer side effects and greater patient satisfaction with AGB Laparoscopic AGB was associated with more late complications and reoperations than lap VBG, but shorter operative time and hospital stay.</td>
</tr>
<tr>
<td>Authors, study design, country, evidence grading</td>
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<tr>
<td>-----------------------------------------------</td>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Colquitt et al. (2005) Cochrane Collaboration Systematic review Evidence grade III-2</td>
<td>No language restrictions Two independent reviewers selected articles Two independent reviewers assessed trials, disagreements resolved by group consensus</td>
<td>Clinical efficacy and safety</td>
</tr>
</tbody>
</table>

Open vs laparoscopic GBY
- 4 RCTs suggest similar weight loss for lap and open GB procedures, and similar patient satisfaction (1 RCT)
- Quality of life was initially better with laparoscopic surgery but was similar to that after open surgery at 3-6 mths follow-up
- Complications were common with both procedures, although wound infection and ventral hernia tended to be more common following open surgery, and stricture of the tunnel through the mesocolon was more common following laparoscopy
- Conversion of laparoscopic surgery to open occurred in 2.3 – 23% of patients in different studies, no conversions for hand-assisted laparoscopy
- Lap surgery took longer in theatre in 3 studies and less time in one, patients went home earlier in 2 studies whereas another 2 studies found no difference

Open vs laparoscopic AGB
- 1 RCT showed similar weight loss at 12 months (greater than 34 kg)
- Laparoscopic surgery led to fewer readmissions and shorter patient stays
- There was little difference in complications
- Two patients were converted from lap to open procedures
- Lap surgery was more difficult and took longer to perform

Open vs laparoscopic VBG
- 1 RCT did not report a statistical comparison of EWL but suggested it was similar between groups, median BMI of 33 for both
- Laparoscopy was associated with higher patient satisfaction, fewer wound problems and fewer pathologic scars at 12 months
- Surgical time was longer with laparoscopic surgery but length of hospital stay was similar

Limitations of the review (acknowledged by authors):
- Included studies with 12 months or longer follow-up. Expert opinion suggests follow-up should consider outcomes beyond five years. Majority of included patients were women in late 30s to early 50s who were morbidly obese. Potential benefits of weight loss may be greater among morbidly obese men of a similar age (CVD risk higher) or younger adults who have a great time to accrue benefit of maintained weight loss.

Implications for practice:
- The limited evidence suggests surgical interventions result in greater weight loss than non-surgical interventions, and that the results are maintained for at least 8 years.
- The weight loss is associated with reductions in comorbidities, such as diabetes and hypertension, and medication use.
- However surgery is associated with adverse effects and the possibility of post-operative mortality.
- There are a number of different operative procedures but the lack of quality evidence means that the comparative safety and effectiveness of these procedures is uncertain.
### Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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<td>Day (2005) New Zealand Health Technology Assessment Technical Brief New Zealand Evidence grade III-2</td>
<td>What is the safety and effectiveness of surgical and non-surgical interventions for morbidly obese patients? BMI 40+ or 35+ with significant comorbidities</td>
<td>• Comparisons of surgical procedures: 10 HTAs and 13 primary studies More evidence for GBY than other procedures OGBY more effective than gastroplasty but increased risk of serious metabolic complications RYGB effective but need further studies VBG was more effective than HGP AGB more effective than VBG Lack of data re RYGB v LAGB</td>
</tr>
<tr>
<td></td>
<td>Included: HTAs and systematic or non-systematic reviews or meta-analyses RCTs, controlled clinical trials Comparative studies e.g. cohort and case control designs</td>
<td>LAGB at least as safe but less effective in weight reduction than RYGB. It was as effective as VBG</td>
</tr>
<tr>
<td></td>
<td>Outcomes: BMI change, EWL, mortality, morbidity, psychosocial outcomes e.g. QoL</td>
<td>• Conclusions: Evidence limited to lower level III-2 Surgical interventions are substantially less than the health risks associated with obesity itself. Relative safety and effectiveness of different procedures was less clear.</td>
</tr>
<tr>
<td></td>
<td>Search date: 2000 - September 2004</td>
<td>GBY and BPD resulted in greater weight loss than LAGB at least initially Relatively short-term follow-up available for AGB procedures OGBY greater weight loss than gastroplasty at 1-3 years follow-up OR YGB and UP YGB similar in weight loss with a slightly different spectrum of complications Insufficient evidence regarding GBY and BPD comparisons OGBY and LAGB - LAGB was at least as safe but less effective LAGB and VBG equally effective VBG more effective than HGP</td>
</tr>
<tr>
<td></td>
<td>Databases: Medline, Cochrane controlled trials register, Cinahl, Embase, review databases (5), guidelines (3)</td>
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**THE SAFETY, EFFECTIVENESS AND COST EFFECTIVENESS OF SURGICAL AND NON-SURGICAL INTERVENTIONS FOR MORBID OBESITY**
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<tbody>
<tr>
<td>Guo and Harstall (2005) Alberta Heritage Foundation Medical research HTA Unit Health Technology Assessment Evidence grade III-2</td>
<td>LAGB for the treatment of clinically severe (morbid) obesity: an update Safety and efficacy of LAGB in comparison with open and or lap RYGB and LVBG, especially in the longer term (≥ 5 years) for adult patients with morbid obesity Is LAGB a safe and effective procedure compared with open and/or laparoscopic RYGB and VBG, especially in the longer term, for adult patients with clinically severe obesity?</td>
<td>3 HTAs and 18 primary studies (1 RCT, 3 non-randomised and 14 case series) 3 HTAs: MSAC (2003) LAGB v ORYGB and VBG McGill TAU [Chen and McGregor, 2004] LAGB v RYGB Blue Cross Blue Shield (2003) LAGB v RYGB Safety: Table 2 - summary of HTAs mean mortality and complication rates Average in 3 reports: LAGB mortality 0.05 – 0.3%, ORYGB 1.7%, LRYGB 0.23%, OVBG 0.5% LAGB as safe as or safer than ORYGB or OVBG in mortality and morbidity, compared with LRYGB mortality and morbidity similar Effectiveness: LAGB seems as effective as VBG but may be less effective than RYGB. Longer-term follow-up data are needed. LAGB can produce significant %EWL at up to 7 years follow-up Resolution or improvement of comorbidity: All 3 procedures in the MSAC report led to improvements in some obesity-related comorbidities, such as diabetes, hypertension, hyperlipidaemia, sleep apnoea. No sig differences between procedures Improvement in QoL MSAC – QoL improved in majority of patients, slightly more with RYGB, no sig difference between LAGB and VBG Primary studies: 18 studies (1 RCT, 2 non-randomised comparative studies and 14 large case series) Marino et al (2003) LAGB v LVBG Weber et al (2004), Majnol et al (2005), Biertho et al (2003) LAGB v LRYGB Effectiveness: 1 RCT and 3 comparative studies but follow-up &lt;3 years RCT, LVBG &gt; LAGB at 3 years, 5%SEWL v 39%SEWL 2 single centre comparative studies: LRYGB (54-73%) &gt; LAGB (42 – 46%) at 2 years , differences in follow-up rates Based on two case series the mean %EWL for LAGB was 47 – 49% at 1 year and 54% at 5 years. Long term effectiveness of LAGB was based on a relatively small number of patients.</td>
</tr>
</tbody>
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<tr>
<td>Guo and Harstall (2005)</td>
<td></td>
<td>Safety:</td>
</tr>
<tr>
<td>Continued</td>
<td></td>
<td>From 1 RCT (Morino et al. 2003) and 3 comparative studies:</td>
</tr>
<tr>
<td>Alberta Heritage Foundation Medical research HTA Unit</td>
<td></td>
<td>Mortality 0 – 0.6% LAGB, 0 – 0.44% LRYGB</td>
</tr>
<tr>
<td>Health Technology Assessment</td>
<td></td>
<td>Conversion 0 – 3% LAGB, 0 – 3.6% LRYGB</td>
</tr>
<tr>
<td>Evidence grade III-2</td>
<td></td>
<td>Early complication 1.7 – 17% LAGB, 4.2 – 20% LRYGB, 9.8% LVBG</td>
</tr>
<tr>
<td></td>
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<td>Late complication 9 – 44% LAGB, 8.1 – 15% LRYGB, 14% LVBG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Late reoperation 24.5 – 26% LAGB, 3.9 – 4.5% LRYGB, 0% LVBG</td>
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<tr>
<td></td>
<td></td>
<td>Definitions of early and late differed between studies.</td>
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<tr>
<td></td>
<td></td>
<td>3 comparative studies demonstrated similar post-operative mortality between LAGB and LRYGB with fewer early complications but significantly higher late complications and reoperation rates following LAGB. Based on 1 RCT, LAGB appeared to be as safe as LVBG in terms of short-term mortality and early complications but was associated with higher rates of late complications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement of comorbidities:</td>
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<tr>
<td></td>
<td></td>
<td>Variation in reporting of comorbidities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 comparative study found both procedures reduced the frequency of comorbidities such as hypertension and diabetes. LRYGB resulted in significantly lower frequencies of diabetes and dyslipidemia compared with LAGB.</td>
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<tr>
<td></td>
<td></td>
<td>3 case series reported improvement of comorbidities in most patients</td>
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<tr>
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<td></td>
<td>QOL:</td>
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<tr>
<td></td>
<td></td>
<td>RCT and 3 comparative studies did not report QOL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 case series evaluated changes in QOL (BAROS). All 3 reported improvements in QOL in patients who received LAGB over 2-8 years follow-up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion:</td>
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<tr>
<td></td>
<td></td>
<td>LAGB and RYGB are the most commonly performed procedures worldwide and VBG is performed in a very small proportion of obese patients. Therefore, the major debate within the surgery community is which procedure is most appropriate for which patient group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lack of RCTs comparing LAGB and LRYGB or ORYGB.</td>
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<tr>
<td></td>
<td></td>
<td>Choice of procedure should be tailored to the patient’s situation.</td>
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<tr>
<td></td>
<td></td>
<td>LAGB appears to be less effective than LRYGB or LVBG.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduction in comorbidities is inconsistently reported, although arguably it is the most important goal of bariatric surgery. Nutritional deficiency not reported very much.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greatest need in research is long-term studies with systematic surveillance and minimal loss to follow-up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Classify patients according to preoperative BMI and subgroup analyses.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All bariatric surgeries are effective in the treatment of morbid obesity but differ in the degree of weight loss and range of early or late post-operative complications.</td>
</tr>
</tbody>
</table>

The Safety, Effectiveness and Cost Effectiveness of Surgical and Non-Surgical Interventions for Morbid Obesity

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THE SAFETY, EFFECTIVENESS AND COST EFFECTIVENESS OF SURGICAL AND NON-SURGICAL INTERVENTIONS FOR MORBID OBESITY

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**Excluded:**
- Focus on non-surgical treatments
- Assessed bariatric surgeries for adolescents
- Focussed on technical differences in LAGB e.g. SAGB vs Lap-Band
- Focus on non-adjustable gastric banding
- Open vs lap procedures

