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1 EXECUTIVE SUMMARY

1.1 EPIDEMIOLOGY AND BURDEN OF OBESITY

The World Health Organization (WHO) describes obesity as an “escalating global epidemic”. The WHO estimated that in 2014, 13% of adults aged > 20 years worldwide met the criteria for obesity, with the prevalence doubling since 1980. Obesity is a key risk factor for a number of conditions that are associated with an elevated risk of morbidity and/or mortality, including type 2 diabetes, osteoarthritis, hypertension, cardiovascular disease, asthma, and cancer. Across the world, obese patients accrue medical costs 6–45% higher than their normal-weight peers, depending on the country. Costs attributable to obesity accounted for 0.7–2.8% of total healthcare expenditure worldwide, with variation observed between countries.

- Obesity is a disease
- Genetics plays a role in obesity
- Globally 13% of the adult population is obese
- Obese individuals are more likely to have comorbid conditions such as type 2 diabetes
- Healthcare utilization and expenditures of obese individuals are significantly higher than normal weight individuals
- Obese individuals have a negative impact on a country’s productivity (GDP)
- Lifestyle interventions, intense medical management, weight loss attempts are often not successful
- The probability of an obese individual attaining normal weight is less than 1%
- Of those indicated, less than 1% actually undergo bariatric surgery

1.2 CLINICAL EFFECTIVENESS

Compared with medical management, bariatric surgery is associated with increased weight loss, increased remission of diabetes, improved glycemic control in patients with diabetes, increased proportions of patients with type 2 diabetes achieving multi-factorial treatment targets, increased remission of co-morbidities, and improved quality of life, irrespective of the procedure performed. Moreover, these benefits have been shown to persist over durations of up to 20 years.

When alternative bariatric surgery procedures are compared, there is strong clinical evidence to show that both RYGB and SG are associated with improved clinical outcomes compared with AGB. There is weaker evidence that suggests that RYGB is more effective than SG and that BPD may be the most effective bariatric surgery procedure.

- Bariatric surgery is safe
- Bariatric surgery has been recommended as a treatment option for obesity by various professional medical organizations
- Bariatric surgery is indicated for patients with BMI>40 kg/m² or patient with BMI 35–40 kg/m² with co-morbidities
- Bariatric surgery has a positive impact on comorbidities, including:
  - Type 2 diabetes mellitus
  - Hypertension
  - Hyperlipidemia
  - Obstructive sleep apnea
  - Cardiovascular disease
  - Joint disease, arthritis and lower back pain
  - Cancer
Infertility and erectile dysfunction
- Bariatric surgery leads to improvement in life expectancy
- Bariatric surgery improves quality of life
- Bariatric surgery has a halo effect on weight of the family and/or friends of the patient

1.3 ECONOMIC IMPACT
Cost studies suggest that bariatric surgery may result in reduced hospitalization and medication cost. In some settings, this leads to reduced costs compared to medical management, with cost savings entirely offsetting the cost of surgery and return on investment occurring after durations as short as 1.25 years. However, other studies suggest that bariatric surgery is associated with increased costs, as cost savings only partially offset the cost of the procedure.

Long-term studies suggest that bariatric surgery is likely to be dominant (improving clinical outcomes and reducing costs) or cost-effective compared to medical management, irrespective of the procedure performed on the country of the analysis
- Bariatric surgery is cost-effective and is cost-saving among extreme cases, to the healthcare system
- Healthcare utilization decreases after bariatric surgery
- Cost of surgery is recouped in a period of 2–5 years, depending on the indication and the healthcare system
- Bariatric surgery improves productivity and employability of an individual
- Bariatric surgery is broadly covered by public and private insurance companies across the world

1.4 CONCLUSIONS
Bariatric surgery is a safe and effective method of weight loss. Surgery is associated with both remission and reduced incidence of obesity-related complications, reducing both the clinical and economic burden of obesity.
2 BURDEN OF OBESITY

KEY MESSAGES

- Obesity is a disease.
- Genetics plays a role in obesity.
- The World Health Organization (WHO) describes obesity as an “escalating global epidemic” and estimated that in 2014, 13% of adults aged > 20 years worldwide met the criteria for obesity.
- It is reported that being overweight or obese is linked to more deaths worldwide than being underweight.
- The worldwide mean body mass index (BMI) increased by 0.4 kg/m\(^2\) per decade in men and 0.5 kg/m\(^2\) per decade in women in the 28-year interval from 1980 to 2008.
- Estimates suggest that the proportion of men who were overweight or obese worldwide increased from 29% to 37% between 1980 and 2013, and that the proportion of women who were overweight or obese increased from 30% to 38%.
- Increases in prevalence were identified in developed and developing countries, with the greatest increases seen from 1992 to 2002. For example:
  - In the USA, the prevalence of obesity increased from 18% in 1980 to 35% in 2014 in males, and from 21% to 40% in females,
  - In Australia, the prevalence of obesity increased from 15% in 1980 to 28% in 2013 in males, and from 17% to 30% in females
  - In Azerbaijan, the prevalence of obesity increased from 5% in 1980 to 9% in 2013 in males, and from 19% to 30% in females
- Obesity is a key risk factor for a number of conditions that are associated with an elevated risk of morbidity and/or mortality, most notably type 2 diabetes.
- The prevalence of diabetes worldwide is 8.8%, and this is projected to increase in both developed and developing countries in the coming years.
- As well as morbidity and mortality, obesity and diabetes are associated with reduced quality of life, increased medical costs, and reduced workplace productivity.
- Early and effective treatment of obesity is required to limit its impact on patients and healthcare services.
- Re-allocation of healthcare resources to prevent and reduce obesity may be the most effective and efficient use of healthcare resources.
- Lifestyle interventions, intense medical management, weight loss attempts are often not successful.
- The probability of an obese individual attaining normal weight is less than 1%.
- Of those indicated, less than 1% actually undergo bariatric surgery.
2.1 DEFINITION OF OBESITY

Body Mass Index (BMI) is a simple index of weight-for-height and is the most commonly used measure to classify overweight and obesity in adults. BMI (Equation 1) is calculated by dividing the individual’s weight (in kilograms) by the square of their height (in meters). For ease of application, BMI values are generally treated as age- and gender-independent. Within different populations, however, the same BMI might not correspond to the same degree of body fat because of variations in body proportions between races.¹

Equation 1

\[ \text{BMI} = \frac{\text{weight (kg)}}{\text{height}^2 (m)} \]

In general, individuals of normal weight have a BMI between 18.5 and 24.99 kg/m². Underweight individuals have a BMI < 18.5 kg/m², while overweight and obese are defined by a BMI ≥ 25 and ≥ 30 kg/m², respectively (Table 2-1).¹² Although these definitions are commonly used throughout the literature, studies indicating that BMI is not independent of height, gender and race have led to a growing debate on alternative measures to define a target body weight or composition.¹³⁴

Although obesity is generally classified using BMI, central adiposity (often measured via waist circumference) is also a marker of obesity and is associated with metabolic syndrome in Asian populations.⁵ Compared with matched, white controls, Asians and in particular south Asians have higher central adiposity at a given body weight.⁵ The International Diabetes Federation (IDF) criteria for metabolic syndrome recommend the use of ethnic group-specific thresholds for waist circumference, specifically ≥ 90 cm in men and ≥ 80 cm in women of Asian origin (excluding the Japanese).⁵

Table 2-1 International classification of adult underweight, overweight and obesity according to BMI

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
<th>Principle cut-offs</th>
<th>Additional cut-offs</th>
</tr>
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<tbody>
<tr>
<td><strong>Underweight</strong></td>
<td></td>
<td>&lt; 18.50</td>
<td></td>
</tr>
<tr>
<td>Severe thinness</td>
<td></td>
<td>&lt; 16.00</td>
<td></td>
</tr>
<tr>
<td>Moderate thinness</td>
<td></td>
<td>16.00–16.99</td>
<td>18.50–22.99</td>
</tr>
<tr>
<td>Mild thinness</td>
<td></td>
<td>17.00–18.49</td>
<td>23.00–24.99</td>
</tr>
<tr>
<td><strong>Normal body weight</strong></td>
<td>18.50–24.99</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Overweight</strong></td>
<td>≥ 25.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-obese</td>
<td>25.00–29.99</td>
<td></td>
<td>25.00–27.49</td>
</tr>
<tr>
<td>Obese</td>
<td>≥ 30.00</td>
<td>30.00–34.99</td>
<td>30.00–32.49</td>
</tr>
<tr>
<td>Class I</td>
<td></td>
<td>30.00–34.99</td>
<td>32.50–34.99</td>
</tr>
<tr>
<td>Class II</td>
<td>35.00–39.99</td>
<td></td>
<td>35.00–37.49</td>
</tr>
<tr>
<td>Class III</td>
<td>≥ 40.00</td>
<td></td>
<td>37.50–39.99</td>
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</table>
2.2 EPIDEMIOLOGY OF OBESITY

2.2.1 Causes of obesity

Although obesity derives when an individual’s energy intake is higher than their energy expenditure, it is also associated with environmental, genetic and behavioral factors. In the United States of America (US), Kant and Graubard showed that as the quantity and energy density of food consumed increased so did the prevalence of obesity. In England, the rise in car ownership and time spent watching television closely parallel the increase in obesity prevalence. In Arab and Asian countries, increased urbanization has been associated with an increase in obesity. The prevalence of obesity in children in rural, south-western Saudi Arabia (4%) is notably lower than the equivalent rates in cities: Ha’il (34%) and Riyadh (22%). Income also seems important, and in Egypt it was reported that poorer people have a lower prevalence of obesity (3%) compared to 10% in those who are more affluent. However, the opposite trend is evident in the US, where a study of 3,139 counties found that obesity prevalence in counties with poverty rates > 35% was 145% higher than in more affluent counties.

Genetics studies have shown that mutations in leptin (LEP), leptin receptor (LEPR), melanocortin-4 receptor (MC4R), or pro-opiomelanocortin (POMC) are responsible for rare forms of monogenic obesity. The α-ketoglutarate-dependent dioxygenase protein, also known as ‘fat mass and obesity-associated protein’, is associated with an increased risk of both obesity and type 2 diabetes. Social factors may also play a role. An analysis of 32 years of Framingham Heart Study data (1971–2003) demonstrated that if an individual’s friend became obese, that individual’s risk of becoming obese increased by 57%.

2.2.2 Trends in BMI

Worldwide, estimates suggest that, in 2014, more than 1.9 billion adults were overweight, and, of these, over 600 million were obese. This equates to 13% of the worldwide adult population being considered obese.

Through the analysis of health surveys and epidemiological studies that included 9.2 million respondents, it was found that the worldwide mean BMI increased by 0.63 kg/m² per decade (95% confidence interval (CI): 0.53–0.73) in men and 0.59 kg/m² per decade (95% CI: 0.49–0.70) in women in the 39-year interval from 1975 to 2014. Mean BMI reached 32.2 kg/m² for men and 34.8 kg/m² for women in American Samoa, the highest observed in any country. The lowest mean BMIs were observed in Ethiopia for men (20.1 kg/m²) and in Timor-Leste (20.8 kg/m²) for women.

From 1975 to 2014, the largest increase in men’s mean BMI occurred in high-income English-speaking countries (1.0 kg/m² per decade) and the largest increases in women were observed in central Latin America (1.3 kg/m² per decade). In contrast, the rise in women’s mean BMI was less than 0.2 kg/m² per decade in Central Europe, South-western Europe, and high-income Asia Pacific. BMI increased more slowly after the year 2000 than in the preceding 25 years in Oceania and in most high-income countries for both sexes, and for women in most countries in Latin America and the Caribbean (Figure 2-1). Conversely, the post-2000 increase was faster than pre-2000 in men in Central and Eastern Europe, East and South-east Asia, and most countries in Latin America and the Caribbean. In other regions, increases in BMI before and after 2000 were similar or they had a mixture of slowdown and acceleration.
Figure 2-1  Change in country age-standardized BMI of males and females between 1975 and 2014

Source: NCD Risk Factor Collaboration.13
2.2.3 Prevalence of Overweight and Obesity

2.2.3.1 Worldwide prevalence of obesity
The World Health Organization (WHO) describes obesity as an “escalating global epidemic”. The WHO estimated that in 2014, 13% of adults aged > 20 years worldwide met the criteria for obesity, with the prevalence doubling since 1980. It is estimated that being overweight or obese is linked to more deaths worldwide than being underweight. The most recent county-specific data on the prevalence of obesity were released by the NCD Risk Factor Collaboration (NCD-RisC) following a large scale review of data from 1975 to 2014.

2.2.3.2 Regional prevalence of obesity

High-income Western countries
In high-income Western countries, the prevalence of overweight in men and women was estimated to be 68.8% and 57.1%, respectively, in 2014. The prevalence of obesity was estimated to be 27.2% in men and 27.8% in women. The prevalence of obesity was highest in the US, at 33.6% in men and 34.9% in women. The Organisation for Economic Co-operation and Development (OECD) also estimated that approximately 33.8% of adults in the US were obese in 2009. In the UK, the obesity rate has risen by approximately one percentage point per year since the mid-1990s, and by 2009 about 57% of UK adults were overweight while almost half of whom (absolute 25%, relative 44%) were classified as obese. Similar values for the prevalence of obesity in the UK were published by the OECD, based on data from 2009.

The Canadian Health Measures Survey estimate of the prevalence of obesity was 26.4% in 2012, slightly higher than the 24.2% estimated by the OECD in 2009.

Central and Eastern Europe
In Central and Eastern Europe, the prevalence of overweight was 61.3% in men and 52.4% in women in 2014. The prevalence of obesity was 20.0% and 23.6% in men and women, respectively.

An older (and less extensive) literature review conducted in 2008 found that the prevalence of obesity in Europe in males ranged from 4.0% to 28.3%, while the obesity prevalence in females ranged from 6.2% to 36.5%. There was significant inter-country variation, with prevalence rates in Central, Eastern, and Southern Europe being higher than those in Western and Northern Europe.

In an analysis using waist circumference to define abdominal obesity, the prevalence of obesity in Europe was 58% in males and 67% in females.

Latin America and the Caribbean
Prevalence of overweight in men and women was estimated to be 57.1% and 58.4%, respectively, in 2014 in Latin American and the Caribbean. The prevalence of obesity in men was 19.0% and in women it was 27.2%.
Central Asia, Middle East and North Africa

In the Central Asia, Middle East and North Africa region in 2014, the prevalence of overweight in men and women was 56.1% and 63.3%, respectively. The prevalence of obesity was 19.1% in men and 31.4% in women.

East and South-east Asia

In East and South-east Asia, the prevalence of overweight in men in 2014 was 33.7%, and in women it was 31.4%. In men, the prevalence of obesity was 6.5%, and in women the prevalence of obesity was 8.1%. When waist circumference was used to define abdominal obesity, the prevalence of obesity in men and women was 38%, and 51% in East Asia and 38% and 51% in South-east Asia.

South Asia

The prevalence of overweight in men in South Asia in 2014 was 16.6%, and in women the prevalence to 22.0%. The prevalence of obesity was 2.4% in men and 5.4% in women. When waist circumference was used to define abdominal obesity, the prevalence of obesity in men and women was 58% and 78% in South Asia.

High-income Asia-Pacific

In countries falling within the high-income Asian-Pacific region, in 2014 the prevalence of overweight 31.7% in men and 22.4% in women. The prevalence of obesity was 4.1% and 4.0% in men and women, respectively.

Oceania

In 2014 in Oceania, the prevalence of overweight was 47.5% in men and 58.9% in women. The prevalence of obesity was 17.4% in men and 27.0% in women.

Sub-Saharan Africa

The prevalence of overweight in sub-Saharan Africa in 2014, the prevalence of overweight was 19.2% in men and 35.7% in women. The prevalence of obesity was 4.2% and 13.7% in men and women, respectively.

2.2.4 Trends in the Prevalence of Obesity

2.2.4.1 Worldwide trends in the prevalence of obesity

Estimates suggest that the proportion of men who were obese increased from 3.2% to 10.8% from 1975 to 2014, and that the proportion of women who were obese increased from 6.4% to 14.9% (Figure 2-2).

Of concern for the future, is that the offspring of overweight or obese parents are more likely to become obese themselves compared with the offspring of two parents who had normal body weight. A study of showed in the UK from 2001–2006 showed that the offspring obesity prevalence with two normal-weight parents was 2.3%, this increased to
4.9% with two overweight parents, 21.7% with two obese parents, and 35.3% with two severely obese parents.

**Figure 2-2  Trends in the prevalence of obesity worldwide**

![Graph showing trends in obesity prevalence worldwide](image)

Source: NCD Risk Factor Collaboration.13

### 2.2.4.2 Regional trends in the prevalence of obesity

**High-income Western countries**

In high-income Western countries, the prevalence of obesity in men increased from 8.5% in 1975 to 27.2% in 2014 and from 10.7% to 27.8% in women (Figure 2-3).13

**Figure 2-3  Trends in the prevalence of obesity in high-income Western countries**

![Graph showing trends in obesity prevalence in high-income Western countries](image)

Source: NCD Risk Factor Collaboration.13

In the USA, a study based on data from the National Health and Nutrition Examination Survey (NHANES) reported that since 1999–2000, the percentage of US adults classified as obese has risen from 27.5% and 33.4% in males and females, respectively, to 35.0% and 40.4% in 2013–2014 (Figure 2-4).20,21,22,23
Figure 2-4  Trends in the prevalence of obesity in US adults aged ≥ 20 years of age by gender

Source: Flegal et al.\textsuperscript{21,20,22,23}

Central and Eastern Europe

The prevalence of obesity in men increased from 6.9% in 1975 to 20.0% in 2014 and from 17.9% to 23.6% in women in Central and Eastern Europe (Figure 2-5).\textsuperscript{13}

Figure 2-5  Trends in the prevalence of obesity in Central and Eastern Europe

Source: NCD Risk Factor Collaboration.\textsuperscript{13}
Latin America and the Caribbean
The prevalence of obesity increased from 5.2% in 1975 to 19.0% in 2014 in men and from 10.1% to 27.2% in women in Latin American and the Caribbean (Figure 2-6).13

Figure 2-6  Trends in the prevalence of obesity in Latin America and the Caribbean

Central Asia, Middle East and North Africa
In the Central Asia, Middle East and North Africa region, the prevalence of obesity increased from 5.0% in 1975 to 19.1% in 2014 in men and from 12.5% to 31.4% in women (Figure 2-7).13

Figure 2-7  Trends in the prevalence of obesity in Central Asia, Middle East and North Africa

Source: NCD Risk Factor Collaboration.13
East and South-east Asia
In East and South-east Asia, the prevalence of obesity in men increased from 0.3% in 1975 to 6.5% in 2014, and from 0.8% to 8.1% in women (Figure 2-8).

Figure 2-8  
Trends in the prevalence of obesity in East and South-east Asia

Source: NCD Risk Factor Collaboration.13

South Asia
The prevalence of obesity in men increased from 0.3% in 1975 to 2.4% in 2014 and from 0.7% to 5.4% in women in Central and Eastern Europe (Figure 2-9).

Figure 2-9  
Trends in the prevalence of obesity in South Asia

Source: NCD Risk Factor Collaboration.13
High-income Asia-Pacific

In the high income Asia-Pacific region, the prevalence of obesity increased from 0.5% to 4.1% from 1975 to 2014 in men, and from 1.3% to 4.0% in women (Figure 2-10).\textsuperscript{13}

Figure 2-10 Trends in the prevalence of obesity in high-income Asia-Pacific

![Graph showing trends in obesity prevalence in high-income Asia-Pacific region for men and women from 1980 to 2015.](source)

Source: NCD Risk Factor Collaboration.\textsuperscript{13}

Oceania

The prevalence of obesity increased from 7.1% in 1975 to 17.4% in 2014 in men and from 12.2% to 27.0% in women in Oceania (Figure 2-11).\textsuperscript{13}

Figure 2-11 Trends in the prevalence of obesity in Oceania

![Graph showing trends in obesity prevalence in Oceania for men and women from 1980 to 2015.](source)

Source: NCD Risk Factor Collaboration.\textsuperscript{13}
Sub-Saharan Africa

In sub-Saharan Africa, the prevalence of obesity in men increased from 0.7% in 1975 to 4.2% in 2014 and from 3.1% to 13.4% in women (Figure 2-12).\textsuperscript{13}

**Figure 2-12**  Trends in the prevalence of obesity in Sub-Saharan Africa

![Graph showing trends in prevalence of obesity in Sub-Saharan Africa](image)

Source: NCD Risk Factor Collaboration.\textsuperscript{13}

2.2.5  Trends in the prevalence of morbid obesity

Cremieux \textit{et al.} identified that, compared with obesity (BMI ≥ 30 kg/m\(^2\)), there was a more rapid rise in the prevalence of morbid obesity (BMI > 40 kg/m\(^2\)), which increased 50%, and the prevalence of extreme obesity (BMI > 50 kg/m\(^2\)), with an increase of 75%, between 2000 and 2005 in the US.\textsuperscript{24} Sturm and Hattori found that in 2010 over 6.6% of the US population had a BMI > 40 kg/m\(^2\), which corresponds to 15.5 million adults.\textsuperscript{25} In agreement with the study of Cremieux \textit{et al.}, the authors found that the prevalence of morbid obesity and the prevalence of extreme obesity were both increasing faster than the prevalence of obesity.\textsuperscript{25} In Spain, the prevalence of obesity increased by 6% between 2004 and 2007, and the increase in the prevalence of morbid obesity was much higher at 40%.\textsuperscript{26} Likewise, in South Korea the prevalence of severe obesity (BMI ≥ 30 kg/m\(^2\)) was increasing faster than the prevalence of obesity (BMI ≥ 25 kg/m\(^2\)): 61.8% versus 15.7% between 1998 and 2009.\textsuperscript{27}

**Figure 2-13**  Faster increases in extreme obesity compared with obesity over the last decade in the United States

![Graph showing percentage increase in prevalence from baseline](image)

Source: Sturm and Hattori.\textsuperscript{25}
2.2.6 Incidence of obesity

Relative to prevalence data, there is a paucity of data relating to incidence of obesity. In the US, the incidences of obesity (BMI ≥ 30 kg/m²) and morbid obesity (BMI ≥ 40 kg/m²) in 2009 were 4% and 0.7% per year, respectively. Amongst individuals of normal weight (BMI 18.5–24.9 kg/m²) in 2008, 9.5% became overweight in 2009, while 0.7% became obese and 0.4% morbidly obese. Only 1.2% of obese individuals in 2008 transitioned to a normal body weight in 2009. The transition between BMI-based health states in this study are detailed in Table 2–2. Assessing the 5-year transition period from adolescent to young adult, Gordon-Larsen et al. found that 12.7% (95% CI: 11.7–13.9%) of adolescents became obese, 9.4% (95% CI: 8.4–10.5%) remained obese and 1.6% (95% CI: 1.3–2.0%) lost sufficient weight to transition from obese to non-obese. The authors noted that the obesity incidence was especially high in non-Hispanic black females, of whom 18.4% (95% CI: 15.2–20.0%) became obese and 16.1% (95% CI: 13.4–19.3%) remained obese. At baseline in 1996, females had a lower incidence of obesity (10.6%) compared with males (11.3%), but over the subsequent 5 years were more likely to become obese and less likely to transition from obese to non-obese. In the study by Pan et al., it was noted that women, young adults, and those who did not participate in any leisure time physical activity had a significantly increased incidence of both obesity and morbid obesity. The authors used multivariate analysis that accounted for BMI at study baseline and identified that the incidences of both obesity and morbid obesity decreased significantly as the level of education increased.

Table 2–2 Change in BMI from 2008 to 2009 among US adults aged ≥ 18 years in the Behavioral Risk Factor Surveillance System

<table>
<thead>
<tr>
<th>2008 BMI (kg/m²)</th>
<th>2009 BMI (kg/m²)</th>
<th>11.7–18.4</th>
<th>18.5–24.9</th>
<th>25.0–29.9</th>
<th>30.0–39.9</th>
<th>≥ 40</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.7–18.4</td>
<td></td>
<td>62.0% (1.37)</td>
<td>35.8% (1.37)</td>
<td>1.6% (0.32)</td>
<td>0.5% (0.13)</td>
<td>0.02% (0.02)</td>
</tr>
<tr>
<td>18.5–24.9</td>
<td></td>
<td>0.9% (0.05)</td>
<td>88.8% (0.19)</td>
<td>9.5% (0.18)</td>
<td>0.7% (0.06)</td>
<td>0.04% (0.01)</td>
</tr>
<tr>
<td>25.0–29.9</td>
<td></td>
<td>0.1% (0.01)</td>
<td>9.0% (0.17)</td>
<td>83.4% (0.22)</td>
<td>7.5% (0.16)</td>
<td>0.1% (0.03)</td>
</tr>
<tr>
<td>30.0–39.9</td>
<td></td>
<td>0.1% (0.02)</td>
<td>1.2% (0.07)</td>
<td>16.7% (0.26)</td>
<td>79.3% (0.29)</td>
<td>2.7% (0.13)</td>
</tr>
<tr>
<td>≥ 40</td>
<td></td>
<td>0.1% (0.08)</td>
<td>0.3% (0.04)</td>
<td>2.4% (0.22)</td>
<td>29.6% (0.71)</td>
<td>67.6% (0.72)</td>
</tr>
</tbody>
</table>

Source: Pan et al. Values are provided as the % (standard error) of each BMI class (sum of rows equals 100)
2.3 PATIENT IMPACT

2.3.1 Co-morbid conditions associated with obesity

Obesity is a key risk factor for a number of conditions that are associated with an elevated risk of morbidity and/or mortality. Estimates from the US suggest that 5.0% of adult deaths among black men, 15.6% of deaths among white men, 26.8% of deaths among black women, and 21.7% of deaths among white women are associated with overweight and obesity.\(^{30}\)

The most comprehensive assessment of the association between overweight or obesity and co-morbid conditions is a meta-analysis of 89 studies published in 2009.\(^{31}\) The strongest association was seen for type 2 diabetes mellitus. Overweight and obese males were 2.40 and 6.74 fold more likely to develop type 2 diabetes than the general population, while relative risks of 3.92 and 12.41 were identified for overweight and obese females, respectively.\(^{31}\) Data from the National Health and Nutrition Examination Survey (NHANES) has also shown that as BMI increases that relative prevalence of type 2 diabetes increases, and similar data from the UK suggests that risk of diabetes increases progressively for each BMI unit above 20 kg/m\(^2\).\(^{32,33}\) An 8-year study of 15,680 participants in China found that overweight accounted for 28.3% of incident type 2 diabetes in men, and 31.3% in women.\(^{34}\) In addition, the IDF has reported that for every 1 kg increase in body weight the risk of diabetes increased by 4.5%.\(^{35}\) Central obesity may be an important risk factor for development of type 2 diabetes. In a study of 22 healthy females, both abdominal and peripheral body fat were associated with reduced insulin sensitivity, the association was much stronger for abdominal fat.\(^{36}\) Increased abdominal fat was also associated with other risk factors for development of type 2 diabetes, including increased fasting non-esterified fatty acids, lipid oxidation, and hepatic glucose output.

The prevalence of diabetes worldwide is 8.8%, and this is projected to increase in the future (Figure 2-14).\(^{37}\) A number of studies have indicated that the global increase in diabetes prevalence, in particular type 2 diabetes, is the consequence of an aging and increasing population.\(^{38,39}\) The IDF also cited an unhealthy diet, overweight/obesity, and sedentary lifestyles as the main reasons for the increasing prevalence of type 2 diabetes.\(^{35}\) In the US, data from the Centers for Disease Control and Prevention (CDC) indicated that there was a total of approximately 1.7 million new cases of diabetes (type 1 and type 2 combined) diagnosed in people aged ≥ 20 years in 2012.\(^{40}\) Previously published data for the US suggest that the incidence of adult onset diabetes (aged ≥18 years) increased during the 4 years from 2004 to 2008; from 8.3 to 8.4 cases per 1,000 males and from 6.8 to 8.1 cases per 1,000 females.\(^{41}\) A subgroup analysis demonstrated that although the overall incidence has increased, the change in incidence varied considerably according to gender, ethnic group and socio-economic status, with the greatest increases seen in low education sub-groups.\(^{42}\)

Of particular importance is the incidence rate in the young, which is expected to increase in parallel with rising levels of obesity and physical inactivity in childhood in many countries. Type 2 diabetes, as well as two pre-diabetes conditions: impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), is increasingly common in obese children and adolescents. Compared with approximately 3% a decade ago, type 2 diabetes now accounts for 45% of newly diagnosed diabetes cases in adolescents worldwide.\(^{43}\)
In addition to type 2 diabetes, overweight and obesity are associated with increased risk of other conditions (Figure 2-15).