**Methodological Quality Appraisal:**
- No formal assessment for systematic reviews or HTAs or primary studies
- Level of evidence assigned to primary studies
- Study selection: 1 researcher
- Synthesis of results: 2 researchers
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<tr>
<td>Medical Advisory Secretariat (2005)</td>
<td>Evidence-based analysis of the effectiveness, safety and cost effectiveness of bariatric surgery to treat morbid obesity</td>
<td>15 systematic reviews or HTAs identified:</td>
<td>Buchwald (2004) – meta-analysis of bariatric surgery outcomes, comparator not reported – e.g. case series included</td>
</tr>
<tr>
<td>Health Technology Assessment systematic review</td>
<td>Bariatric surgery compared with optimal conventional management or another type of bariatric procedure</td>
<td>ECR (2004) – systematic review of bariatric surgery to 2004– graded evidence as strong, moderate or weak based on quality, quantity, consistency and magnitude of effect. Inclusion criteria included control group who did not receive surgery. Results (weight loss, safety and comorbidities) reported separately for different surgical procedures – AGB, VBG, and RYGB. Also compared different bariatric procedures for effectiveness, safety and comorbidities (RCTs, controlled trials). Also reviewed studies of surgery in nonmorbidly obese adults (1 RCT), and morbidly obese adolescents (5 studies)</td>
<td></td>
</tr>
<tr>
<td>Ontario, Canada</td>
<td>Search date: April 2004 Subsequent search of Medline and Embase in December 2004 Included: Systematic reviews, RCTs, non-RCTs or cohort studies with ≥ 100 patients Cost effectiveness studies Excluded: Case reports Animal studies Non-systematic reviews</td>
<td>AHRQ (2004) – literature search of controlled studies of surgical treatments for obesity (2002 – 2003, RCTs, non RCTs, case series). Overall conclusions were that surgery results in greater sustained weight loss than non-surgical interventions in very obese [BMI 40+1] individuals. This results in improved comorbidity outcomes but AHRQ review team did not comment on poor quality of the evidence on comorbid conditions. RYGB results in greater weight loss than VBG, post-operative mortality rates of less than 1% have been achieved by a number of surgeons.</td>
<td></td>
</tr>
<tr>
<td>Evidence grade III-2</td>
<td>Databases: Cochrane library, ACP journal club, DARE, INAH, EMBASE, MEDLINE, reference sections from reviews and articles Outcomes: Improvement in comorbid conditions Short and long-term weight loss Quality of life Adverse effects Economic analysis data</td>
<td>Blue Cross Blue Shield Association Technology Evaluation Centre (2003): effectiveness of different of surgical procedures, especially effectiveness of newer less invasive procedures. Found insufficient evidence to form conclusions about the relative efficacy of less invasive procedures. Some comments about higher short-term adverse events with laparoscopic procedures. Information lacking on long-term outcomes (more than 12 months). For laparoscopic gastric banding, the evidence suggests weight loss at 1 year is less than that achieved with GB, higher rate of long-term adverse events. Limited data on outcomes of BPD and/or long-limb gastric bypass. This report has been updated since.</td>
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<td></td>
<td></td>
<td>Australian Medical Services Advisory Committee (2003); LAGB vs VBG and RYGB in morbidly obese patients [search July 2002]. RCTs and nonrandomised studies. Second search including non comparative studies of LAGB. No RCTs identified, so RCTs with a LAGB, VBG or RYGB arm included. Minimum BMI 35. Reoperation, mortality, morbidity, and complications for each comparison reported. Overall, LAGB found to be as safe as the comparators. Effectiveness: patients who had RYGB lost significantly more weight than LAGB patients, VBG patients lost more weight than LAGB patients immediately after surgery but the difference disappeared by 2 years. Overall, LAGB less effective than RYGB and as effective as VBG.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>United States Centers for Medicare and Medicaid Services (Nov, 2004). Evidence for bariatric surgery in beneficiaries with comorbid conditions, and in beneficiaries who are obese without comorbid conditions</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>United Kingdom NHS HTA (2002): systematic review of the clinical effectiveness of surgery to manage morbid obesity (search October 2001, RCTs, prospective cohort studies). Overall, surgery resulted in greater weight loss than nonsurgical interventions and QOL and comorbidities improved. Gastric bypass seemed to produce greater weight loss and improvements in comorbid conditions than gastroplasty or jejunoileal bypass.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Australian Safety and Efficacy Register of New Interventional Procedures (2002): systematic review of safety and efficacy of LAGB compared with VBG and gastric bypass in morbidly obese patients [search 1988 – 2001, RCTs, controlled trials, prospective case series]. Gastric bypass produced greater weight loss than LAGB or VBG up to 2 years. LAGB is safer than VBG and RYGB in terms of short-term mortality.</td>
<td></td>
</tr>
</tbody>
</table>
Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
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<tr>
<td>Medical Advisory Secretariat (2005) continued</td>
<td></td>
<td>• Alberta Heritage Foundation for Medical Research (2000): safety, efficacy and effectiveness of LAGB</td>
</tr>
<tr>
<td>Health Technology Assessment systematic review</td>
<td></td>
<td>• Technology Assessment Unit of McGill University Health Centre (2004): systematic review of the safety and efficacy of LAGB compared with lap RYGB. No RCTs identified but some cohort follow-up studies. Authors concluded that LAGB is an effective procedure but not based on randomised trials.</td>
</tr>
<tr>
<td>Ontario, Canada Evidence grade III-2</td>
<td></td>
<td>• Canadian Coordinating Office for HTA (2003): preassessment of LAGB for clinically severe obesity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• National Agency for Accreditation and Evaluation in Health (2002): reviewed VBG, gastric bypass and adjustable gastroplasty rings. Concluded that gastroplasty ring is simplest technique, and has the advantage of being reversible, slightly less effective in terms of weight loss and lack of follow-up means long-term benefits not yet evaluated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ICSI (2000): review of recent evidence regarding bariatric surgery. VBG and RYGB result in weight loss that may be sustained for 7 years or longer and are safe (mortality &lt;1%), patients should be followed up for nutrient deficiencies and medical complications for their lifetime.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Primary Literature reviewed. Detailed summary of the Swedish Obese Subjects study.</td>
</tr>
</tbody>
</table>

Conclusions:
Bariatric surgery is effective for sustained weight loss of about 16% for morbidly obese people (BMI 40+ or 35+ with comorbid conditions). Also effective at resolving comorbid conditions. This is largely based on evidence from the SOS study (10 year outcomes).
There is evidence that malabsorptive procedures are better than other banding techniques for weight loss and comorbid conditions. However there are no long-term prospective published comparisons available for these comparisons.
A recent RCT systematic review (Tsau, 2005) suggested that major commercial and organised self-help weight loss programmes were in general not effective.
A recent RCT reported 1 year outcomes in people assigned to either low-carbohydrate or conventional weight loss diet. At the end of 1 year weight loss was similar for both groups (mean 2-5 kg).

Comments:
Robust and thorough review. High quality.
## Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
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<th>Clinical efficacy and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maggard et al. (2005)</td>
<td>Meta-analysis of effectiveness and adverse events associated with surgical treatment of obesity</td>
<td>Different surgical procedures: Case series limited by incomplete reporting; 25% did not state whether consecutive patients were studied, &lt;50% reported follow-up rates</td>
<td>S RCTs compared surgical procedures and had sufficient data for pooling:</td>
</tr>
<tr>
<td>United States</td>
<td>Search date: To July 2003</td>
<td>5 RCTs included surgical procedures and had sufficient data for pooling:</td>
<td>- RYGB vs VBG (2 RCTs)</td>
</tr>
<tr>
<td>Evidence grade III-3</td>
<td>Databases: Medline, Embase, CCTR, systematic reviews</td>
<td>Pooled weight loss substantial for both procedures (≥30kg at 36 months) and favoured RYGB at 12 and 36 months (+9kg)</td>
<td>VBG &gt; LAGB, 14kg greater WL with VBG at 12 months but only 3 kg more at 36 months</td>
</tr>
<tr>
<td></td>
<td>Assessors: 3 reviewers independently reviewed the studies, abstracted data</td>
<td>Combined RCT and case series data support this</td>
<td>Combined RCTs and case series showed similar weight loss for both procedures at 12 months and ≥36 months</td>
</tr>
<tr>
<td></td>
<td>Consensus reached for disagreements (2 reviewers)</td>
<td>5 RCTs excluded because they did not report weight loss in kg but support these findings</td>
<td>• Open v LRYGB (1 RCT)</td>
</tr>
<tr>
<td></td>
<td>Included: Initially, RCTs, controlled clinical trials and cohort studies</td>
<td>No sig difference in weight loss</td>
<td>No sig difference between procedures reported</td>
</tr>
<tr>
<td></td>
<td>After scan of the literature decided to include case series with 10+ patients to augment efficacy data and look at adverse events</td>
<td>Safety: Early death mortality</td>
<td>30 day mortality rates in unselected patients</td>
</tr>
<tr>
<td></td>
<td>Outcomes: Weight loss, mortality, complication rates, control of comorbidities, QoL</td>
<td>RYGB 1.0% (0.5 – 1.9%) controlled trials, 0.3% (0.2 – 0.4%) case series</td>
<td>Flum and Dellinger (2004) 1.9% all surgeries</td>
</tr>
<tr>
<td></td>
<td>Statistical analyses: Category by type of surgery</td>
<td>AGB 0.4% (0.01 – 2.1%) controlled trials, 0.02% (0.0 – 0.78%) case series</td>
<td>Liu (2003) 0.3% GBP</td>
</tr>
<tr>
<td></td>
<td>Mean weight loss and SD at 12 months follow-up was extracted and maximum follow-up (≥36 months)</td>
<td>VBG 0.2% (0 – 1.4%) controlled trials, 0.3% (0.1 – 0.5%) case series</td>
<td>Courcoulas 0.6% GBP</td>
</tr>
<tr>
<td></td>
<td>Deaths within 30 days of surgery classified as ‘early’ as well as those self-classified as ‘early’ or ‘post-operative’</td>
<td>BPD NR controlled trials, 0.9% (0.5 – 1.3%) case series</td>
<td>Comorbidities: N=114 case series</td>
</tr>
<tr>
<td></td>
<td>After 30 days classified as ‘late deaths’</td>
<td>No sig differences between procedures reported</td>
<td>Diabetes (21 studies): 64-100% improvement (initial range 3-100% with condition)</td>
</tr>
<tr>
<td></td>
<td>Missing data – assumed no deaths</td>
<td>Safety:</td>
<td>Hypertension (19 studies): 25 – 100% improvement from initial range 16-83% with condition.</td>
</tr>
<tr>
<td></td>
<td>Comorbidities – data extracted for diabetes, hypertension, dyslipidemia and sleep apnoea</td>
<td></td>
<td>Dyslipidemia (11 studies): 60-100% improvement from initial range 3-65% with condition.</td>
</tr>
</tbody>
</table>
### Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Maggard et al. (2005)</td>
<td>Safety:</td>
<td>Adverse events:</td>
</tr>
<tr>
<td>continued</td>
<td>Adverse events – extracted number of events or number of people who experienced the event</td>
<td>No strong conclusions and mostly case series</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>Classified events into different subgroups e.g. respiratory</td>
<td>Gastrointestinal (included reflux and vomiting): higher for BPD, RYGB and VBG similar, AGB lower</td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td>Nutritional and Electrolyte abnormalities: higher for RYGB than VBG but not reported for BPD and AGB</td>
</tr>
<tr>
<td>Evidence grade III-3</td>
<td></td>
<td>Surgical, preventable and nonpreventable (included anastomotic, stoma-related, bleeding, reoperation, wound and others): Highest for VBG (23.7%) followed by RYGB (18.7%), AGB (13.2%) and BPD (5.9%). Adverse event % reported for each category of surgical events separately as well.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Open vs laparoscopic procedures: Wounds, wound infection, minor wound infection, incisional hernia all lower for lap but reoperation more common</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Learning curve: Flum and Dellinger (2004) &lt;20 procedures performed mortality rate 6% &gt;250 procedures performed mortality rate 0% Schauer et al. (2003) First 50 procedures anastomotic leak rate 10% following LRYGB 100-150 procedures 0% Use of bariatric surgery in adolescents and children: Insufficient data 12 case series</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conclusions: Surgery results in greater weight loss in severely obese individuals than does medical treatment (20-30kgs maintained for 10 years+). This is accompanied by significant improvements in comorbid conditions. Direct comparisons of surgery and pharmaceutical or diet treatments cannot be made because the samples are different (initial BMI) and follow-up is different. However, findings suggest weight loss of 20-40kg for surgery and 2-5kg for conventional treatment. Very little information re adolescents or children. Controlled trials or well matched observational studies are needed to address different procedures effectiveness and safety. Selection of procedure depends on patient type (age, sex, BMI, comorbidity profile).</td>
</tr>
</tbody>
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Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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<tr>
<td>Metfessel et al. (2005) ICSI report Evidence grade III-2 but lack of information about inclusion criteria</td>
<td>Gastric restrictive surgery for clinically severe obesity in adults</td>
<td>Comparative analysis of surgical techniques:</td>
</tr>
<tr>
<td></td>
<td>Search date: Not reported</td>
<td>• Buchwald (2004) sys review and meta-analysis: bariatric surgery in clinically severe obesity</td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: Not reported</td>
<td>• Mean %EWL 61.6% GBY, 68.2% gastroplasty, 47.5% GB</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Not reported</td>
<td>• Operative mortality (30 days) was 0.1% restrictive and 0.5% GBY</td>
</tr>
<tr>
<td></td>
<td>Outcomes: Not reported</td>
<td>• Diabetes, hyperlipidaemia and hypertension and sleep apnoea resolved or improved in 70-86% of patients</td>
</tr>
<tr>
<td></td>
<td>Databases: Medline and bibliographies</td>
<td>• VBG group (504 patients) much smaller than other procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Heterogeneity of follow-up times</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hell et al (2000) non randomised RYGB, VBG, LAGB (age, gender matched)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average BMI 45-47, 3-8 year follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RYGB 90%EWL, VBG and LAGB 60%EWL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comorbidity improvement same for all procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RYGB BAROS score 7.15, VBG 6.13, LAGB 5.99 (p&lt;0.05)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lee et al (2004) LVBG and LRYGB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Randomised</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LRYGB more post-operative and long-term complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mean follow-up 20 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LRYGB 71.4% LVBG 53.1% at 2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Biertho et al (2003) LRYGB v LAGB Non randomised</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LRYGB 74.6% EWL and LAGB 40.4% EWL at 2 years (increase at 4 years to 58%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LAGB sustained weight loss although initially smaller</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GBY followed for less time than LAGB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LAGB v VBG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suter et al (1999) non randomised LAGB v OVBG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post-operative complications higher in VBG 23.8 v 8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EWL 60-65% for both groups at 2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disparity in baseline BMI between 2 groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Morino et al (2003) RCT n=100 LAGB v LVBG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>%EWL 63.5% LVBG and 41.4% LAGB at 2 years and 58.9 v 39% at 3 years (not significant)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LAGB shorter operating and hospital stay, LVBG fewer late complications and reoperations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18% band slippage for LAGB</td>
</tr>
</tbody>
</table>
### Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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<tr>
<td>Metfessel et al. (2005) continued</td>
<td>Gastric restrictive surgery for clinically severe obesity in adults</td>
<td>• Chapman et al (2004) sys review of bariatric surgery</td>
<td>• LAGB mortality 0.05%, morbidity 11.3%</td>
</tr>
<tr>
<td>ICSI report</td>
<td>Search date: Not reported</td>
<td>• RYGB mortality 0.5% and morbidity 23.6%</td>
<td>• High variability in morbidity rates (learning curve, definition of complications)</td>
</tr>
<tr>
<td>Evidence grade III-2 but lack of information about inclusion criteria</td>
<td>Inclusion Criteria: Not reported</td>
<td>• VBG mortality 0.31% and morbidity 25.7%</td>
<td>• Large amount of weight loss data but less ability to draw conclusions about the relative safety of different procedures</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Not reported</td>
<td></td>
<td>• 4 year period LAGB EWL 44-68%, RYGB 50-67% and VBG 40-77%</td>
</tr>
<tr>
<td></td>
<td>Outcomes: Not reported</td>
<td>• RYGB &gt; VBG for weight loss, mortality and reoperation</td>
<td></td>
</tr>
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<td>Databases: Medline and bibliographies</td>
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- LAGB mortality 0.05%, morbidity 11.3%
- RYGB mortality 0.5% and morbidity 23.6%
- VBG mortality 0.31% and morbidity 25.7%
- High variability in morbidity rates (learning curve, definition of complications)
- Large amount of weight loss data but less ability to draw conclusions about the relative safety of different procedures
- 4 year period LAGB EWL 44-68%, RYGB 50-67% and VBG 40-77%
- RYGB > VBG for weight loss, mortality and reoperation
- Learning curve 100 procedures (Shikora, 2005)
- Conditions and setting of surgery
- Factors that increase the risk
- Potential inappropriate use of surgery
- Alternative treatments: Pharmacological v placebo
- 5-10% weight loss over 2 years (2-4 kg compared with placebo)
- Rimonabant and Topiramate
- BPD-DS 70%EWL on medium term basis but constant vigilance needed for nutritional and metabolic complications
- Conclusions:
  - Gastric surgery an option for BMI 40+ or 35+ with comorbidities
  - RYGB, VBG, and LAGB relatively safe, <1.0% perioperative mortality
  - Increase in complications with high surgical risk
  - RYGB 60-70% EWL
  - VBG < RYGB, high rate of serious morbidity, reoperation rate
  - Long-term follow-up of LAGB lacking, preliminary results show 40-60% EWL, band slippage 12-18%, higher rate of reoperation
  - Comorbidities improved with surgery
  - Lifelong surveillance needed
Table 3. Evidence table of secondary research studies comparing different surgical interventions for patients with morbid obesity

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</tr>
</thead>
<tbody>
<tr>
<td>Manterola et al. (2005) Systematic review Chile Evidence grade III-3</td>
<td>What are the best surgical options for the treatment of morbid obesity? Included procedures: VBG, HG, AGB, non-AGB, BGY, open and laparoscopic techniques</td>
<td>31 articles included: 4 comparative studies of different surgical procedures, 2 comparative studies of the same procedure performed laparoscopically vs open surgery, 25 case series</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Search date: Jan 1990 – Dec 2002 Databases: Medline, Lilacs, Cochrane Database Included:  ▪ Adults &gt;19 years old with morbid obesity (BMI ≥ 40 or ≥ 35 with comorbidity) and no prior bariatric surgery ▪ RCTs, non-comparative studies, case series ▪ Spanish, English, French, Italian publications included Excluded: Review articles, comments, letters to the editor and clinical guidelines Outcomes: Weight loss Comorbidity %EWL Complications, reoperations, hospital stay, follow-up, % success and failure, mortality, Quality assessment: Ad-hoc scoring system assessing design, sample size, methodological aspects (range 6-36 points) Analyses: Descriptive statistics calculated for included studies</td>
<td>Results: BMI reduction at 36 months: LGB (8 studies) 13.7% LGP (1 study) 19.4% LGBY (5 studies) 40.2% LBPD (2 studies) NR OGB (4 studies) 34.8% OGP (9 studies) 28.9% OGBY (7 studies) 30% OBPD (1 study) 40.2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>41 articles met inclusion criteria but 31 included in the review</td>
<td>Comments: 41 articles met inclusion criteria but 31 included in the review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10/41 not included because they were unobtainable (24%)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Limited databases searched</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Many studies included were of relatively poor quality e.g. case series</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Means and 95% CIs calculated but no test of heterogeneity reported. It is unclear whether the data were suitable for analysis in this manner.</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>95% CIs or p-values not reported, so impossible to determine whether the differences in weight loss, morbidity, mortality or other complications are statistically significant. In addition, the percentages of weight loss, BMI reduction, morbidities etc were calculated based on widely varying numbers and types of studies for different procedures, making comparison between them very difficult.</td>
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<tr>
<td></td>
<td>Search date in 2002 but not published until 2005. Given the speed at which bariatric surgery techniques have developed, this review probably does not provide a reliable representation of the current state of research in the area.</td>
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<td></td>
</tr>
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</table>
### Table 4. Evidence table of primary studies comparing different surgical interventions for patients with morbid obesity

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<tr>
<th>Authors, study design, country, evidence grading</th>
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<th>Results</th>
<th>Clinical efficacy and safety</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angrisani et al. (2007)</td>
<td>LAGB v LRYGB: 5 year follow-up</td>
<td>Method: LAGB pars flaccida technique</td>
<td>Results: Operative time LAGB 60 +/- 20 mins LRYGB 220 +/- 100 (p&lt;.001) Hospital stay LAGB 2 +/- 1 days LRYGB 4 +/- 2 days (p&lt;.05)</td>
<td>Conclusions: LRYGB resulted in better weight loss and reduced number of failures compared with LAGB LRYGB has significantly longer operating time and life-threatening complications</td>
</tr>
<tr>
<td>RCT</td>
<td>LAGB standard</td>
<td>1 LRYGB patient required a long intensive care unit stay</td>
<td>Four retrospective single-centre comparative studies have investigated LAGB v LRYGB Jan, Kim, Galvani, Cottom 2 studies: similar weight loss and complication rates at 2 and 3 years follow-up 1 of these found no differences in resolution of comorbidities 1 further study: weight loss, complications and need for reoperation similar Cottom reported superior weight loss and comorbidity reduction for LRYGB, no diff in complications Two further studies found better weight loss from LRYGB as well as better comorbidity resolution and lower complications - both 2 year follow-up only</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>LAGB n=27 (5 men, 22 women) n= 24 LRYGB (2 men, 20 women) Random allocation</td>
<td>Participants: LAGB m=24</td>
<td>Early complications (n=30 days) 2/24 LRYGB 0/26 LAGB Late complications LAGB 2/26 LRYGB 1/24</td>
<td>Limitations: Beginning of learning curve for LRYGB Pars flaccida - reduce band slippage, pouch dilatation, intragastric migration</td>
</tr>
<tr>
<td>Evidence grade II</td>
<td>Mean age 33.3 years Mean weight 120kg Mean BMI 43.4 kg/ m²</td>
<td>LRYGB m=24</td>
<td>Comorbidities: Diabetes, hypertension, cardiac disorders assessed preoperatively LAGB n=3 hypertension, 1 sleep apnoea</td>
<td>Small sample size QOL not measured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mean age 34.7 years Mean weight 120kg Mean BMI 43.8 kg/ m²</td>
<td>LRYGB 2 hyperlipidaemia, 1 hypertension, 1 type 2 diabetes 5 year follow-up: hyperlipidaemia, sleep apnoea and diabetes had all resolved</td>
<td>LRYGB Greater life-threatening risks - may have been because of surgical learning curve, intra-operative - laparoscopic suturing inaccurate bowel manipulation, internal hernia formation</td>
</tr>
<tr>
<td></td>
<td>Outcomes: Operative time, complications, reoperations, weight, BMI, EWL, comorbidities collected yearly</td>
<td>Outcomes: Operative time, complications, reoperations, weight, BMI, EWL, comorbidities collected yearly</td>
<td>Weight loss: Average weight (kg) LAGB 102.4 at 12 months 98.7 at 36 months 97.9 at 60 months LRYGB 92.8 at 12 months 83.5 at 36 months 84.0 at 60 months (p&lt;.001) BMI Weight loss failure (BMI &gt;35 at 5 years) 9/26 LAGB 1/24 LRYGB (p&lt;.001) BMI &lt;30 at 5 years 3/26 LAGB 15/24 LRYGB (p&lt;.001) 5 year follow-up LAGB 34.9 BMI LRYGB 29.8 BMI LAGB 47.5% EWL LRYGB 66.6% EWL (p&lt;.001)</td>
<td>Not possible to say how the procedures effected comorbidity resolution because of low baseline occurrence</td>
</tr>
<tr>
<td>Authors, study design, country, evidence grading</td>
<td>Interventions and methods</td>
<td>Results</td>
<td>Clinical efficacy and safety</td>
<td>Conclusions</td>
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<td>Alami et al. (2007)</td>
<td>Pre-operative weight loss v no pre-operative weight loss in LRYGB surgeries</td>
<td>Results: Of 100 randomised patients, 61 eventually underwent surgery (weight loss group = 26, no weight loss group = 35)</td>
<td>Withdrawn from surgery (n=39): 3 weight loss group patients gained weight (2 decided to continue trying to lose weight before surgery) 13 deemed ineligible after randomisation because of previous surgery, too high risk for GBY, opted for another surgery, diagnosed with bipolar 1 patient in non-weight loss group decided to lose weight prior to surgery N=23 lost to follow-up – moved, decided not to undergo surgery, chose other treatment centre</td>
<td>Conclusions: Many centres and surgeons advocate pre-operative weight loss for surgery candidates on the premise that these patients are more motivated, better adapted and have a better understanding of post-operative nutritional and activity requirements. This may also lead to safer procedures both in anaesthetic risk and ease of surgery. Average time between initial consultation and surgery was the same for both groups indicating no extra delay for the weight loss group. Patients in the weight loss group lost an average of 23.5 lb (8.2% of initial weight) during the preoperative workup period. No difference in weight loss at 6 months follow-up. No difference in resolution of comorbidities – almost all had completely resolved by 3 months follow-up. Shorter operating times for weight loss group could be explained by lower BMI for that group. No difference in major complication rates, conversion rates or hospital stays. Limitations acknowledged by authors: High withdrawal or exclusion rate prior to surgery because randomisation had to occur as soon as the patients presented to the clinic. Most common reason for exclusion was to undergo LAGB instead of LRYGB. Comments: It is possible that those in the weight loss group were more motivated to adhere to post-operative dietary requirements and thus initially lost more weight post surgery. Short follow-up times and very small number of patients available for 12 month follow-up data. It is unclear whether the study had enough analytical power to detect differences between the two groups, considering 39% were excluded or withdrew after random allocation. More data may be available as more patients reach the 6 and 12 month follow-up time points.</td>
</tr>
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<td>RCT United States Evidence grade II</td>
<td>Method: Pre-operative random allocation to either a weight loss groups with 10% weight loss requirement or a group with no weight loss requirements Randomisation occurred once the person was deemed an appropriate candidate for LRYGB All patients had to demonstrate serious weight loss attempts in the past Weight loss group: Had to demonstrate a 10% weight loss prior to surgery, were allowed to use any means to achieve loss, access to nutritionist for support No weight loss group: Routine pre-operative workup Excluded patients who had previously undergone bariatric surgery Participants: Weight loss Initially n=50 Follow-up available for n=26 Initial weight 288.5 lb Initial mean BMI 48.7 kg/m² Preoperative BMI 44.5 kg/m² No weight loss Initially n=50 Follow-up available n=35 Initial weight 305.8 lb Initial mean BMI 50.7 kg/m² Preoperative BMI 50.7 kg/m²</td>
<td>Participants: Weight loss Initially n=50 Follow-up available for n=26 Initial weight 288.5 lb Initial mean BMI 48.7 kg/m² Preoperative BMI 44.5 kg/m²</td>
<td>Weight loss prior to surgery: WL group = 8.2% of initial weight lost (3.4 – 41.4 lb) BMI prior to surgery 44.5 kg/m² (sig diff from NWL group) Incidence of comorbidities was also comparable</td>
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<td>Outcomes: Operative time, peri-operative complications, post-operative weight loss, resolution of comorbidities</td>
<td>Complications: No intra- or post-operative mortalities in either group No anastomotic leaks and no conversions to ORYGB in either group Complication rates similar in each group</td>
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<td>Estimated blood loss not different Length of hospital stay similar (WL 3.4 and NWL 3.1 days)</td>
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<td>Weight loss following surgery: Initial sig diff in %EWL, weight and BMI at 2 weeks, 6 weeks and 3 month checks No difference between groups by 6 months (~30%EWL in both groups) Similar resolution of comorbidities in both groups from ~4.5 comorbidities prior to surgery to 0.6 comorbidities at 3 months.</td>
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<td>Follow-up rates: 3 months = 82% 6 months = 61% 12 months = 20%</td>
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SECTION 2: COST EFFECTIVENESS OF BARIATRIC SURGERY

Primary research: Study designs and quality

The search identified five eligible primary economic research studies. This section includes an overview of study designs and aspects of quality represented by these studies.

Study designs and quality assessments

There was only one comparison for which more than one study could be included in this review: the comparison of laparoscopic Roux-en-Y gastric bypass (LRYGB) with open Roux-en-Y gastric bypass (ORYGB) (Paxton and Matthews 2005; Siddiqui et al. 2006). One primary research study included two comparisons: Adjustable gastric banding with conventional treatment and gastric bypass with conventional treatment (Ackroyd et al. 2006). All five studies had significant limitations. The small number of primary economic research studies, particularly the small number of studies addressing each question, as well as the overall weak quality of studies provides for a very low level of evidence on the economic merits of bariatric surgery in general.

Methods and data

Four studies presented cost effectiveness information that did not rely on simulation or projection. Three of these were standard cost effectiveness analyses. One of these was a cost effectiveness analysis based directly on the 12-month follow-up of an RCT (van Mastrigt et al. 2006). Another was based on previously published data from various sources, allowing for a three year time scope (Paxton and Matthews 2005). The third was also based on previously published data but with a scope of five years post-surgery (Ackroyd et al. 2006). The fourth study was also based on previously published data but this was applied to a decision analytic model to determine cost effectiveness over a 12 month period post-surgery (Siddiqui et al. 2006). The fifth study applied microsimulation techniques on a hypothetical cohort of patients, using previously published data, to project results for longer term costs and benefits (Finkelstein and Brown 2005).