Source: Guh et al.\textsuperscript{31} OA: osteoarthritis; CRC: colorectal cancer; HTN: hypertension; CHF: chronic heart failure; CAD: coronary artery disease. Error bars indicate the 95\% confidence interval around the calculated relative risk.
The largest assessment of the relationship between cancer and BMI is a meta-analysis of 221 studies (282,137 incident cases). Disordered Breathing had demonstrated that an increase in weight was linked to an increase in BMI. The prevalence of OSA within the obese population has been placed at about 40%, and the development of obstructive sleep apnea (OSA) has also been strongly linked to obesity. Overweight and obesity have been linked to increased risk of cardiovascular disease in a number of studies. The meta-analysis published by Guh et al. identified increased risk of stroke, coronary artery disease, congestive heart failure and pulmonary embolism in males and females who were overweight or obese. Analysis of data from NHANES has shown that coronary heart disease is more prevalent in obese males, and overweight or obese females. A 15-year study of 220,000 men in China reported that mortality from stroke and coronary heart disease (CHD) increased by 50% for each 5 kg/m² increase in BMI. A similar study in the UK found that every 1 kg/m² increase in BMI 22 kg/m² resulted in a 10% increase in the rate of coronary events. A 30-year study of obesity determined that a longer duration of obesity was associated with an increased incidence of coronary artery calcification, a subclinical predictor of coronary heart disease. It was estimated that for each year an individual was classified as obese, their risk increased by 2–4%. The impact of body weight on hypertension has been assessed in a number of studies. The meta-analysis by Guh et al. found that incidence of hypertension was significantly higher in overweight and obese individuals than those of healthy body weight. An earlier review from 2000 identified studies that suggested that being obese raised the risk of being diagnosed with hypertension by a factor of three, and data from the Framingham Heart Study that found that for every gain of 10 lbs (4.5 kg) in body weight, systolic blood pressure increased by 4.5 mmHg. Data from the Nurses’ Health Study found that women gaining weight increased the risk of hypertension. An increase of 2.1–4.9 kg increased the risk of hypertension by 29%, whereas larger increases in risk of 74% and 500% were identified for weight gains of 5.0–9.9 kg and ≥ 25 kg, respectively. Data from NHANES has shown that the relative prevalence of hypertension increases as BMI increases. Weight gain in children has also been shown to increase the risk of hypertension. Analysis of data from the Bogalusa Heart Study indicated that overweight children (aged 5–17 years) were 4.5 times more likely to have elevated systolic blood pressure (SBP) compared with children of normal body weight. The development of obstructive sleep apnea (OSA) has also been strongly linked to obesity. The prevalence of OSA within the obese population has been placed at about 40%, and approximately 70% of patients with OSA are obese. It has been reported that the odds ratio for an apnea-hypopnea index (AHI) above 15 increased by 2.4 for every 10 kg/m² increase in BMI. The earlier Longitudinal Study of Moderate Weight Change and Sleep-Disordered Breathing had demonstrated that an increase in weight was linked to an increase in AHI, while weight loss was associated with a decrease in symptoms (Figure 2-16). OSA impacts negatively on sleep and can result in reduced motivation and increased incidence of depression. Furthermore, patients with OSA have higher fasting blood glucose, insulin,
and glycated hemoglobin (HbA1c) compared with weight matched controls without OSA, which may be important given the association between obesity and type 2 diabetes.\textsuperscript{54}

**Figure 2-16** Weight gain is associated with an increase in obstructive sleep apnea symptomatology as measured by the apnea-hypoxia index

Meta-analysis data and analysis of NHANES have also shown that overweight and obesity are associated with increased risk of gall bladder disease, osteoarthritis, chronic back pain and asthma.\textsuperscript{31,32}

### 2.3.2 Impact of obesity and diabetes on patient quality of life

A large scale study assessed health-related quality of life in a cohort of 1,187 apparently healthy individuals (mean age 57 years), of whom 24% were of normal weight, 49% overweight, 20% obese and 7% severely obese.\textsuperscript{55} Among females, all scales that comprise the physical health summary measure in the Short Form Health Survey (SF-36) decreased in a linear manner as BMI increased. In males, however, this linear trend was only observed in the physical functioning scale. The mental health scales did not show a relationship with BMI in either males or females. A previously published meta-analysis of studies assessing quality of life measured using the SF-36 in overweight and obese individuals found that the physical health summary measure was significantly reduced in overweight individuals compared to normal weight, and showed greater reductions in obese and morbidly obese individuals.\textsuperscript{56} The mental health summary measure was only significantly reduced compared to normal weight individuals in class III obesity. Other studies have also shown that mental health may be affected in severely obese patients, with 25–30% of patients presenting for bariatric surgery showing elevated symptoms of depression.\textsuperscript{57}

In a study of 98 paired samples of obese and healthy weight adolescents in Kuwait, quality of life was assessed using the Pediatric Quality of Life Inventory (PedsQL 4.0).\textsuperscript{58} The physical health summary score was significantly higher in the healthy weight adolescents than in the obese individuals, but the psychosocial health summary score and total scale score showed no significant difference. Similarly, a study of 774 patients attending a pediatric obesity care center found that almost 40% had experienced bullying at home or at school.\textsuperscript{59} In contrast, a study of 4,824 children in the US found that the total health-related quality of life was
significantly reduced in obese and extremely obese children, compared to those of normal weight, with no significant difference observed for overweight children. In extremely obese children, reductions were seen in both the physical health summary score and the psychosocial health summary score, but in obese children only the psychosocial health summary score was reduced.

The detrimental effect on quality of life may not derive purely from obesity, and a number of studies have demonstrated that obesity-related co-morbid conditions, such as diabetes, also influence patient quality of life. A study quantifying the impact of diabetes on quality of life in Brazil found that diabetes accounted for 5.1% of all disability-adjusted life years (DALYs), with a greater impact seen in women than in men. In a pooled analysis of five studies comparing quality of life based on the SF-36 in individuals with and without diabetes in Germany found that diabetes was associated with a statically significant reduction in the physical health summary measure in both males and females (with a greater reduction in females), but that the mental health summary score was only reduced in women.

Furthermore, diabetes is predicted to have an increasing impact on quality of life. A burden of disease study reported that by 2030 diabetes will be the eleventh leading cause of reduced disability-adjusted life expectancy (DALE) globally. However, owing to the association between increased diabetes prevalence and a number of features associated with epidemiologic transition including changes in diet, increased urbanization and an increasingly sedentary lifestyle, DALE projections vary according to income. In high-income countries, diabetes is projected to be the fifth leading cause of reduced DALE by 2030, whereas in middle-income countries diabetes is projected to be the tenth leading cause. These findings are echoed by an earlier study assessing both the global and regional burden of disease and risk factors in 2001.
2.4 HEALTHCARE AND ECONOMIC IMPACT OF OBESITY

2.4.1 Directs cost of treating obesity

Worldwide

A systematic review of studies assessing the economic burden of obesity worldwide found that obese patients were found to accrue medical costs 6–45% higher than their normal-weight peers. Costs attributable to obesity accounted for 0.7–2.8% of total healthcare expenditure. When costs associated with being overweight were also included, the upper limit of this range increased to 9.1% of total healthcare expenditures.

Europe

Estimates suggest that in the UK, the annual cost of treating overweight and obesity was GBP 4.2 billion in 2007. In Germany, it has been estimated that the total direct cost of obesity and overweight was EUR 4,854 million in 2002. The largest driver of this was endocrine disorders (such as diabetes), followed by cardiovascular disease, cancer and digestive disease. A long-term study in Germany found that increased BMI was associated with increased pharmacy costs and that a 1 kg/m² increase in BMI over 10 years was associated with a 6% increase in healthcare expenditure compared to remaining at a constant weight. In the Republic of Ireland and Northern Ireland, the direct costs of overweight and obesity were estimated to be EUR 437 million and EUR 127 million respectively.

North America

The most recent data on the cost of health conditions causally related to obesity and overweight in the US, collected in 2014, suggest that the direct cost of medical treatment for health conditions causally related to obesity and overweight totaled USD 427.8 billion (Figure 2-17). Among those conditions, type 2 diabetes had the highest treatment costs, at USD 111.9 billion, accounting for 26.1% of the total direct medical costs for diseases caused by obesity and being overweight. Alzheimer’s disease and vascular dementia were associated with the second largest cost at USD 56.0 billion. In total, the direct medical expenses associated with treating diseases caused by obesity accounted for 14.3% of US health-care spending in 2014.
Older estimates of the direct cost of obesity in the US have consistently identified lower total costs. Estimates based on clinical data from the 2006 Medical Expenditure Panel Survey and the 2008 National Health and Wellness Survey found that the total direct cost of obesity and overweight was USD 30.3 billion.\(^71\)

An analysis of 2005–2009 data from the Healthcare Cost and Utilization Project and the Nationwide Inpatient Sample identified that hospital costs incurred by obese patients were 3.7% than in non-obese patients, driven by increased length of stay and increased daily resource use.\(^72\) Estimates from 2005 suggest each additional BMI point is, on average, associated with USD 149 higher annual expenditure and that 20.6% of total healthcare spending in the US is attributable to obesity.\(^73\) Analysis of the 2005 Nationwide Inpatient Sample found that hospital charges for obese and morbidly obese patients were 6.1% and 18.7%, respectively, higher than non-obese patients when diabetes status, sex, age, race, hospital admission type, and length of hospital stay were controlled for.\(^74\) Projections suggest that the healthcare costs attributable to overweight and obesity will double every decade up to 2030.\(^75\)

In the US Compared with normal-weight individuals, obese patients in the US have been found, on average, to incur 27% more physician visits and outpatient costs, 46% more inpatient costs, and an 80% increase in spending on prescription drugs.\(^76\)
Costs of obesity are also increasing in children in the US. Analysis of obesity-related hospitalizations in patients aged 2–19 years from 1999–2005 found that hospitalizations increased 23.9% and 11.5% per annum for cases in which obesity was the primary and secondary diagnosis, respectively (Figure 2-18). Costs increased at a faster rate, going up by 42.4% and 36.5% for primary and secondary diagnosis of obesity, respectively. When obesity was classified as a secondary diagnosis, obesity was associated with increased length of stay by 0.85 days in increased hospital costs by USD 1,634. When potential confounders were controlled for, statistically significant increases in obesity-associated hospitalizations were detected for asthma, pregnancy-related conditions, diabetes, pneumonia, skin/subcutaneous tissue infections, appendicitis, other mental disorders, and biliary tract disease, which could not be explained by increases in hospitalizations for the primary condition. For example, over the study period, asthma hospitalizations had an annual decrease of 3.9%, whereas obesity-related asthma hospitalizations increased 7.2% year on year.

Figure 2-18 Trends in hospitalizations and costs for patients aged 2–19 years, in whom obesity was secondary diagnosis in the USA

In Canada in 2006, the direct cost of obesity was CAD 6 billion, representing 4.1% of the national healthcare budget. Of this, 66% was directly associated with obesity, while a quarter of the increase from previous estimates was attributed to conditions newly associated with obesity.

South America

A cost of illness study in Brazil in 2011 found that the direct cost attributable to obesity was USD 269.6 million. Morbid obesity accounted for 23.8% of this expenditure, despite being 18 times less prevalent than obesity.

In Mexico, estimates suggest that obesity related conditions were associated with an annual cost of USD 806 million in 2010, and this is projected to increase to USD 1.2 billion in 2030 and USD 1.7 billion in 2050.
Asia

A systematic review of cost studies relating to Asia-Pacific found that overweight and obesity accounted for 1.5–9.9% of total healthcare expenditure across the region.\textsuperscript{81} Compared to normal weight individuals, healthcare spending per patent was 7–9.8% higher for overweight individuals and 17–22% higher for obese individuals.

Australia and Oceania

Based on data up to 2009, Keating \textit{et al.} reported that severely obese people in Australia use significantly more medical services (mean 22.8 services/person/year) compared with an age and sex matched sample from the general population (mean 12.1 services/person/year).\textsuperscript{82} The authors also found that mean annual healthcare costs in severely obese people were over twice those in the general population (AUD 1,140 vs. 567). Cost increases were mostly due to increased use of services, such as consultations with GPs, specialists and psychologists regarding co-morbid conditions, as well as increased prescription medication, notably anti-hyperglycemic and lipid-modifying agents.

An earlier study projected the annual cost of overweight and obesity in Australia to be AUD 21 billion in 2005.\textsuperscript{83} Estimates suggested that increased BMI was associated with increased healthcare costs.

In New Zealand, estimates from 2006 suggest that healthcare costs attributed to overweight and obesity were NZD 868 million annually, equivalent to 4.5% of the total healthcare expenditure.\textsuperscript{84}

### Table 2-3 Direct costs per person at different body weight classifications in Australia

<table>
<thead>
<tr>
<th>Weight status</th>
<th>Direct health costs (AUD)</th>
<th>Direct non-health costs (AUD)</th>
<th>Total direct costs (AUD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>1,313 (1145–1482)</td>
<td>397 (262–532)</td>
<td>1,710 (1464–1956)</td>
</tr>
<tr>
<td>Overweight</td>
<td>1,559 (1418–1701)</td>
<td>551 (397–705)</td>
<td>2,110 (1887–2334)</td>
</tr>
<tr>
<td>Obese</td>
<td>2,027 (1839–2215)</td>
<td>513 (343–684)</td>
<td>2,540 (2275–2805)</td>
</tr>
</tbody>
</table>

Source: Colagiuri \textit{et al.}\textsuperscript{83} Values presented are means with 95% confidence intervals, with weight status determined by BMI. AUD, 2005 Australian dollars.

2.4.2 Impact of obesity on productivity

**Worldwide**

A meta-analysis of 28 studies carried out in a variety of settings worldwide identified that overweight and obesity were associated with a statistically significant increase in the proportion of patients leaving employment and receiving disability pension.\textsuperscript{85}

**Europe**

Estimates in the UK from 2007 suggest that the annual cost of lost productivity due to overweight and obesity was GBP 15.8 billion.\textsuperscript{66} In Germany, it has been estimated that the indirect costs of obesity and overweight in 2002 were EUR 5,019 million, based on a human capital approach.\textsuperscript{67} The key driver of this was early mortality. In addition, overweight and
obesity and their co-morbid conditions resulted in 317,355 hospital stays, 5.8 million days of missed work and 3,736 people taking early retirement. Estimates for the Republic of Ireland suggest that the indirect cost of obesity is EUR 865 million, and in Northern Ireland productivity losses of EUR 362 million have been estimated.69

North America

Estimates from 2014 found that the indirect cost of health conditions causally related to obesity and overweight in the USA found that the total indirect cost was USD 988.8 billion (Figure 2-19).

Figure 2-19 Indirect cost of medical treatment for health conditions causally related to obesity and overweight in the USA (in USD million)

As with direct costs, older estimates of indirect costs were much lower, with the indirect costs of both obesity and overweight estimated to be USD 42.8 billion per year in 2008.71

The cost of obesity-related absenteeism was estimated to be USD 8.65 billion in 2012, based on data from NHANES.86 Analysis of the Medical Expenditure Panel Survey collected by the Agency for Healthcare Research and Quality suggests that the probability of missing

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work, number of days missed, and the cost of absenteeism all increased in line with increasing weight classification.\textsuperscript{87} Data from the Thomson Reuters MarketScan Databases for 2004–2009 found that increased BMI was associated with increased work-days missed, with a worker with BMI of 40 kg/m\textsuperscript{2} missing 77\% more days than a worker with BMI of 25 kg/m\textsuperscript{2}.\textsuperscript{88} Similarly, an analysis of worker compensation claims for missed work due to illness between 1997 and 2004 found that increased BMI was associated with increased number of claims and increased lost workdays.\textsuperscript{89}

Obesity also has an important impact at a local level. In the South Plains region of Texas in 2008, estimates suggest that obesity was responsible for the loss of over 1,977 jobs and a decrease in indirect business tax revenues by over USD 13 million per year.\textsuperscript{90} For the state of Texas as a whole, 5-year losses due to obesity have been estimated to be USD 4.59 billion and 31,807 person-years of work.\textsuperscript{91} In New Mexico, annual losses related to obesity were reported as USD 200 million in labor income, USD 48 million in tax revenues and 7,300 jobs in annually between 2003 and 2005.\textsuperscript{92} An analysis of 6,483 participants in the Atherosclerosis Risk in Communities (ARIC) study found that overweight or obesity was associated with a statistically significant increase in retirement before the age of 65 or 62 in African-American men, African-American women and white men, but not in white women.\textsuperscript{93}

In Canada, indirect costs of obesity in 2006 were estimated to be CAD 5 billion.\textsuperscript{78}

**Australia and Oceania**

Obesity-linked productivity losses in Australian productivity have been referenced at AUD 637 million in 2005 and AUD 3.6 billion in 2008.\textsuperscript{83} The study also assessed the effect of overweight and obesity on government subsidies, with the mean subsidy received by a person classified as overweight or obese was AUD 3,917 per person, approximately AUD 1,378 more than the average for people of normal body weight.

In New Zealand, costs of lost productivity in 2006 were estimated at NZD 98 million when a friction approach was applied and NZD 225 million when a human capital approach was used.\textsuperscript{84}

### 2.4.3 Direct costs of treating diabetes

**Worldwide**

The total annual global health expenditure for diabetes in 2015 was estimated to fall between USD 673 billion and USD 1,197 billion, representing approximately 11.6\% of total healthcare expenditure worldwide.\textsuperscript{37} More than 75\% of this expenditure is in patients aged 50–80 years, and 81\% of expenditure was in high-income countries. Projections suggest that by 2040, healthcare expenditure as a result of diabetes will increase to between USD 802 billion and USD 1,452 billion.\textsuperscript{37}
Europe

In Europe, direct costs of diabetes were estimated to be between USD 156 billion and USD 290 billion (Figure 2-20), with projections suggesting that this will increase to between USD 174 billion and USD 330 billion by 2040. Older data from the Cost of Diabetes in Europe – Type 2 study (CODE-2) found that total healthcare costs for patients with type 2 diabetes increased as patients experienced micro- and macrovascular complications.

It has been estimated that the direct costs of type 2 diabetes in the UK in 2010-11 was GBP 8.8 billion.

North America

The majority of healthcare spending as a result of diabetes worldwide in 2015 occurred in North America, with estimates suggesting that spending was between USD 348 billion and USD 610 billion (Figure 2-20). This is projected to increase to be between USD 390 billion and USD 694 billion in 2040.

Estimates released by the American Diabetes Association in 2012 found that the annual direct cost of diagnosed diabetes was USD 176 billion. The largest components of medical expenditure hospital inpatient care (43% of the total medical cost), prescription medications to treat complications of diabetes (18%), anti-diabetic agents and diabetes supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%). Patients with type 2 diabetes visit healthcare providers 2.9 times as often as the general population.
South America

In Central and Southern America, healthcare expenditure as a result of diabetes was estimated to fall between USD 34 billion and USD 59 billion (Figure 2-20). Estimates suggest that by 2040 this will have increased to between USD 56 billion and USD 100 billion. In Brazil, a retrospective analysis of medical records in 2007 found that the average direct cost per patient per year was USD 1,335. Costs were higher as duration of diabetes and number of complications increased. Estimates from 2006 suggest that the total direct cost of diabetes in Mexico was USD 1,165 million.

Asia

Estimates suggest that in Southeast Asia, direct costs of diabetes in 2015 were between USD 7 billion and USD 12 billion (Figure 2-20), with this projected to increase to between USD 13 billion and USD 22 billion in 2040. In the Western Pacific region (including both Asian countries [such as China, Vietnam, and South Korea] but also countries in Australasia and Oceania [such as Australia and New Zealand]), healthcare expenditure resulting from diabetes was estimated to be between USD 106 billion and USD 191 billion in 2015 (Figure 2-20), with projections suggesting that this will rise to between USD 44 billion and USD 85 billion in 2040.

In China, annual direct medical and direct nonmedical costs per patient with type 2 diabetes were USD 1,320.90 and USD 180.80 per patient in 2007, resulting in total direct medical costs of USD 26 billion per year and total direct nonmedical costs of USD 4 billion per year. Projections suggest that, by 2030, total direct medical costs will increase to USD 47.2 billion per year and total direct nonmedical costs will increase to USD 7.2 billion per year.

Estimates suggest that the total direct cost of diabetes in India in 2010 was USD 26.7 billion. An analysis of costs of hospitalizations for patients with diabetes in India found that total costs were higher in patients with complications than in patients without complications. Costs were highest in patients with foot complications and two complications.

Australia and Oceania

In the Western Pacific region (including Australasia and Oceania but also a number of countries in Asia), healthcare expenditure resulting from diabetes was estimated to be between USD 106 billion and USD 191 billion in 2015 (Figure 2-20), with projections suggesting that this will rise to between USD 44 billion and USD 85 billion in 2040.

The direct costs accrued in the year that a patient with diabetes in Australia experiences a diabetes-related complication have been estimated based on Medicare data. With a mean cost of AUD 28,661, the most expensive complication identified was renal failure.

Africa

In 2015, healthcare expenditure in Africa was estimated to be between USD 3 billion and USD 6 billion (Figure 2-20), and this is expected to rise to between USD 5 billion and USD 10 billion by 2040.
2.4.4 Impact of diabetes on productivity

Europe

Estimates in the French setting over 15 years of follow-up suggest that between the age of 35 and 60 years subjects with diabetes lost an estimated 1.1 years in the workforce due to early withdrawal, in comparison with subjects without diabetes.\(^{104}\) Patients with diabetes had significantly increased incidence of transition from the workforce participation to disability, retirement and death. Patients with diabetes also showed increased absence from work, driven by an increase in the incidence of long absence spells.\(^{105}\)

In the UK, the annual indirect cost of type 2 diabetes was estimated to be GBP 13 billion in 2010-11.\(^{95}\) The most significant drivers of cost were premature mortality and informal care. In relation to the work environment, presenteeism and absenteeism due to type 2 diabetes cost the UK economy more than GBP 2.9 billion and 851 million, respectively.

In the UK and Denmark, it has been estimated that diabetes results in a reduction in lifetime earnings of USD 73,243 and USD 114,101, respectively.\(^{106}\)

North America

In the US, at a national level, the indirect cost of diabetes was estimated to be USD 69 billion in 2012.\(^{96}\) At a personal level, it has been estimated that diabetes reduces average lifetime earnings by USD 186,565 per patient.\(^{106}\) An earlier study from 2002 suggested that the total cost of informal care received by community-dwelling elderly individuals with diabetes mellitus was USD 3–6 billion per year.\(^{107}\)

South America

In Brazil, an analysis of patients with diabetes in 2007 identified a mean indirect cost of USD 773 per patient.\(^{98}\) In Mexico, a 2005 estimate suggest that the total indirect cost as a result of diabetes was USD 177 million.\(^{99}\)

Asia

In India and China, lifetime reductions in earnings of USD 10,980 and USD 14,033, respectively, have been estimated.\(^{106}\) The total indirect cost of diabetes in India in 2010 was estimated to be USD 5.2 billion.\(^{101}\) In China in 2007, indirect costs of diabetes were estimated to by USD 2.2 billion, and this is projected to increase to USD 4.0 billion by 2030.\(^{100}\)
2.5 UNMET NEEDS IN OBESITY MANAGEMENT

Obesity and obesity-related co-morbid conditions have a substantial impact on an individual’s general health status and quality of life. Obesity and related conditions such as diabetes also place a significant burden on healthcare providers. Early and effective treatment of obesity is required to limit its impact on patients and healthcare services. Reallocation of healthcare resources to prevent and reduce obesity may be the most effective and efficient use of healthcare resources. Analysis of the UK Clinical Practice Research Datalink found that the annual probability of an obese male attaining normal weight was 1 in 210, and that the annual probability of an obese female attaining normal body weight was 1 in 124 for women.\textsuperscript{108}

One issue still to be resolved is the definition of obesity. In general, BMI is the reference standard for defining appropriate weight and is used in most guidelines (Section 0). However, other factors such as waist circumference or percentage body fat may also be considered. It has been suggested that in Indian individuals, BMI and waist circumference should be used together with equal importance for cardiovascular risk stratification.\textsuperscript{109} Asian individuals have higher adiposity at a given BMI, and a further consensus meeting concluded that an optimal method to define obesity requires a combination of BMI, waist, and waist–hip ratio.\textsuperscript{110}

Data from long-term studies of first-line lifestyle intervention and nutrition education for overweight and obesity suggest that whilst initial weight loss may be observed, this is not maintained over the long-term, with body weight tending to increase after 1 year.\textsuperscript{111} Furthermore, weight loss achieved may not be clinically meaningful with first line therapies.\textsuperscript{112} In the context of early obesity resolution, determination, on a per patient basis, of the optimal obesity management and treatment pathway is critical. This is one of the largest current unmet needs in obesity management. After evaluating obesity management and care provision in New Zealand, Dixon et al. called for an integrated model of care that could provide practical clinical pathways for the assessment and management of severe obesity, in particular in adolescents.\textsuperscript{113} To be successful, the authors noted that such a pathway would need to incorporate all effective therapies, including bariatric surgery, which is often reserved for a later line of treatment or restricted in its application in adolescents. Similarly, a review of German practices in the management of obesity suggested that age restrictions on bariatric surgery (previously available to those aged 18–60 years) should be removed, but that procedures in patients outside this age range should be individually justified.\textsuperscript{114}

2.6 BENEFITS OF IMPROVED OBESITY MANAGEMENT

Obesity is associated with a multitude of co-morbid conditions and negative lifestyle impacts. Preventing, delaying or reducing the time with obesity may lower the risk of developing co-morbid conditions. Studies have shown that not only weight loss but also the metabolic effects of bariatric surgery result in reduced incidence of obesity-related co-morbidities. Significant and sustained weight loss has been found to improve patient quality of life, lead to resolution of co-morbid conditions, and reduce the number and cost of prescription medications and healthcare resource use.\textsuperscript{115,116,117,118,119,120,121,122,123} Timely identification of overweight and obesity and early and effective intervention are, therefore, crucial in promoting optimal outcomes.
3 BARIATRIC SURGERY

KEY MESSAGES

- Bariatric surgery is safe and has been recommended as a treatment option for obesity by various professional medical organizations in worldwide, European, Asian, and US treatment guidelines.
- Bariatric surgery is indicated for patients with BMI > 35 kg/m² or patient with BMI 30–35 kg/m² with co-morbidities
- A number of bariatric surgery procedures are available, including:
  - Adjustable gastric banding (AGB)
  - Sleeve gastrectomy (SG)
  - Roux-en-Y gastric bypass (RYGB)
  - Biliopancreatic diversion (BPD)
- Over the last decade, the majority of bariatric surgeries have been carried out using laparoscopic techniques, as these are associated with reduced post-operative mortality, reduced length of hospital stay and a significantly reduced incidence of surgical site infection (SSI) in comparison with open surgery.
- Compared with medical management, clinical studies and meta-analyses have shown that bariatric surgery is associated with:
  - Increased weight loss
  - Increased remission of diabetes
  - Improved glycemic control in patients with diabetes
  - Increased proportions of patients with type 2 diabetes achieving multi-factorial treatment targets
  - Increased remission of co-morbidities
  - Improved life expectancy
  - Improved quality of life
- Clinical studies and meta-analyses comparing various bariatric procedures have also been conducted, suggesting:
  - Both RYGB and SG are associated with improved outcomes compared with AGB
  - RYGB may be associated with improved outcomes versus SG, but other studies suggest that the procedures are associated with similar outcomes
  - There is a paucity of evidence comparing BPD with other procedures, but meta-analyses suggest that it may be associated with improved outcomes compared to AGB, RYGB and SG
- Cost studies suggest that bariatric surgery may result in reduced hospitalization and medication costs following surgery
- Studies in some settings suggest that bariatric surgery is associated with reduced costs compared to medical management, while other studies suggest that bariatric surgery is associated with increased costs (as cost savings only partially offset the cost of the procedure)
- Long-term studies suggest that bariatric surgery is likely to be dominant or cost-effective compared to medical management, irrespective of the procedure performed on the country of the analysis
3.1 OVERVIEW OF BARIATRIC SURGERY

There are a number of surgical procedures currently available to promote weight loss, so-called bariatric surgery. Reviews of weight loss management strategies have concluded that:

“Bariatric surgery is the most effective treatment of morbidly obese patients to allow substantial, sustained weight loss and to improve or resolve obesity-associated comorbidities, thereby reducing mortality”\(^{124}\)

Bariatric surgery was originally intended to either reduce calorific intake by restricting the size of the stomach, limit the absorption of nutrients in the intestine, or combine restrictive and malabsorptive components, but it is now thought that these play a relatively small part in improving outcomes, with the metabolic effects of surgery playing the most important role. Changes in the levels of hormones released from the gastrointestinal tract, the way bile acids move through the gastrointestinal tract, and gut microbiota play a key role in improved outcomes following bariatric surgery.