The perspective of an economic analysis is important to help the reader understand which costs and benefits were relevant to the question being addressed. Often the availability of data dictates the perspective. Two of the five studies included analysis which took a societal perspective (Paxton and Matthews 2005; van Mastrigt et al. 2006). That is, they were concerned not only with medical outcomes and costs, but also with indirect and non-medical factors such as the value of lost or gained productivity and/or informal care costs. Two studies excluded non-medical costs and, therefore, performed analysis from a health system perspective which is concerned with achieving the best medical outcome considering total medical costs (Ackroyd et al. 2006; Siddiqui et al. 2006). In these studies, the benefit to society or to the individual of increased productivity, for example, is excluded. One study was an economic analysis based on the perspective of a typical American employer who must consider whether to offer bariatric surgery to employees whose medical costs are covered by the employer (Finkelstein and Brown 2005). This study included the medical costs of surgery as well as the medical costs associated with obesity and all the positive and negative implications for productivity. In this sense, the perspective tended towards a societal one, however the study did not address the experience of the patient at all and therefore cannot be considered a complete societal perspective even though it is, in some ways, wider than a health system perspective. In this review, the perspective taken by the latter study has been termed “quasi-societal”.

Interventions and comparators

One study compared bariatric surgery in general with no treatment (Finkelstein and Brown 2005). In terms of specific interventions, gastric bypass was the most common intervention evaluated. In one study, this was compared to conventional treatment (Ackroyd et al. 2006). The same study compared adjustable gastric banding to conventional treatment. In two studies laparoscopic and open techniques of gastric bypass were compared (Paxton and Matthews 2005; Siddiqui et al. 2006). The remaining study compared vertical banded gastroplasty with LapBand surgery (van Mastrigt et al. 2006).

Outcomes

There was a wide range of outcomes used to determine cost effectiveness, with some studies presenting results for more than one measure of cost effectiveness. Only two studies presented results on quality-adjusted life years gained (Ackroyd et al. 2006; van Mastrigt et al. 2006). Two studies presented results on cost per percentage of excess weight loss (Ackroyd et al. 2006; van Mastrigt et al. 2006). One study presented results on
cost per diabetes-free year added, based on the observation that bariatric surgery often results in cases of type-II diabetes mellitus being resolved (Ackroyd et al. 2006). One study used the time required to allow benefits to outweigh costs, such that “break-even” would be achieved (Finkelstein and Brown 2005). The two studies comparing laparoscopic gastric bypass and open gastric bypass both assumed that the techniques were equal in terms of quality of life outcomes and weight loss (Paxton and Matthews 2005; Siddiqui et al. 2006). These two studies, therefore, defined other measures of effectiveness for the comparison. One used a measure of successful surgery (defined by a lack of major complications), (Siddiqui et al. 2006) and the other used three separate measures: the rate of complications, the length of stay in hospital, and mortality (Paxton and Matthews 2005).

Bariatric surgery compared with no treatment

The study by Finkelstein and Brown (2005) consisted of a cost-benefit simulation model of health insurance coverage for full-time employees to determine whether the productivity gains and reduction in medical costs associated with obesity would be enough to offset the costs associated with bariatric surgery for full-time employees. Thus the perspective was equivalent to that of third party payer but also capturing the lost productivity which would be a concern from a societal perspective. The utility improvement to the patient is excluded. The simulation generated the expected number of years of full-time employment required to achieve cost-savings.

The value of lost productivity was estimated by regression analysis, controlling for other factors which may be associated with decreased productivity, such as age, education, family factors, race, ethnicity, income, smoking, alcohol use, etc. These estimates were generated for the surgery eligible population as well as for the surgery ineligible population in order to generate the productivity loss that is attributable to obesity-related ill health.

Data

The population used for the simulation consisted of hypothetical full-time employed adults between the ages of 18 and 64 years with BMI of at least 40 or BMI of at least 35 with significant comorbidities (including type-II diabetes mellitus (T2DM), hypertension, angina, asthma, and/or osteoarthritis).

Medical data for the simulation was derived from previously published sources. Productivity loss and the medical costs associated with obesity were derived from the 2002 National Health Interview Survey and the 2000-2001 Medical Expenditure Panel Survey. Medical costs were adjusted to 2004 dollars.

In the base case, it was assumed that obesity-attributable costs for patients who have bariatric surgery would be reduced by 75 percent (based on a meta-analysis of studies reporting weight loss, reduction in T2DM, reduction in hypertension, and reduction in sleep apnoea). For sensitivity analysis, a 100 per cent reduction in medical costs and a 50 per cent reduction in medical costs were also modelled.

Results

Results of the simulation indicate that for obese patients incurring mean obesity-related medical costs prior to surgery, the time required after surgery to generate break-even would be 13.5 years if only medical costs are considered and 10.3 years if both medical costs and productivity losses are considered. For patients incurring obesity-related medical costs at the 90th percentile, the time required to generate break-even would be 6.6 years if only medical costs are considered and 5 years if both medical costs and productivity losses are considered.

Sensitivity analysis

Sensitivity analysis revealed that an assumption of higher wages significantly reduces the time to break-even and that less optimistic assumptions (50 per cent reduction in medical costs after surgery) regarding ongoing costs significantly increases the time to break-even. The model is, therefore, sensitive to variations in the base case assumptions.

Conclusions

The results suggest that there is wide variation in the cost effectiveness of bariatric surgery depending on the pre-surgery medical costs incurred by morbidly obese patients. From a societal perspective, as well as from a health system perspective, those with higher obesity-related medical costs would be treated most cost effectively.
by bariatric surgery. The results also suggest that non-medical costs, such as productivity loss, may have a significant impact on the cost effectiveness of surgery from a societal perspective.

Limitations

The authors point out that morbidly obese people who are employed full-time are likely to be healthier and to incur lower obesity-related medical costs. Because of this, the results of this analysis may not be generalisable to the entire morbidly obese population. Other limitations of the study include the exclusion of benefits to the patient, such as improvement in quality of life or increase in wages as a result of increased productivity, the exclusion of plastic surgery costs, and the likely unrealistic assumption of full-time employment for morbidly obese patients.

Adjustable gastric banding (AGB) compared with conventional treatment

The cost effectiveness analysis and budget impact model described in the study by Ackroyd et al (2006) was based on previously published data reflecting practice in 2005 in three European countries: Germany, France, and the United Kingdom. The time horizon of the study was five years post-surgery. The study included a comparison of adjustable gastric banding (AGB) with conventional treatment as well as a comparison of gastric bypass (GBY) with conventional treatment (described in the next section). There were 1000 patients included and all of these had a BMI of 35 or more as well as T2DM. The perspective taken is that of third party payer or health care system perspective. Effectiveness of treatment was defined in terms of reduction in BMI and reduction in prevalence of T2DM.

Data

The cost of conventional treatment in each country was based on the identification of the main cost-driving health-care resources during prior research. In order to estimate cost effectiveness, QALYs were calculated for each treatment and each follow-up year using annual mean EQ-5D scores. A large cumulative utility was taken as an indication of greater and/or longer-lasting BMI reduction and/or greater and/or longer-lasting reduction in prevalence of T2DM with one treatment than with the other.

In order to estimate surgery-related costs, the total cost of treatment and of related complications were estimated. The cost of AGB in each country was estimated by prior research on the main cost-driving health-care resources utilised with the addition of the cost of complications. It was assumed that the average complication cost would be incurred during the first year after surgery. The cost of conventional treatment in each country was based on the identification of the main cost-driving health-care resources during prior research.

The cost of treatment of T2DM was also included in the analysis as a reduction in prevalence of T2DM resulting from surgery would be expected to result in cost-savings with regards to the treatment of T2DM.

Basic cost data were extracted from medical cost databases in each country.

Results

The study found that the incremental cumulative effectiveness and utility of AGB over the five year range is 57.8 kg/m² years, 2.5 T2DM-free years, and 1.03 QALYs gained over what would be expected for patients having conventional treatment. The incremental cumulative cost over the five year range was estimated to be €-3,586 (cost-saving) for AGB in Germany; €-4,480 (cost-saving) for AGB in France; and, £1,984 for AGB in the UK. These results yielded the following incremental cost effectiveness ratios for AGB:

- €3,488/QALY gained, €62/BMI.year, and -€1,463.7/T2DM-free year in Germany;
- €4,357/QALY gained, €77.5/BMI.year, and -€1,828.5/T2DM-free year in France; and,
- £1,929/QALY gained, £34.3/BMI.year, and £810/T2DM-free year in the U.K.

Sensitivity analysis

By way of sensitivity analysis, the authors perform a worst-case scenario analysis in which surgery was 20 per cent less effective than in the base case and conventional treatment had no effect on BMI or T2DM prevalence.
at all. Under this scenario, AGB remains cost-saving in Germany and dominates conventional treatment in terms of cost effectiveness; it becomes slightly cost-increasing in France but remains very cost effective; and it becomes a little less cost effective in the U.K. but remains well within the acceptable range (under £20,000 per incremental QALY gained).

Conclusions

The authors conclude that AGB is a dominant strategy over conventional treatment for these patients in Germany and France, being more effective and less costly than conventional treatment, and that AGB is cost effective although not cost-saving in the U.K. when compared with conventional treatment.

Limitations

Limitations of the analysis include the exclusion of the cost of plastic surgery, the exclusion of indirect costs (due to the perspective of the analysis), and the limited sensitivity analysis which did not allow for variations in costs.

Gastric bypass (GBY) compared with conventional treatment

The cost effectiveness analysis and budget impact model described in the study by Ackroyd et al. (2006) was based on previously published data reflecting practice in 2005 in three European countries: Germany, France, and the United Kingdom. The time horizon of the study was five years post-surgery. The study also included a comparison of adjustable gastric banding with conventional treatment (described separately). There were 1000 patients included and all of these had a BMI of 35 or more as well as T2DM. The perspective taken is that of third party payer or health care system perspective.

Effectiveness of treatment was defined in terms of reduction in BMI and reduction in prevalence of T2DM.

Data

The cost of conventional treatment in each country was based on the identification of the main cost-driving health-care resources during prior research. In order to estimate cost effectiveness, QALYs were calculated for each treatment and each follow-up year using annual mean EQ-5D scores. A large cumulative utility was taken as an indication of greater and/or longer-lasting BMI reduction and/or greater and/or longer-lasting reduction in prevalence of T2DM with one treatment than with the other.

In order to estimate surgery-related costs, the total cost of treatment and of related complications were estimated. The cost of GBY in each country was estimated by prior research on the main cost-driving health-care resources utilised with the addition of the cost of complications. It was assumed that the average complication cost would be incurred during the first year after surgery.

The cost of treatment of T2DM was also included in the analysis as a reduction in prevalence of T2DM resulting from surgery would be expected to result in cost-savings with regards to the treatment of T2DM. The cost of conventional treatment in each country was based on the identification of the main cost-driving health-care resources during prior research. Cost data were extracted from medical cost databases in each country.

Results

The study found that the incremental cumulative effectiveness and utility of GBY over the five year range is 80.8 kg/m² years, 2.6 T2DM-free years, and 1.34 QALYs gained over what would be expected for patients having conventional treatment. The incremental cumulative cost over the five year range was estimated to be -€5,030 (cost-saving) for GBY in Germany; -€5,877 for GBY in France; and, £2,033 for GBY in the UK. These results yielded the following incremental cost effectiveness ratios for GBY:

- £3,754/QALY gained, £62.3/BMI.year, and £1,920/T2DM-free year in Germany;
- £4,385/QALY gained, £72.7/BMI.year, and £2,243/T2DM-free year in France; and,
- £1,517/QALY gained, £25.2/BMI.year, and £776/T2DM-free year in the U.K.
Sensitivity analysis

By way of sensitivity analysis, the authors perform a worst-case scenario analysis in which surgery was 20 per cent less effective than in the base case and conventional treatment had no effect on BMI or T2DM prevalence at all. Under this scenario, GBY remains cost-saving in Germany and dominate conventional treatment in terms of cost effectiveness; it also remains cost-saving in France and dominates conventional treatment; and it becomes a little less cost effective in the U.K. but remains well within the acceptable range (under 20,000 pounds per incremental QALY gained).

Conclusions

The authors conclude that GBY is a dominant strategy over conventional treatment for these patients in Germany and France, being more effective and less costly than conventional treatment, and that GBY is cost effective although not cost-saving in the U.K when compared with conventional treatment.

Limitations

Limitations of the analysis include the exclusion of the cost of plastic surgery, the exclusion of indirect costs (due to the perspective of the analysis), and the limited sensitivity analysis which did not allow for variations in costs.

LapBand surgery compared with Vertical banded gastroplasty (VBG)

The study by van Mastrigt et al. (2006) was a cost effectiveness analysis conducted in conjunction with a clinical trial. Amongst the included studies, it is the economic study that is most closely linked to a primary source of data. The study was based on a single blinded prospective, controlled, randomised clinical trial in which 100 patients were randomly assigned to VBG or Lap-Band surgery between April 1999 and December 2002. The time horizon of the analysis is from the day before surgery to 12 months after surgery.

Data

Effectiveness estimates were based on the reported outcomes of cost per percentage excess weight loss (%EWL) and cost per QALY gained. Quality of life was measured preoperatively and at 3, 6, and 12 months postoperatively using the EQ-5D Questionnaire. The %EWL at 12 months was the primary medical outcome for the economic analysis.

Medical and non-medical costs (i.e. costs of informal care and productivity loss) were identified and measured during the course of the trial based on medical resource utilisation determined by hospital billing systems, an observation study and cost-diary. Unit costs were cost prices where available and, where unavailable, tariffs or shadow prices were used. The total cost of treating each patient was defined as the sum of direct medical costs, including inpatient days, clinical procedures, surgery, outpatient clinics, dietician consult, GP consultation and prescribed medication as well as out-of-pocket expenses by patients, and indirect non-medical costs, including unpaid help and productivity losses.

Results

Results reported include the finding that mean total costs per patient were estimated to be higher for the VBG than for the Lap-Band (€13,185 and €11,299, respectively), however this was not considered to be a significant difference. After one year, quality of life was found to be not significantly different between the VBG and Lap-band groups. However, weight loss outcomes were significantly higher in the VBG group. The cost effectiveness ratios lead to different conclusions depending on the measure of effectiveness used: The incremental cost of VBG per additional percentage point of excess weight loss was estimated to be €105.80; however, when QALYs gained are used as the measure of effectiveness, Lap-Band surgery dominates VBG due to its lower cost and the lack of difference in QALYs gained.

Sensitivity analysis

The analysis included some sensitivity analysis relating to the inclusion of non-medical costs as well as the unit costs of surgery personnel and the unit costs of inpatient days.
The authors note that non-medical costs were a significant portion of total costs, resulting in a marked difference between evaluation from a third party payer perspective and a societal perspective. This was the only significant variation resulting from sensitivity analysis. Other results were robust under sensitivity analysis.

**Conclusions**

The authors conclude that the results after one year are insufficient to inform the choice of procedure for morbidly obese patients and that longer term follow-up is needed.

**Limitations**

The limitations of the study include the short follow-up time (12 months), which according to the authors may explain the poor results in terms of weight loss for Lap-Band surgery as well as the lack of observed difference in QoL (the relatively small number of patients reduced the power of the statistical analysis). Furthermore, the study was limited by the exclusion of costs associated with plastic surgery, and the small number of patients in the trial.

Laparoscopic Roux-en-Y gastric bypass (LRYGB) compared with open Roux-en-Y gastric bypass (ORYGB)

Two studies compared LRYGB with ORYGB in terms of cost effectiveness. Both studies assumed that weight loss and the reduction in obesity-related illness would be the same for LRYGB patients as for ORYGB patients and, therefore, used other measures of effectiveness in the comparison. One study defined success for the surgery as a lack of major complications and this was used as the measure of effectiveness. The other study measured the rates of complications, mortality and hospital stay separately and used these separately as measures of effectiveness. Neither study produced cost effectiveness ratios as both of these found LRYGB to be both more effective and less costly than ORYGB.

**Siddiqui, Livingston and Huerta (2006)**

Siddiqui et al (2006) conducted a study using a decision-analysis model used to compare LRYGB and ORYGB for both morbidly obese and super obese patients. A decision analytic model was created to determine the preferred treatment strategy, failure rates, complications rates, and costs for three patient categories: those with BMI between 35 and 49; those with BMI between 50 and 60; and, those with BMI over 60. The time horizon of the model was one year post-surgery.

**Data**

Medical data were derived from published literature. Average costs were obtained from the Agency for Healthcare Research and Utilization Project (HCUPnet) national online database for 2002. Estimates of the marginal cost of additional hospital days were obtained from the Health Economic Research Center inpatient average costs datasets for the Veterans Administration health care system.

**Results**

Results of the model suggest that in patients with BMI between 35 and 49, LRYGB was the strategy with higher overall success rate (success was defined as no major procedure-related complications and no long-term complications over one year after surgery), with a success rate of 86 per cent compared with a success rate of 82 per cent for ORYGB. This result was found to be robust under sensitivity analysis. LRYGB was also found to be associated with a lower cost, making it the dominant strategy for this group.

For patients with BMI between 50 and 60, the results suggest that LRYGB is more effective, with an overall success rate of 82 per cent, compared with the overall success rate of 77 per cent for ORYGB. This result was found to be slightly less robust than the result for the less obese group. Again, the analysis suggested that LRYGB was less costly than ORYGB, making it the dominant strategy for this group.

For patients with BMI over 60, LRYGB was also found to be associated with a greater success rate: 67 per cent compared with 63 per cent for ORYGB. This result was found to be somewhat sensitive to the assumptions of...
the model. Again, the overall cost of LRYGB was found to be lower, indicating that LRYGB is the dominant strategy for this group.

**Sensitivity analysis**

Variations in assumptions regarding the rates of different possible complications as well as different mortality rates were introduced to the model to determine threshold rates that would alter the treatment strategy. The model was robust for most realistic rates of complications and mortality. Some sensitivity was observed for potentially realistic variations in the categories of obese patients with BMI of 50 to 60 and those of BMI of 60 or more.

**Conclusions**

The authors conclude that LRYGB is a more cost effective method for surgical weight loss than ORYGB across any BMI range.

**Limitations**

Limitations of this study include the lack of quality of life data, the exclusion of non-medical costs, the exclusion of the cost of plastic surgery, and the lack of sensitivity analysis on cost assumptions. The authors also suggest that the relatively small amount of data available on LRYGB on the super obese and publication bias in this area may also make the results less robust.

**Paxton and Matthews (2005)**

Paxton and Matthews (2005) produced a cost effectiveness analysis comparing laparoscopic RYGB with open RYGB. The comparison exposed differences in cost, perioperative complication rates, medical outcomes, and cost effectiveness. The study included medical as well as non-medical costs. Productivity estimates were based on the assumption that patients were employed at average wages and that they would remain employed for most of their remaining lives so that the cost of death was calculated as the value of lost income. The risk of conversion from LRYGB to ORYGB was included and was assumed to be 2.25 per cent. The time horizon of the study was three years post-surgery.

**Data**

Data on 6,425 ORYGB patients and 5,867 LRYGB patients was derived from published literature and used to compare the outcomes of the two approaches. 84.8 per cent of patients were female, 15.2 per cent were male. The average age was 39.9 years and the average pre-surgical BMI was 49.6 kg/m².

Estimates of total health care costs associated with complications were derived from the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUPnet) national online database for 2002. Estimates on the marginal cost of additional hospital data were obtained from the Health Economic Resource Center (HERC) inpatient average costs datasets for the Veterans Administration healthcare system for June 2004. Average procedural costs were extracted from published sources. Wage and labour data were extracted from the US Bureau of Labor Statistics national employment, hours and earnings figures. It was assumed that LRYGB would be as effective as ORYGB at achieving weight loss and a reduction in obesity-related morbidity.

**Results**

Both LRYGB and ORYGB were found to be associated with a wide range of perioperative complications and ORYGB was found to be more likely to result in perioperative mortality. LRYGB was associated with a reduction in length of stay compared with ORYGB even though the operating time was typically longer for LRYGB. The total direct medical cost of ORYGB was found to be US$8,004 whereas the total direct medical cost of LRYGB was found to be $8,671. Complications were found to add $5,079 to the cost of ORYGB and $4,634 to the cost of LRYGB. The costs associated with death and lost productivity brought the total cost of ORYGB to $20,443 and the total cost of LRYGB to $17,660.
Results also supported previously published findings that certain risk factors (revisional surgery, male sex, extreme age, increasing pre-operative BMI, and smoking or hypertension) increase the likelihood of major complications following GBV and are, therefore, expected to be associated with higher costs.

Sensitivity analysis

The study did not report on sensitivity analysis.

Conclusions

The authors conclude that with a lower rate of mortality and a shorter length of stay as well as a lower overall cost, LRYGB dominates ORYGB.

Limitations

Limitations of the study include the exclusion of the cost of plastic surgery and the potentially unrealistic assumption that patients are employed and remain employed at average wages despite being morbidly obese and possibly suffering from significant obesity-related illness. This last assumption was a major causal factor in the result of superior cost effectiveness of LRYGB. The other factor responsible for this result was productivity, which was based on assumption and not tested.
Secondary research: Study designs and quality

The search identified five eligible secondary research studies. An overview of these studies is provided here. In some cases, the reports included economic evaluations which only reported on costs and did not report any measure of effectiveness or cost effectiveness. In that sense, the inclusion criteria for economic evaluations appears to have been slightly different for some systematic reviews.

**Canadian Agency for Drugs and Technologies in Health (CADTH) (2007)**

CADTH (Boudreau and Hodgson 2007) set out to determine the effectiveness and cost effectiveness of Laparoscopic adjustable gastric banding (LAGB) compared with Roux-en-Y gastric bypass (RYGB) and vertical banded gastroplasty (VBG), with either of the two latter surgeries performed laparoscopically or as open surgery. The report consisted of a systematic review of publications from 2004 to 2007.

The report notes that three studies found that LAGB patients experienced significant improvements in quality of life after surgery. These findings were based on the Bariatric Analysis and Reporting Outcome System (BAROS), the SF-36 survey (a generic health survey with 36 questions on pain, emotional health, mental health, etc.), and the Beck Depression Inventory.

The van Mastrigt et al. (2006) study was one of three primary economic studies included in the review. The report noted that the van Mastrigt study found no difference in quality of life one year after patients were randomised to LAGB and VBG, although weight loss was greater in the VBG group. The short term follow-up was considered to be the major limitation of this study. The CADTH notes that some literature has shown that LAGB patients continue to lose weight beyond 12 months. It is also pointed out that long term complications are excluded from the calculations.

Wasowicz-Kemps et al. (2006) is another study discussed in the review. This study analysed the costs of LAGB as an outpatient procedure compared with the costs of an inpatient procedure involving an overnight stay in hospital. It was found that although the overnight stay made inpatient LAGB more costly, patients who had LAGB as an inpatient procedure experienced significantly less postoperative pain, even though pain medication was similar in the two groups.

The third study noted by the review (Dixon et al. 2004) compared LAGB patients to a control group who had not had surgery 36 months later. This study found that LAGB patients scored significantly higher on quality of life measured using several commonly accepted tools.

The CADTH report indicated that the major factors limiting the availability of useful economic literature on bariatric surgery were:

- A lack of long term follow-up (i.e. five or more years);
- the small number of RCTs; and,
- the variation and inconsistency in the definitions and reporting of complications;

The report concludes that the economic literature on the subject is weak but that what evidence exists is indicative of the cost of LAGB being reasonable. The report cautions, however, that there is uncertainty about the rate of complications beyond three years post-surgery.

**The Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS), Québec (2006)**

The Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS) (2006) (Hassen-Khodja and Lance 2006) prepared a report updating the state of evidence since its 1998 report on bariatric surgery. The primary sources of evidence were scientific articles and health technology assessment reports published since 1998. The report notes that none of the economic studies reviewed was complete enough to provide a significant contribution to an evaluation of cost effectiveness of bariatric surgery. However, the report nevertheless makes note of some key points from the studies associated with primary sources of data:

- The cost-utility ratio estimated in one study was favourable to surgery, suggesting savings of U.S.$3,928 to U.S.$4,004 per QALY gained, based on an economic burden of disease approach including patients’ own productivity est. The study in question, however, included only 21 patients.
- Several studies (Agren et al. 2002; Martin et al. 1995; Narbro et al. 1999), whilst not providing a full...
economic evaluation, compared resource utilization and associated costs and these also demonstrated an advantage to surgery. Agren et al., however, found that even though total resource use was lower for patients who underwent surgery, these patients were still incurring higher hospitalisation costs six years after surgery. Furthermore, Martin et al. found that a weight reduction surgery programme would cost U.S. $24,000 while medical treatment would cost U.S. $3,000.

- Gallagher et al. (2003) found a significant reduction in the cost of obesity-related diseases and symptoms as a result of weight reduction surgery.
- Nguyen et al. (2001) and Chua and Mendiola (1995) found that laparoscopic surgery is likely to offer greater cost savings than open surgery.
- Christou et al. (2004) report that although direct health care costs in the first year are higher for the surgery group than for the control group, the surgery costs were amortised by three and a half years. By five years post-surgery, there were significant savings in mean cumulative costs for the surgery group.

The AETMIS also reviewed several economic models which attempted to provide a more complete economic assessment of bariatric surgery by making use of previously published data and simulation and forecasting techniques:

- The model developed by Clegg et al. (Clegg et al. 2002) which compared GBY, VBG, and AGB with no treatment based on a hypothetical cohort of 100 patients over a 20 year time horizon generated cost effectiveness ratios which were based on conservative assumptions and robust under sensitivity analysis: £6,289 per QALY gained for GBY, £10,237 per QALY gained for VBG, and £8,527 per QALY gained for AGB. The conservative assumptions of the model suggest that these are high estimates. The model did not include productivity gains, which makes the estimates relevant from a health system perspective rather than a societal perspective, or suggests the estimates are conservative if the societal perspective is sought.

- The model developed by Craig and Tseng (2002) made use of decision analysis to compare GBY with no treatment from a 3rd party payer, or health system, perspective (i.e. not including productivity or lost wages), based on lifetime costs and QALYs gained. The results were that for women, GBY is associated with a cost of US$5,000 to $16,000 per QALY gained, and for men GBY is associated with a cost of US$10,000 to $35,600 per QALY gained. The model found that surgery offered no cost savings compared with no treatment but that the cost-utility ratios were acceptable.

Particular attention was paid by the AETMIS report to estimates based on countries where public health care systems predominate. From these, it was concluded in the report that direct costs are likely to vary between Cdn$4,968 and Cdn$10,870. It was also noted that these estimates suggested that the cost of LAGB is higher than that of RYGB and that of VGB whereas VBG is likely to cost less than RYGB. The higher cost of the LAGB was thought to be mainly due to the cost of the adjustable bands. The direct cost of biliopancreatic diversion was estimated to be Cdn$10,719.