There is a long history of bariatric surgery, with the first reported bariatric procedure carried out by Kremen and colleagues in 1954, and the first instance of gastric bypass was published by Mason and Ito in 1967.\(^{125,126}\) Complications, such as severe diarrhea, limited the application of bariatric surgery in its formative years, over the last 20 years, however, new surgical techniques and the associated improvements in patient outcomes have led to a large increase in bariatric surgery.\(^{127,128}\) When bariatric surgery is not offered to patients, it is often due to lack of knowledge and stigma.\(^{129}\)

3.1.1 Types of procedures in bariatric surgery

3.1.1.1 Adjustable gastric band (AGB)

Adjustable gastric banding is the least invasive bariatric procedure and is more commonly performed in older patients or those with lower severity obesity.\(^{130}\) The procedure is generally carried out using laparoscopic techniques and is unique as a bariatric procedure in that it can be easily reversed. In this procedure, a band is placed around the upper part of the stomach (Figure 3-1) and connected to an access port positioned just beneath the skin. By adding or removing saline solution via the port, the band can be inflated or deflated to decrease or increase, respectively, the rate at which food passes into the rest of the stomach. Decreasing the rate of passage results in a faster onset of satiety and reduced calorific intake, and changes in gut hormones also result in improved outcomes.

Figure 3-1  Adjustable gastric band
3.1.1.2 Sleeve gastrectomy (SG)

The sleeve gastrectomy (SG) procedure was first published as an initial stage of biliopancreatic diversion (BPD) with a duodenal switch (BPD-DS).\textsuperscript{127} SG was considered as a standalone procedure after it was noted that a number of patients that had undergone this initial stage of BPD had lost sufficient weight that further surgery was not required.\textsuperscript{127} In SG a section of the stomach is removed to leave a sleeve-like tube (Figure 3-2). The reduced stomach size results in earlier onset of satiety and reduced caloric intake. Data suggest that resolution of co-morbidities is independent of weight loss, and therefore that the metabolic effects of SG are crucial in improving long-term outcomes.\textsuperscript{131}

![Figure 3-2 Sleeve gastrectomy](image)

3.1.1.3 Roux-en-Y Gastric Bypass (RYGB)

Roux-en-Y gastric bypass (RYGB) is often considered to be the gold standard in bariatric surgery.\textsuperscript{127,130,132,133,134} During the RYGB procedure, the size of stomach is reduced by stapling across the upper section and then the proximal and distal sections of the stomach are physically separated (Figure 3-3). This part of the operation reduces the amount of food that can be ingested at meal times. The new stomach pouch is then attached directly to the small intestine via a Roux limb. By bypassing the majority of the stomach and parts of the small intestine, digestion and nutrient absorption are reduced. This bypass also results in food entering the jejunum almost immediately after ingestion, which can lead to symptoms including pain and nausea.\textsuperscript{135,136} So called dumping syndrome is usually linked to ingestion of energy-dense foods and it has become an expected and desired part of the behavior modification after surgery, as it may help deter patients from consuming unhealthy foods.\textsuperscript{135}
3.1.1.4 Biliopancreatic diversion (BPD)

Benefits of BPD derive from malabsorption, reduction of calorie intake, and metabolic changes following surgery. First, a small stomach pouch is created by dividing the top of the stomach from the rest of the stomach, with preservation of the pylorus. Next, the first portion of the small intestine is divided, and the distal end of the divided small intestine is connected to the newly created small stomach pouch. The procedure is completed by connecting the top portion of the divided small intestine to the small intestine further down, so that the stomach acids and digestive enzymes from the bypassed stomach and first portion of small intestine will eventually mix with the food (Figure 3-4). The high complexity of the procedure means that complications are relatively common and in many cases the increased weight loss compared with other bariatric techniques does not justify the increased risk of complications.

Figure 3-3 Roux-en-Y gastric bypass

Figure 3-4 Biliopancreatic diversion
3.1.2 Laparoscopic versus open procedures

Over the last decade laparoscopic techniques have come to dominate within bariatric surgery (Figure 3-5) and the benefits of laparoscopic compared with open surgery might be one reason underpinning the increase in bariatric surgeries performed.\textsuperscript{139,140,141} Traditional, open bariatric procedures are performed through an upper abdominal midline incision, after which the target area is exposed using abdominal wall retractors and mechanical retraction of the abdominal viscera.\textsuperscript{142} In contrast, five or fewer small abdominal incisions are required for laparoscopic procedures and pneumoperitoneum is used to create a space between the abdominal wall and abdominal viscera.\textsuperscript{140}

![Figure 3-5 Increase in laparoscopic bariatric surgery from 1998 to 2008](chart)

There is now a large body of literature demonstrating the benefits of laparoscopic techniques in comparison with open surgery. Compared to open surgery, laparoscopic surgery is consistently associated with:

- Reduced length of hospital stay\textsuperscript{142,143,144,145,146,147,148,149}
- Reduced rates of early and late complications (Table 3-1)\textsuperscript{142,143,144,146,148,149,150,151}
- Reduced post-operative mortality\textsuperscript{142,150,149}
- Lower hospital charges\textsuperscript{142,143,144,147,148,149}
- Reduced rates of surgical site infection\textsuperscript{142,143,147,150,152}
- Reduced requirement for blood transfusion\textsuperscript{142}
- Reduced post-operative pain\textsuperscript{144}
- Faster recovery\textsuperscript{144,147}

### Table 3-1 Comparison of complications after open or laparoscopic bariatric surgery

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence after open RYGB, %</th>
<th>Incidence after laparoscopic RYGB, %</th>
<th>Odds Ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrhythmia</td>
<td>4.3</td>
<td>2.8</td>
<td>0.69 (0.64–0.68)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>2.7</td>
<td>1.9</td>
<td>0.76 (0.70–0.82)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Other pulmonary</td>
<td>2.6</td>
<td>1.2</td>
<td>0.55 (0.50–0.60)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Genitourinary tract</td>
<td>2.3</td>
<td>1.3</td>
<td>0.64 (0.58–0.70)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Gastrointestinal leak</td>
<td>1.9</td>
<td>1.2</td>
<td>0.66 (0.60–0.73)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.3</td>
<td>0.1</td>
<td>0.24 (0.17–0.34)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1.1</td>
<td>0.5</td>
<td>0.50 (0.43–0.57)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Sepsis</td>
<td>0.9</td>
<td>0.4</td>
<td>0.51 (0.44–0.60)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Source: Banka et al.\textsuperscript{142} CI: Confidence interval; RYGB: Roux-en-Y gastric bypass.
In recent years, laparoscopic-assisted (or robotic) bariatric surgery has become available. This procedure builds on the minimally invasive laparoscopic approach. After the initial incisions, cannulas are used to insert a camera and specialized instruments into the site of operation. Observing the site of operation on a video monitor, the surgeon is connected to a system that translates their movements into smaller, more precise movements at the site of operation. The operation is, thus, carried out by the surgeon remotely. Recent reviews found that assisted/robotic bariatric surgery was associated with equivalent or lower complication rates than laparoscopy bariatric surgery.\textsuperscript{153,154,155,156} Compared with traditional laparoscopic surgery, the time required for operations using the robotic system was shorter in two studies and longer in four studies.\textsuperscript{154} In general, the reviews concluded that there was great promise in digitally assisted bariatric surgery, as it has a shorter learning curve and provides improved visualization of the surgical target.\textsuperscript{153,154}

### 3.1.3 Improvements in bariatric surgery as frequency increases

As more bariatric surgery procedures have been performed, clinical outcomes for patients and outcomes relevant to healthcare providers, such as operating time, have improved. In a private hospital based in Oslo, Norway, from 2005 to 2010 mean surgical time was reduced from 102 minutes to 54 minutes (p<0.01) and mean hospital stay was reduced from 3.0 to 2.0 days (p<0.01), with no increase in complication rates.\textsuperscript{157} In the US, an analysis of 3,410 RYGB procedures conducted by 31 surgeons found that a 10% increase in the number of cases performed by a surgeon per year resulted in a 10% reduction in the risk of the composite event of death, venous thrombosis, pulmonary embolism, re-operation, non-discharge at 30-days, or re-hospitalization within 30 days following initial discharge.\textsuperscript{158} Similarly, a 3-year study in Pennsylvania found that increasing the number of RYGB procedures performed by surgeons was associated with a reduced frequency of adverse events.\textsuperscript{159} A review of 24 studies containing 458,032 patients undergoing all forms of bariatric surgery found that increasing both surgeon and hospital volume were associated with improved patient outcomes.\textsuperscript{160} In Brazil, bariatric surgeries carried out in hospitals carrying out large numbers of operations resulted in shorter length of stay than those carried out in hospitals conducting fewer operations.\textsuperscript{161}

Improved training for surgeons is also driving improvements in outcomes. There is evidence the experience of the surgeon is linked to improved patient outcomes, and that intensive training with an expert mentor can optimize surgery.\textsuperscript{162,163} Interaction with the mentor does not have to be face-to-face, with evidence suggesting that tele-mentoring is in reducing operating times and length of hospital stay.\textsuperscript{164} Within the US, bariatric procedures conducted within centers accredited by the American Society for Metabolic and Bariatric Surgery (ASMBS) or the American College of Surgeons (ACS) have a lower mortality rate, length of stay and cost than procedures conducted in non-accredited centers, but no differences in complication rates have been observed.\textsuperscript{165,166}
3.2 CLINICAL GUIDELINES RELATING TO BARIATRIC SURGERY

Worldwide

Worldwide treatment guidelines have been released by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO, in 2016), the Diabetes Surgery Summit (in 2016), the IDF (in 2011), and the Endocrine Society (in 2009).167,168,169,170

The guidelines released by IFSO state:

- Surgery for obesity and weight-related diseases has proven to be effective in the treatment of obesity resulting in long-term weight loss, improvement in or resolution of comorbidities, and the lengthening of life expectancy
- Surgery for obesity and weight-related diseases is a safe and effective therapeutic option for the management of type 2 diabetes in patients with obesity
- Surgery for obesity and weight-related diseases has proven to be a cost-effective and, in some instances, a cost-saving approach for the management of patients with obesity and type 2 diabetes
- Surgery for obesity and weight-related diseases demonstrated an excellent short- and mid-term risk/benefit ratio in patients with BMI 30–35 kg/m² suffering from type 2 diabetes and/or other comorbidities
- Weight loss induced by surgery for obesity and weight-related diseases is associated with a reduction in the incidence of major cardiovascular events in patients with obesity
- The improvement in the quality of life of the patient with obesity treated by surgery for obesity and weight-related diseases is independent from the type of procedure performed

Following the Diabetes Surgery Summit, a consensus statement was released, stating:

- Metabolic surgery should be a recommended option to treat patients with type 2 diabetes with class BMI ≥ 40 kg/m², regardless of the level of glycemic control or complexity of glucose-lowering regimens, as well as in patients with BMI 35.0–39.9 kg/m² with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy.
- Metabolic surgery should also be considered to be an option to treat patients with type 2 diabetes with BMI 30.0–34.9 kg/m² and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin).

The consensus statement released by the IDF states:

- Bariatric surgery should be considered in patients with type 2 diabetes and a BMI ≥ 35 kg/m² or BMI 30–35 kg/m² who cannot by adequately controlled by an optimal medical regimen
- In Asian, and some other ethnicities of increased risk, BMI action points may be reduced by 2.5 kg/m²
- RYGB, AGB, BPD and BPD–DS are accepted procedures

The guidelines released by the Endocrine Society are specific to pediatric patients and state:

- Bariatric surgery is not recommended for pre-adolescent children, pregnant or breastfeeding adolescents, those planning pregnancy within the next 2 years, and patients unable to master healthy dietary and exercise habits
- Consider the use of pharmaceutical therapy and bariatric surgery for the subset of children for whom lifestyle intervention alone is unsuccessful
Bariatric procedures in children should be performed at medical centers that plan to engage in data collection and long-term follow-up, which will help inform future recommendations.

**Europe**

In 2012, following a meeting by International Federation for the Surgery of Obesity-European Chapter (IFSO-EC) and the European Association for the Study of Obesity (EASO), a revised set of guidelines were released, updating those published in 2008.171,172,173 These state:

- Bariatric surgery is indicated in patients with BMI≥40 kg/m², or BMI≥35 kg/m² with co-morbidities which would be expected to improve the disorder
- Weight loss as a result of intensified treatment before surgery is not a contraindication for the planned bariatric surgery
- Consideration should be given to reducing the BMI threshold by 2.5 for individuals of Asian genetic background
- Patients with BMI 30–35 kg/m² with type 2 diabetes may be considered for bariatric surgery on an individual basis
- A laparoscopic technique should be considered as the preferable approach to the surgery

European guidelines relating to children and adolescents have also been published.174 These recommend surgery for:

- Surgery is indicated for patients with BMI>40 kg/m² with severe co-morbidities
- Surgery is indicated for patients with BMI>50 kg/m² with mild co-morbidities
- Additional criteria for surgery in adolescents include a documented attempt to lose weight by diet and lifestyle intervention, a Tanner stage of 4 or greater, 95% skeletal maturity, a demonstrated commitment to complimentary lifestyle change and a stable psychosocial environment.

In addition, country-specific guidelines have been released for the UK and Germany. Guidelines released by the National Institute for Health and Care Excellence in 2014 state:175

- Bariatric surgery is indicated in patients with BMI≥40 kg/m², or BMI≥35 kg/m² with co-morbidities which would be expected to improve the disorder, and all non-surgical measures have been tried
- Patients with recent-onset type 2 diabetes and a BMI≥35 kg/m² may be considered for bariatric surgery
- The type of surgery should by chosen jointly with the person

Consensus guidelines for Germany were developed and published in in 2011.114 These state:

- Bariatric surgery is indicated in patients with a BMI≥40 kg/m² and patients with a BMI of 35–40 kg/m² and with one or more obesity-associated disorders (e.g., type 2 diabetes mellitus, coronary heart disease, etc.) if conservative treatment has failed
- Previous age restrictions of 18–60 years no longer apply, though cases outside this range should be individually justified
- Effective surgical procedures are AGB, SG, RYGB and BPD–DS
- Laparoscopic procedures are preferred
North America

A number of guidelines relating to bariatric surgery in the US have been released. The American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic & Bariatric Surgery (ASMBS) collaborated to release guidelines in 2013. These state:

- Bariatric surgery should be offered to patients with BMI $\geq 35$ kg/m$^2$ and patients BMI $\geq 30$ kg/m$^2$ with type 2 diabetes
- Effective surgical procedures are AGB, SG, RYGB and BPD–DS

The American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines were released in 2013. These state:

- Advise adults with a BMI $\geq 40$ kg/m$^2$ or BMI $\geq 35$ kg/m$^2$ with obesity-related co-morbidities who have not responded to behavioral treatment with or without pharmacotherapy that bariatric surgery may be an appropriate option

In 1998, the National Institute of Health and the National Heart, Lung and Blood Institute collaborated to release a consensus statement. These state:

- Bariatric surgery is an option for patients with a BMI $\geq 40$ kg/m$^2$ or a BMI $\geq 35$ kg/m$^2$ with co-morbidities
- Bariatric surgery should only be used when non-invasive methods have not been successful

Guidelines specific to patients with diabetes have been released by the American Diabetes Association. These state:

- Metabolic surgery should be recommended to treat type 2 diabetes in appropriate surgical candidates with BMI $>40$ kg/m$^2$ (BMI $>37.5$ kg/m$^2$ in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with BMI 35.0–39.9 kg/m$^2$ (32.5–37.4 kg/m$^2$ in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy.
- Metabolic surgery should be considered for adults with type 2 diabetes and BMI 30.0–34.9 kg/m$^2$ (27.5–32.4 kg/m$^2$ in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin).
- Patients with type 2 diabetes who have undergone bariatric surgery need lifelong lifestyle support and annual medical monitoring

The AACE has also released diabetes treatment guidelines. These state that:

- Bariatric surgery can be considered for patients with a BMI $\geq 35$ kg/m$^2$ and comorbidities, especially if therapeutic goals are not achieved in using lifestyle modifications and weight-loss medications
- Bariatric surgery has good-to-excellent short to-intermediate-term benefits for the prevention of type 2 diabetes

Asia

Treatment guidelines for Asia-Pacific have been released by the International Federation for the Surgery of Obesity and Metabolic Disorders–Asia Pacific Chapter (IFSO-APC) in 2012. These state that:

- Bariatric surgery should be considered for the treatment of obesity for Asian candidates with BMI $\geq 35$ kg/m$^2$ with or without co-morbidities
Bariatric surgery should be considered for the treatment of type 2 diabetes or metabolic syndrome in Asians with BMI ≥ 30 kg/m² if lifestyle and pharmaceutical intervention have failed.

Surgery can be considered if type 2 diabetes is inadequately controlled in Asians with a BMI ≥ 27.5 kg/m².

Recommended procedures are: RYGB, SG, AGB, and BPD.

Bariatric surgery is indicated for patients aged 18–65 years, but older or younger candidates should be evaluated on a per case basis.

Earlier treatment guidelines for Asian patients were released following Asian Consensus Meeting on Metabolic Surgery (ACMOMS). These state that:

- Bariatric surgery should be considered as a treatment option for obesity in people with Asian ethnicity with BMI more than 35 kg/m² with or without co-morbidities.
- Bariatric surgery should be considered as a treatment option for obesity in people with Asian ethnicity above a BMI of 32 kg/m² with co-morbidities.
- Bariatric surgery should be considered as a treatment option for obesity in people with Asian ethnicity above a BMI of 30 kg/m² if they have central obesity (waist circumference more than 80 cm in females and more than 90 cm in males) along with at least two of the additional criteria for metabolic syndrome: raised triglycerides, reduced HDL cholesterol levels, high blood pressure, and raised fasting plasma glucose levels.

A consensus statement for patients in India was published in 2009, based on opinions gathered from over 100 experts. These guidelines state that:

- Bariatric surgery should be considered as treatment in patients with BMI > 32.5 kg/m² plus a co-morbid condition or BMI > 37.5 kg/m².
- Surgical options include AGB, SG, RYGB, and BPD.

The Dubai Health Authority released guidelines in 2016. These state that:

- Bariatric procedures are an option for carefully selected patients with clinical obesity when less invasive methods of weight loss have failed and the patient is at high risk of obesity-associated morbidity or mortality.
- Surgery is indicated for patients with BMI > 40 kg/m² with or without co-morbidities, patients with BMI 35–39.9 kg/m² with one or more co-morbidities, and patients with BMI 30–34.9 kg/m² with two or more co-morbidities.
- Physicians should take a pragmatic approach to selecting the surgical procedure, and laparoscopic procedures should be the primary choice.

In 2013, the Health Authority–Abu Dhabi released guidelines on weight management and obesity. These guidelines state that:

- Healthcare providers must ensure that bariatric surgery is delivered to patients with:
  - BMI > 50 kg/m² (no co-morbidities or evidence of failed non-invasive interventions are necessary).
  - BMI 40–50 kg/m² with evidence of failed non-invasive interventions, weight loss and pharmacotherapy (no comorbidities are necessary).
  - BMI 35–39.9 kg/m² with evidence of failed non-invasive interventions, weight loss and pharmacotherapy and at least 2 comorbidities.
  - BMI 30–34.9 kg/m² with evidence of failed non-invasive interventions, weight loss and pharmacotherapy and at least 3 comorbidities.
- Options for surgery including AGB, RYGB, and SG.
Australia and Oceania

In Australia, the National Health and Medical Research Council has released guidelines on the management of overweight and obese individuals. These state that:

- Bariatric surgery is currently the most effective intervention for severe obesity
- For adults with BMI> 40 kg/m² or adults with BMI>35 kg/m² and comorbidities that may improve with weight loss, bariatric surgery may be considered
- Bariatric surgery may be a consideration for people with a BMI>30 kg/m² who have poorly controlled type 2 diabetes and are at increased cardiovascular risk
- Bariatric surgery, when indicated, should be included as part of an overall clinical pathway for adult weight management that is delivered by a multidisciplinary team (including surgeons, dietitians, nurses, psychologists and physicians) and includes planning for continuing follow-up
- For post-pubertal adolescents with a BMI>40 kg/m² (or BMI>35 kg/m² with obesity-related complications), laparoscopic adjustable gastric banding via specialist bariatric/pediatric teams may be considered if other interventions have been unsuccessful in producing weight loss
3.3 TRENDS IN BARIATRIC SURGERY

Worldwide

The global status of bariatric surgery in 2011 was assessed through a survey of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO). Worldwide, 340,768 bariatric surgery procedures were performed by 6,705 surgeons. The majority of procedures (46.6%) were RYGB, followed by SG (27.8%) and AGB (17.8%), with no other procedure exceeding 1%.

From 2003 to 2008, the percentage of RYGB procedures performed fell from 65.1% to 49.0%, before remaining fairly constant to 2011 (46.6%). The frequency of AGB peaked in 2008 (42.3%) and then in 2011 fell to 17.8%, which is below the 2003 value of 24.4%. The frequency of SG has shown the largest increase over time, increasing from 0% in 2003 to 5.3% in 2008 and 27.8% in 2011. BPD-DS has remained relatively rare, falling from 4.8% in 2003 to 2.2% in 2011.

Figure 3-6  Frequency of bariatric procedures worldwide

Europe

Within Europe, the use of AGB has fallen drastically from 2003 (63.7% of procedures) to 2011 (17.8% of procedures). This has been matched by increases in the proportion of RYGB and SG procedures, rising from 11.1% and 0%, respectively in 2003 to 43.5% and 27.8%, respectively in 2011.

A study of elective bariatric surgical procedures from 2005 to 2011 in France found a 2.5-fold increase in bariatric procedures over the time period. It was noted that since 2007 the use of AGB has decreased in France and that by 2011 SG and RYGB were the dominant bariatric procedures.

North America

SG is now the most commonly conducted bariatric procedure in the US, with the proportion increasing from 3% in 2008 to 54% in 2014 (Figure 3-7). RYGB was the most commonly conducted surgery in 2008 at 52%, but fell to 32% in 2014. The use of AGB remained relatively low across the time period from 2008 to 2014. The requirement for revisional surgery has fallen from 2008 to 2014.
South America

In South America, the frequency of AGB fell from 61.5% in 2003 to 20.4% in 2008 and as low as 5.3% in 2011. Concurrently, RYGB rose from 20.2% in 2003 to 65.9% in 2008 and then fell slightly to 57.9%. SG climbed from 0.0% to 30.1% from 2003 to 2011.

Asia/Pacific

Between 2003 and 2008, the frequency of AGB in the Asia/Pacific region increased slightly from 80.4% to 82.5%, but then fell to 55.1% in 2011. The proportion of SG increased from 0.0% in 2003 to 4.1% in 2008 and then to 55.1% in 2011. The frequency of RYGB remained between 8.4% and 9.6% at all three time points.

A survey of the Asia-Pacific Metabolic and Bariatric Surgery Society (APMBSS) provided data on bariatric surgeries performed between 2005 and 2009. Overall, the most common procedure was LAGB (35.9%), followed by LRYGB (24.3%) and LSG (19.5%), and almost all procedures (99.8%) were undertaken using laparoscopic techniques. The use of both LSG and LRYGB were increasing, with a 24.8-fold increase in the use of LSG (from 1% to 24.8%) and a 2.3-fold increase in the use of LRYGB (from 12% to 27.7%) from 2003 to 2008. In line with the rise of LSG and LRYGB, the use of LAGB and mini-gastric bypass decreased from 44.6% to 35.6% and from 41.7% to 6.7%, respectively.

A survey conducted by the Japan Research Society for Endoscopic and Laparoscopic Treatments of Obesity found that between 2000 and 2009 only 340 laparoscopic bariatric procedures were undertaken in 9 of 64 hospitals surveyed. Although LRYGB was the most common during this time (n = 147), the utilization of LRYGB has been decreasing and there has been a rapid rise in the use of LSG (n = 102).
3.4 CLINICAL EVIDENCE OF THE EFFICACY OF BARIATRIC SURGERY

3.4.1 Bariatric surgery versus standard medical management

Although bariatric surgery has a long history, it is only in recent years that randomized controlled trials (RCTs) comparing bariatric surgery with intensive lifestyle intervention have been published frequently. Although key medical evidence is best derived from RCTs, there are a large number of long-term follow-up studies of bariatric surgery compared with lifestyle intervention that provide valuable data from a non-trial, clinical setting. Studies that do not have a comparator arm (i.e. outcomes after bariatric surgery where compared with baseline) are outlined in appendix 1.

3.4.1.1 AGB versus medical management

A total of 5 studies have compared AGB with medical management (Table 3-2). All of these were RCTs, with 2 years of follow-up, conducted in Australia.

- Weight loss: In all studies AGB was associated with greater weight loss than medical management. This was reported in a number of ways, including change in BMI, change in body weight, and percentage change in body weight (Figure 3-8).\(^{190,191,192,193,194}\)
- Remission of diabetes: One study assessed remission of diabetes, with a statistically significant benefit in the AGB arm. A total of 73% achieved remission in the AGB arm compared to only 13% in the medical management group.\(^{192}\)
- Resolution of metabolic syndrome: Greater resolution of metabolic syndrome compared to medical management was observed in both adults and adolescents.\(^{191,194}\)
- Quality of life: Changes in quality of life where assessed in two studies, one in adults and one in adolescents, with AGB associated with greater improvements compared to medical management in both populations.\(^{191,194}\)
- Sleep apnea: In the single study which assessed sleep apnea, a greater but non-statistically significant improvement in symptoms was observed in the AGB arm compared to the medical management arm.\(^{190}\)
- Efficacy in adolescents: Of the five studies, one assessed the efficacy of AGB in patients aged 14–18 years. AGB was associated with greater weight loss, resolution of metabolic syndrome, and improved quality of life in this subpopulation.\(^{191}\)

![Figure 3-8](image)

Reduction in body weight with AGB and medical management in obese patients

3.4.1.2 SG versus medical management

SG has been compared with medical management in two RCTs, both conducted in the US (Table 3-2). Both trials enrolled patients with type 2 diabetes.

- Weight loss: SG was associated with greater reductions in body weight in both studies (Figure 3-9).\(^{195,196}\)
- Glycemic control: SG was associated with greater proportion of patients achieving an HbA1c target of 6.0% in one study in which this was the primary endpoint, and was associated with greater reductions in HbA1c in both studies (Figure 3-10).\(^{195,196}\)

**Figure 3-9 Reduction in body weight with SG and medical management in patients with type 2 diabetes**

![Graph showing reduction in body weight with SG and medical management.](image)


**Figure 3-10 Reduction in HbA1c with SG and medical management in patients with type 2 diabetes**

![Graph showing reduction in HbA1c with SG and medical management.](image)

3.4.1.3 RYGB versus medical management

RYGB is the most commonly investigated bariatric procedure, with 13 studies comparing the surgery with medical management (Table 3-2). Of these, five were RCTs, two were prospective studies, and six were retrospective studies. The majority of studies were conducted in the US, but studies were also based in Taiwan, Italy and Norway. Study duration ranged from 1 year to 7.1 years. The majority of the studies (eight) were conducted exclusively in patients with type 2 diabetes.

- **Weight loss:** In all studies which reported weight loss (two studies did not report measures of change in body weight), RYGB was associated with increased weight loss, as measured by percentage reduction in body weight, absolute change in body weight, excess weight loss, or change in BMI (Figure 3-11).\(^{195,196,197,198,199,200,201,202,203,204,205,206,207}\) A long-term study has shown that weight loss is maintained over the long-term with RYGB, with 76% of patients maintaining at least 20% weight loss at 6 years, while a 1-year study has shown that weight loss with medical management may not persist.\(^{199,204}\)

- **Development of new onset co-morbidities:** Over 3 years of follow-up, rates of new onset diabetes, hypertension, OSA, gastroesophageal reflux and lipid disorders were lower in patients undergoing RYGB compared to patients receiving medical management.\(^{205}\) However, a study comparing RYGB with nonsurgical weight loss methods found that there was no difference in the resolution of existing complications.\(^{204}\)

- **Mortality:** In a study with mean follow-up of 7.1 years, RYGB was associated with low rates of all mortality (37.6 versus 57.1 deaths per 10,000 patient years), death due to diabetes (0.4 versus 3.4 deaths per 10,000 patient years) and death due to cancer (5.5 versus 13.3 deaths per 10,000 patient years) than medical management.

- **Remission of diabetes:** RYGB was consistently associated with remission of type 2 diabetes in large proportions of patients, while this was very rare in patients receiving medical management (Figure 3-12).\(^{198,199,200,206}\) Duration of follow-up in these studies was up to six years, with patients remaining in remission over this time period, showing the long-term benefit of RYGB.\(^{207}\) Where remission of diabetes was not assessed, RYGB has been shown to be associated with improved beta cell function compared to medical management.\(^{202}\)

- **Glycemic control:** In studies conducted in patients with type 2 diabetes, RYGB was consistently associated with greater improvements in glycemic control (Figure 3-13) and greater proportions of patients achieving HbA1c targets.\(^{195,196,198,200,201,203,206}\)

- **Multi-factorial diabetes treatment targets:** Patients with type 2 diabetes benefit from multi-factorial control, with management of cardiovascular risk factors, such as blood pressure and serum lipids, as well as improving glycemic control. The proportion of patients achieving a composite endpoint of HbA1c<7%, low-density lipoprotein (LDL) cholesterol<100 mg/dL and SBP<130 mmHg, representing good control, has been assessed in two studies, with greater proportions of patients achieving the composite endpoint in the RYGB arm of both studies (49% versus 19% and 38.2% versus 17.4%).\(^{197,201}\)
**Figure 3-11**  Reduction in body mass index with RYGB and medical management

<table>
<thead>
<tr>
<th>Source</th>
<th>Reduction in body mass index (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mingrone et al. 2012</td>
<td>15.54</td>
</tr>
<tr>
<td>Dorman et al. 2012</td>
<td>14.3</td>
</tr>
<tr>
<td>Leslie et al. 2012</td>
<td>15</td>
</tr>
<tr>
<td>Serrot et al. 2011</td>
<td>8.8</td>
</tr>
<tr>
<td>Al Harakeh et al. 2010</td>
<td>0.5</td>
</tr>
</tbody>
</table>


**Figure 3-12**  Remission of type 2 diabetes with RYGB and medical management

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage of patients achieving remission (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mingrone et al. 2012</td>
<td>75</td>
</tr>
<tr>
<td>Adams et al. 2012</td>
<td>62</td>
</tr>
<tr>
<td>Dorman et al. 2012</td>
<td>65</td>
</tr>
<tr>
<td>Mumme et al. 2009</td>
<td>54</td>
</tr>
</tbody>
</table>


**Figure 3-13**  Change in HbA1c in patients with type 2 diabetes with RYGB and medical management

<table>
<thead>
<tr>
<th>Source</th>
<th>Change in HbA1c (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kashyap et al. 2013</td>
<td>-3.1</td>
</tr>
<tr>
<td>Dorman et al. 2012</td>
<td>-1.4</td>
</tr>
<tr>
<td>Leslie et al. 2012</td>
<td>-1.2</td>
</tr>
<tr>
<td>Serrot et al. 2011</td>
<td>-2.1</td>
</tr>
<tr>
<td>Mumme et al. 2009</td>
<td>-1.7</td>
</tr>
</tbody>
</table>

3.4.1.4 BPD versus medical management

Only one study compared BPD with medical management (Table 3-2). This was an RCT carried out over two years in Italy in patients with a history of at least 5 years of diabetes.

- **Weight loss:** BPD was associated with a reduction in BMI of 15.95 kg/m² compared with a reduction of 2.55 kg/m² in the medical management arm.
- **Remission of diabetes:** In the BPD arm, remission of diabetes was achieved by 95% of patients, compared to none in the medical management arm.
- **Glycemic control:** HbA1c was improved in both the BPD and medical management arms, but a greater reduction was observed with BPD.

3.4.1.5 Bariatric surgery (data not presented for separate procedures) versus medical management

A total of twelve studies have compared bariatric surgery with medical management, with data not presented for separate procedures (Table 3-2). Of these, six were retrospective studies, and six were prospective studies. Studies were conducted in the US, Canada, Sweden, South Korea and Brazil, with follow-up of up to 20 years. Only one study was conducted in patients with type 2 diabetes, with the other nine studies in mixed populations or excluding patients with diabetes.

- **Weight loss:** Of the six studies which presented information on weight loss, bariatric surgery was consistently associated with statistically significant improvements compared to medical management.208,209,210,211,212,213 Follow-up of up to 20 years found that these differences were maintained over the long-term (Figure 3-14).209 Six studies did not present change in body weight.214,215,216,217,218,219
- **Cardiovascular events:** Bariatric surgery has been shown to be associated with a reduced incidence of cardiovascular events and reduced cardiovascular mortality.208,209
- **Onset of diabetes:** In analyses of patients without diabetes, studies with 5, 10 and 15 years of follow-up have shown that bariatric surgery is associated with reduced incidence of diabetes compared to medical management.210,213,216,219
- **Remission of diabetes:** Bariatric surgery has consistently been associated with greater rates of resolution of diabetes than medical management.211,212,213
- **Remission of co-morbidities:** Bariatric surgery is associated with increased resolution of hypertension and dyslipidemia compared to medical management.211,213 Patients have also been shown to be less likely to be diagnosed with an obesity-related co-morbid condition, and require fewer diabetes and cardiovascular medications216
- **Onset of complications:** Bariatric surgery has been shown to be associated with reduced risk of new onset complications, including cancer, cardiovascular disease, infectious disease, and respiratory disease over 5 years of follow-up.219
- **Hospital stays:** Bariatric surgery is associated with increased hospital days in the first 6 years following a procedure, but no differences compared to medical management after this period.215
- **Mortality:** The impact of bariatric surgery on mortality is unclear. Over a mean follow-up period of 6.7 years, bariatric surgery has been shown to be associated with reduced crude mortality rates and reduced mortality in a covariate-adjusted Cox regression. However, in a propensity matched analysis the difference was no longer statistically significant.217 In a 5-year analysis, surgery was associated with a reduced relative risk of mortality.219 In a shorter study, surgery was associated with
significantly lower all-cause mortality, but no differences in cardiovascular mortality or non-cardiovascular mortality were observed.\textsuperscript{217}

- Quality of life: Only one study has assessed quality of life in patients receiving bariatric surgery compared to those receiving medical management, with bariatric surgery associated with statistically significant improvements.\textsuperscript{212}

- Pregnancy outcomes: In a study assessing pregnancy outcomes in women with BMI > 40 kg/m\textsuperscript{2}, bariatric surgery was associated with lower rates of hypertensive disorders, premature rupture of membrane, chorioamnionitis, cesarean delivery, instrumental delivery, postpartum hemorrhage, and postpartum infection.\textsuperscript{214} However, induction of labor, postpartum blood transfusions, venous thromboembolisms, and intrauterine fetal growth restriction were more common in the bariatric surgery group. No differences were observed in preterm births, fetal deaths, or reported congenital anomalies.

**Figure 3-14** Change in body weight over 20 years in patients receiving bariatric surgery and medical management

![Change in body weight over 20 years in patients receiving bariatric surgery and medical management](image)

Source: Sjöström et al. 2012.\textsuperscript{209}
Table 3-2  Studies assessing bariatric surgery versus medical management in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
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<tbody>
<tr>
<td><strong>AGB versus medical management</strong></td>
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<tr>
<td>Dixon et al. 2012&lt;sup&gt;190&lt;/sup&gt;</td>
<td>Australia</td>
<td>Patients with BMI 35–55 kg/m&lt;sup&gt;2&lt;/sup&gt; with recently diagnosed obstructive sleep apnea and an apnea-hypopnea index of 20 events per hour or more AGB n=30 Medical management n=30</td>
<td>2 years</td>
<td>Weight loss: AGB −27.8 kg versus medical management −5.1 kg (p&lt;0.001) OSA: AGB −25.5 events per hour versus medical management −14.0 events per hour (p=0.18)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>O’Brien et al. 2010&lt;sup&gt;191&lt;/sup&gt;</td>
<td>Australia</td>
<td>Patients aged 14–18 years, with BMI&gt;35 kg/m&lt;sup&gt;2&lt;/sup&gt; AGB n=25 Medical management n=25</td>
<td>2 years</td>
<td>≥50% excess weight loss: 84% with AGB versus 12% of lifestyle patients (p&lt;0.001) Mean weight loss: 34.6 kg for AGB versus 3 kg for medical management (p&lt;0.001) Metabolic syndrome resolution: 9 (of 9) AGB patients and 6 (of 10) lifestyle patients (p=0.13) Quality of life: AGB associated with improvements over medical management (p values not presented)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Dixon et al. 2008&lt;sup&gt;192&lt;/sup&gt;</td>
<td>Australia</td>
<td>Patients with BMI 30–40 kg/m&lt;sup&gt;2&lt;/sup&gt; with recently diagnosed (within 2 years) diabetes AGB n=30 Medical management n=30</td>
<td>2 years</td>
<td>Remission of type 2 diabetes: 73% for AGB, 13% for medical management (p&lt;0.001) Weight loss: 20.7% for AGB versus 1.7% for medical management (p&lt;0.001)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Dixon et al. 2007&lt;sup&gt;193&lt;/sup&gt;</td>
<td>Australia</td>
<td>Patients aged 20–50 years with BMI 30–35 kg/m&lt;sup&gt;2&lt;/sup&gt;, with identifiable problems relating to obesity AGB n=40 Medical management n=40</td>
<td>2 years</td>
<td>Weight loss: 20.3 kg for AGB, 5.9 kg for medical management (p&lt;0.001) Fat free mass: −2.9 kg with AGB, −1.3 kg medical management (p=0.002)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>O’Brien et al. 2006&lt;sup&gt;194&lt;/sup&gt;</td>
<td>Australia</td>
<td>Patients with BMI 30–35 kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td>2 years</td>
<td>Weight loss: 21.6% for AGB, 5.5% for medical management (p&lt;0.001) Metabolic syndrome resolution: 8 (of 15) in the AGB group and 1 (of 15) in the medical management group (p&lt;0.002) Quality of life: significantly greater improvement in AGB versus medical management (p&lt;0.05)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td><strong>SG versus medical management</strong></td>
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<tr>
<td>Kashyap et al. 2013&lt;sup&gt;195&lt;/sup&gt;</td>
<td>US</td>
<td>Patients with uncontrolled type 2 diabetes (mean HbA1c 9.7%) and moderate obesity (mean BMI 36 mg/m&lt;sup&gt;2&lt;/sup&gt;) SG n=19 Medical management n=17</td>
<td>2 years</td>
<td>Weight loss: 22.3 kg for SG, 0.5 kg for medical management (p=0.001) HbA1c reduction: 2.5% with SG versus 1.1% with medical management (p=0.06)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
<td>Study design</td>
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</tbody>
</table>
| Schauer et al. 2012<sup>196</sup> | US | Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m²  
SG n=49  
Medical management n=41 | 1 year | Proportion achieving HbA1c ≤6.0%: 37% for SG, 12% for medical management (p=0.008)  
Reduction in HbA1c: −2.9% for SG, −1.4% for medical management (p<0.001)  
Reduction in body weight: 25.1 kg for SG, −5.4 kg for medical management (p<0.001) | Randomized controlled trial |
| Schauer et al. 2012 | US | Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m²  
SG n=50  
Medical management n=41 | 1 year | Proportion achieving HbA1c ≤6.0%: 42% for RYGB, 12% for medical management (p=0.002)  
Reduction in HbA1c: −2.9% for RYGB, −1.4% for medical management (p<0.001)  
Reduction in body weight: −29.4 kg for RYGB, −5.4 kg for medical management (p<0.001) | Randomized controlled trial |
| Ikramuddin et al. 2013<sup>197</sup> | US and Taiwan | Patients with type 2 diabetes with HbA1c≥8.0% and BMI 30–40 kg/m²  
RYGB n=60  
Medical management n=60 | 1 year | HbA1c<7%, LDL<100 mg/dL and SBP<130 mmHg (composite endpoint): achieved by 49% of RYGB group, 19% of medical management group (p<0.05)  
Reduction in body weight: 26.1% for RYGB, 7.9% for medical management arm (p<0.05) | Randomized controlled trial |
| Kashyap et al. 2013<sup>198</sup> | US | Patients with uncontrolled type 2 diabetes (mean HbA1c 9.7%) and moderate obesity (mean BMI 36 mg/m²)  
RYGB n=18  
Medical management n=17 | 2 years | Weight loss: −25.4 kg for RYGB, −0.5 kg for medical management (p<0.001)  
Change in HbA1c: -3.1% with RYGB versus −1.1% with medical management (p<0.001) | Randomized controlled trial |
| Mingrone et al. 2012<sup>199</sup> | Italy | Patients aged 30–60 years with BMI>35 kg/m², a history of at least 5 years of diabetes, and an HbA1c>7.0%  
RYGB n=20  
Medical management n=20 | 2 years | Diabetes remission: 75% for RYGB, 0 for medical management (p<0.001)  
Change in HbA1c: reduced in all arms, but greater reduction in the RYGB arm (p=0.003)  
Reduction in BMI: 15.54 kg/m² with RYGB versus 2.55 kg/m² with medical management (p<0.001) | Randomized controlled trial |
| Schauer et al. 2012 | US | Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m²  
RYGB n=418  
Control group 1 n=417  
Control group 2 n=321 | 6 years | Weight loss: 27.7% of bodyweight for RYGB versus 0.2% gain for control group 1 and 0% in control group 2 (p<0.05 versus both control groups)  
Maintenance of weight loss: 94% and 76% of RYGB group maintained at least 20% weight loss 2 and 6 years after surgery, respectively (p value not presented)  
Remission of diabetes at 6 years: 62% for RYGB versus 8% in control group 1, and 6% in control group 2 (p<0.001) | Prospective controlled study with long-term follow-up |
<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorman et al. 2012</td>
<td>US</td>
<td>Patients with type 2 diabetes with BMI $&gt;$ 35 kg/m$^2$ RYGB n=86 Medical management n=29</td>
<td>1 year</td>
<td>Change in BMI: mean BMI was 14.3 kg/m$^2$ lower in the RYGB group ($p&lt;0.05$) Reduction in body weight: 37.4% greater in the RYGB group ($p&lt;0.05$) Change in HbA1c: 1.4% lower in the RYGB group ($p&lt;0.05$) Resolution of diabetes: 65% for RYGB versus 3.4% for medical management ($p&lt;0.001$)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Leslie et al. 2012</td>
<td>US</td>
<td>Patients aged 18–67 with type 2 diabetes with BMI $\geq$ 35 kg/m$^2$ RYGB n=152 Routine medical management n=115</td>
<td>2 years</td>
<td>Change in BMI: BMI decreased from 47.4 kg/m$^2$ to 32.4 kg/m$^2$ in the RYGB group, versus no significant change for medical management group ($p&lt;0.001$) Change in HbA1c: HbA1c fell from 7.6% to 6.4% in the RYGB group, versus no significant change in the medical management group ($p&lt;0.01$) Composite endpoint of HbA1c $&lt;$ 7%, LDL $&lt;$ 100 mg/dL, SBP $&lt;$ 130 mmHg: 38.2% of patients in the RYGB group versus 17.4% in the medical management group ($p&lt;0.01$)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Hofso et al. 2011</td>
<td>Norway</td>
<td>Morbidly obese patients without known diabetes RYGB n=64 Intensive lifestyle intervention n=55</td>
<td>1 year</td>
<td>Reduction in body weight: 30% for RYGB versus 9% for intensive lifestyle intervention ($p&lt;0.001$) Measures of beta cell function (disposition index and proinsulin to insulin ratio): improved to a greater extent in the RYGB group than in the intensive lifestyle intervention group (both $p&lt;0.05$)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Serrot et al. 2011</td>
<td>US</td>
<td>Patients with type 2 diabetes with BMI $&lt;$ 35 kg/m$^2$ RYGB n=17 Nonsurgical control n=17</td>
<td>1 year</td>
<td>Decrease in BMI: BMI decreased from 34.6 kg/m$^2$ to 25.8 kg/m$^2$ in the RYGB group and did not change in the nonsurgical control group ($p&lt;0.001$) Change in HbA1c: HbA1c decreased from 8.2% to 6.1% in the RYGB group, with no change observed in the nonsurgical control group ($p&lt;0.001$) At 1 year of follow-up, patients in the RYGB group received fewer medications than in the nonsurgical control group ($p&lt;0.001$)</td>
<td>Retrospective cohort with long term follow-up</td>
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<tr>
<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
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</table>
| Martins et al. 2011<sup>204</sup> | Norway        | Patients aged 18–60 years with a BMI>40 kg/m<sup>2</sup> or BMI<35 kg/m<sup>2</sup> and co-morbidities  
RYGB n=55  
Weight loss camp n=30  
Residential intermittent program n=64  
Hospital outpatient program n=57 | 1 year          | RYGB was associated with significantly greater reduction in body weight versus all comparator arms (p<0.05 versus all comparators)  
Maintenance of weight loss: The RYGB showed sustained weight loss, whilst other interventions were associated with initial weight loss that was not maintained (p<0.05)  
Resolution of co-morbidities: no difference reported between the treatment groups (p value not presented) | Prospective controlled study with long-term follow-up |
| Al Harakeh et al. 2010<sup>205</sup> | US            | Patients evaluated for RYGB who underwent or were denied surgery due to an insurance-related reason  
RYGB n=587  
Denied surgery n=189 | 3 years         | Decrease in BMI: Mean BMI fell from 48.5 kg/m<sup>2</sup> (baseline) to 30.5 kg/m<sup>2</sup> at 2 years for RYGB and from 47.3 kg/m<sup>2</sup> to 46.8 kg/m<sup>2</sup> in the denied surgery group (p value for difference between arms not presented)  
Incidence of new onset complications: greater incidence of new-onset diabetes, hypertension, obstructive sleep apnea, gastroesophageal reflux disease, and lipid disorders were observed in the denied group versus the RYGB group (all p<0.001) | Retrospective cohort with long term follow-up |
| Mumme et al. 2009<sup>206</sup>    | US            | Patients aged 18–67 with type 2 diabetes with BMI>35 kg/m<sup>2</sup>  
RYGB n=51  
Conventional treatment n=51 | 3 years         | Change in HbA1c (at 3 years): decrease from 7.8% to 6.1% for RYGB group versus an increase from 7.1% to 7.8% for conventional treatment (p=0.01)  
Remission of diabetes (at 1 year): 59% in the RYGB group versus 5% in the conventional treatment group (p value not presented)  
Remission of diabetes (at 3 years): 54% in the RYGB group and 3% in the conventional treatment group (p value not presented) | Retrospective cohort with long term follow-up |
| Adams et al. 2007<sup>207</sup>   | US            | Patients undergoing RYGB and patients with BMI≥35 kg/m<sup>2</sup> applying for a driver’s license or identification card  
RYGB n=9,949  
Control group n=9,628 | Mean 7.1 years | Deaths per 10,000 patient years: 37.6 for surgery patients versus 57.1 in the control group (p<0.001)  
Deaths due to diabetes: 0.4 versus 3.4 per 10,000 patient years for bariatric surgery group versus control group (p=0.005) (92% reduction)  
Deaths due to cancer: 5.5 versus 13.3 per 10,000 patient years for bariatric surgery versus control group (p<0.001) (60% reduction)  
Deaths not due to disease: 11.4 versus 6.1 per 10,000 patient years for bariatric surgery versus control group (p=0.04) | Retrospective cohort with long term follow-up |
<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
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</thead>
<tbody>
<tr>
<td><strong>BPD versus medical management</strong></td>
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<tr>
<td>Mingrone et al. 2012</td>
<td>Italy</td>
<td>Patients aged 30–60 years with BMI&gt;35 kg/m², a history of at least 5 years of diabetes, and an HbA1c&gt;7.0%</td>
<td>2 years</td>
<td>Diabetes remission: 95% for BPD group, versus 0 for medical management (p&lt;0.001)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BPD n=20 Medical management n=20</td>
<td></td>
<td>HbA1c: reduced in all treatment arms, but greater reductions in the BPD arm (p&lt;0.001)</td>
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<td>Reduction in BMI: 15.95 kg/m² with BPD versus 2.55 kg/m² with medical management (p&lt;0.001)</td>
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<tr>
<td><strong>Bariatric surgery (data not presented for separate procedures) versus medical management</strong></td>
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<tr>
<td>Abenhaim et al. 2016</td>
<td>US</td>
<td>Women giving birth who had undergone bariatric surgery versus women with BMI&gt;40 kg/m²</td>
<td>-</td>
<td>Women with bariatric surgery had lower rates of hypertensive disorders, premature rupture of membrane, chorioamnionitis, cesarean delivery, instrumental delivery, postpartum hemorrhage, and postpartum infection (p&lt;0.001)</td>
<td>Retrospective cohort study</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgery n=9,587 Controls n=221,580</td>
<td></td>
<td>Induction of labor, postpartum blood transfusions, venous thromboembolisms, and intrauterine fetal growth restriction were more common in the bariatric surgery group (p&lt;0.001)</td>
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<td>No differences observed in preterm births, fetal deaths, or reported congenital anomalies</td>
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<tr>
<td>Romeo et al. 2012</td>
<td>Sweden</td>
<td>Patients with type 2 diabetes aged 37–60 years with BMI≥34 kg/m² for men and BMI≥38 kg/m² for women</td>
<td>20 years</td>
<td>Body weight, blood glucose, serum triglycerides, and systolic and diastolic blood pressure (2 years): bariatric surgery was associated with significant decreases versus medical management (p&lt;0.001)</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgery n=345 Medical management n=262</td>
<td></td>
<td>HDL cholesterol (2 years): bariatric surgery was associated with significant decreases versus medical management versus medical management (p&lt;0.001)</td>
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<td>Significant reduction in incidence of all cardiovascular events (adjusted HR 0.53, p=0.002) and myocardial infarction (adjusted HR 0.56, p=0.025) with bariatric surgery</td>
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<td>No significant difference in incidence of stroke (adjusted HR 0.73, p=0.29)</td>
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</tr>
<tr>
<td>Neovius et al. 2012</td>
<td>Sweden</td>
<td>Patients aged 37–60 years with BMI≥34 kg/m² for men and BMI≥38 kg/m² for women</td>
<td>20 years</td>
<td>Hospital days (20 years): mean cumulative hospital stay was 54 hospital days for bariatric surgery versus 40 hospital days for the medical management (p=0.03)</td>
<td>Prospective controlled study with long-term follow-up</td>
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<tr>
<td></td>
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<td>Surgery n=2,010 Medical management n=2,037</td>
<td></td>
<td>During years 2–6, surgery patients had an accumulated annual mean of 1.7 hospital days versus 1.2 days among control patients (p=0.001)</td>
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<td>From year 7 to 20, both groups had a mean annual 1.8 hospital days (p=0.95)</td>
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<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
<td>Study design</td>
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<tr>
<td>Sjöström et al. 2012</td>
<td>Sweden</td>
<td>Patients aged 37–60 years with BMI≥34 kg/m² for men and BMI≥38 kg/m² for women</td>
<td>20 years</td>
<td>Mean change in body weight at 2, 10, 15, and 20 years: −23%, −17%, −16%, and −18% in the surgery group and 0%, 1%, −1%, and −1% in the control group (p&lt;0.001 at all time points) Cardiovascular deaths: significant reduction in number of events with bariatric surgery (28 events among 2,010 patients in the surgery group vs 49 events among 2,037 patients in the control group, adjusted HR 0.47, p=0.02)</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
<tr>
<td>Carlsson et al. 2012</td>
<td>Sweden</td>
<td>Patients aged 37–60 years with BMI≥34 kg/m² for men and BMI≥38 kg/m² for women, without diabetes</td>
<td>15 years</td>
<td>Mean weight loss was 31 kg at 1 year in the bariatric surgery group versus 3 kg in the medical management group (p&lt;0.001) Maintenance of weight loss: partial weight regain observed in the bariatric surgery group, but weight loss remained stable at 20 kg from 10 to 15 years, versus no change from baseline at these time periods in control group (p&lt;0.001) Type 2 diabetes incidence: 28.4 cases per 1,000 person-years for surgery group versus 6.8 cases per 1000 person-years for medical management, adjusted HR 0.17, p&lt;0.001</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
<tr>
<td>Bolen et al. 2012</td>
<td>US</td>
<td>Patients with BMI&gt;35 kg/m²</td>
<td>5 years</td>
<td>Outcomes: bariatric surgery patients more likely to have a serious (OR 1.9, p&lt;0.05) or less serious (OR 2.5, p&lt;0.05) clinical outcome during the first 365 days following surgery; this risk remained elevated until year 4 post-surgery Co-morbidities: bariatric surgery group had a 55% lower likelihood of having an obesity-related co-morbidity diagnosis 1 year post-surgery (OR 0.4, p&lt;0.05) versus controls, which remained lower throughout 5 years of follow-up</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Johnson et al. 2012</td>
<td>US</td>
<td>Patients aged 40–79 years, with a diagnosis code of morbid obesity, a primary surgical procedure of interest, and a cardiovascular event history</td>
<td>Surgery mean follow-up of 28.1 months Controls mean follow-up of 35.2 months</td>
<td>Mortality: surgery associated with significantly lower all-cause mortality (HR 0.60, 95% CI 0.36–0.99) Cardiovascular mortality: no significant difference in deaths due to cardiovascular (HR 0.63, 95% CI, 0.29–1.38) and non-cardiovascular causes (HR 0.58, 95% CI, 0.30–1.13)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
<td>Study design</td>
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| Heo et al. 2012\(^{211}\) | South Korea | Patients aged ≥17 years with a BMI ≥30 kg/m\(^2\) surgery n=261 medical management n=224 | 18 months         | Weight loss: mean weight loss significantly greater for bariatric surgery than for medical management (~22.6% versus ~6.7%, *p*<0.05)  
Co-morbidities: percentage of patients whose diabetes (75% versus 10%), hypertension (47% versus 20%) or dyslipidemia (84% versus 24%) resolved was higher in surgery patients than in controls  
(all *p*<0.001)                                                                                       | Retrospective cohort with long term follow-up                                                   |
| Maciejewski et al. 2011\(^{218}\) | US          | Veterans undergoing bariatric surgery and nonsurgical controls surgery n=850 nonsurgical unmatched controls n=41,244 | Mean follow-up 6.7 years | Mortality: crude mortality rates at 1, 2 and 6 years were 1.5% (p=0.17), 2.2% (p<0.001), and 6.8% (p<0.001) for bariatric surgery group versus 2.2%, 4.6%, and 15.2% for nonsurgical controls  
Mortality: in Cox regressions bariatric surgery was associated with reduced mortality (unadjusted HR 0.64, *p*<0.001; adjusted HR 0.80, *p*=0.45)  
Mortality: in propensity-matched patients, bariatric surgery not significantly associated with reduced mortality in unadjusted and time-adjusted Cox regressions (p values not presented) | Retrospective cohort with long term follow-up                                                   |
| Pimenta et al. 2010\(^{212}\) | Brazil      | Patients aged 18–55 years with BMI ≥40 kg/m\(^2\) with at least 2 years of ongoing clinical or surgical treatment surgery n=76 medical management n=89 | Mean follow-up 38 months | Weight loss: surgery associated with significantly greater weight loss (from 33.6 kg to 81.9 kg versus 117.3 kg to 110.9 kg, *p*<0.001) and reduction in BMI (from 49.4 kg/m\(^2\) to 30.2 kg/m\(^2\) versus 45.3 kg/m\(^2\) to 42.6 kg/m\(^2\), *p*<0.001)  
Resolution of diabetes: in the surgery group 12 (of 12) cases, versus 5 (of 10) in medical management group (*p*<0.001)  
Quality of life: significantly better in the surgery arm than the medical management arm (*p*<0.001) | Retrospective cohort with long term follow-up                                                   |
| Sjöström et al. 2004\(^{213}\) | Sweden      | Patients aged 37–60 years with BMI ≥34 kg/m\(^2\) for men and BMI ≥38 kg/m\(^2\) for women surgery n=851 medical management n=852 | 10 years          | Weight change: for surgery group - 23.4% and -16.1% at Years 2 and 10, respectively, versus +0.1% and +1.6%, respectively, in the control group (both *p*<0.001)  
Co-morbidities: 2- and 10-year remission rates for diabetes, hypertriglyceridemia and hypertension higher after surgery versus control group (all *p*<0.05 at both time points)  
Co-morbidities: surgery group had lower 2- and 10-year incidence rates of diabetes, hypertriglyceridemia, and hyperuricemia versus medical management group (all *p*<0.05 at both time points) | Prospective controlled study with long-term follow-up                                           |
<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christou et al. 2004²¹⁹</td>
<td>Canada</td>
<td>Patients undergoing bariatric surgery for morbid obesity</td>
<td>5 years</td>
<td>Mortality: 5-year mortality as reduced with surgery compared with medical management (relative risk or RR 0.11, p=0.001) New onset co-morbidities: surgery was associated with lower incidence of cancer (RR 0.24, p=0.001), cardiovascular disease (0.18, p=0.001), endocrine disease (0.35, p=0.001), genitourinary disease (0.77, p=0.027), infectious disease (0.23, p=0.001), musculoskeletal disease (0.41, p=0.001), nervous system disorders (0.61, p=0.010), psychiatric and mental disorders (0.53, p=0.001), respiratory disease (0.24, p=0.001), skin disease (0.69, p=0.027)</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
</tbody>
</table>


### 3.4.2 Comparison of alternative bariatric procedures

As well as comparing bariatric surgery with medical management, studies have been conducted in which two (or more) bariatric procedures are compared. Data are available from RCTs and non-randomized studies.