The AETMIS report concludes that the efficacy of bariatric surgery is well-established and that improvements in health and quality of life from bariatric surgery are likely to be at a high cost but at a cost that is comparable to many other medical treatments. The report points out that the surgery itself is likely to be relatively expensive and that economic assessments have tended to ignore the need for plastic surgery which often arises for bariatric surgery patients. The cost of plastic surgery was thought to have the potential to increase costs significantly. Overall, the AETMIS felt that there was a lack of sufficiently detailed economic studies to draw strong conclusions about the cost effectiveness of bariatric surgery.


The Institute of Health Economics of Edmonton, Alberta, published a working paper in 2006 (Jacobs et al. 2006) which consisted mainly of a systematic review but which also included a basic cost analysis. The report notes that five studies included some type of economic comparison of bariatric surgery with non-surgical alternatives:

- The finding of interest in Narbro et al. (1999) was that although obese individuals have significantly higher medication costs than the general population and that bariatric surgery effectively reduces weight, the medication costs up to six years after surgery are not significantly different for patients who have had surgery than for those who have not.
- Agren et al. (2002), which was based on the same Swedish study as Narbro et al., found that the surgical group had higher hospitalization rates and costs during the follow-up period, resulting in increased costs over the non-surgical group of US$1,200 per year.
A Canadian study (Christou et al. 2004; Sampalis et al. 2004) found that patients with no significant comorbidities who had bariatric surgery had significantly lower hospitalization costs than patients who had not had surgery and that this reduction led to cost savings after 3 years.

Studies using secondary data and economic modelling produced cost-utility estimates that were noted by the report:

- Clegg et al. (Clegg et al. 2003; Clegg et al. 2002) found a cost-utility ratio of less than £11,000 per QALY gained for all bariatric surgeries.
- Craig et al. (2002) estimated ratios of between U.S.$5,000 and U.S.$35,000 depending on the age, sex, and pre-surgery BMI of patients.
- A study by MSAC, Australia (Medical Services Advisory Committee (MSAC) 2003) demonstrated that all cost-utility ratios for the different bariatric surgeries were within the acceptable range of U.S.$7,000 to U.S.$33,000 per QALY gained.

The report also noted that there was some evidence on the relative costs of LAGB and Laparoscopic Roux-en-Y procedures:

- Chen and McGregor (2004) estimated that the direct cost of providing an LAGB would be Cdn$7,178 and that the direct cost of providing a laparoscopic Roux-en-Y procedure would be Cdn$5,207. These estimates included professional costs of Cdn$8,460 and Cdn$6,490, respectively). Follow-up costs for two years post-surgery were also estimated at Cdn$416 and Cdn$180 respectively.

The report comprised cost-utility evidence from only four studies and noted that this was an area lacking research. Three of the studies providing cost-utility estimates were based on secondary or previously published data:

- Clegg et al. (Clegg et al. 2003; Clegg et al. 2002) and Craig et al. (2002) modelled cost-utility ratios for bariatric surgery and found that results ranged between U.S.$5,000 and U.S.$35,000 per QALY gained, depending on the sub-group and type of procedure.
- MSAC (Medical Services Advisory Committee (MSAC) 2003) found all cost-utility ratios to be within an acceptable range.

One study estimating cost-utility ratios was based on a primary data source (van Gemert et al. 1999). This study found that over patients’ lifetimes, bariatric surgery generated small incremental cost savings and increases in QALYs and, therefore, dominated non-surgical options.

The report notes that there was a lack of enough economic research into bariatric surgery and that what research existed was limited in a way that restricts decision-making. It was also noted that not enough information was available to compare the cost effectiveness of lap-bandings to other bariatric surgeries.

The cost analysis conducted by the Institute, and detailed in the report, sought to estimate the average annual cost of health services for one year prior to, and three years after, bariatric surgery for all people in the province of Alberta who underwent bariatric surgery in 1999/2000. Bariatric surgery was defined as gastric partitioning for obesity either alone or in combination with small-to-small intestinal anastomosis. The analysis was from the perspective of the Alberta Ministry of Health. 91% of patients were female, 92% of patients were in the 20-50 year age range, 61% of patients had a gastric partitioning procedure and 39% had partitioning combined with small-to-small intestinal anastomosis.

The analysis found that the highest average annual cost was in the year of surgery, reflecting primarily the cost of the surgery itself. Average annual costs were found to decline in the two years after surgery but were still higher than the average annual cost for the year prior to surgery, suggesting several years of increased resource utilisation by patients who undergo surgery. The report explains this increase in costs by the increase in hospitalisation for patients who have had surgery. Outpatient costs, on the other hand, were found to be more consistent from year to year and, at their maximum, these were still less than 20 per cent of the pre-surgery level. Forty per cent of surgery patients were admitted to hospital for apronectomy.

Cost analysis suggested that in Alberta a morbidly obese person is likely to incur up to Cdn$366 per year in additional medical costs over what would be expected for a person with BMI in the normal range, depending on the exact BMI. The cost of surgery was estimated at Cdn$5,207 for an open bypass procedure and Cdn$7,178 for a laparoscopic procedure. No comparative information was available on post-surgery costs. The report notes
that considering the cost of surgery and the relatively small additional medical costs incurred by morbidly obese people, the payback period is likely to be substantial.

The report concludes that there were very few studies which allow a clear identification of costs and of the economic impact of the various methods for treating obesity. It is suggested that “the very slight burden of evidence favours bariatric surgery on the grounds that subsequent costs are reduced; but there is some contradictory evidence as well.” Little evidence was found that would allow comparison of one bariatric method over another. Finally, the report points out that there was no evidence of a reduction in post-surgery medical costs relative to costs prior to surgery due to an absence of long range data.

The Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (2005)

This report was a systematic review conducted by the Ontario Medical Advisory Secretariat in order to gain evidence to inform recommendations for the provision of bariatric surgery in Ontario (Medical Advisory Secretariat 2005). At the time the report was prepared, a substantial proportion of morbidly obese patients deemed eligible for bariatric surgery either did not receive surgery or received surgery through the out-of-country approvals process due to a lack of capacity within Ontario.

The Medical Advisory Secretariat reviewed the literature with the objective of assessing the safety, effectiveness, and cost effectiveness of bariatric surgery compared with optimal conventional management or other type of bariatric procedure. In addition to the literature review, the Medical Advisory Secretariat also conducted a basic cost analysis.

The report notes that MSAC’s comparison of LABG and open VBG suggested that LAGB would be more costly than VBG and that the cost difference is accounted for primarily by the cost of the adjustable gastric band’s adjustment procedures as well as its higher prosthetic, intensive care unit and operating room costs and that these costs are not offset by shorter duration of hospitalization. These findings need to be weighed against the evidence that LABG was found to be associated with lower rates of revision and complications than open VBG. MSAC found that, overall, an incremental cost effectiveness ratio of $26,178 (it is unclear whether costs are reported in Australian or Canadian dollars, although it would make very little difference at current exchange rates) per QALY gained for LABG compared with VBG.

The Medical Advisory Secretariat noted that many primary studies ignored certain costs which are expected to be significant. Clegg et al. (2002) was found to be supportive of bariatric surgery in general over non-surgical options but the lack of good quality economic assessments was again noted and was perhaps the reason the costs of plastic surgery and of bariatric operating room equipment were not included in the analysis. Similarly, Gallagher et al. (2003) ignored the costs of plastic surgery and of bariatric operating room equipment in their cost analysis.

Craig et al. (2002) was deemed by the reviewers to be a more complete economic analysis, which suggested that the cost effectiveness ratios of gastric bypass compared with no treatment ranged between U.S.$5,000 and U.S.$16,000 per QALY gained for women and U.S.$10,000 and U.S.$35,600 for men, depending on age and pre-surgery BMI. Overall, results were suggestive that cost effectiveness is greater for women and those with higher pre-surgery BMI. Although it was found to be within an acceptable range of cost effectiveness, bariatric surgery was not found to be cost-saving. It was noted that the Craig et al. study was done from a health system or third party payer’s perspective and that, for this reason, non-medical costs such as productivity loss, lost wages, and other indirect costs were not included.

Due to a lack of cost effectiveness evidence, most of the evidence reviewed by the Medical Advisory Secretariat was on costs alone and this evidence, it was noted, was generally incomplete with each study focusing on a small number of cost factors.

The report also included a basic cost estimation for the Ontario health care system. Total cost per patient of bariatric surgery in Ontario including pre-operative consultation and testing, hospital and surgery costs on the day of surgery, and post-operative care costs and costs of services rendered during eight days post surgery was found to be Cdn$17,350. This was considered to be significantly lower than the cost of out-of-country procedures.
It was noted that there may be downstream savings associated with bariatric surgery if the reduction in comorbidities is associated with a cost reduction over the longer term. However, no evidence was provided to support this speculation.

The cost estimate derived by the Medical Advisory Secretariat did not include medical costs beyond eight days post-surgery or capitalization costs for the start-up of new bariatric surgery centres and was done from a third party payer perspective, excluding productivity losses, lost wages, and other indirect costs.

Salem, Jensen, and Flum (2005)

This 2005 systematic review focused specifically on identifying and appraising articles on the cost effectiveness of bariatric surgery. (Salem et al. 2005) The systematic review covered the period from 1966 to December 2003. Twelve articles met the inclusion criteria and are discussed in the report. Each study was judged on quality using accepted standards for CEAs, the study’s conclusions, strengths, and weaknesses reported. Only studies that reported cost per QALY gained were considered in the aggregate analysis but all studies of cost effectiveness were reviewed.

The reviewers found that only three publications reported the cost effectiveness of bariatric surgery as cost per QALY gained. In all of these, bariatric surgery was found to be cost effective at less than US$50,000 per QALY gained and, in one study the surgery was found to be associated with cost-savings. The most comprehensive study (Clegg et al. 2002 and Clegg et al. 2003) used data on effectiveness and utilities derived from RCTs, prospective clinical trials, and economic evaluations of different surgical procedures as well as non-surgical management and estimated costs over a projected 20-year period after treatment. This study found that bariatric surgery was cost effective at £11,000 per QALY gained. This was potentially a conservative estimate of cost effectiveness as the study only accounted for the costs of diabetes and not of other comorbidities and also ignored potential productivity gain. The authors of the review did not discuss whether the study had included the cost of plastic surgery.

Another publication noted in the review (Craig and Tseng 2002)had demonstrated that GBY was cost effective as an alternative to no treatment. GBY was also found to be more cost effective for women and for those with higher BMI before surgery. Cost effectiveness ratios varied from U.S.$5,000 to U.S.$35,600 depending on age, sex, and BMI. Again the reviewers suggest that these cost effectiveness estimates may be conservative as this study did not include the full costs of obesity (i.e. the costs of obesity-related illness) to help to balance out the cost of surgery.

A third study discussed in the review provided a lifetime simulation study of 21 patients who had had VBG. The perspective of this study was societal and, therefore, included not only direct medical costs but also indirect and non-medical costs. This study found the surgery to be cost-saving but no sensitivity analysis was performed and the sample population was very small.

In conclusion the authors note the relative paucity of data on the cost effectiveness of bariatric surgery, however it is also suggested that what evidence exists is indicative of bariatric surgery being cost effective.
Table 5. Evidence table of research studies comparing the cost effectiveness of different bariatric procedures for morbidly obese patients