#### 3.4.2.1 AGB versus SG

A total of seven publications have compared AGB with SG. No RCTs have been conducted, with four prospective studies and three retrospective studies identified. Studies were based in the US, Italy and Japan. The majority of studies were relatively small, but one study enrolled over 13,000 participants across the AGB and SG study arms.

- Weight loss: Change in body weight was measured in a variety of ways across the studies, including percentage change in BMI, absolute change in BMI, percentage excess weight loss, and absolute change in body weight (Figure 3-15).¹⁸⁹,²²⁰,²²¹,²²²,²²³ SG was consistently associated with greater weight loss. However, only one study assessed statistical significance of differences between the procedures (other studies assessed statistical significance of change from baseline in each arm). In this study, no statistically significant difference was identified at 3 months, but weight loss was significantly greater with SG at 6 and 12 months (Figure 3-16).²²² Two publications either did not report change in body weight at all or did not report it for all patients undergoing bariatric surgery.²²⁴,²²⁵

- Resolution of diabetes: Four studies assessed the effect of AGB and SG on resolution of diabetes, with rates greater in the SG arm in all studies (Figure 3-17).¹⁸⁹,²²¹,²²²,²²₅ However, only two studies assessed statistical significance, with one finding no significant difference and one finding a statistically significant improvement in the SG arm. One study also assessed time to discontinuation of diabetes medications, with this occurring sooner after surgery in the SG arm, although statistical significance was not assessed.²²₅
• Remission of co-morbidities: Studies have shown that both AGB and SG are associated with remission of co-morbidities, but differences in rates of resolution between the two procedures are unclear. Of the four studies which assessed resolution of hypertension, SG was associated with a statistically significant improvement over AGB in three studies, with statistical significance not assessed in one study.\textsuperscript{189,221,222,225} Studies have shown a significantly greater resolution of hyperlipidemia with SG, while other studies have shown no difference between AGB and SG.\textsuperscript{221,222,225} In one study, remission of gastroesophageal reflux disease was greater with AGB, but another study found no difference between AGB and SG.\textsuperscript{221,222} Similarly, one study found that SG was associated with a significantly greater reduction in OSA, but another study found no difference between the procedures.\textsuperscript{221,222}

• Quality of life: Only one study assessed the impact of AGB and SG on quality of life.\textsuperscript{220} Quality of life increased in both arms following surgery, but a greater increase was observed in the SG arm (statistical significance not assessed).

• Length of hospital stay: In the single study that assessed length of hospital stay, median length of stay was shorter with AGB than SG (significance not assessed).\textsuperscript{224}

**Figure 3-15** Reduction in BMI following AGB and SG

<table>
<thead>
<tr>
<th>Reduction in body mass index (kg/m(^2))</th>
<th>Inge et al. 2016</th>
<th>Hutter et al. 2011</th>
<th>Strain et al. 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGB</td>
<td>3.8</td>
<td>7.05</td>
<td>7.5</td>
</tr>
<tr>
<td>SG</td>
<td>13</td>
<td>11.87</td>
<td>18.2</td>
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</tbody>
</table>


**Figure 3-16** Change in body weight over 12 months with AGB and SG

<table>
<thead>
<tr>
<th>Percentage change in body weight (%)</th>
<th>Month of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGB</td>
<td>20.6</td>
</tr>
<tr>
<td>SG</td>
<td>18.5</td>
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<td>12</td>
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</table>

Source: Omana et al. 2010.\textsuperscript{222} AGB: Adjustable gastric band, SG: Sleeve gastrectomy.
Figure 3-17  Resolution of diabetes with AGB and SG in patients with type 2 diabetes


Table 3-3  Studies assessing AGB versus SG in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inge et al. 2016</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery</td>
<td>3 years</td>
<td>Body weight: reduced by 10.4 kg and BMI by 3.8 kg/m² in the AGB arm, versus 38 kg and 13 kg/m² in the SG arm (p values not presented) Quality of life: increased by 11.7% in the AGB arm and 27.8% in the SG arm (p values not presented)</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
<tr>
<td>Inge et al. 2014</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery</td>
<td>30 days</td>
<td>Major complication rate: 7.1% for AGB versus 4.5% for SG (p values not presented) Minor complication rate: 7.1% for AGB and 11.9% for SG (p values not presented) Median length of hospital stay: 1 day for AGB and 3 days for SG (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Hutter et al. 2011</td>
<td>US</td>
<td>Patients undergoing bariatric surgery</td>
<td>1 year</td>
<td>Reduction in BMI: for AGB versus SG change was 2.45 versus 3.36 kg/m² at 30 days, 5.02 versus 8.75 kg/m² at 6 months, 7.05 versus 11.87 kg/m² at 1 year (p values not presented) Resolution of co-morbidities: SG associated with greater resolution of hypertension (68% versus 44%, p&lt;0.05) and obstructive sleep apnea (62% versus 50%, p&lt;0.05) Resolution of co-morbidities: AGB associated with greater resolution of gastroesophageal reflux disease (64% versus 50%, p&lt;0.05) Rates of resolution of diabetes and hyperlipidemia were not significantly different</td>
<td>Prospective controlled study</td>
</tr>
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</table>
### Study Details

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
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</table>
| Ohta et al. 2011<sup>189</sup> | Japan   | Survey of 64 member institutes of the Japan Research Society for Endoscopic and Laparoscopic Treatments of Obesity (JELTO) AGB n=55 SG n=102 | AGB 4 years SG 2 years | Morbidity rate: 10.9% with AGB and 7.8% with SG (p values not presented)  
Mean weight loss: 23 kg, 30 kg, 29 kg and 30 kg at Years 1, 2, 3 and 4, respectively with AGB, versus 41 kg and 32 kg at Year 1 and 2 with SG (p values not presented)  
Diabetes remission rate: 63% for AGB, and 91% for SG (p values not presented)  
Hypertension resolution rate: 43% for AGB and 62% for SG (p values not presented) | Retrospective survey of clinicians |
| Omana et al. 2010<sup>222</sup> | US      | Patients undergoing bariatric surgery AGB n=74 SG n=49                       | Mean follow-up AGB 17 months Mean follow-up SG 15 months | Weight loss: for AGB versus SG, excess weight loss was 18.5 % versus 20.6% at 3 months (p>0.05), 25.2% versus 39.5% at 6 months (p<0.05) and 40.3% versus 50.6% beyond 12 months (p<0.05)  
Co-morbidities: resolution of diabetes (100% versus 46%, p<0.01) hypertension (78% versus 48%, p=0.03), hyperlipidemia (87% versus 50%, p=0.02) were all greater with SG than AGB  
Resolution of co-morbidities: no significant difference between arms for degenerative joint disease, gastroesophageal reflux disease, obstructive sleep apnea and asthma (p>0.05 for all) | Retrospective cohort with long term follow-up |
| Abbatini et al. 2010<sup>225</sup> | Italy   | Morbidly obese patients with diabetes AGB n=24 SG n=20                       | 3 years           | Diabetes resolution rate: 60.8% for AGB and 80.9% for SG (p values not presented)  
Mean time to discontinuation of diabetes therapy: 12.6 months and 3.3 months with AGB and SG, respectively (p values not presented)  
Resolution co-morbidities: resolution of hypertension (66.6 versus 44.0%), hypertriglyceridemia (66.6 versus 40.0%) and hypercholesteremia (66.6% versus 14.2%) were all greater with SG than AGB (p values not presented) | Retrospective cohort with long term follow-up |
| Strain et al. 2009<sup>223</sup> | US      | Patients with BMI>40 kg/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> and at least one co-morbidity AGB n=41 SG n=30 | AGB mean follow-up 21.4 months SG mean follow-up 16.7 months | Reduction in BMI (adjusted for baseline BMI): 7.5 kg/m<sup>2</sup> in the AGB arm and 18.2 kg/m<sup>2</sup> in the SG arm (p values not presented)  
Percentage excess weight loss: 38% with AGB and 49% with SG (p values not presented) | Prospective controlled study |


### 3.4.2.2 AGB versus RYGB

A total of 14 studies compared AGB with RYGB. These comprised one RCT, eight prospective studies and five retrospective studies. The majority of studies were conducted in the US, but studies also took place in Switzerland, Japan, the UK, Italy, and Taiwan. Duration of follow-up was up to 6 years.
- Weight loss: A total of five studies found that weight loss, as measured by percentage excess weight loss (Figure 3-18) or change in BMI, was significantly greater with RYGB than AGB.\textsuperscript{200,226,227,228,229} Differences were apparent from 1 month after surgery, and persisted for over 4 years. However, one study found no statistically significant difference between percentage weight loss associated with AGB and RYGB at either 1 year or 2 years.\textsuperscript{230} Statistical significance of differences in weight loss was not assessed in four of the publications, but RYGB was associated with numerically greater weight loss in all of these studies.\textsuperscript{189,220,223,231} A further four of the identified studies did not present data around change in body weight.\textsuperscript{224,225,232,233}

- Complication rates: Data around complication rates was mixed. One study found that complications rates were significantly lower with AGB than RYGB, with this supported by two studies with numerically lower complication rates but no assessment of statistical significance.\textsuperscript{224,228,232} However, one study found no significant difference in complication rates between the procedures.\textsuperscript{227} In a study assessing complications over 6 years, AGB was associated with a significantly increased rate, resulting in an increased frequency of re-operation.\textsuperscript{226}

- Resolution of diabetes: RYGB was consistently associated with greater resolution of type 2 diabetes (Figure 3-19), with a statistically significant difference in three studies.\textsuperscript{200,227,230} In an additional three studies, RYGB was associated with increased rates of resolution, but no assessment of statistical significance was made.\textsuperscript{189,225,229} Furthermore, RYGB was also associated with a reduced time to remission.\textsuperscript{225,230}

- Glycemic control: Only two studies compared glycemic control in patients with type 2 diabetes. Improvements in HbA1c with RYGB were greater than with AGB, but only one study assessed statistical significance.\textsuperscript{200,230}

- Remission of co-morbidities: Only one study assessed the statistical significance of differences in remission of co-morbidities, with RYGB associated with greater remission of dyslipidemia, but no difference in resolution of hypertension.\textsuperscript{229} A further two studies found that RYGB was associated with greater resolution of hypertension, hypertriglyceridemia, and hypercholesteremia, but statistical significance was not assessed (Figure 3-20).\textsuperscript{189,225}

- Operation time: In the three studies which compared operation time with the two procedures, AGB was associated with a significantly reduction compared to RYGB (Figure 3-21).\textsuperscript{228,229,231}

- Blood loss: Two studies assessed blood loss during surgery, with AGB associated with significantly lower blood loss in both.\textsuperscript{228,229}

- Morbidity: AGB has been shown to be associated with significantly lower post-operative morbidity than RYGB in one study.\textsuperscript{226} In an additional study, morbidity was lower following AGB than RYGB, but statistical significance was not assessed.\textsuperscript{189}

- Quality of life: Only one study assessed the impact of AGB and RYGB on quality of life.\textsuperscript{220} Quality of life increased in both arms following surgery, but a greater increase was observed in the RYGB arm (statistical significance not assessed).

- Length of hospital stay: In the single study that assessed length of hospital stay, median length of stay was shorter with AGB than RYGB (statistically significance not assessed).\textsuperscript{224}
Figure 3-18  Reducing excess body weight with AGB and RYGB

![Reduction in excess body weight with AGB and RYGB](image)


Figure 3-19  Resolution of diabetes with AGB and RYGB in patients with type 2 diabetes

![Resolution of diabetes with AGB and RYGB](image)


Figure 3-20  Resolution of hypertension with AGB and RYGB

![Resolution of hypertension with AGB and RYGB](image)

Figure 3-21  Operation time with AGB and RYGB

![Bar chart showing operation times for AGB and RYGB across different studies.]


Table 3-4  Studies assessing AGB versus RYGB in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inge et al. 2016&lt;sup&gt;220&lt;/sup&gt;</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery AGB n=14 RYGB n=161</td>
<td>3 years</td>
<td>Weight and BMI reduction: 10.4 kg and 3.8 kg/m&lt;sup&gt;2&lt;/sup&gt;, respectively, in the AGB arm, versus 42 kg and 15 kg/m&lt;sup&gt;2&lt;/sup&gt; in the RYGB arm (p values not presented) Quality of life: increased by 11.7% in the AGB arm and 50.5% in the RYGB arm (p values not presented)</td>
<td>Prospective controlled study with long-term follow-up</td>
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<tr>
<td>Inge et al. 2014&lt;sup&gt;224&lt;/sup&gt;</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery AGB n=14 RYGB n=161</td>
<td>30 days</td>
<td>Major complication rate: 7.1% for AGB versus 9.3% for RYGB (p values not presented) Rates for minor complications were 7.1% for AGB and 16.8% for RYGB (p values not presented) Median length of hospital stay: 1 day for AGB and 3 days for RYGB (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Greenstein et al. 2012&lt;sup&gt;232&lt;/sup&gt;</td>
<td>US</td>
<td>Patients aged over 18 years undergoing bariatric surgery AGB n=1,608 RYGB n=3,770</td>
<td>30 days</td>
<td>Rates of any adverse intraoperative event: 3.0% with AGB and 5.5% with RYGB (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Romy et al. 2012&lt;sup&gt;226&lt;/sup&gt;</td>
<td>Switzerland</td>
<td>Patients with BMI&gt;40 kg/m&lt;sup&gt;2&lt;/sup&gt; or BMI&gt;35 kg/m&lt;sup&gt;2&lt;/sup&gt; and at least one severe co-morbidity, after failed conservative therapy AGB n=221 RYGB n=221</td>
<td>6 years</td>
<td>Early morbidity rate: 17.2% for RYGB versus 5.4% for AGB (p&lt;0.001) Maximal percentage excess weight loss: 78.5% in the RYGB group, 64.8% in the AGB group (p&lt;0.001) The 6-year complication rate: higher after AGB (41.6% vs 19%, p&lt;0.001) resulting in more reoperations (26.7% vs 12.7%, p&lt;0.001)</td>
<td>Retrospective study with long term follow-up</td>
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<tr>
<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
<td>Study design</td>
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<tr>
<td>Dorman et al. 2012&lt;sup&gt;200&lt;/sup&gt;</td>
<td>US</td>
<td>Patients with type 2 diabetes with BMI&gt;35 kg/m² AGB n=30 RYGB n=30</td>
<td>1 year</td>
<td>Mean BMI: at 1 year, mean BMI was 8.9 kg/m² lower in the RYGB group (p&lt;0.05) HbA1c: 0.9% lower in the RYGB group (p=0.009) Diabetes resolution: 60% in the RYGB arm versus 20% in LAGB arm (p=0.004)</td>
<td>Retrospective cohort with long term follow-up</td>
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<tr>
<td>Campos et al. 2011&lt;sup&gt;227&lt;/sup&gt;</td>
<td>US</td>
<td>Patients with BMI&gt;40 kg/m² or 35–40 kg/m² and at least one high risk co-morbidity for 5 years, and 6 months of supervised medical therapy for weight loss AGB n=100 RYGB n=100</td>
<td>1 year</td>
<td>Mean excess weight loss: 36% with AGB and 64% with RYGB (p&gt;0.001) Resolution/improvement of diabetes: 76% in the RYGB arm versus 50% in the AGB arm (p=0.04) Overall complications rate: 12% in the AGB arm versus 15% in the RYGB arm (p=0.83)</td>
<td>Retrospective cohort with long term follow-up</td>
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<tr>
<td>Ohta et al. 2011&lt;sup&gt;139&lt;/sup&gt;</td>
<td>Japan</td>
<td>Survey of 64 member institutes of the Japan Research Society for Endoscopic and Laparoscopic Treatments of Obesity (JELTO) AGB n=55 RYGB n=147</td>
<td>AGB 4 years RYGB 5 years</td>
<td>Morbidity rate: 10.9% with AGB and 12.2% with RYGB (p values not presented) Mean weight loss: 23 kg, 30 kg, 29 kg and 30 kg at years 1, 2, 3 and 4, respectively with AGB, versus 46 kg, 44 kg, 41 kg, 36 kg and 42 kg at years 1, 2, 3, 4 and 5, respectively, with LRYGB (p values not presented) Diabetes remission rate: 63% for AGB, and 88% for RYGB (p values not presented) Hypertension resolution rate: 43% for AGB and 79% for RYGB (p values not presented)</td>
<td>Retrospective survey of clinicians</td>
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<tr>
<td>Pournaras et al. 2010&lt;sup&gt;230&lt;/sup&gt;</td>
<td>UK</td>
<td>Patients with type 2 diabetes undergoing bariatric surgery AGB n=12 RYGB n=22</td>
<td>2 years</td>
<td>Percentage weight loss: not significantly different between the AGB and RYGB arms at 1 year (20.4% versus 25.2%, p=0.14) or 2 years (28.5% versus 29.5%, p=0.76) Diabetes remission rate: at 1 year 68% for RYGB patients and 0% for AGB patients (p&lt;0.001), at 2 years 72% for RYGB patients and 17% for AGB patients (p=0.01) Time to remission: shorter for patients receiving RYGB than AGB (hazard ratio 8.2, p=0.001) HbA1c reduction: 1.9% after AGB and 2.9% after RYGB (p values not presented)</td>
<td>Prospective study with long term follow-up</td>
</tr>
<tr>
<td>Abbatini et al. 2010&lt;sup&gt;225&lt;/sup&gt;</td>
<td>Italy</td>
<td>Morbidly obese patients with diabetes AGB n=24 RYGB n=16</td>
<td>3 years</td>
<td>Diabetes resolution rate: 60.8% for AGB and 81.2% for RYGB (p values not presented) Mean time to discontinuation of diabetes therapy: 12.6 months and 3.2 months with AGB and RYGB, respectively (p values not presented) Resolution of co-morbidities: resolution of hypertension (72.2 versus 44.0%) hypertriglyceridemia (50.0% versus 40.0%) and hypercholesteremia (66.6% versus 14.2%) were greater with RYGB than AGB (p values not presented)</td>
<td>Retrospective cohort with long term follow-up</td>
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<tr>
<td>Study</td>
<td>Setting</td>
<td>Population</td>
<td>Duration of study</td>
<td>Key findings</td>
<td>Study design</td>
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| Nguyen et al. 2009<sup>228</sup> | US            | Patients with BMI 40–60 kg/m<sup>2</sup> or 35–60 kg/m<sup>2</sup> with co-morbidities AGB n=86 RYGB n=111 | 4 years           | Operation time: significantly lower with AGB than RYGB (68 versus 137 minutes, p<0.001)  
Blood loss: significantly lower with AGB than RYGB (21.9 versus 80.9 mL, p<0.001)  
Complication rate: significantly lower with AGB versus RYGB (17.4% versus 45.0%, p<0.001)  
Percentage excess weight loss: greater with RYGB than AGB at year 2 (68.9% versus 41.8%, p<0.05), year 3 (67.5% versus 41.5%, p<0.05), and year 4 (68.4% versus 45.4%, p<0.05) | Randomized controlled trial   |
| Flum et al. 2009<sup>233</sup>  | US            | Morbidly obese patients undergoing bariatric surgery AGB n=1,198 RYGB n=3,412 | 30 days           | Death within 30 days of surgery: 0% in patients receiving AGB versus 0.4% in patients receiving RYGB (p>0.001)  
Incidence of the composite endpoint of death, deep-vein thrombosis or venous thromboembolism, re-intervention with the use of a percutaneous, endoscopic, or operative technique, or failure to be discharged from hospital within 30 days was 1.0% in the AGB arm and 5.1% in the RYGB arm (p<0.001) | Prospective controlled study  |
| Strain et al. 2009<sup>223</sup> | US            | Patients with BMI>40 kg/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> and at least one co-morbidity AGB n=41 RYGB n=101 | AGB mean follow-up 21.4 months RYGB mean follow-up 19.1 months | BMI reduction (adjusted for baseline BMI): 7.5 kg/m<sup>2</sup> for AGB arm and 15.6 kg/m<sup>2</sup> for RYGB arm (p values not presented)  
Percentage excess weight loss: 38% with AGB and 70% with RYGB (p values not presented) | Prospective controlled study  |
| Lee et al. 2008<sup>311</sup>    | Taiwan        | Patients with BMI>32 kg/m<sup>2</sup> with diabetes or other co-morbidities AGB n=116 RYGB n=544 | 30 months         | Operation time: significantly lower with AGB than RYGB (88 versus 118 minutes, p<0.0001)  
Blood loss: significantly lower with AGB versus RYGB (15.9 versus 33.5 mL, p<0.0001)  
Mean percentage excess weight loss with AGB and RYGB was 18.1% versus 40.6% at 3 months, 25.0% versus 57.1% at 6 months, 34.7% versus 71.5% at 1 year and 42.7% versus 73.6% at 2 years (p values not presented) | Prospective, study with long term follow-up |
### Weber et al. 2004

**Setting**: Switzerland  
**Population**: Patients with BMI > 40 kg/m² or BMI > 35 kg/m² with co-morbidities, failed conservative treatment for more than 2 years, and age between 18–60 years  
**Duration of study**: 2 years  
**Key findings**:  
- Operation time: significantly lower with AGB than RYGB (145 versus 190 minutes, p<0.001)  
- Percentage excess weight loss: significantly greater with RYGB than AGB (50.0% versus 42.1%, p<0.05), with differences observed as early as 1 month  
- Diabetes prevalence: decreased from 44% to 18% with AGB, versus from 37% to 6% with RYGB (p=0.007)  
- Prevalence of dyslipidemia: increased from 62% to 65% with AGB, but fell from 74% to 37% with RYGB (p=0.001)  
- Hypertension resolution: no significant difference, decreased from 60% to 18% with AGB and from 52% to 13% with RYGB (p=0.18)  
**Study design**: Prospective, study with long term follow-up

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
</table>
| Weber et al. 2004 | Switzerland | Patients with BMI > 40 kg/m² or BMI > 35 kg/m² with co-morbidities, failed conservative treatment for more than 2 years, and age between 18–60 years  | 2 years           | Operation time: significantly lower with AGB than RYGB (145 versus 190 minutes, p<0.001)  
- Percentage excess weight loss: significantly greater with RYGB than AGB (50.0% versus 42.1%, p<0.05), with differences observed as early as 1 month  
- Diabetes prevalence: decreased from 44% to 18% with AGB, versus from 37% to 6% with RYGB (p=0.007)  
- Prevalence of dyslipidemia: increased from 62% to 65% with AGB, but fell from 74% to 37% with RYGB (p=0.001)  
- Hypertension resolution: no significant difference, decreased from 60% to 18% with AGB and from 52% to 13% with RYGB (p=0.18) | Prospective, study with long term follow-up |


### 3.4.2.3 AGB versus BPD

Only one study compared AGB with BPD. This was a prospective study carried out in the US.

- Weight loss: BPD was associated with greater weight loss than AGB both in terms of reduction in BMI and percentage excess weight loss. However, statistical significance of the difference between the two arms was not assessed.

### Table 3-5 Studies assessing AGB versus BPD in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
</table>
| Strain et al. 2009 | US      | Patients with BMI > 40 kg/m² or BMI > 35 kg/m² and at least one co-morbidity  | AGB mean follow-up 21.4 months  
BPD mean follow-up 27.5 months | BMI reduction (adjusted for baseline): 7.5 kg/m² in the AGB arm and 23.6 kg/m² in the BPD arm (p values not presented)  
Percentage excess weight loss: 38% with AGB and 84% with BPD (p values not presented) | Prospective controlled study |


### 3.4.2.4 SG versus RYGB

A total of 17 publications have assessed SG versus RYGB, reflecting four RCTs, eight prospective studies and five retrospective studies. The majority of studies were carried out in the US, but studies were also based in France, Spain, Italy, Austria, Greece, Japan, Taiwan and India. Most commonly studies enrolled patients with diabetes, but studies also assessed outcomes in patients with other co-morbidities, the general population undergoing bariatric surgery, and adolescents. Study follow up ranged from 30 days to over three years.
Weight loss: Data around weight loss with RYGB and SG was mixed (Figure 3-22). A total of three studies found that RYGB was associated with significantly greater weight loss than SG at the end of the study period.\textsuperscript{196,234,235} However, a single study found that at three months, weight loss was significantly greater with SG, but that differences between the treatment arms were not significant at 1 year, while an RCT found that SG was associated with greater weight loss for two years but no difference at three years.\textsuperscript{236,237} Four studies found that no significant difference in weight loss between patients receiving SG and RYGB, as measured by absolute change in body weight or percentage excess weight loss.\textsuperscript{195,238,239,240} Five studies did not assess statistical significance of the difference in weight loss.\textsuperscript{189,220,223,241,242} A further three publications did not report change in body weight.\textsuperscript{224,225,243}

Remission of diabetes: Outcomes around remission of diabetes were mixed, with three studies finding greater rates of resolution with RYGB than SG, but eight studies finding no difference between the procedures (Figure 3-23).

Glycemic control: Across the three studies that assessed improvements in glycemic control (either based on reductions in HbA1c or proportions of patients achieving an HbA1c target), one study found a greater improvement with RYGB than SG but two studies found no difference between the procedures (Figure 3-24).\textsuperscript{195,196,234}

Multi-factorial diabetes treatment targets: In the only study assessing multi-factorial treatment of type 2 diabetes, RYGB was associated with a significantly greater proportion of patients achieving a treatment target of HbA1c<7.0%, LDL cholesterol<100 mg/dL, and triglycerides>150 mg/dL than SG.\textsuperscript{234}

Remission of co-morbidities: One study identified a statistically significant improvement in gastroesophageal reflex disease with RYGB versus SG.\textsuperscript{238} However, other studies found no difference in rates of various complications or did not assess statistical significance, including OSA, hyperlipidemia, hypercholesteremia, hypertension, musculoskeletal disease and joint pain.\textsuperscript{189,225,235,236,238,239,242}

Complication rates: In an 8 week study, SG was associated with significantly lower rates of major and minor complications than RYGB.\textsuperscript{243} An additional study also identified lower complication rates with SG than RYGB, but statistical significance was not assessed.\textsuperscript{224}

Morbidity: SG has been shown to be associated with significantly lower post-operative morbidity than RYGB in one study.\textsuperscript{239} In an additional study, morbidity was lower following SG than RYGB, but statistical significance was not assessed.\textsuperscript{189}

Length of hospital stay: Only on study assessed length of hospital stay, with equivalence in the SG and RYGB arms.\textsuperscript{224}

Quality of life: Of the two studies that assessed changes in quality of life, one study found that quality of life increased following both SG and RYGB, with a larger improvement associated with SG but no assessment of statistical significance was made.\textsuperscript{224} A further study identified no difference in post-operative quality of life.\textsuperscript{235}
Figure 3-22  Reduction in body weight with SG and RYGB


Figure 3-23  Remission of type 2 diabetes with SG and RYGB


Figure 3-24  Reduction in HbA1c with SG and RYGB in patients with type 2 diabetes

### Table 3-6: Studies assessing SG versus RYGB in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
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<tbody>
<tr>
<td>Inge et al. 2016</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery SG n=67 RYGB n=161</td>
<td>3 years</td>
<td>Body weight and BMI reduction: 38 kg and 13 kg/m², respectively, in the SG arm, versus 42 kg and 15 kg/m² in the RYGB arm (p values not presented) Quality of life: increased by 27.8% in the SG arm and 50.5% in the RYGB arm (p values not presented)</td>
<td>Prospective controlled study with long-term follow-up</td>
</tr>
<tr>
<td>Inge et al. 2014</td>
<td>US</td>
<td>Adolescents undergoing bariatric surgery SG n=67 RYGB n=161</td>
<td>30 days</td>
<td>Major complication rate: 4.5% for SG versus 9.3% for RYGB (p values not presented) Minor complication rate: 11.9% for AGB and 16.8% of SG (p values not presented) Median length of hospital stay: 3 days for SG and 3 days for RYGB (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Kashyap et al. 2013</td>
<td>US</td>
<td>Patients with uncontrolled type 2 diabetes (mean HbA1c 9.7%) and moderate obesity (mean BMI 36 mg/m²) SG n=19 RYGB n=18</td>
<td>2 years</td>
<td>Weight loss: no significant difference observed between SG and RYGB (~22.5 kg versus ~25.4 kg, p=0.37) HbA1c reduction: no significant difference between SG and RYGB (~2.5% versus ~3.1%, p=0.37)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Zhang et al. 2013</td>
<td>US</td>
<td>Patients with BMI≥40 kg/m² or BMI&gt;35 kg/m² and at least one co-morbidity SG n=200 RYGB n=358</td>
<td>1 year</td>
<td>Excess weight loss with SG and RYGB was 10.2% versus 9.3% at 30 days, 23.0% versus 24.5% at 6 months, and 30.7% versus 33.4% at 1 year (p&gt;0.05 at all time points) GERD resolution: 50% for RYGB, but prevalence increased in the SG arm (p&lt;0.001) Co-morbidities: SG and RYGB were associated with similar improvements in OSA (91.2% versus 82.8%, p=0.338), hyperlipidemia (63.0% versus 55.8%, p=0.633), hypertension (38.8% versus 52.9%, p=0.0624), diabetes (58.6% versus 65.5%, p=0.638) and musculoskeletal disease (66.7% versus 79.4%, p=0.473)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Schauer et al. 2012</td>
<td>US</td>
<td>Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m² SG n=49 RYGB n=50</td>
<td>1 year</td>
<td>Proportions achieving HbA1c&lt;6.0%: no significant difference between SG and RYGB (37% versus 42%, p=0.59) Mean reduction in HbA1c: no significant difference, reduction of 2.9% in both arms (p=0.85) Weight loss: significantly greater with RYGB versus SG (~29.4 kg versus ~25.1 kg, p=0.02)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Bayham et al. 2012</td>
<td>US</td>
<td>Obese patients with type 2 diabetes SG n=139 RYGB n=123</td>
<td>8 weeks</td>
<td>Resolution of diabetes on discharge: 77.0% of SG patients and 77.2% of patients receiving RYGB (p&gt;0.05) Major complication rate: significantly lower with SG versus RYGB (3.6% versus 24.8%, p&lt;0.001) Minor complication rate: significantly lower with SG versus RYGB (22.8% versus 6.0%, p&lt;0.001)</td>
<td>Retrospective cohort</td>
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<td>Study</td>
<td>Setting</td>
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<td>Duration of study</td>
<td>Key findings</td>
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| Kehagias et al. 2011<sup>237</sup> | Greece | Patients with BMI≤50 kg/m<sup>2</sup>  
SG n=30  
RYGB n=30 | 3 years | Operating time: 126 minutes for SG versus 186 minutes for RYGB (p<0.01)  
Percentage excess weight loss: 72.9% with SG versus 65.6% with RYGB at 1 year (p=0.05), 73.2% with SG versus 65.3% at 2 years (p=0.05), 68.5% with SG versus 62.1% with RYGB at 3 years (p=0.13) | Randomized controlled trial |
| Lee et al. 2011<sup>234</sup> | Taiwan | Patients with BMI 25–35 kg/m<sup>2</sup>, aged 30–60 years, with type 2 diabetes and HbA1c>7.5%  
SG n=30  
RYGB n=30 | 1 year | Remission of type 2 diabetes: significantly higher remission rate with RYGB versus SG (93% versus 47%, p=0.02)  
Mean reduction in HbA1c: 3.0% with SG versus 4.2% with RYGB (p<0.05)  
57% of patients receiving RYGB versus 0% receiving SG achieved successful treatment of diabetes (defined as HbA1c<7.0%, LDL cholesterol<100 mg/dL, and triglycerides>150 mg/dL)  
Percentage weight loss: 19.2% with SG and 23.3% with RYGB (p=0.02) | Randomized controlled trial |
| Chouillard et al. 2011<sup>239</sup> | France | Patients with BMI>40 kg/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> with significant co-morbidities  
SG n=200  
RYGB n=200 | 18 months | Morbidity rate: significantly lower with SG than RYGB (6.5% versus 20.5%, p<0.05)  
Excess weight loss: 48.3% versus 49.1% for SG and RYGB at 6 months, 58.9% versus 64.2% at 12 months, and 64.9% versus 69.2% at 18 months (all p>0.05)  
Diabetes remission rate: significantly higher with RYGB than SG at 18 months (86% versus 62%, p<0.05)  
Rates of resolution of hypertension and OSA did not differ between the arms | Prospective controlled study |
| Benaiges et al. 2011<sup>236</sup> | Spain | Patients aged 18–55 years with BMI>40 kg/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> and at least one co-morbidity  
SG n=45  
RYGB n=95 | 1 year | Excess weight loss: at 3 months, greater with SG than RYGB (58.3% versus 50.6%, p=0.017), but differences were not significant at 6 months (72.0% versus 68.5%, p=0.602) or 1 year (82.7% versus 80.9%, p=0.632)  
Co-morbidities: SG and RYGB were associated with similar rates of resolution of hypertension (64.3% versus 74.4%, p=0.463), hypercholesteremia (66.7% versus 86.4%, p=0.174), and diabetes (85.7% versus 96.0%, p=0.536) | Prospective controlled study |
| Mohos et al. 2011<sup>235</sup> | Austria | Patients with BMI>40 kg/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> and at least one co-morbidity  
SG n=47  
RYGB n=47 | SG mean follow-up 38.3 months  
RYGB mean follow-up 15.7 months | Percentage excess weight loss: 70% with SG and 88% with RYGB (p=0.0001)  
Post-operative SF-36 score: no significant difference between arms (p=0.0615)  
Co-morbidities: compared with SG, RYGB was associated with greater remission of diabetes (90% versus 55%, p values not presented), hypertension (73% versus 43%, p values not presented), GERD (92% versus 25%) and OSA (72% versus 6%, p values not presented) | Prospective controlled study |
<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nocca et al. 2011</td>
<td>France</td>
<td>Patients with BMI &gt; 35 mg/m² and type diabetes</td>
<td>1 year</td>
<td>Excess weight loss: similar with SG and RYGB (60.12% versus 56.35%, p values not presented) Diabetes remission rate: similar with SG and RYGB (72.0% versus 68.5%, p=0.3876)</td>
<td>Prospective controlled study</td>
</tr>
<tr>
<td>Ohta et al. 2011</td>
<td>Japan</td>
<td>Survey of 64 member institutes of the Japan Research Society for Endoscopic and Laparoscopic Treatments of Obesity (JELTO)</td>
<td>SG 2 years</td>
<td>Morbidity rate: 7.8% with SG and 12.2% with RYGB (p values not presented) Mean weight loss: 41 kg, 32 kg at Years 1 and 2, respectively with SG versus 46 kg, 44 kg, 41 kg, 36 kg and 42 kg at Years 1, 2, 3, 4 and 5 for RYGB (p values not presented) Diabetes remission rate: 91% for SG and 88% for RYGB (p values not presented) Resolution of hypertension: 43% for SG and 79% for RYGB (p values not presented)</td>
<td>Retrospective survey of clinicians</td>
</tr>
<tr>
<td>de Gordejuela et al. 2011</td>
<td>Spain</td>
<td>Morbidly obese patients with type 2 diabetes</td>
<td>2 years</td>
<td>Excess weight loss: at 1 year, 68.6% and 69.4% with SG and RYGB respectively (p&gt;0.05), and at 2 years 72.4% and 72.3% (p&gt;0.05) Remission of diabetes: similar with SG and RYGB at 1 year (80.7% versus 91.8%, p&gt;0.05) and at 2 years (88.9% versus 91.8%, p&gt;0.05)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Lakdawala et al. 2010</td>
<td>India</td>
<td>Patients undergoing bariatric surgery</td>
<td>1 year</td>
<td>Excess weight loss: greater with SG than RYGB at 1 year (76.1% versus 62.2%, p values not presented) Diabetes resolution rate: similar for SG and RYGB (98% versus 100%, p values not presented) Co-morbidities: similar resolution rated for SG and RYGB for hypertension (91% versus 95%, p values not presented), OSA (100% versus 100%, p values not presented), dyslipidemia (75% versus 78%, p values not presented), and joint pain (97% versus 96%, p values not presented)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Abbatini et al. 2010</td>
<td>Italy</td>
<td>Morbidly obese patients with diabetes</td>
<td>3 years</td>
<td>Diabetes resolution rate: 80.9% for SG and 81.2% for RYGB (p values not presented) Mean time to discontinuation of diabetes therapy: 3.3 and 3.2 months with and SG and RYGB, respectively (p values not presented) Resolution of hypertension (66.6 versus 72.2%), hypertriglyceridemia (66.6 versus 50.0%) and hypercholesteremia (66.6% versus 66.6%) were all similar with SG and RYGB (p values not presented)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Strain et al. 2009</td>
<td>US</td>
<td>Patients with BMI &gt; 35 kg/m² and at least one co-morbidity</td>
<td>SG mean follow-up 16.7 months RYGB mean follow-up 19.1 months</td>
<td>BMI reduction (adjusted for baseline BMI): 18.2 kg/m² in the SG arm and 15.6 kg/m² in the RYGB arm (p values not presented) Percentage excess weight loss: 49% with SG and 70% with RYGB (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
</tbody>
</table>

3.4.2.5 SG versus BPD

Only one study compared SG with BPD. This was a prospective study carried out in the US.

- Weight loss: BPD was associated with greater weight loss than SG both in terms of reduction in BMI and percentage excess weight loss.\(^{221}\) However, statistical significance of the difference between the two arms was not assessed.

**Table 3-7**  
**Studies assessing SG versus BPD in the treatment of obesity and obesity-related co-morbid conditions**

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
</table>
| Strain et al. 2009\(^{221}\) | US      | Patients with BMI>40 kg/m\(^2\) or BMI>35 kg/m\(^2\) and at least one co-morbidity  | SGB mean follow-up 16.7 months  
BPD mean follow-up 27.5 months | BMI reduction (adjusted for baseline): 18.2 kg/m\(^2\) in the SG arm and 23.6 kg/m\(^2\) in the BPD arm (p values not presented)  
Percentage excess weight loss: 49\% with SG and 84\% with BPD (p values not presented) | Prospective controlled study |


3.4.2.6 RYGB versus BPD

A total of four studies have compared RYGB with BPD, two RCTs, one prospective study, and one retrospective studies. These studies were conducted in Italy, the US, Norway and Sweden. Two studies were in patients with diabetes, one study was in super obese patients, and one study was in the general population undergoing bariatric surgery.

- Weight loss: RYGB and BPD were associated with similar weight loss in the two studies in patients with diabetes, with no significant differences at 1 and 2 years of follow-up.\(^{198,200}\) In the study of super obese patients, BPD was associated with statistically significant BPD was associated with significantly greater weight loss at 6 weeks, 6 months, and 1 year.\(^{244}\) The study in the general population did not assess statistical significance of differences in weight loss between the two procedures.\(^{223}\)

- Remission of diabetes: In both studies in patients with diabetes, BPD was associated with a greater proportion of patients achieving remission of diabetes (Figure 3-25). In the retrospective study the difference was statistically significant, but statistical significance was not assessed in the RCT.

- Glycemic control: BPD was associated with greater improvements in glycemic control versus RYGB in both studies enrolling patients with diabetes, with differences between the arms reaching statistical significance.\(^{198,200}\)

- Operating time: In super obese patients, RYGB was associated with significantly shorter operating time.\(^{244}\)
Figure 3-25  Remission of type 2 diabetes with RYGB and BPD

![Bar chart showing remission rates with RYGB and BPD](chart.png)


Table 3-8  Studies assessing RYGB versus BPD in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mingrone et al. 2012198</td>
<td>Italy</td>
<td>Patients aged 30–60 years with BMI&gt;35 kg/m², a history of at least 5 years of diabetes, and an HbA1c&gt;7.0% RYGB n=20 BPD n=20</td>
<td>2 years</td>
<td>Diabetes remission rate: 75% for RYGB, 95% for BPD (p values not presented)  HbA1c reduction: significantly greater with BPD versus RYGB (p=0.001) BMI reduction: 15.54 kg/m² with RYGB versus 15.95 kg/m² with BPD (p=1)</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Dorman et al. 2012200</td>
<td>US</td>
<td>Patients with type 2 diabetes with BMI&gt;35 kg/m² RYGB n=27 BPD n=27</td>
<td>1 year</td>
<td>BMI change at 1 year: no significant difference when baseline characteristics were controlled for (p=0.41) HbA1c: 1.2% lower in the BPD arm than the RYGB arm (p=0.001) Diabetes resolution rate: 48.1% of patients in the RYGB arm versus 81.5% in the BPD arm (p=0.02)</td>
<td>Retrospective cohort with long term follow-up</td>
</tr>
<tr>
<td>Søvik et al. 2010244</td>
<td>Norway and Sweden</td>
<td>Patients aged 20–50 years with BMI 50–60 kg/m² RYGB n=31 BPD n=29</td>
<td>1 year</td>
<td>Mean operating time: 91 minutes with RYGB versus 206 minutes with BPD (p&lt;0.001) Median length of stay: 2 days for RYGB versus 4 days with BPD (p&lt;0.001) Complications: Rates of early (p=0.327) and late (p=0.121) complications did not differ between the treatment groups Percentage excess weight loss: 22.3% with RYGB versus 28.1% with BPD at 6 weeks (p=0.001), 44.0% with RYGB versus 56.9% with BPD at 6 months (p&lt;0.001), and 54.4% with RYGB versus 74.8% with BPD a 1 year (p&lt;0.001)</td>
<td>Randomized controlled trial</td>
</tr>
</tbody>
</table>
### Study Setting Population Duration of study Key findings Study design

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Duration of study</th>
<th>Key findings</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strain et al. 2009 [223]</td>
<td>US</td>
<td>Patients with BMI &gt; 40 kg/m² or BMI &gt; 35 kg/m² and at least one co-morbidity</td>
<td>RYGB mean follow-up 19.1 months BPD mean follow-up 27.5 months</td>
<td>Reduction in BMI (adjusted for baseline BMI): 15.6 kg/m² in the RYGB arm and 23.6 kg/m² in the BPD arm (p values not presented) Percentage excess weight loss: 70% with RYGB and 84% with BPD (p values not presented)</td>
<td>Prospective controlled study</td>
</tr>
</tbody>
</table>


### 3.4.3 Meta-analyses

In addition to trials directly comparing bariatric procedures, a total of 11 meta-analyses collating data from a series of studies have been published. These consistently demonstrated that bariatric surgery was associated with significant decreases in BMI as well as improvement or resolution of co-morbid conditions including diabetes, hypertension and OSA. Systematic reviews that did not conduct some form of evidence synthesis are outlined in appendix 2.

- **Weight loss:** In meta-analyses comparing different procedures BPD was consistently associated with the greatest reduction in BMI, followed by either SG or RYGB, and AGB was consistently associated with the smallest reduction in BMI following surgery. [245,246,247,248,249,250,251]
- **Weight loss in obese children and adolescents:** In a meta-analysis of 23 studies in obese children and adolescents RYGB was associated with a larger reduction in BMI than SG and AGB. [246]
- **Resolution of diabetes:** Findings from two separate meta-analyses showed that rates of resolution of diabetes were highest with BPD, followed by RYGB then AGB. [248,251]
- **Improvement in co-morbidities:** In one meta-analysis of 15 studies, over 65% of obese patients with non-alcoholic fatty liver disease showed improvement in steatohepatitis and fibrosis following bariatric surgery. [252]
- **Length of stay:** In a meta-analysis of 31 RCTs in severely obese patients, AGB was associated with a significantly shorter length of stay compared with RYGB. [245]
- **Cancer risk:** The risk for cancer was significantly reduced for obese patients undergoing bariatric surgery compared with controls not undergoing surgery. [253] However, sub-group analysis according to gender showed that this reduction was significant in women but not in men.
- **Sleep apnea:** In a meta-analysis of 12 primarily small-scale (<50 patients) studies in obese patients with OSA bariatric surgery was associated with a significant reduction in symptoms determined using the apnea hypopnea index. [254]
## Table 3-9: Meta-analyses examining the efficacy of bariatric surgery in the treatment of obesity and obesity-related co-morbid conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Details</th>
<th>Procedures</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washington State HTA 2015&lt;sup&gt;245&lt;/sup&gt;</td>
<td>N=275 studies including RCTs, prospective cohort studies and case series (of which 100 were rated as “good” or “fair” in quality) Number of patients not presented</td>
<td>RYGB, laparoscopic AGB, SG and BPD with or without DS, non-surgical management</td>
<td>BMI change: pooled mean (95% CI) difference in BMI between bariatric surgery and non-surgical management was 7.4 (6.2, 8.6) kg/m&lt;sup&gt;2&lt;/sup&gt; (p&lt;0.001) BMI change: in a comparison of RYGB versus SG, mean (95% CI) difference was 0.296 (−0.828, 1.421) kg/m&lt;sup&gt;2&lt;/sup&gt; in favor of SG, which was not significant (p=0.605) Diabetes resolution in studies exclusively in type 2 diabetes patients: OR (95% CI) for resolution of diabetes with bariatric surgery versus non-surgical management was 3.62 (2.49, 4.74) (p&lt;0.001)</td>
</tr>
<tr>
<td>Black et al. 2013&lt;sup&gt;246&lt;/sup&gt;</td>
<td>N=23 studies including controlled trials and before/after studies N=637 patients (obese children and adolescents) Random effects model</td>
<td>AGB, SG, and BPD</td>
<td>Change in BMI from baseline: WMD (95% CI) was greatest for RYGB at −17.20 (−20.09, −14.31) kg/m&lt;sup&gt;2&lt;/sup&gt; (p=0.003 versus change in BMI for overall bariatric surgery), followed by SG at −14.53 (−17.33, −11.73) kg/m&lt;sup&gt;2&lt;/sup&gt; (p=0.116), then AGB at −10.47 (−11.80, −9.14) kg/m&lt;sup&gt;2&lt;/sup&gt; (p=0.166) (BDP not reported)</td>
</tr>
<tr>
<td>Tee et al. 2013&lt;sup&gt;253&lt;/sup&gt;</td>
<td>N=6 observational studies N=51,740 patients Random effects model</td>
<td>Bariatric surgery</td>
<td>Cancer risk: RR (95% CI) for obese patients undergoing bariatric surgery was significantly reduced versus those not undergoing surgery at 0.55 (0.41, 0.73) (p&lt;0.0001) Gender and cancer risk: reduction in cancer risk was significant for women (RR [95% CI] 0.68 [0.60, 0.77] p&lt;0.0001) but not for men (RR [95% CI] 0.99 [0.74, 1.32] p=0.930)</td>
</tr>
<tr>
<td>Vest et al. 2012&lt;sup&gt;255&lt;/sup&gt;</td>
<td>N=73 studies including randomized and non-randomized studies N=19,543 patients Fixed and random effects models used</td>
<td>Bariatric surgery (including BPD, RYGB, AGB, SG, DS and VBG)</td>
<td>Percentage excess weight loss: overall excess weight loss was 54% Resolution of co-morbidities: overall rates of resolution/improvement were 73.2% for diabetes, 62.5% for hypertension and 65.2% for hyperlipidemia Resolution of co-morbidities: RR (95% CI) for hypertension for obese patients who underwent bariatric surgery versus those not undergoing surgery was 0.36 (0.31, 0.42) (p=0.000), the corresponding value for diabetes was 0.24 (0.20, 0.30) (p=0.000) and for hyperlipidemia this value was 0.32 (0.26, 0.40) (p=0.000)</td>
</tr>
<tr>
<td>Padwal et al. 2011&lt;sup&gt;247&lt;/sup&gt;</td>
<td>N=31 RCTs in severely obese adults (≥40 kg/m&lt;sup&gt;2&lt;/sup&gt; or ≥35 kg/m&lt;sup&gt;2&lt;/sup&gt; with ≥1 obesity-related co-morbidity) N=2,619 patients Bayesian NMA</td>
<td>BPD, SG, RYGB, AGB</td>
<td>Change in BMI, relative to standard care: differences (95% CI) from baseline in BMI were greatest for BPD at −11.2 (−15.7, −6.9) kg/m&lt;sup&gt;2&lt;/sup&gt; followed by SG at −10.1 (−17.8, −2.6) kg/m&lt;sup&gt;2&lt;/sup&gt;, then RYGB at −9.0 (−15.1, −3.1) kg/m&lt;sup&gt;2&lt;/sup&gt; and AGB at −2.4 (−9.1, 3.9) kg/m&lt;sup&gt;2&lt;/sup&gt; (p values not presented) Length of stay: AGB associated with significantly shorter length of hospital stay versus RYGB; mean (95% CI) difference of −1.7 (−2.00, −1.30) days (p value not stated)</td>
</tr>
<tr>
<td>Heneghan et al. 2011&lt;sup&gt;248&lt;/sup&gt;</td>
<td>N=52 studies including controlled and uncontrolled studies with &gt;50 patients N=16,867 patients</td>
<td>RYGB, BPD, laparoscopic AGB and SG</td>
<td>Percentage estimated weight loss: highest for BPD (69%), followed by RYGB (65%) then SG (50%) and laparoscopic AGB (42%) (p values not presented) Diabetes remission rates: highest with BPD (100%), followed by RYGB (79%) then laparoscopic AGB (SG not reported) (p values not presented) Hypertension remission rates: highest with BPD (79%), followed by RYGB (60%) then laparoscopic AGB (SG not reported) (p values not presented) Dyslipidemia remission rates: highest with BPD (90%) followed by laparoscopic AGB (60%) then RYGB (57%) (SG not reported) (p values not presented)</td>
</tr>
<tr>
<td>Chang et al. 2011&lt;sup&gt;256&lt;/sup&gt;</td>
<td>N=91 studies included trials and observational studies N=280,315 patients Fixed and random effects model</td>
<td>Bariatric surgery</td>
<td>Mean (95% CI) change in BMI at 1 year: −15.65 (−16.11, −15.19) kg/m&lt;sup&gt;2&lt;/sup&gt; using fixed effects model and −12.30 (−14.06, −10.39) kg/m&lt;sup&gt;2&lt;/sup&gt; using random effects model Mean (95% CI) change in BMI at 5 years: −13.71 (−16.73, −10.69) kg/m&lt;sup&gt;2&lt;/sup&gt; using fixed effects model and −14.13 (−18.61, −9.64) kg/m&lt;sup&gt;2&lt;/sup&gt; with random effects model Mean (95% CI) post-surgery complication rate: 14.2 (12.5, 15.9%) using fixed effects model and 14.2 (10.8, 17.5%) using random effects model Mean (95% CI) remission rate for obesity related diseases at 1 year: 64.7 (61.0, 68.5%) using fixed effects model and 64.7 (47.3, 82.2%) using random effects model</td>
</tr>
<tr>
<td>Study</td>
<td>Details</td>
<td>Procedures</td>
<td>Key findings</td>
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<td>------------------------</td>
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<tr>
<td>Klarenbach et al. 2010</td>
<td>N=159 studies, including trial and observational studies</td>
<td>AGB, SG, RYGB, BPD and medical management</td>
<td>Mean difference (95% CI) in BMI at 1 year: −9.8 kg/m² (−18.9 to −1.3) SG versus medical management, −7.8 kg/m² (−13.7 to −1.4) for SG versus AGB, −8.6 kg/m² (−16.0 to −2.2) for RYGB versus medical management, −6.6 kg/m² (−9.5 to −3.4) for RYGB versus AGB, −11.0 mg/m² (−16.0 to −6.5) for BPD versus medical management, −9.0 kg/m² (−14.7 to −2.9) for BPD versus APD. No significant difference for AGB versus medical management, SG versus RYGB, BPD versus SG, or BPD versus RYGB. Mortality: No difference in all-cause mortality was identified. Resolution of co-morbidities: No difference in resolution of co-morbidities was identified. Length of stay: AGB was associated with shorter length of stay than RYGB (mean difference: −1.9, 95% CI −2.0 to −1.3).</td>
</tr>
<tr>
<td>Garb et al. 2009</td>
<td>N=28 studies including RCT, non-randomized trials and case series N=7,383 patients (adults with BMI ≥35 kg/m²) Random effects model</td>
<td>Laparoscopic AGB, Laparoscopic RYGB</td>
<td>Percentage excess weight loss (95% CI): 49.4 (44.9, 54.0)% for laparoscopic AGB versus 62.6 (58.6, 66.6)% for laparoscopic RYGB (p&lt;0.001) Mean percentage excess weight loss at Year 1, 2 and 3: 42.6%, 50.3% and 55.2%, respectively, for laparoscopic AGB versus 61.5%, 69.7% and 71.2%, respectively, for laparoscopic RYGB Improvement in percentage excess weight loss for laparoscopic RYGB over laparoscopic AGB was approximately 19% at 1 year and 16% at &gt;3 years.</td>
</tr>
<tr>
<td>Buchwald et al. 2009</td>
<td>N=621 studies including trials, observational studies and case series N=135,246 Random effects model</td>
<td>AGB, RYGB and BDP-DS</td>
<td>Mean (95% CI) reduction in BMI: −10.62 (−11.36, −9.89) kg/m² for AGB, −16.33 (−17.08, −15.58) kg/m² for RYGB and −18.72 (−21.17, −16.27) kg/m² for BPD-DS (p values not presented) Mean (95% CI) reduction in BMI in patients with diabetes: −8.34 (−10.61, −6.08) kg/m² for AGB, −16.14 (−16.86, −15.42) kg/m² for RYGB and −16.47 (−26.06, −6.89) kg/m² for BPD-DS (p values not presented) Diabetes resolution rate (in studies in patients with diabetes only): 62.7 (55.4, 70.0)% for AGB, 80.5 (74.8, 86.2)% for AGB and 99.4 (98.3, 100.0)% for BPD-DS (p values not presented) Mean (95% CI) change in HbA1c (in studies in patients with diabetes only): −1.40 (−3.20, 0.40)% for AGB, −2.18 (−2.71, −1.65)% for RYGB (data not presented for BDP-DS) (p values not presented)</td>
</tr>
<tr>
<td>Greenburg et al. 2009</td>
<td>N=12 studies including trials, observational studies and before/after studies N=342 patients Random effects model</td>
<td>Bariatric surgery</td>
<td>Mean (95% CI) change in BMI: −17.9 (16.5, 19.3) kg/m² Reduction in apnea hypopnea index: bariatric surgery associated with a significant reduction (by 38.2 [31.9, 44.4] events per hour in the random effects model; in an analysis of individual patient data this improvement was 49.4 events per hour.</td>
</tr>
<tr>
<td>Mummadi et al. 2008</td>
<td>N=15 studies (prospective and retrospective) with paired liver biopsies N=766 patients with non-alcoholic fatty liver disease Random effects model</td>
<td>Bariatric surgery</td>
<td>Improvement or resolution of steatohepatitis (95% CI): 81.3 (61.9, 94.9)%; proportion (95% CI) of patients with complete resolution of steatohepatitis was 69.5 (42.4, 90.8)% Improvement in fibrosis (95% CI): 65.5% (38.2, 88.1)% patients with liver biopsies showed improvement of fibrosis following bariatric surgery</td>
</tr>
</tbody>
</table>

3.5 **ECONOMICS OF BARIATRIC SURGERY**

Obesity and obesity-related co-morbidities have an important impact on healthcare spending worldwide (Section 0) and improving clinical outcomes through bariatric surgery may result in reduced cost. However, performing bariatric surgery is associated with significant costs. Therefore understanding the impact of bariatric surgery on costs and whether procedures are cost-effectiveness is essential.

### 3.5.1 Europe

#### 3.5.1.1 Impact of bariatric surgery on healthcare resource use and costs

A total of six studies assessed the impact of bariatric surgery on healthcare costs in Europe, with studies based in France, Sweden and the UK.

- **Hospital stay:** A 20-year study in Sweden found that bariatric surgery was associated with a statistically significant increase in cumulative hospital stay compared with medical management.\(^1\) This was driven by differences over the first 6 years of the study, with no difference in annual hospital days from year 7 onwards. However, in the UK, bariatric surgery was associated cost fewer outpatient clinic visits and fewer hospital admissions when pre-operative and post-operative periods were compared.\(^2\)

- **Medication use:** In an analysis in the UK, medication use fell by 26% following bariatric surgery.\(^3\)

- **Hospital costs:** Both outpatient clinic and hospital admission costs were lower following bariatric surgery than before surgery in the UK.\(^4\)

- **Workplace productivity:** In the UK, bariatric surgery was associated with an increased proportion of patients in work and increased working hours per week.\(^5\)

- **Benefits claimed:** In the UK bariatric surgery was associated with a significant in state benefit claims.\(^6\) Outcomes in Sweden were mixed, with bariatric surgery associated with reduced disability claims in men, but no difference in women, when confounders were adjusted for.\(^7\)

- **Medication costs:** In Sweden, medication costs were significantly lower when surgery and medical management were compared, and in the UK, medication costs were reduced following bariatric surgery.\(^8\) In France, prescription costs initially increased following surgery, but cost savings versus the pre-operative period were observed from 1 year onward.\(^9\)

- **Procedure costs:** In the UK, costs of AGB, SG, and RYGB were estimated to be GBP 4,500, GBP 7,300 and GBP 8,500, respectively.\(^10\)

- **Cost savings:** Excluding the cost of the procedure, bariatric surgery has been estimated to be associated with annual cost savings of GBP 30,404 and USD 32,593–41,777 in the UK.\(^11\)

#### 3.5.1.2 Cost-effectiveness of bariatric surgery

Seven studies assessing the cost-effectiveness of bariatric surgery procedures in Europe have been conducted. Two studies covered multiple settings, and therefore studies relate to Austria, Finland, France, Germany, Italy, Portugal, Spain and the UK. The time horizon of the studies varied from 5 years to patient lifetimes. A total of three studies were specific to patients with type 2 diabetes, with the remainder including general patients undergoing bariatric surgery.
Quality-adjusted life expectancy: In all studies, all bariatric surgery procedures were associated with improved quality adjusted life expectancy compared to medical management (Figure 3-26). Benefits were as large as 1.88 quality-adjusted life years (QALYs). Where studies assessed more than one bariatric procedure, RYGB was associated with greater quality-adjusted life expectancy than AGB or SG. Costs: In Austria, Italy, Finland, Portugal, France and Germany, AGB and RYGB were associated with reduced costs compared with medical management. In addition, SG was associated with reduced costs versus medical management in Finland. In Spain and the UK, AGB and RYGB were associated with increased costs versus medical management.