<table>
<thead>
<tr>
<th>Authors, study design, country, evidence grading</th>
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<tr>
<td>Ackroyd et al. (2006)</td>
<td>Adjustable gastric banding (AGB) and gastric bypass (GBY) compared with conventional treatment (CT)</td>
<td>Outcomes: incremental number diabetes free years gained and incremental QALYs gained.</td>
<td>Compared to CT, GBY yielded: +80.8kg/m²-years (absolute value), +2.6 T2DM free years, +1.34 QALYs. Compared to CT, AGB yielded: -57.8kg/m²-years (absolute value), +2.3 T2DM free years, +1.03 QALYs. For Germany: -€3,754/QALY gained (GBY); -€3,488/QALY gained (AGB); -€62.3/BMI.year (GBY); -€62/BMI.year (AGB); -€1,920/T2DM-free year (GBY); -€1,463/T2DM-free year (AGB). For France: -€4,385/QALY gained (GBY); -€4,357/QALY gained (AGB); -€72.7/BMI.year (GBY); -€77.5/BMI.year (AGB); -€2,243/T2DM-free year (GBY); -€1,828.5/T2DM-free year (AGB). For the U.K.: -€1,517/QALY gained (GBY); -€1,929/QALY gained (AGB); -€25.2/BMI.year (GBY); -€34.3/BMI.year (AGB); -€776/T2DM-free year (GBY); -€810/T2DM-free year (AGB). The overall cost was lower for GBY and AGB than for CT in both France and Germany, making GBY and AGB dominant strategies for these countries. In the U.K., GBY and AGB were associated with an increased cost relative to CT but were still cost effective.</td>
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<tr>
<td>Cost effectiveness analysis and budget impact model based on published data</td>
<td>5-year time scope</td>
<td>Third party payer or health system perspective.</td>
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<td>van Mastigt et al. (2006)</td>
<td>Vertical Banded Gastroplasty (VBG) compared with Lap-Band surgery.</td>
<td>Cost effectiveness analysis based directly on data collected during a single blinded prospective, controlled, randomised clinical trial in which 100 patients were randomly assigned to VBG or Lap-Band surgery between April 1999 and December 2002. Medical and non-medical costs (i.e. costs of informal care and productivity loss) were identified and measured over the course of the trial.</td>
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<tr>
<td>Cost effectiveness analysis conducted in conjunction with an RCT</td>
<td>Outcomes: Total cost, QALYs gained, and percentage of excess weight loss relative to the patients’ preoperative state.</td>
<td>Outcomes are reported as cost per percentage excess weight loss and cost per QALY gained. QoL was measured preoperatively and at 3, 6, and 12 months postoperatively using the EQ-5D Questionnaire. Estimates are generated over the time period from the day before surgery to 12 months after surgery. Sensitivity analysis regarding the inclusion of non-medical costs as well as the unit costs of surgery personnel and the unit costs of inpatient days was conducted. Results suggested that non-medical costs are an important portion of total costs. Consequently, significantly different results are obtained when the perspective of the analysis is changed. Other results were robust. Limitations: Short-term scope (potentially the reason for lack of observed difference in QoL); and, relatively small number of patients (reduced the power of the statistical analysis).</td>
<td>Mean total costs per patient were higher for the VBG than for the Lap-Band (13,185 Euros and 11,299 Euros respectively), however this was not considered to be a significant difference. After one year, results suggest that the QALY gain is not significantly different between the VBG and Lap-Band groups. However, SEWL was significantly higher in the VBG group. Lap-Band is expected to be less costly than VBG, so that, in terms of cost per QALY, Lap-Band dominates VBG. Cost effectiveness results are considered insufficient to inform the choice of surgery. Longer term follow-up is needed.</td>
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<td>Finkelstein and Brown (2005)</td>
<td>Bariatric surgery for patients who are employed full-time is compared with no treatment. Outcomes: Benefits included increased productivity and decreased medical costs. Costs included lost productivity and surgery-related costs</td>
<td>Cost benefit simulation model used to estimate productivity loss and medical costs associated with obesity to inform an employer’s decision to provide financial coverage for the cost of bariatric surgery for full-time employees whose medical costs are being met by the employer. Using work loss and medical cost estimates, the cost implications of bariatric surgery were simulated. A breakeven point was generated, indicating how many years would be required post-surgery for any increase in productivity and decrease in ongoing medical costs to compensate for the cost of bariatric surgery. The model assumed that the reduction in obesity-attributable medical costs after surgery would be 75% based on published evidence of the reduction in comorbidities: 61% of excess weight would be lost, 77% of diabetes mellitus were resolved, 62% of hypertension cases were resolved, and 86% of sleep apnoea cases were resolved. Data to create the hypothetical cohort of morbidly obese people and their medical costs was obtained from the 2002 National Health Interview Survey and the 2000-2001 Medical Expenditure Panel Survey. The sample of patients was restricted to those aged between 18 and 64 years who reported working at least 35 hours per week and had a BMI≥40 or ≥35 with comorbidities. Sensitivity analysis applied to wage rates showed that those with higher wages had a substantially shorter time to break-even. Less optimistic assumptions regarding the outcomes of surgery significantly lengthened the time to break-even. The model was, therefore, sensitive to variations in assumptions. Limitations: The results may not be generalisable to the obese population as a whole (Obese people who are employed full-time are likely to be healthier than those who are not. As a result, they would have lower health care costs in the absence of surgery). The study also excluded the cost of plastic surgery and benefits to the patient [such as improved QoL].</td>
<td>For a surgery eligible patient whose pre-operative medical costs were at the mean, and considering both the change in medical costs as well as the change in productivity, the surgery is estimated to require 10.3 years post-surgery to achieve break-even. Patients at the 90th percentile in terms of pre-operative medical costs and productivity loss would require 5 years. If only medical costs are considered (ignoring productivity as a decision factor), these break-even points increase to 13.5 years and 6.6 years respectively. There are likely to be wide variations in the cost effectiveness of bariatric surgery depending on the pre-surgery medical costs incurred by morbidly obese patients. From a societal perspective, productivity pre- and post-surgery would also have a significant impact on the cost effectiveness of bariatric surgery.</td>
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<td>Paxton and Matthews (2005)</td>
<td>Laparoscopic Roux-en-Y gastric bypass surgery (LRYGB) compared with open Roux-en-Y gastric bypass surgery (ORYGB); Outcomes: Total costs, complication rates, mortality, and length of stay.</td>
<td>A cost effectiveness analysis based on the data of 6,425 ORYGB patients and 5,867 LRYGB patients derived from published literature. Estimates of costs associated with complications were obtained from the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUPnet) national online database for 2002. Estimates of the marginal cost of additional hospital days were obtained from the Health Economic Resource Center (HERC) inpatient average costs datasets for the Veterans Administration healthcare system (2004). Average procedural costs were drawn from published sources. Average weekly salary and average age of retirement were obtained from the US Bureau of Labor and Statistics (2004). The risk of conversion from LRYGB to ORYGB was assumed to be 2.25%. No Sensitivity analysis. Limitations: Cost of plastic surgery excluded. Assumption that morbidly obese patients are employed at average wages may be unrealistic.</td>
<td>Both LRYGB and ORYGB were found to be associated with a wide range of perioperative complications. ORYGB is associated with a greater rate of perioperative mortality, a significantly lower mean operating time, a greater estimated blood loss and a longer length of stay in hospital. It is not clear whether the analysis controlled for the facts that ORYGB patients comprised a greater proportion of females, were younger on average, and had a higher mean preoperative BMI. Although procedural costs were estimated to be lower for ORYGB ($8,671 compared with $8,004 for LRYGB), once complications and lost income are accounted for, ORYGB is associated with a higher total cost than LRYGB ($20,443 versus $17,660). If lost income is not included, the total costs (including procedural costs and costs associated with complications) are $16,331 for ORYGB and $15,143 for LRYGB. LRYGB is the dominant strategy due to its lower rate of mortality, shorter duration of hospitalization, and lower cost. Results are said to confirm previously published findings that certain risk factors (revisinal surgery, male sex, extreme age, increasing pre-operative BMI, and smoking or hypertension] increase the likelihood of major complications following GBY and are, therefore, likely to be associated with increased costs.</td>
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<td>Siddiqui et al. (2006) Decision analytic model</td>
<td>Laparoscopic Roux-en-Y gastric bypass (LRYGB) is compared with open Roux-en-Y gastric bypass (ORYGB). Outcomes: Total medical costs, success rate of surgery.</td>
<td>A decision model was constructed to determine the preferred treatment strategy for 3 categories of obese patient: Those with BMI between 35 and 49; Those with BMI between 50 and 60; and, Those with BMI over 60.</td>
<td>In patients with BMI between 35 and 49, LRYGB was the strategy with higher overall success rate and lower 1-year mortality. This result was shown to be robust under sensitivity analysis. LRYGB was also found to be more cost effective than ORYGB over a 1-year follow-up period due to the greater average overall cost associated with ORYGB ($27,630 compared with $23,629 for LRYGB).</td>
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<tr>
<td>U.S.A.</td>
<td></td>
<td>Clinical data for the model was derived from the published literature. Average costs at the national level were obtained from the Agency for Healthcare Research and Quality healthcare Cost and Utilization Project (HCUPnet) national online database for 2002. Estimates of the marginal cost of additional hospital days were obtained from the Health Economic Resource Center (HERC) inpatient average costs datasets for the Veterans Administration healthcare system (2004). Sensitivity analysis: Variations in assumptions regarding complication rates and mortality rates were tested. The model was found to be slightly sensitive to realistic variations in probability values. Limitations: Cost of plastic surgery was excluded. Cost assumptions were not tested by sensitivity analysis. Small amount of data on the super obese and publication bias may make results less robust.</td>
<td>In patients with BMI of 50 to 60, LRYGB was the dominant strategy, with greater effectiveness and lower cost ($28,654 versus $34,312 for ORYGB). In patients with BMI over 60, LRYGB was also dominant with greater effectiveness and lower cost ($30,769 versus $39,770 for ORYGB). This result was less robust under sensitivity analysis owing to the higher risk of surgical complications in this group. LRYGB is more cost effective than ORYGB across any BMI range.</td>
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Surgical and non-surgical interventions for morbid obesity
The effectiveness and safety of surgical compared with non-surgical interventions

The reviews included in this report all concluded that surgical interventions are significantly more effective than non-surgical interventions in terms of weight loss among morbidly obese patients. The evidence for these findings was of lower quality with no randomised controlled trials being identified. Some comparative studies have been conducted however most are of low to average quality with a lack of adequate matching between surgical and non-surgical patients. Because obese patients are more often recommended for non-surgical interventions, such as pharmacological therapy, and morbidly obese patients are more likely to be offered surgical treatment options, there are often initial weight differences between the surgical and non-surgical groups and a lack of studies comparing the two strategies in matched populations. This makes it very difficult to judge their relative effectiveness.

The best evidence for the relative effectiveness of surgical and non-surgical interventions comes from the SOS study, which was included in all reviews. The SOS longitudinal study involves more than 4000 obese subjects (BMI ≥ 34 for men, BMI ≥ 38 for women) who were assigned to non-surgical or surgical intervention groups based on patient preference and eligibility for surgery (Sjostrom et al. 2004; 2007). Patients in the non-surgical and surgical groups were matched on the basis of 18 baseline variables, including weight characteristics, blood pressure and cholesterol levels, smoking, diabetes and some psychosocial characteristics. Patients were followed up at 6 months, 1, 2, 3, 4, 6, 8, and 10 years following the surgical candidate’s operation. The surgical group underwent GB, VBG or GBY. The intervention utilised by the non-surgical control group was not standardised and varied from lifestyle and behavioural interventions to no treatment. No anti-obesity drugs were approved in Sweden until 1998.

Using the most recently available follow-up data, at 10 years post-surgery the surgical group had achieved on average a 16.1% weight loss while the non-surgical group had a weight gain of 1.6%. Weight loss was maximal at 1 year follow-up for the surgical group and 6 months for the non-surgical group. More favourable changes in insulin, glucose, uric acid, triglyceride, and high density lipid cholesterol levels were seen in the surgical group compared with the non-surgical group and incidence rates of hypertriglyceridemia, diabetes, and hyperuricemia were markedly lower in the surgical group. Incidence rates of hypertension and hypercholesterolemia did not differ between the groups at the 10-year follow-up. This study, which is ongoing, continues to show better weight loss and the improvement of obesity-related comorbid conditions for surgical patients compared with patients who did not undergo bariatric surgery. In addition, a very recent publication from the study (Sjostrom et al. 2007), which includes mortality data for 99.9% of the original study members, reports a lower overall mortality rate for patients who underwent bariatric surgery compared with the non-surgical intervention group. The adjusted hazard ratio for surgical compared with non-surgical patients was 0.71 (95%CI 0.54-0.92, p=0.01), indicating that surgical patients had a significantly lower risk of death than non-surgical patients, with 101 deaths in the surgical group (5.0%) compared with 129 in the non-surgical group (6.3%).

The evidence for the relative effectiveness and safety of different bariatric procedures for morbidly obese patients was less clear. The quality of studies available for inclusion in reviews limited the ability of the reviewers to draw conclusions about the benefits of one type of surgical procedure over another. Generally the stronger reviews excluded case series in their search strategy but this restricted the data available to them, especially with regards to safety, complications and the resolution of comorbidities. The reviews seem to have identified and included similar studies for the most part, with the main distinction between those of higher and lower quality arising from the inclusion of case series, which diminished the reliability of the findings in some reports. There was wide variation in patient populations, the length of follow-up, the reporting of loss-to-follow-up, and baseline and postoperative measures of comorbidities. The reporting of weight loss varied as well, being presented as kilograms or pounds lost compared with pre-surgery weight, pre- and post-operative BMI, percent of excess weight lost, or change in BMI. All of these factors made it very difficult to gain reliable estimates of the weight loss and resolution of comorbidities associated with different procedures, or to recommend one surgical treatment over another.

Many reviews suggested that excess weight loss of at least 50% could be expected following bariatric surgery with some studies suggesting gastric bypass and biliopancreatic diversion procedures are associated with higher weight loss compared with adjustable gastric banding or gastroplasty procedures. A limitation of these studies...
was the lack of long-term follow-up data provided, with most including data up to a maximum of 3 years post-
surgery and many being limited by a low patient follow-up rate. One meta-analysis with some methodological
flaws attempted to look at the longer-term effectiveness (3-10 years) of bariatric surgery (O’Brien et al. 2006).
This report suggested that the early higher weight loss seen following gastric bypass was subject to a fading
effect and that there was no significant difference between procedures at later time points. Gastric banding
was associated with more stable weight loss with little difference between short- and longer-term follow-up data,
however there was a noticeable lack of follow-up data available at later time points (5-10 years). All of the
surgical procedures were associated with a substantial amount of weight loss (20-30kg) compared with
preoperative measures. A second meta-analysis (Maggard et al. 2006) suggested average weight loss of 20-40kg
was likely following bariatric surgery compared with 2-5kg if non-surgical treatments were utilised.

In general, reviews relied on inconsistently reported data when considering the influence on comorbidities.
Loss-to-follow-up rates and a lack of baseline measures made it difficult for reviewers to ascertain the relative
effectiveness of different procedures. It did seem however, that most obesity-related comorbid conditions, in
particular, diabetes, hyperuricemia, hyperlipidemia, and sleep apnoea, resolved or improved with postoperative
weight loss and that this was not dependent on surgical procedure. Less clear was the effect of surgery on
hyperension, with some evidence being presented that this did not always resolve following surgery.

All the reviews included in this report acknowledged that bariatric surgery carries with it a risk of death or
serious complications, but that well-controlled trials are still needed to address the safety and complication rates
of bariatric surgery procedures. There were five post-operative deaths (0.25%) in the SOS study and 13% of
patients experienced postoperative complications. Mortality rates were judged to be relatively low for all the
considered procedures but the quality of studies available for the calculation of rates was overall poor and often
based on data from case series. The meta-analysis by Maggard et al. (2005) suggested a 30 day mortality rate of
0-2.1% (95% CI) for RYGB, AGB, VBG based on controlled trials and a rate of 0-0.8% using case series data
for the same procedures. The mortality rate for BPD was 0.5 – 1.3% based on case series alone. A recent high
quality systematic review (Boudreau et al. 2007) suggested that bariatric surgery was overall safe in terms of
mortality rates.

The incidence and type of complications varied depending on the type of surgical procedure performed but
inconsistency in the definition of early and late complications, as well as differences in the way incidence rates
were calculated, led to wide variation in complication rates being reported in the literature. A meta-analysis
suggested rates of 6-25% for surgical complications, such as pulmonary embolism, anastomotic leaks, incisional
hernias, and wound infections, and these seemed to be less common following laparoscopic procedures.
Gastrointestinal side effects, such as dumping syndrome, vomiting, reflux and dysphagia, occurred between 7-
38% with the highest rates being reported following BPD and the lowest following AGB. LAGB consistently
demonstrated fewer short-term complications but may be associated with more long-term complications
requiring further operations. Surgeon experience or a surgical learning curve effect was highlighted by several
reports as a possible explanation for the variation in mortality and adverse event rates.

Many reviews commented on the importance of pre- and post-operative nutritional, psychological and medical
services and support, however none were able to comment on the evidence base for these services. There was
also very limited evidence available in the primary literature regarding the effect of pre- and postoperative
services on surgical success. One randomised controlled trial with some limitations (Alami et al. 2007)
compared the effectiveness of LRYGB surgery in patients who were requested to lose weight before surgery and
those who were not. No differences in weight loss or resolution of comorbidities were detected, but shorter
operating times were experienced by patients in the weight loss group. Clearly further research is needed in this
area before conclusions regarding preoperative weight loss can be made.

The cost effectiveness of bariatric surgery

Overall, the quantity and quality of economic information on bariatric surgery since 2005 is poor. Long term
results of economic assessments associated with RCTs are not yet available. Analysis of economic data beyond
12 months relied heavily on published data from a wide range of sources, assumptions on key parameters, and
modelling techniques. Major limitations included the exclusion of the cost of plastic surgery (none of the
primary research studies included this cost, which was noted as likely to be substantial by the AETMIS) and the
use of potentially unreasonable assumptions regarding productivity. It is also true that very few studies clearly
identify the cost factors which have been included or excluded, as noted by the Ontario Medical Advisory
Secretariat, and this lends uncertainty to the results.
In general, cost effectiveness analyses of bariatric surgery indicate that surgery is more cost effective than conventional treatment mainly due to a more or less assumed reduction in obesity-related medical costs. This longer term reduction in costs does not, however, appear to be well supported by evidence. The economic evaluations which suggest long term reductions in medical costs have achieved these results by assuming that the observed weight loss and reduction in comorbidities will, over the longer term, translate into reduced costs (for example, Ackroyd et al. 2006 and Finkelstein et al. 2005). This may be a reasonable assumption but it has not yet been verified. Furthermore, as noted by the Canadian Agency for Drugs and Technologies in Health, the rate of complications for bariatric surgery beyond three years remains unknown. Nevertheless, the small amount of evidence does provide some general indication regarding the cost effectiveness of bariatric surgery and of specific surgical techniques:

- The limited evidence suggests that GBY and AGB are cost effective compared with conventional treatment. Both of these surgeries have been found to be either cost-saving or cost effective in terms of QALYs gained, in terms of reduction in BMI, and in terms of diabetes-free years gained.
- The evidence on VBG compared with LapBand (AGB) surgery since 2005 is based on the 12 month follow-up of an RCT. The two surgeries were found to result in equal QALYs and not significantly different costs. Weight loss was found to be greater for VBG, suggesting more favourable cost effectiveness for VBG at 12 months post-surgery. It is expected that LapBand surgery would be shown to be more effective at reducing weight over the longer term, but this evidence is not yet available.
- Based on the assumption that laparoscopic and open GBY result in the same weight loss and reduction in comorbidities, laparoscopic GBY has been found to be more cost effective due to its lower mortality rate, lower rate of complications, shorter length of stay in hospital, and lower costs.

**Final conclusions**

Many reviewers highlighted that there is no ideal procedure and that the choice and success of bariatric procedures depends largely on patient characteristics, such as baseline BMI, comorbidities, food habits and psychological profile, as well as patient and surgeon preference. Patients must be selected carefully and fully informed of the dietary consequences of surgery, potential short- and long-term risks, and the likely lifetime follow-up they are committing themselves to. Current research is focusing on the identification of the best treatment options for patients with differing BMI and comorbidity profiles but there is still a need for well-controlled long-term trials to ascertain which procedures may be the most appropriate and most effective for different patient groups. Many of the studies, for example, include a very high proportion of female patients aged between 30 and 50 years, and it is not clear whether the results of surgery are similar in male patients or younger or older patient groups. Similarly, because these patients are often excluded from selection for surgery, there is a lack of information regarding the effectiveness and safety of bariatric procedures in people with psychological problems, addictions, or disabilities.

Overall bariatric surgery seems to be an effective and cost effective treatment option compared with non-surgical interventions, resulting in significantly greater weight loss but carrying with it the possibility of increased complications, including death. Less clear is the relative clinical effectiveness of different surgical procedures, mainly due to a lack of randomised controlled trials with long-term follow-up of an adequate proportion of patients. The cost effectiveness literature is also limited and does not allow for the recommendation of one surgical procedure over another.
REFERENCES


Medical Services Advisory Committee (MSAC) (2003). Laparoscopic adjustable banding for morbid obesity. Canberra: MSAC.


National Health and Medical Research Council (NHMRC) (2000). How to use the evidence: assessment and application of scientific evidence. Canberra: NHMRC.


APPENDIX I: LEVELS OF EVIDENCE

Level I  Evidence obtained from a systematic review (or meta-analysis) of relevant randomised controlled trials.

Level II  Evidence obtained from at least one randomised controlled trial.

Level III. 1 Evidence obtained from pseudorandomised controlled trials (alternate allocation or some other method).

2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.

3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.

Level IV  Evidence obtained from case series, either post-test or pretest/post-test.
APPENDIX 2: SEARCH STRATEGY

**Medline – trials**

1. gastroplasty/ (1672)
2. (gastrectomy or bariatric surgery or gastric band$ or gastric bypass or lap-band$).mp. (4244)
3. ("roux en y" or biliopancreatic diversion or biliopancreatic bypass).mp. (2613)
4. gastro?gastrostomy.mp. (1)
5. (restrictive surgery or malabsorptive surgery or jejunoileal bypass or jejunooideal bypass).mp. (236)
6. (jejunoideal bypass or jejunooideal bypass).mp. (2)
7. or/1-6 (6199)
8. obesity, morbid/ (4217)
9. (obesity or weight loss or weight reduction).mp. (71142)
10. or/8-9 (71142)
11. 7 and 10 (3943)
12. limit 11 to english (3569)
13. limit 12 to yr=2005-2007 (1700)
14. (letter or news or editorial).pt. (496615)
15. 13 not 14 (1595)
16. randomized controlled trial.pt. (144909)
17. clinical trial.pt. (236646)
18. randomized.ab. (110138)
19. placebo.ab. (58182)
20. clinical trials/ (51068)
21. randomly.ab. (75345)
22. trial.ti. (39235)
23. or/16-22 (411011)
24. 13 and 23 (114)

**Medline- economics**

1. gastroplasty/ (1665)
2. (gastrectomy or bariatric surgery or gastric band$ or gastric bypass or lap-band$).mp. (4190)
3. ("roux en y" or biliopancreatic diversion or biliopancreatic bypass).mp. (2596)
4. gastro?gastrostomy.mp. (1)
5. (restrictive surgery or malabsorptive surgery or jejunoideal bypass or jejunooideal bypass).mp. (234)
6. (jejunoideal bypass or jejunooideal bypass).mp. (2)
7. or/1-6 (6136)
8. obesity, morbid/ (4184)
9. (obesity or weight loss or weight reduction).mp. (70482)
10. or/8-9 (70482)
11. 7 and 10 (3899)
12. limit 11 to english (3532)
13. limit 12 to yr=2005-2007 (1664)
14. (letter or news or editorial).pt. (493401)
15. 13 not 14 (1565)
16. exp economics/ (175378)
17. quality of life/ (47435)
18. value of life/ (1769)
19. quality adjusted life years/ (2909)
20. models, economic/ (2315)
21. markov chains/ (3624)
22. monte carlo method/ (8097)
23. decision tree/ (4363)
24. ec.fs. (133027)
25. economic$.tw. (46805)
26. (cost? or costing? or costly or costed).tw. (114742)
27. (price? or pricing).tw. (7774)
THE SAFETY, EFFECTIVENESS AND COST EFFECTIVENESS OF SURGICAL AND NON-SURGICAL INTERVENTIONS FOR MORBID OBESITY

(maxpharmacoeconomic or pharmacoadj economic)).mp. (1199)
19 budget$.tw. (6113)
20 (value adj1 (money or monetary)).tw. (126)
21 (fee or fees).tw. (4015)
22 "quality of life".tw. (52124)
23 qol$.tw. (6988)
24 hqol.tw. (2102)
25 "quality adjusted life year$".tw. (1864)
26 (qaly$ or cba or cea or cua).tw. (9238)
27 (utilit$ or markov$ or monte carlo).tw. (51295)
28 (decision adj2 (tree$ or analys$ or model$)).tw. (4248)
29 exp "costs and cost analysis"/ (71006)
30 (expenditure$ not energy).tw. (6289)
31 or/16-41 (424790)
32 (energy or oxygen) adj2 cost).tw. (954)
33 42 not 43 (423836)
34 15 and 44 (233)

Embase – trials

1 Morbid Obesity/ (3200)
2 (obesity or weight loss or weight reduction).mp. (88937)
3 1 or 2 (88937)
4 GASTROPLASTY/ (984)
5 (gastric surgery or bariatric surgery or gastric band$ or gastric bypass or lap band$).mp. (4642)
6 ("roux en y" or biliopancreatic diversion or biliopancreatic bypass).mp. (2077)
7 gastro?gastrostomy.mp. (3)
8 (restrictive surgery or malabsorptive surgery).mp. (55)
9 (jejunoileal bypass or jejuno-ileal bypass or jejeunoileal bypass or jejeuno-ileal bypass).mp. (179)
10 gastroplasty.tw. (662)
11 or/4-10 (6144)
12 3 and 11 (4274)
13 limit 12 to yr=2005-2007 (2110)
14 limit 13 to english (1942)
15 letter.pt. (254212)
16 14 not 15 (1863)
17 clinical trial/ (385786)
18 randomized controlled trial/ (120771)
19 random$.tw. (249794)
20 double blind procedure/ (47952)
21 (double blind$ or single blind$).tw. (46750)
22 trial.ti. (39683)
23 or/17-22 (524998)
24 16 and 23 (310)
25 case report/ or case report.ti. (479402)
26 24 not 25 (310)
27 editorial.pt. (151230)
28 26 not 27 (298)

Embase - economics

1 Morbid Obesity/ (3182)
2 (obesity or weight loss or weight reduction).mp. (88022)
3 1 or 2 (88022)
4 GASTROPLASTY/ (980)
5 (gastric surgery or bariatric surgery or gastric band$ or gastric bypass or lap band$).mp. (4604)
6 ("roux en y" or biliopancreatic diversion or biliopancreatic bypass).mp. (2067)
Current Contents

Morbid SAME (obese OR overweight)
Morbid obesity
Gastroplasty OR gastric band* OR laparoscopic band* OR lap band* OR gastric surgery OR bariatric surgery OR gastric bypass
“roux en y” OR biliopancreatic diversion OR biliopancreatic bypass OR restrictive surgery OR malabsorptive surgery
Jejunoileal bypass OR jejuno-ileal bypass OR jejeunoileal by pass OR jejeuno-ileal bypass
#1 OR #2
#3 OR #4 OR #5
#6 AND #7
Random*
Double blind*
Trial
#8 AND (#9 OR #10 OR #11)

Current Contents and Science Citation Index- economics

Morbid SAME (obese OR overweight)
Morbid obesity
Gastroplasty OR gastric band* OR laparoscopic band* OR lap band* OR gastric surgery OR bariatric surgery OR gastric bypass
“roux en y” OR biliopancreatic diversion OR biliopancreatic bypass OR restrictive surgery OR malabsorptive surgery
Jejunoileal bypass OR jejuno-ileal bypass OR jejeunoileal by pass OR jejeuno-ileal bypass
#1 OR #2
#3 OR #4 OR #5
#6 AND #7
Quality SAME life
Cost OR costs OR costing* OR costly
Economic*
#8 AND (#9 OR #10 OR #11)

**PubMed**

The PubMed searches were substantially the same as that for Current Contents but were restricted to items added in the last 60 days so as to locate references that had not yet appeared on the other databases.

**Cochrane Central Register of Trials**

The Cochrane Trials database was searched simply using the phrase “morbid obesity” and all references scanned for inclusion.
APPENDIX 3: EXCLUDED RETRIEVED REVIEWS


APPENDIX 4: APPRAISED RETRIEVED PAPERS