Cost-effectiveness: Bariatric surgery (procedures combined) was dominant, reducing costs and improving clinical outcomes, over medical management in Finland. When the procedures were considered individually, AGB was found to be dominant over medical management in Austria, Italy, Finland, Portugal, France, and Germany, SG was dominant over medical management in Finland, and RYGB was found to be dominant over medical management in Austria, Italy, Finland, Portugal, France, and Germany. AGB was associated with increased costs and improved clinical outcomes versus medical management in Spain (associated with an incremental cost-effectiveness ratio [ICER] of EUR 1,456 per QALY gained) and the UK (associated with ICERs ranging from GBP 1,929–3,863 per QALY gained across three analyses). RYGB was associated with increased costs and improved clinical outcomes versus medical management in Spain (associated with an incremental cost-effectiveness ratio [ICER] of EUR 2,664 per QALY gained) and the UK (associated with ICERs ranging from GBP 1,517–4,127 per QALY gained across two analyses).

Figure 3-26 Long-term projections of quality-adjusted life expectancy with bariatric procedures in Europe

### Table 3-10: Economic studies of bariatric surgery in Europe

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<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
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<td><strong>Cost studies</strong></td>
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<tr>
<td>Gesquiere et al. 2014(^{261})</td>
<td>France</td>
<td>Patients undergoing RYGB with retrospective comparison of costs before and up to 4 years after surgery Surgery n=143</td>
<td>RYGB</td>
<td>EUR (cost year not stated)</td>
<td>Total prescription costs: Versus the pre-operative period, 171% increase at 1 month, 22% increase at 3 months, 1% increase at 6 months, 32% decrease at 1 year, 42% decrease at 2 years, 40% decrease at 3 years, 34% decrease at 4 years</td>
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<td>Neovius et al. 2012(^{215})</td>
<td>Sweden</td>
<td>Patients aged 37–60 years with BMI≥34 kg/m(^2) for men and BMI≥38 kg/m(^2) for women followed for 20 years in prospective controlled study Surgery n=2,010 Medical management n=2,037</td>
<td>Bariatric surgery (AGB, RYGB, VBG) Medical management</td>
<td>Converted to USD from SEK (2011)</td>
<td>Mean cumulative hospital stay (20 years): 54 hospital days for bariatric surgery versus 40 hospital days for the medical management (p=0.03) During years 2–6, surgery patients had an accumulated annual mean of 1.7 hospital days versus 1.2 days among control patients (p=0.001) From year 7 to 20, both groups had a mean annual 1.8 hospital days (p=0.95) Mean annualized drug costs (data only available for years 7 to 20 of the study): USD 930 in the surgery arm versus USD 1,123 in the control arm (p=0.001)</td>
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<tr>
<td>Gripeteg et al. 2012(^{260})</td>
<td>Sweden</td>
<td>Patients aged 37–60 years with BMI≥34 kg/m(^2) for men and BMI≥38 kg/m(^2) for women with prospective collection of disability pension claims data over 10 years Surgery n=2,010 Medical management n=2,037</td>
<td>Bariatric surgery Medical management</td>
<td>-</td>
<td>Incidence of disability pension claims: When adjusted for confounders, surgery was associated with lower incidence of claiming disability pension in men (adjusted HR 0.79, p=0.05), but no difference in women (adjusted HR 0.95, p=0.44) Disability pension days: When adjusted for confounders, the number of disability pension days taken by men was 609 the surgery group compared with 734 in the control group (p=0.01), but no differences were identified in women (p=0.97)</td>
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<tr>
<td>Karim et al. 2013a(^{257})</td>
<td>UK</td>
<td>Patients aged 18–65 years with BMI≥30 kg/m(^2), with retrospective comparison of costs before and after surgery (median pre-operative period 60 months, median post-operative period 24 months) Surgery n=73</td>
<td>Bariatric surgery (AGB, SG, RYGB)</td>
<td>Converted from GBP to USD (cost year not stated)</td>
<td>Outpatient clinics: 53.56 per year before surgery versus 46.16 per year after surgery (p=0.04) Hospital admissions: 17.9 per year before surgery versus 10.69 per year after surgery (p=0.01) Medication use: Number of medications required fell by 26% after surgery (p=0.003) Total cost savings: Cost savings following surgery were estimated to be USD 32,593–41,777 per year (p values not presented)</td>
</tr>
<tr>
<td>Karim et al. 2013b(^{258})</td>
<td>UK</td>
<td>Patients aged 18–65 years with BMI≥30 kg/m(^2), with retrospective comparison of costs before and after surgery (median pre-operative period 60 months, median post-operative period 24 months) Surgery n=88</td>
<td>Bariatric surgery (AGB, SG, RYGB)</td>
<td>GBP (cost year not stated)</td>
<td>Outpatient clinic costs: GBP 7,567 per patient per year before surgery versus GBP 5,035 per patient per year after surgery (p&lt;0.05) Hospital admissions costs: GBP 50,759 per patient per year before surgery versus GBP 34,339 per patient per year after surgery (p&lt;0.05) Medication costs: GBP 29,027 per patient per year before surgery versus GBP 17,575 per patient per year after surgery (p&lt;0.05) Total costs (excluding cost of procedure): GBP 87,353 per patient per year before surgery versus GBP 56,949 per patient per year after surgery (p values not presented) Procedure costs: GBP 4,500 for AGB, GBP 7,300 for SG and GBP 8,500 for RYGB</td>
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### Study Details

<table>
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<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
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| Hawkins et al. 2007²⁵⁹ | UK      | Retrospective survey of patients with BMI≥35 kg/m² with comorbidities or BMI≥40 kg/m² with comparison of work and benefits 3 months before and 3 months after surgery | Bariatric surgery (AGB and RYGB) | -                    | Percentage of patients in paid work: 58% before surgery versus 76% after surgery (p<0.05)  
Average weekly time work: 30.1 hours before surgery versus 35.8 hours after surgery (p<0.01)  
Benefits: 19 respondents claimed 32 benefits before surgery versus 6 respondents claiming 8 benefits after surgery (p<0.01) |
| Anselmino et al. 2009²⁶² | Austria, Italy, Spain | Cost-effectiveness analysis in patients BMI≥35 kg/m² with type 2 diabetes over a 5-year time horizon | AGB, RYGB, Medical management | EUR (2009) | Discounted quality-adjusted life expectancy (Austria, Italy and Spain): 3.03 QALYs with AGB versus 3.34 QALYs with RYGB versus 2.00 QALYs with medical management  
Discounted direct costs (Austria): Cost savings of EUR 2,942 and EUR 1,938 with AGB and RYGB, respectively, versus medical management  
Discounted direct costs (Italy): Cost savings of EUR 1,107 and EUR 1,670 with AGB and RYGB, respectively, versus medical management  
Discounted direct costs (Spain): Cost increases of EUR 1,497 and EUR 3,570 with AGB and RYGB, respectively, versus medical management  
ICERs (Austria and Italy): AGB and RYGB were dominant over medical management  
ICERs (Spain): EUR 1,456 per QALY gained for AGB versus medical management, EUR 2,664 per QALY gained for RYGB versus medical management |
Discounted quality-adjusted life expectancy (SG versus medical management): 7.57 versus 7.04 QALYs  
Discounted quality-adjusted life expectancy (RYGB versus medical management): 7.67 versus 7.04 QALYs  
Discounted direct costs (AGB versus medical management): EUR 34,594 versus EUR 29,254 with RYGB versus EUR 42,497 with medical management  
Discounted direct costs (SG versus medical management): EUR 34,934 versus EUR 50,667 with RYGB versus EUR 50,667 with medical management  
Discounted direct costs (RYGB versus medical management): EUR 33,379 versus EUR 50,667 with RYGB versus EUR 50,667 with medical management  
ICERs: AGB, SG, RYGB and bariatric surgery were dominant over medical management |
| Faria et al. 2013²⁶⁴  | Portugal| Cost-effectiveness analysis in patients with BMI>35 kg/m² over a lifetime time horizon | AGB, RYGB, Medical management | EUR (cost year not stated) | Discounted quality-adjusted life expectancy: 15.09 QALYs with AGB versus 16.36 QALYs with RYGB versus 14.48 QALYs with medical management  
Discounted direct and indirect costs: EUR 41,056 with AGB versus EUR 29,254 with RYGB versus EUR 42,497 with medical management  
ICERs: AGB and RYGB were dominant over medical management |
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<th>Study</th>
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<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
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</table>
| Ackroyd et al. 2006<sup>265</sup> | France Germany UK | Cost-effectiveness analysis in patients BMI≥35 kg/m² with type 2 diabetes over a 5-year time horizon | AGB RYGB Medical management | EUR and GBP (2005) | Discounted quality-adjusted life expectancy (France, Germany and UK): 3.03 QALYs with AGB versus 3.34 QALYs with RYGB versus 2.00 QALYs with medical management  
Discounted direct costs (France): EUR 14,796 with AGB versus EUR 13,399 with RYGB versus EUR 19,276 with medical management  
Discounted direct costs (Germany): EUR 13,610 with AGB versus EUR 12,166 with RYGB versus EUR 17,197 with medical management  
Discounted direct costs (UK): GBP 9,072 with AGB versus GBP 9,121 with RYGB versus GBP 7,088 with medical management  
ICERs (France and Germany): AGB and RYGB were dominant over medical management  
ICERs (UK): GBP 1,929 per QALY gained for AGB versus medical management, GBP 1,517 per QALY gained for RYGB versus medical management |
Discounted quality-adjusted life expectancy: 10.05 QALYs with AGB versus 9.14 QALYs with medical management  
Discounted direct costs: GBP 23,562 with AGB versus GBP 20,263 with medical management  
ICER based on life expectancy: GBP 5,163 per life year gained  
ICER based on quality-adjusted life expectancy: GBP 3,602 per QALY gained |
| Picot et al. 2009<sup>267</sup> (update of Avenell et al. 2004<sup>268</sup>) | UK               | Cost-effectiveness analysis in patients with BMI≥45 kg/m² who have failed to achieve or maintain weight loss using medical management over a 20-year time horizon (with optimistic and pessimistic scenarios) | AGB RYGB Medical management | GBP (2008)       | Discounted quality-adjusted life expectancy (optimistic scenario): 12.68 QALYs with AGB versus 12.78 QALYs with RYGB versus 10.80 QALYs with medical management  
Discounted quality-adjusted life expectancy (pessimistic scenario): 11.72 QALYs with AGB versus 12.32 QALYs with RYGB versus 10.80 QALYs with medical management  
Discounted direct costs: GBP 17,126 with AGB versus GBP 19,824 with RYGB versus GBP 13,561 with medical management  
ICERs (optimistic scenario): GBP 1,897 per QALY gained for AGB versus medical management, GBP 3,160 per QALY gained for RYGB versus medical management  
ICERs (pessimistic scenario): GBP 3,863 per QALY gained for AGB versus medical management, GBP 4,127 per QALY gained for RYGB versus medical management |

3.5.2 North America

3.5.2.1 Impact of bariatric surgery on healthcare resource use and costs

A total of 24 studies assessed the impact of bariatric surgery on costs in North America. A single study was conducted in Canada, with the other studies conducted in the US.

- Workplace productivity: A study in Texas found that bariatric surgery could result in significant increases in economic productivity within the local economy. This is supported by a further study which found that a higher proportion of patients returned to employment following surgery compared to patients receiving medical management.

- Hospital stay: A study in Canada found that bariatric surgery was associated with reduced number of hospitalizations, reduced duration of hospital stay and reduced physician visits over 5 years compared to medical management. In the US, a 5-year study has suggested that bariatric surgery is associated with a reduction in annual primary care visits and annual specialist visits, but an increase in the number of annual inpatient days. Over the short-term, RYGB was associated with a statistically significant reduction in office visits and outpatient visits, but an increase in inpatient visits when 6 months before and after surgery were compared. When length of stay was compared across bariatric procedures, open AGB was associated with the longest length of hospital stay (4 days) and laparoscopic AGB and laparoscopic RYGB were associated with the shortest length of stay (both 2 days).

- Medication use: Studies consistently show that bariatric surgery is associated with reduced use of diabetes, cardiovascular, respiratory system, hypolipidemic, anti-infective, asthma, and all drugs.

- Hospital costs: Costs of hospitalization was reported in relatively few studies, with studies suggesting that inpatient costs were increased in the initial post-surgical period but costs with bariatric surgery were equal or lower than medical management in later years.

- Medication costs: Data around medication costs was mixed, but the majority of studies found that bariatric surgery was associated with lower costs immediately following surgery which persisted for up to 6 years. A meta-analysis supported this, identifying mean monthly prescription cost savings of USD 78.82 following bariatric surgery, with higher cost savings (USD 180.98) identified in patients with diabetes. However, one study concluded that bariatric surgery was associated with increased pharmacy costs up to 6 years. Other studies found that surgery was associated with a short term increase in pharmacy costs, but cost savings in later year.

- Procedure costs: A 2010 study in the US found that the mean cost of RYGB was USD 11,144, with costs lower in patients undergoing laparoscopic compared with open procedures. Older studies identified costs, ranging from USD 10,421 for RYGB to USD 29,952 for all bariatric procedures combined. When costs up to 6 months following surgery were included, total costs of the surgery was increased to USD 29,921 on average and was higher for patients experiencing complications. A 2013 comparison of hospital costs associated with each procedure found that RYGB was associated with the highest cost, followed by SG, with AGB associated with the lowest cost.

- Total costs: In Canada, total direct costs over 5 years were found to be lower in patients undergoing bariatric surgery than those receiving medical management. Data in the US were more varied. In a study comparing AGB and RYGB with medical management in morbidly obese and an overall surgical cohort, both procedures were associated with 5-year costs savings in morbidly obese patients, but increased 5-year costs in the general surgical population. A total 2 of studies suggested
that total annual costs were increased at 5 years post-surgery (compared to either medical management or pre-surgical costs). In contrast, two studies concluded that while initial annual costs following surgery were higher, cost savings occurred in later years. An additional five studies found that cost savings were apparent immediately following surgery.

- **Time to breakeven:** In the six studies which reported time to break even, time to return on investment in surgery ranged from 1.25 years (in morbidly obese patients with type 2 diabetes undergoing AGB) to over 10 years (in the general surgical population undergoing RGB).

### 3.5.2.2 Cost-effectiveness of bariatric surgery

In North America, 12 studies assessing the cost-effectiveness of bariatric surgery have been conducted. A single study was conducted in Canada, with the remaining studies assessing outcomes in the US. The majority of studies projected costs and clinical outcomes over patient lifetimes, although time horizons as short as 2 years were also used. Analytes were conducted in general patients, patients with co-morbidities, patients without co-morbidities, patients with diabetes, and adolescents.

- **Quality-adjusted life expectancy:** In all studies, bariatric surgery was associated with improved quality-adjusted life expectancy compared with medical management. This was observed for AGB, SG, RYGB, BPD and combinations of procedures in both Canada and the US (Figure 3-27). Where studies compared more than one bariatric procedure, RYGB was consistently associated with the highest quality-adjusted life expectancy.

- **Costs:** In a single study, bariatric surgery was associated with reduced costs compared to medical management, with outcomes assessed in patients with BMI>50 kg/m² and co-morbidities. In the remaining studies, AGB, SG, RYGB, BPD and combinations of procedures were associated with increased costs over medical management in both the US and Canada. In studies comparing multiple procedures, RYGB was associated with the highest cost in four studies, BPD in one study and AGB in one study.

- **Cost-effectiveness:** In Canada, AGB and RYGB were associated with ICERs of CAD 9,398 and CAD 12,212 per QALY gained, respectively, versus medical management. In the US, ICERs for AGB versus medical management ranged from USD 5,400 to USD 35,680 per QALY gained, with the highest ICER identified over a 10-year time horizon. In the single study assessing SG and BPD, ICERs of USD 29,087 and USD 46,508 per QALY gained, respectively, were identified in patients with BMI≥30 kg/m² over a 10-year time horizon. The highest and lowest ICERs for RYGB versus medical management were identified in the same study, with RYGB associated with an ICER of USD 48,662 per QALY gained over a 2-year time horizon and an ICER of USD 1,425 per QALY gained over patient lifetimes. One study assessed cost-effectiveness of all bariatric surgery, rather than for each procedure. ICERs were lower in patients with higher BMI at baseline and with co-morbidities (versus no co-morbidities). In adolescents, RYGB was associated with an ICER of USD 36,570 per QALY gained over a 7-year time horizon.
Figure 3-27  Long-term projections of quality-adjusted life expectancy with bariatric procedures in North America


Table 3-11  Economic studies of bariatric surgery in North America

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<th>Procedures</th>
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<tr>
<td>Christou et al. 2004219</td>
<td>Canada</td>
<td>Observational two cohort study in morbidly obese patients undergoing bariatric surgery versus age- and sex-matched non-surgical controls with follow-up of up to 5 years Surgery n=1,035 Non-surgical control n=5,746</td>
<td>Bariatric surgery (RYGB and VBG) Medical manageme nt</td>
<td>CAD (1996)</td>
<td>Total mean (SD) direct costs over 5 years: CAD 8,813 (2,344) for surgery versus CAD 11,854 (21,220) for non-surgical controls (p=0.001) Mean (SD) hospitalizations over 5 years: 2.75 (3.44) for surgery versus 3.17 (3.22) for non-surgical controls (p=0.001) Mean (SD) hospital stay over 5 years: 21.05 (38.97) days for surgery versus 36.59 (25.41) for non-surgical controls (p=0.001) Mean (SD) physician visits over 5 years: 9.62 (15.8) for surgery versus 17.00 (21.74) for non-surgical controls (p=0.001)</td>
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<td>Study title</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currency (cost year)</td>
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<tr>
<td>Lopes et al. 2015</td>
<td>US</td>
<td>Meta-analysis of drug use and drug costs pre- and post-surgery in adults with BMI&gt;35 kg/m² undergoing bariatric surgery N=9 studies</td>
<td>Bariatric surgery</td>
<td>USD (2014)</td>
<td>Drug cost: Monthly saving (95% CI) in drug costs following bariatric surgery was USD 78.82 (111.04–46.60, p&lt;0.00001) Drug cost: Monthly savings (95% CI) were highest (USD 180.98 [251.15–110.82] per month) in studies with a diabetes prevalence of &gt;30% (p&lt;0.00001) Drug use: Mean (95% CI) reduction in drug use of 2.03 (2.38–1.69) drugs following bariatric surgery (p=0.00001)</td>
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<tr>
<td>Finkelstein et al. 2013</td>
<td>US</td>
<td>Non-randomized case control study of costs in patients (aged 18–64 years) undergoing AGB or RYGB versus two different propensity matched non-surgical control groups (one general non-surgical control and one restricted to morbidly obese patients only) AGB n=9,631 RYGB n=9,631 Non-surgical control (all) n=9,631 Morbidly obese non-surgical control n=9,639</td>
<td>AGB RYGB Medical management</td>
<td>USD (cost year not stated)</td>
<td>Versus morbidly obese non-surgical control group Time to break even: 1.5 years with AGB (1.25 years in diabetes sub-sample) and 2.25 years for RYGB (1.75 years in diabetes sub-sample) (p values not presented) 5 year net savings with surgery: USD 78,980 with AGB (USD 127,590 in diabetes sub-sample) and USD 61,420 with RYGB (USD 103,340 in diabetes sub-sample) (p values not presented) Versus overall non-surgical control group Time to break even: 5.25 years with AGB (4.25 years in diabetes sub-sample) and &gt;10 years for RYGB (&gt;10 years in diabetes sub-sample) (p values not presented) 5 year incremental costs: USD 690 higher with AGB versus control (USD 3,060 saving versus control in diabetes sub-sample) and USD 18,940 higher with RYGB versus non-surgical control (USD 21,610 higher versus control for diabetes sub-sample) (p values not presented)</td>
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<tr>
<td>Weiner et al. 2013</td>
<td>US</td>
<td>Retrospective database analysis of costs for patients undergoing bariatric surgery versus matched non-surgical controls Bariatric surgery n=29,820 Non-surgical control n=29,820</td>
<td>Bariatric surgery (gastric bypass, laparoscopic banding, other) Medical management</td>
<td>USD (2005)</td>
<td>Mean costs 1 year pre-surgery: USD 8,850 for surgery group versus USD 9,590 for non-surgical controls (p values not presented) Mean costs post-surgery: For surgery group USD 8,905, USD 9,908 and USD 9,259 at 1, 2 and 6 years post-surgery versus USD 9,908, USD 9,264 and USD 8,714 the non-surgical group (p values not presented) Mean pharmacy costs: For surgery group USD 1,232, USD 1,223 and USD 1,368 at 1, 2, and 6 years post-surgery versus USD 2,038, USD 2,044 and USD 1,878, for the non-surgical group (p values not presented)</td>
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<td>Nguyen et al. 2013</td>
<td>US</td>
<td>Retrospective database analysis of costs in morbidly obese patients with minor severity of illness undergoing bariatric surgery SG n=2,441 AGB n=571 RYGB n=4,627</td>
<td>AGB SG RYGB</td>
<td>USD (cost year not stated)</td>
<td>Mean (SD) total hospital cost of procedure: USD 13,081 (4,471) for SG, USD 9,399 (2,554) for AGB (p&lt;0.05 versus SG), USD 14,401 (3,851) for RYGB (p&lt;0.05 versus SG)</td>
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<tr>
<td>Study</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currency (cost year)</td>
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<tr>
<td>Bleich et al. 2012&lt;sup&gt;270&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective comparison of pre-versus post-surgery resource utilization and costs in patients with type 2 diabetes undergoing bariatric surgery</td>
<td>Bariatric surgery</td>
<td>USD (cost year not stated)</td>
<td><strong>Annual total mean (SD) costs:</strong> pre-surgery costs USD 9,326 (17,258) versus USD 13, 400 (22,368) at 1 year and USD 13,664 (28,703) at 5 years post-surgery (p values not presented) <strong>Mean (SD) annual pharmacy costs:</strong> pre-surgery USD 1,781 (3,579) versus USD 1,825 (3,558) at 1 year and USD 1,561 (2,744) at 5 years post-surgery (p values not presented) <strong>Mean (SD) annual primary care visits:</strong> 5.2 (5.0) visits per person pre-surgery versus 4.1 (4.8) and 2.6 (4.1) visits per person at 1 and 5 years post-surgery, respectively (p values not presented) <strong>Mean (SD) annual specialist visits:</strong> 6.1 (5.7) visits per person pre-surgery versus 4.8 (6.1) and 3.6 (5.0) visits per person at 1 and 5 years, post-surgery, respectively (p values not presented)</td>
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<tr>
<td>Maciejewski et al. 2012&lt;sup&gt;278&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective comparison of costs pre- and post-surgery in patients undergoing bariatric surgery (mean BMI of 47 kg/m²) versus propensity-matched non-surgical controls</td>
<td>Bariatric surgery (RYGB and VBG) Medical management</td>
<td>USD (2006)</td>
<td><strong>Total costs (adjusted):</strong> USD 28,400 higher (p&lt;0.001) for surgical patients versus control in 6 months up to and including surgery (driven by surgery costs), USD 4,397 higher (p&lt;0.001) for surgical patients in first 6 months post-surgery, but similar (p=0.75) to non-surgical controls at 31–36 months post-surgery</td>
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<tr>
<td>Myers et al. 2012&lt;sup&gt;279&lt;/sup&gt;</td>
<td>US</td>
<td>Comparison of costs in obese adults aged 35–60 years with BMI 40–60 kg/m² undergoing bariatric surgery versus non-surgical controls, with 6 years of follow-up</td>
<td>RYGB Medical management</td>
<td>USD (cost year not stated)</td>
<td><strong>Total average medical claims cost:</strong> In the surgery group USD 6,270 in the year prior to surgery and USD 30,631, USD 5,588 and USD 2,041 at 1, 2 and 6 years post-surgery. In the no-surgery group USD 7,149 in 1 year prior to operation for surgical group versus USD 10,888, USD 5,298 and USD 7,729 at 1, 2 and 6 years after surgery was performed for surgical group (p values not presented) <strong>Total pharmacy costs:</strong> USD 1,167, USD 916 and USD 2,450 at 1, 2 and 6 years, respectively, post-surgery in the surgery group and USD 1,608, USD 1,583 and USD 2,601, respectively for the no-surgery group (p values not presented)</td>
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<tr>
<td>Ghiassi et al. 2012&lt;sup&gt;280&lt;/sup&gt;</td>
<td>US</td>
<td>Database analysis of prospectively collected cost data pre- and 1 year post surgery in consecutive patients undergoing RYGB</td>
<td>RYGB</td>
<td>USD (cost year not stated)</td>
<td><strong>Mean (SE) annual cost of hypertension medication:</strong> pre-surgery USD 63.52 (9.42) versus USD 20.50 (4.45) at 1 year post-surgery (65% reduction, p&lt;0.0001) <strong>Mean (SE) annual cost of diabetes medication:</strong> pre-surgery USD 532.06 (97.01) versus USD 64.58 (37.95) at 1 year post-surgery (88% reduction, p&lt;0.0001)</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currency (cost year)</td>
<td>Key findings</td>
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<tr>
<td>Ewing et al. 2011(^{295})</td>
<td>US</td>
<td>Analysis of economic impact of bariatric surgery in a region of Texas (South Plains) Surgery n=150</td>
<td>Bariatric surgery (laparoscopic gastric banding and laparoscopic bypass)</td>
<td>USD (2008)</td>
<td>Estimated net benefit of bariatric surgery (gains in lost output) in South Plains region of Texas: USD 9.9 billion, USD 5.0 billion and USD 1.4 billion at discount rates of 3%, 5% and 10% per annum, respectively</td>
</tr>
<tr>
<td>Mullen et al. 2010(^{287})</td>
<td>US</td>
<td>Observational analysis of costs pre- and post-surgery in obese patients undergoing RYGB, with projected costs for no surgery RYGB n=224</td>
<td>RYGB No surgery</td>
<td>USD (cost year not stated)</td>
<td>Mean cost in pre-surgical year: USD 10,470 for patients undergoing surgery Mean cost in surgical year: USD 35,743 for RYGB versus projection of USD 11,726 (p value not presented) Mean annual costs post-surgery: USD 7,885, USD 8,046, USD 6,575, USD 5,952 and USD 8,576 in years 1, 2, 3, 4 and 5, respectively; versus projections of USD 13,134, USD 14,710, USD 16,475, USD 18,452 and USD 20,667 (p value not presented) Time to breakeven in patients undergoing RYGB: 3.5 years</td>
</tr>
<tr>
<td>McEwen et al. 2010(^{382})</td>
<td>US</td>
<td>Review of medical claims data of patients with BMI≥35 kg/m(^2) with two life threatening co-morbidities or BMI≥40 kg/m(^2) for 18 months before and 24 months after surgery RYGB n=221</td>
<td>RYGB</td>
<td>USD (cost year not stated)</td>
<td>Mean cost of procedure: USD 11,144 for all surgeries (USD 10,393 for laparoscopic RYGB, USD 11,705 for open RYGB) Total per patient per month costs: USD 428 18–6 months before surgery, USD 653 6–0 months before surgery, USD 523 1–13 months post-surgery, USD 569 13–24 months post-surgery</td>
</tr>
<tr>
<td>Perryman et al. 2010(^{31})</td>
<td>US</td>
<td>Database analysis of direct and indirect costs in class II and III obese patients undergoing AGB Patient number not stated</td>
<td>AGB</td>
<td>USD (2008)</td>
<td>Time to break even: 23–24 months from payer perspective and 17–19 months from employer perspective Monthly savings post-surgery: USD 192 moths 3–6, USD 592 months 7–12, USD 1,110 months 13–18, USD 1,154 month 19 onwards</td>
</tr>
<tr>
<td>Makary et al. 2010(^{275})</td>
<td>US</td>
<td>Retrospective review of Blue Cross/Blue Shield health care plans for claims for diabetes medications before and after bariatric surgery Surgery n=2,235</td>
<td>Bariatric surgery</td>
<td>USD (cost year not stated)</td>
<td>Medication use: 3 months before surgery 85.8% of patients were receiving diabetes medications, compared with to 25.3% at 6 months post-surgery, 19.4% at 1 year post-surgery, and 15.5% at 2 years post-surgery, and 13.9% at 3 years post-surgery Cost of procedure: The median cost of the surgical procedure and hospitalization was USD 29,959 Annual healthcare costs: USD 6376 per person 2 years pre-surgery, USD 10,592 1 year pre-surgery, USD 6,992 in the year of the surgery (excluding the procedure), USD 4,197 1 year post-surgery and USD 1,878 2 year post-surgery</td>
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<tr>
<td>Study</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currenc (cost year)</td>
<td>Key findings</td>
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<tr>
<td>Cremieux et al. 2010&lt;sup&gt;274&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective review of insurance claims 90 days before and 30–1,110 after bariatric surgery Surgery n=5,502</td>
<td>Bariatric surgery</td>
<td>-</td>
<td>Medication use 30–120 days post-surgery versus before surgery: statistically significant reductions in anti-infective, psychotropic, pain relief, respiratory system, hypolipidemic, cardiovascular, and diabetes medication use, no difference in anti-histamine and gastroenterological medication use. Medication use 1,020–1,110 days post-surgery versus before surgery: statistically significant reductions in anti-infective, respiratory system, hypolipidemic, anti-histamine, cardiovascular, diabetes and gastroenterological medication use, no difference in psychototropic or pain relief medication use.</td>
</tr>
<tr>
<td>Cremieux et al. 2008&lt;sup&gt;24&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective break even analysis for bariatric surgery versus propensity-matched non-surgical controls Bariatric surgery n=7302 (n=3,651 matched) Non-surgical controls n=3,651</td>
<td>Bariatric surgery</td>
<td>USD (2005)</td>
<td>Cost of surgery: Overall USD 24,500, cost for laparoscopic surgery was USD 17,000 and cost for open surgery was USD 26,000 (p values not presented) Time to breakeven (95% CI): 53 (42–64) months for bariatric surgery overall, 49 (35–63) months for open surgery (performed in 2003–2005) and 25 (16–34) months for laparoscopic bariatric surgery.</td>
</tr>
<tr>
<td>Hodo et al. 2008&lt;sup&gt;271&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective cohort study comparing medication use and costs and resource utilization before and 6 months after bariatric surgery RYGB n=605</td>
<td>RYGB</td>
<td>USD (cost year not stated)</td>
<td>Mean (SD) prescription costs: USD 221.30 (341.25) at 3–6 months pre-surgery versus USD 158.90 (454.13) at 3–6 months post-surgery (p&lt;0.001) Medication prescription: significant decrease in mean (SD) number of prescriptions for asthma (0.04 [0.27] versus 0.14 [0.57]), cardiac (0.40 [1.23] versus 1.03 [1.97]), diuretic (0.14 [0.50] versus 0.34 [0.85]), and diabetes (0.15 [0.78] versus 0.56 [1.75]) medications at 3–6 months post-surgery versus 3–6 months pre-surgery (p&lt;0.001 for all)</td>
</tr>
<tr>
<td>Frezza et al. 2007&lt;sup&gt;283&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective single-center study comparing charges in bariatric surgery cases AGB n=26 RYGB n=92</td>
<td>AGB RYGB</td>
<td>USD (cost year not stated)</td>
<td>Median cost of surgery: USD 10,491 with AGB versus USD 10,421 with RYGB (p=0.82)</td>
</tr>
<tr>
<td>Wagner et al. 2007&lt;sup&gt;269&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective single-center analysis of return to full-time employment in patients undergoing RYGB versus non-surgical controls RYGB n=38 Non-surgical control n=16</td>
<td>RYGB Medical management</td>
<td>NA</td>
<td>Return to work: At last follow-up, 37% of the bariatric surgery group versus 6% of the non-surgical control group were in employment (p value not presented)</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currency (cost year)</td>
<td>Key findings</td>
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<tr>
<td>Encinosa et al. 2006&lt;sup&gt;285&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective analysis of costs and resource utilization in patients undergoing bariatric surgery in the 6 months following surgery</td>
<td>Bariatric surgery (gastric bypass, banding and gastroplasty)</td>
<td>USD (cost year not stated)</td>
<td>Total costs in 6 months following surgery: USD 29,921 overall (USD 36,542 for patients with complications versus USD 25,337 for patients without complications [p&lt;0.01])</td>
</tr>
<tr>
<td>Nguyen et al. 2006&lt;sup&gt;281&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective review of prescriptions before and after surgery in patients with BMI 35–50 kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td>RYGB</td>
<td>USD (cost year not stated)</td>
<td>Cost of procedure: USD 13,800 Mean (SD) monthly prescription costs pre surgery: USD 69 (48) for hypertension, USD 209 (443) for diabetes, USD 95 (49) for hyperlipidemia, USD 98 for GERD, total USD 196 (297) Reduction in monthly prescription costs at 1 month post-surgery: hypertension 43%, diabetes 69%, hyperlipidemia 53%, GERD 81%, total 72% Mean cost saving 1 year post-surgery: USD 2,016 Reduction in monthly prescription costs at 2 years post-surgery: USD 176 (90%) Time to break even: 7 years</td>
</tr>
<tr>
<td>Livingston et al. 2005&lt;sup&gt;272&lt;/sup&gt;</td>
<td>US</td>
<td>Retrospective analysis of surgery costs for patients undergoing bariatric surgery</td>
<td>Open and laparoscopic RYGB, BPD and gastric banding</td>
<td>USD (cost year not stated)</td>
<td>Median total costs of procedures: Highest (USD 12,678) with laparoscopic banding, followed by laparoscopic BPD (USD 11,605), open BPD (USD 11,256), open RYGB (USD 11,157), laparoscopic RYGB (USD 9,897) and open banding (USD 9,677) (p values not presented) Median length of stay: Longest (4 days) with open banding, followed by open RYGB, and open and laparoscopic BPD (3 days for each) then laparoscopic RYGB and shortest with laparoscopic banding (both 2 days) (p values not presented)</td>
</tr>
<tr>
<td>Finkelstein et al. 2005&lt;sup&gt;288&lt;/sup&gt;</td>
<td>US</td>
<td>Modeling analysis of costs in patients with BMI ≥35 kg/m&lt;sup&gt;2&lt;/sup&gt; with angina, asthma, osteoarthritis, diabetes mellitus, or hypertension or BMI ≥40 kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Bariatric surgery</td>
<td>USD (2004)</td>
<td>Time to break even: 10.3 years when medical costs and work loss were included, 13.5 years when only medical costs were included</td>
</tr>
</tbody>
</table>
### Study Details

#### Makary et al. 2002²⁷⁵

**Setting:** US  
**Study details:** Retrospective comparison of pre- and post-surgery diabetes medication use and healthcare costs in adults with type 2 diabetes undergoing bariatric surgery  
**Procedures:** Bariatric surgery (RYGB, AGB, VBG, BPD and other)  
**Currenc y (cost year):** USD (cost year not stated)  
**Key findings:** Median total healthcare costs: USD 10,592 in the year prior to surgery, versus USD 6,992, USD 4,197 and USD 1,878 in years 1, 2, and 3, respectively, post-surgery (p values not presented)  
Mean number of diabetes medications used: 5.3 per patient immediately prior to surgery versus 1.3, 1.1, 0.9, 0.8, 0.7 and 0.5 per person at 3, 6, 9, 12, 24 and 36 months, respectively, post-surgery (p values not presented)

### Cost-effectiveness studies

#### Klarenbach et al. 2010²⁴⁹

**Setting:** Canada  
**Study details:** Cost-effectiveness analysis in patients with BMI>45 kg/m² or BMI>35 kg/m² with at least one co-morbidity over patient lifetimes  
**Procedures:** RYGB, AGB  
**Currenc y (cost year):** CAD (2009)  
**Key findings:** Discounted quality-adjusted life expectancy: 13.20 with AGB versus 14.72 QALYs with RYGB versus 12.42 QALYs with medical management  
Discounted direct costs: CAD 60,106 with RYGB versus CAD 48,021 with AGB versus CAD 38,454 with medical management  
ICERs: CAD 9,398 per QALY gained for RYGB versus medical management, CAD 12,212 per QALY gained versus medical management

#### Washington State HTA 2015²⁴⁵

**Setting:** US  
**Study details:** Cost-effectiveness analysis in patients with BMI≥30 kg/m² over a 10-year time horizon  
**Procedures:** AGB, SG, RYGB, BPD  
**Currenc y (cost year):** USD (cost year not stated)  
**Key findings:** Discounted quality-adjusted life expectancy: 7.93 QALYs with AGB versus 8.04 QALYs with SG versus 8.08 QALYs with RYGB versus 8.23 versus BPD versus 7.57 QALYs with medical management  
Discounted direct costs: USD 47,668 with AGB versus USD 48,702 with SG versus USD 54,110 with RYGB versus USD 65,741 with BPD versus USD 34,923 with medical management  
ICERs: USD 35,680 per QALY gained for AGB versus medical management, USD 29,087 for SG versus medical management, USD 37,423 per QALY gained for RYGB versus medical management, USD 46,508 per QALY gained for BPD versus medical management

#### Bairdain et al. 2015²⁸⁹

**Setting:** US  
**Study details:** Cost-effectiveness analysis of bariatric surgery in adolescents over 7 years  
**Procedures:** RYGB  
**Currenc y (cost year):** USD (2013)  
**Key findings:** Discounted life expectancy: increased by 0.16 years with RYGB  
Discounted quality-adjusted life expectancy: increased by 0.46 QALYs with RYGB  
Discounted direct costs: increased by USD 14,842 with RYGB  
ICER: USD 36,570 per QALY gained for RYGB versus medical management
<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang et al. 2014290</td>
<td>US</td>
<td>Cost-effectiveness analysis in a 53-year-old female with a baseline BMI of 44 kg/m² over patient lifetimes</td>
<td>Laparoscopic AGB Laparoscopic RYGB Medical management</td>
<td>USD (2010)</td>
<td>Discounted quality-adjusted life expectancy: 12.8 QALYs with AGB versus 13.2 QALYs with open RYGB versus 13.2 QALYs versus 13.4 QALYs with laparoscopic RYGB versus 10.6 QALYs with medical management Discounted direct costs: USD 164,313 with AGB versus USD 194,858 with open RYGB versus USD 169,074 with laparoscopic RYGB versus USD 150,934 with medical management ICERs: USD 6,200 per QALY gained for AGB versus open RYGB versus medical management, USD 17,300 per QALY gained for RYGB versus medical management, USD 6,600 per QALY gained for laparoscopic RYGB versus medical management</td>
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<tr>
<td>Chang et al. 2011291</td>
<td>US</td>
<td>Cost-effectiveness analysis in patients with BMI 35–40, 40–50 and ≥50 kg/m² with and without co-morbidities over patient lifetimes</td>
<td>Bariatric surgery Medical management</td>
<td>USD (2010)</td>
<td>With co-morbidities ICERs: USD 2,413 per QALY gained for BMI 35–40 kg/m², USD 1,853 per QALY gained for BMI 40–50 kg/m², dominant for BMI≥50 kg/m² for bariatric surgery versus medical management Without co-morbidities ICERs: USD 3,972 per QALY gained for BMI 35–40 kg/m², USD 3,770 per QALY gained for BMI 40–50 kg/m², USD 1,904 per QALY for BMI≥50 kg/m² for bariatric surgery versus medical management</td>
</tr>
<tr>
<td>McEwen et al. 2010282</td>
<td>US</td>
<td>Cost-effectiveness analysis in patients with BMI≥35 kg/m² with two life threatening co-morbidities or BMI≥40 kg/m² over 2-year and patient lifetime time horizons</td>
<td>RYGB Medical management</td>
<td>USD (cost year not stated)</td>
<td>2-year time horizon Discounted quality-adjusted life expectancy: 1.76 QALYs with RYGB versus 1.48 QALYs with medical management Discounted direct costs: USD 23,980 with RYGB versus USD 10,282 with medical management ICER: USD 48,662 per QALY gained for RYGB versus medical management Patient lifetime time horizon Discounted quality-adjusted life expectancy: 9.95 QALYs with RYGB versus 8.19 QALYs with medical management Discounted direct costs: USD 83,813 with RYGB versus USD 81,308 with medical management ICER: USD 1,425 per QALY gained for RYGB versus medical management</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Study details</td>
<td>Procedures</td>
<td>Currency (cost year)</td>
<td>Key findings</td>
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</table>
| Campbell et al. 2010 $^{292}$ | US      | Cost-effectiveness analysis in patients with BMI ≥35 kg/m$^2$ with co-morbidities or BMI ≥40 kg/m$^2$ over patient lifetimes | AGB        | USD (2006)           | Discounted life expectancy: 21.79 years with AGB versus 22.21 years with RYGB versus 20.62 years with medical management  
Discounted quality-adjusted life expectancy: 18.20 QALYs with AGB versus 19.05 QALYs with RYGB versus 16.16 QALYs with medical management  
Discounted direct costs: USD 119,487 with AGB versus USD 124,811 with RYGB versus USD 108,523 with medical management  
ICERs based on quality-adjusted life expectancy: USD 5,400 for AGB versus medical management, USD 5,600 per QALY gained for RYGB versus medical management, USD 6,200 per QALY gained for RYGB versus AGB |
Discounted quality-adjusted life expectancy: 11.12 QALYs with AGB versus 11.76 QALYs with RYGB versus 9.55 QALYs with medical management  
Discounted direct costs: USD 89,029 with AGB versus USD 86,665 with RYGB versus USD 71,130 with medical management  
ICERs: USD 11,000 for AGB versus medical management and USD 7,000 for RYGB versus medical management  
Established diabetes  
Discounted quality-adjusted life expectancy: 9.02 QALYs with AGB versus 9.38 QALYs with RYGB versus 7.68 QALYs with medical management  
Discounted direct costs: USD 96,021 with AGB versus USD 99,944 with RYGB versus USD 79,618 with medical management  
ICERs: USD 13,000 for AGB versus medical management and USD 12,000 for RYGB versus medical management |
Discounted quality-adjusted life expectancy: 6.78 QALYs with RYGB versus 5.88 QALYs with medical management  
Discounted direct costs: USD 83,482 with RYGB versus USD 63,722 with medical management  
ICER based on life expectancy: USD 29,676 per life year gained for RYGB versus medical management  
ICER based on quality-adjusted life expectancy: USD 21,973 per QALY gained for RYGB versus medical management |
### Study Details

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<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
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</table>
| Salem et al. 2008<sup>295</sup> | US      | Cost-effectiveness analysis in patients without obesity-related co-morbidities, with a BMI of 40, 50, and 60 kg/m², and aged 35, 45, and 55 years over patient lifetimes | AGB, RYGB, Medical management | USD (2004)            | ICERs (males aged 35 years with a BMI of 40 kg/m²): USD 11,604 per QALY gained for AGB versus medical management and USD 18,543 per QALY gained for RYGB versus medical management  
ICERs (females aged 35 years with a BMI of 40 kg/m²): USD 8,878 per QALY gained for AGB versus medical management and USD 14,608 per QALY gained for RYGB versus medical management  
ICERs: ICERs for all analyses were below USD 25,000 per QALY gained  
ICERs: The ICER was lower for AGB versus medical management that RYGB versus medical management for all analyses |
| Jensen et al. 2005<sup>296</sup> | US      | Cost-effectiveness analysis in white women over patient lifetimes               | RYGB, Medical management | USD (2004)            | Discounted life expectancy: increased by 0.61 years with RYGB  
Discounted quality-adjusted life expectancy: increased by 0.65 QALYs with RYGB  
Discounted direct costs: increased by USD 4,600 with RYGB  
ICER: USD 7,126 per QALY gained for RYGB versus medical management |
| Craig et al. 2002<sup>297</sup>  | US      | Cost-effectiveness analysis in patients with BMI 40–50 kg/m² aged 35–55 years over patient lifetimes | RYGB, Medical management | USD (2001)            | ICERs (patients aged 35 years): Men with BMI of 40 kg/m² USD 28,600 per QALY gained, men with BMI of 50 kg/m² USD 10,700 per QALY gained, women with BMI of 40 kg/m² USD 14,700 per QALY gained, women with BMI of 50 kg/m² USD 5,700 per QALY gained (all for RYGB versus medical management)  
ICERs (patients aged 55 years): Men with BMI of 40 kg/m² USD 35,600 per QALY gained, men with BMI of 50 kg/m² USD 13,300 per QALY gained, women with BMI of 40 kg/m² USD 16,100 per QALY gained, women with BMI of 50 kg/m² USD 5,400 per QALY gained (all for RYGB versus medical management) |


#### 3.5.3 South America

#### 3.5.3.1 Impact of bariatric surgery on healthcare resource use and costs

A total of four studies examined the impact of bariatric surgery on healthcare costs in South America. Two of the studies were based in the Mexican setting, with two studies conducted in Brazil.

- **Procedure costs**: The cost of an RYGB procedure in Mexico was estimated to be MXN 64,000 (approximately USD 3,300), but this increased to USD 8,300 when other aspects, such as hospital stay and physiotherapy, were included.<sup>298,299</sup> In Brazil, the cost of an RYGB procedure was estimated to be USD 4,951.80.<sup>300</sup>
 Costs before and after surgery: Results relating to costs before and after bariatric surgery in Brazil were mixed. In one study, annual costs in the 4 years after surgery were higher than the annual costs in the 4 years before surgery. However, a 3-year study found that costs were lower in the year following surgery and continued to fall for 3 years.

 Costs with surgery versus medical management: In Mexico, costs over 10 years were lower with bariatric surgery than medical management, with return on investment on the surgical procedure occurring after 6.8 years.

### 3.5.3.2 Cost-effectiveness of bariatric surgery

No studies assessing the cost-effectiveness of bariatric surgery in South America have been conducted.

### Table 3-12  Economic studies of bariatric surgery in South America

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
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<tr>
<td><strong>Cost studies</strong></td>
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<tr>
<td>Zanela et al. 2012</td>
<td>Mexico</td>
<td>Modeling analysis assessing costs in morbidly obese patients over a 10-year time horizon</td>
<td>Bariatric surgery Medical management</td>
<td>MXN (2011)</td>
<td>Cost of bariatric surgery: MXN 64,000 Total cost: MXN 127,963 with bariatric surgery versus MXN 266,527 with medical management over 10 years Time to return on investment: 6.8 years</td>
</tr>
<tr>
<td>Mosti et al. 2007</td>
<td>Mexico</td>
<td>Comparison of estimated costs and actual costs accrued in consecutive patients undergoing surgery RYGB n=150</td>
<td>RYGB</td>
<td>USD (cost year not stated)</td>
<td>Mean hospital stay 3.0 days Estimated total cost: USD 8,300 Actual costs accrued: Mean total costs were 98.5% of the estimated costs and in 95.3% of patients, the total expenses were within 10% of the estimated costs</td>
</tr>
<tr>
<td>Bruschi Kelles et al. 2015</td>
<td>Brazil</td>
<td>Patients aged &gt;18 years with BMI&gt;40 kg/m2 or BMI&gt;35 kg/m2 and at least two co-morbidities with comparison of costs in the 4 years before and in the 4 years after surgery RYGB n=4,006</td>
<td>RYGB</td>
<td>Converted from BRL to USD (2011)</td>
<td>Cost of RYGB: USD 4,951.80 Annual cost: USD 112.86 after surgery versus USD 69.42 before surgery</td>
</tr>
<tr>
<td>Sussenbach et al. 2012</td>
<td>Brazil</td>
<td>Retrospective chart review of patients undergoing surgery with comparison of costs before surgery and in the 3 years after surgery RYGB n=194</td>
<td>RYGB</td>
<td>Converted from BRL to USD (2011)</td>
<td>Median total cost: USD 1,706 before surgery, USD 1,174 1–12 months after surgery, USD 713 13–24 months after surgery, USD 431 25–32 months after surgery Costs were higher in patients with more co-morbidities both before and after surgery</td>
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</table>

3.5.4 Asia

3.5.4.1 Impact of bariatric surgery on healthcare resource use and costs
No studies assessing the impact of bariatric surgery on healthcare costs in Asia were identified.

3.5.4.2 Cost-effectiveness of bariatric surgery
One study was identified which assessed the cost-effectiveness of bariatric surgery in Asia. This was a modeling study of all bariatric procedures in South Korea. A time horizon of patient lifetimes was used.

- Quality-adjusted life expectancy: Bariatric surgery was associated with increased quality-adjusted life expectancy compared with medical management (Figure 3-28).302
- Costs: Projections suggested that costs were higher with bariatric surgery than medical management (Figure 3-28).302
- Cost-effectiveness: Bariatric surgery was associated with an ICER of USD 1,771 per QALY gained versus medical management.302

Figure 3-28 Health economic outcomes of bariatric surgery and medical management in South Korea

Table 3-13 Economic studies of bariatric surgery in Asia

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
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<tbody>
<tr>
<td>Song et al. 2013302</td>
<td>South Korea</td>
<td>Cost-effectiveness analysis patients with BMI 30–40 kg/m² with a lifetime time horizon</td>
<td>Bariatric surgery (AGB, SG, RYGB)</td>
<td>Converted from KRW to USD (2009)</td>
<td>Discounted quality-adjusted life expectancy: 16.29 QALYs with bariatric surgery versus 15.43 QALYs with medical management. Discounted direct costs: USD 17,914 with bariatric surgery versus USD 16,393 with medical management. ICER: USD 1,771 per QALY gained</td>
</tr>
</tbody>
</table>

3.5.5 Australasia and Oceania

3.5.5.1 Impact of bariatric surgery on healthcare resource use and costs

A single study relating to the impact of bariatric surgery in Australasia and Oceania has been conducted. This was a cost-collection study carried out alongside a 2 year RCT of AGB versus medical management in patients with type 2 diabetes in Australia.

- Surgery cost: AGB was associated with a cost of AUD 8,527.\(^{303}\)
- Total cost: Over 2 years, costs were AUD 9,987 higher with AGB than medical management.\(^{303}\) This was predominantly driven by costs of surgery and in the following 6 months, with no differences between the arms in the last 6 months of the study.

3.5.5.2 Cost-effectiveness of bariatric surgery

One study assessing the cost-effectiveness of AGB versus medical management in Australia was identified. The study projected long-term clinical outcomes over patient lifetimes in a cohort with type 2 diabetes at baseline.

- Quality-adjusted-life expectancy: AGB was associated with improved quality-adjusted life expectancy and increased years free of diabetes compared with medical management.\(^{304}\)
- Costs: AGB was associated with lower costs than medical management over patient lifetimes.\(^{304}\)
- Cost-effectiveness: Long-term projections suggested that AGB was dominant over medical management.\(^{304}\)

Figure 3-29 Health economic outcomes of AGB and medical management in Australia

![Graph showing health economic outcomes of AGB and medical management in Australia.](Source: Keating et al. 2009.\(^{304}\))

### Table 3-14  Economic studies of bariatric surgery in Australasia and Oceania

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Study details</th>
<th>Procedures</th>
<th>Currency (cost year)</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost studies</strong></td>
<td></td>
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<tr>
<td>Keating et al. 2009a&lt;sup&gt;103&lt;/sup&gt;</td>
<td>Australia</td>
<td>A 2-year randomized controlled trial in patients with BMI 30–40 kg/m² with recently diagnosed type 2 diabetes Surgery n=30 Medical management n=30</td>
<td>AGB Medical management</td>
<td>AUD (2006)</td>
<td>Surgery cost: AUD 8,527 per patient in the AGB arm Total cost: AUD 13,383 per patient with AGB versus AUD 3,396 per patient with medical management Costs over time: In the first 6 months of the study, costs were seven fold higher with AGB than medical management, but costs were equivalent in months 18–24 of the study</td>
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<tr>
<td><strong>Cost-effectiveness studies</strong></td>
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<td></td>
</tr>
<tr>
<td>Keating et al. 2009b&lt;sup&gt;104&lt;/sup&gt;</td>
<td>Australia</td>
<td>Cost-effectiveness analysis in trial in patients with BMI 30–40 kg/m² with recently diagnosed type 2 diabetes with a lifetime time horizon</td>
<td>AGB Medical management</td>
<td>AUD (2006)</td>
<td>Years in diabetes remission: 11.4 with AGB versus 2.1 with medical management Discounted life expectancy: 20.0 years with AGB versus 19.2 years with medical management Discounted quality-adjusted life expectancy: 15.7 QALYs with AGB versus 14.5 QALYs with medical management Discounted direct costs: AUD 98,931 with AGB versus AUD 101,376 with medical management ICER based on life expectancy: AGB dominant ICER based on quality-adjusted life expectancy: AGB dominant</td>
</tr>
</tbody>
</table>


**3.5.6 Africa**

No studies assessing the impact of bariatric surgery on healthcare costs or cost-effectiveness in Africa were identified.
4 CONCLUDING REMARKS

The WHO describes obesity as an “escalating global epidemic” and estimated that in 2014, 13% of adults aged > 20 years worldwide met the criteria for obesity.\textsuperscript{14} Obesity and obesity-related co-morbidities represent one of the major healthcare challenges currently faced by healthcare providers, policy makers and payers. Direct medical costs are 6–45% higher in obese patients than their normal-weight peers, and costs attributable to obesity account for 0.7–2.8% of total healthcare expenditure.\textsuperscript{65} There is substantial evidence that weight loss is associated with improvement and/or remission of co-morbid conditions, prevention of development of further co-morbid conditions, and improved quality of life, and that this is directly associated with the amount of weight lost. These improvements reduce the clinical burden on patients and the economic burden associated with obesity, resulting in cost savings.

RCTs, other clinical studies and meta-analyses have shown that, compared with medical management, bariatric surgery is associated with increased weight loss, increased remission of diabetes, improved glycemic control in patients with diabetes, increased proportions of patients with type 2 diabetes achieving multi-factorial treatment targets, increased remission of co-morbidities, and improved quality of life, irrespective of the procedure performed. Cost studies suggest that bariatric surgery may result in reduced hospitalization and medication cost. In some settings, this leads to reduced costs compared to medical management, with cost savings entirely offsetting the cost of surgery and return on investment occurring after durations as short as 1.25 years. However, other studies suggest that bariatric surgery is associated with increased costs, as cost savings only partially offset the cost of the procedure. Long-term studies suggest that bariatric surgery is likely to be dominant (improving clinical outcomes and reducing costs) or cost-effective compared to medical management, irrespective of the procedure performed on the country of the analysis.

However, the efficacy and safety of alternative bariatric surgery procedures may vary. There is strong clinical evidence to show that both RYGB and SG are associated with improved clinical outcomes compared with AGB. There is weaker evidence that suggests that RYGB is more effective than SG and that BPD may be the most effective bariatric surgery procedure. Trends in the utilization of bariatric surgery indicate that laparoscopic RYGB and SG are currently the most commonly used procedures in weight loss surgery.

The majority of bariatric surgery procedures are carried out using a laparoscopic approach, rather than a traditional open surgery approach. No differences in weight loss outcomes have been reported as methods of calorie restriction are equivalent, but laparoscopic surgery has been shown to be associated with reduced length of hospital stay, reduced rates of early and late complications, reduced post-operative mortality, lower hospital charges, reduced rates of surgical site infection, reduced requirement for blood transfusion, reduced post-operative pain, and faster recovery.
5 REFERENCES

5 Ramachandran A, Snehalatha C. Rising burden of obesity in Asia. J Obes. 2010;868573
Global Value Dossier: Bariatric Surgery


The Economist Intelligence Unit. The silent epidemic: An economic study of diabetes in developing and developed countries.


183 Health Authority--Abu Dhabi. HAAD Standard for diagnosis and management of interventions for weight management and obesity. https://www.haad.ae/HAAD/LinkClick.aspx?fileticket=Ctt3gdbWv0o%3D&tabid=820


Appendix 1: Non-comparative clinical studies

6.1 Introduction
The main text of the systematic review contains summaries of studies which have compared bariatric surgery procedures with medical management, or compared two (or more) bariatric procedures. This appendix aims to collate studies of bariatric surgery which have not included a control arm, and therefore represent lower quality evidence. The majority of studies compared outcomes after bariatric surgery with baseline.

6.2 Non-comparative studies

6.2.1 Non-comparative studies of adjustable gastric banding

6.2.2 Non-comparative studies of sleeve gastrectomy
6.2.3 Non-comparative studies of Roux-en-Y gastric bypass


6.2.4 Non-comparative studies of bariatric surgery (data not presented for separate procedures)


7 APPENDIX 2: SYSTEMATIC REVIEWS OF CLINICAL STUDIES

7.1 INTRODUCTION

The main text of the systematic review contains summaries of meta-analyses which have compared bariatric surgery procedures with medical management, or compared two (or more) bariatric procedures. This appendix aims to collate systematic reviews which have not included evidence synthesis.

7.2 SYSTEMATIC REVIEWS


