Title:
Cost-utility analysis for bariatric surgery compared with usual care for the treatment of obesity in Australia

Running Title: Cost-utility analysis for bariatric surgery

Word Count: 3550 words

Funding: None

Disclosure: The authors have no conflicts of interest or pecuniary interests to declare.
Abstract

**Background:** The uptake of bariatric surgery in Australia has been hampered by the lack of funding and lack of evidence on relative value for money.

**Objectives:** To determine the cost-effectiveness of adjustable gastric banding (AGB), Roux-En-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) versus usual care (UC).

**Setting:** Perspective of the Australian public healthcare system

**Methods:** A Markov model was constructed to simulate the costs and outcomes for four approaches to managing obesity. The base-case was a 30-year-old Australian female with a BMI > 35. Subgroup analysis was conducted to account for the effect of diabetes as well as various differences in cohort characteristics. Uncertainty was characterised by one-way and probabilistic sensitivity analyses.

**Results:** All bariatric surgeries were effective. The incremental cost-effectiveness ratios were similar at $24,454 for AGB, $22,645 for RYGB and $27,523 for SG compared to UC. At a willingness to pay threshold of $70,000 per quality-adjusted life year (QALY), the probabilities of being cost-effective were 64%, 75% and 71% for AGB, RYGB and SG, respectively. Subgroup analysis showed that bariatric procedures are less cost-effective for older cohorts. For those with diabetes, all the procedures were dominant in comparison to UC.

**Conclusions:** This model shows that all bariatric procedures are a cost-effective treatment for the management of obese patients. When given to a subgroup with diabetes, bariatric interventions become cost-saving.

**Keywords:** Cost-effectiveness, Cost-utility, Obesity, Bariatric, Markov
Introduction

Obesity is of global concern. In Australia, 63% of adults are overweight or obese[1]. Given this large proportion of the population, it is prudent to ascertain which interventions are cost-effective to tackle this condition. A recent systematic review and meta-analysis concluded that conventional pharmacotherapy combined with diet and exercise was not efficacious at helping obese people lose weight[2]. Currently, bariatric surgery is the only option providing long-term weight loss[3]. Clinical effectiveness of bariatric surgeries have been demonstrated in numerous studies[2, 4-6]; however, there is a lack of cost-effectiveness research regarding these interventions.

This study is the first to address the value for money of introducing bariatric surgery procedures into publicly funded and provided healthcare in Australia. Thus, the aim of this study is to estimate the cost-effectiveness of three common bariatric surgical procedures compared with usual care of conventional pharmacotherapy, diet and exercise. Additional aims were to identify population sub-groups where surgery may provide the best value for money.
Methods

Study perspective | Setting | Model | Assumptions

The perspective of the study is that of payers i.e. the Australian public healthcare system. As such, costs relating to pre- and post-surgery management, medication use and follow-up care were included as direct medical costs. However, non-direct health care costs, such as travel and patient out of pocket costs, and indirect costs such as productivity and out-of-pocket expenses, were not included.

A Markov model, a tool used in health economics to aid in estimating the costs and outcomes of chronic diseases, was developed in the specialist software TreeAge Pro 2015 (Release 15.1.0.0, TreeAge Software Inc.). Patients are placed into distinct health states (BMI categories) taken from the National Institute for Health and Care Excellence (NICE): these were 18.5-24.9 for normal weight, 25-29.9 for overweight, 30-34.9 for obesity class I (OB1), 35-39.9 for obesity class II (OB2) and 40+ for obesity class III (OB3)[7]. Transition probabilities are then used to estimate the movement of patients between these health states. Each state has its own costs and outcomes, and over many time periods, these are summed and used in the generation of a cost-effectiveness verdict.

Changes in BMI categories determine movements between health states in this Markov model (Figure 1). When applying the treatment effect to these categories, the mid-point of the range was chosen. The only exception was the OB3 category, where a BMI of 45 was
chosen for those with a BMI >40; this was done to more closely reflect the distribution of obese individuals above 40 BMI[8]. In addition, it reduces any bias towards surgery.

For the base-case, the proportions of Australian females who fall into the OB2 and OB3 categories were used; these were approximately 52% and 48%, respectively[1]. Weight loss resulting from surgery tended to be concentrated in the first year then remains relatively constant; therefore, effectively there are no state transitions beyond the first year[2, 9]. However, in order to account for the effect on the incremental cost-effectiveness ratios of any weight gain, we ran scenarios where patients regained the weight they had lost via surgery. For AGB, a proportion of patients regained their weight with band removal.

**Target Population and Subgroups**

Based on typical demographics in the literature, the base-case modelled was a 30-year-old Australian female[2, 6, 9]. A subgroup analysis varying the starting cohort between OB2 and OB3 was conducted in order to account for the prevailing selection criteria for bariatric surgery[7]. The effect of gender and age on the cohort was also investigated. Finally, a subgroup with diabetes was analysed as others have shown that bariatric surgery in those with diabetes may be proved better value for money to the health system[3, 7]. The healthcare (direct) costs associated with newly acquired diabetes was estimated from Lee et al. (2013)[10]. This figure was converted to 2015 Australian dollars using the Consumer-Price-Index [11].
Comparators

For this study, Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB) and sleeve gastrectomy (SG) were compared to usual care (UC). RYGB, AGB and SG were the most frequently performed bariatric surgical procedures globally [12]. Usual care was pharmacotherapy, diet and exercise management; this included periodic outpatient visits to dieticians/nutritionists, exercise physiologist and a psychologist (see Table 1).

Treatment Effect

A meta-analysis by Chang et al (2014) was used for the BMI reductions in favour of other reviews [4-6]; this was chiefly due to the latter studies utilising data from older studies that are considered unreflective of contemporary surgical practice. Chang et al (2014) conducted a meta-regression to control for baseline characteristics with typical demographics being 79% female, age of 45 with a BMI of 45; this is broadly similar to the figures reported in other reviews mentioned above.

Outcomes

The outcome of health benefits were quality-adjusted-life-years (QALYs) based on utility estimates sourced from a combination of two studies. The utility values for the average Australian were based on Norman et al (2013); the SF-36 was used to measure health status.
and the responses were converted to utility weights using the Australian SF-6D scoring algorithm[13]. The SF-6D provides valuations of the SF-36 health states, derived from the preferences of an Australian population, to assign utility values to some 18,000 health states; responses from the SF-36 can be matched to any of these states to generate a utility weight to be used in calculation of QALYs. Utility changes are then applied to these baseline utilities to reflect the effect of changes in BMI and co-morbidities. These utility weights were based on a regression model reported in Kortt & Clarke (2005)[14].

**Estimating resources and costs**

One of the chief problems of estimating resource use is the high variability in the management of obese patients[3, 15]. For this study, most resource use data were based on review of the literature and major guidelines (Table 1); the actual costs of these resources were obtained from the Australian Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS)[16, 17]. The costs for surgery were obtained from de-identified sample data provided by Queensland Health (the public hospital and healthcare provider in Queensland, the third most populous Australian state with close to 5 million residents)[18]. The costs for bariatric surgery were obtained from the Australian-Refined Diagnostic-Related-Groups and matched with the surgical procedure codes[19].

Following consideration of variability of studies in defining usual care, it was decided to use resource use from Picot et al (2012), as this was the most transparent, comprehensive and
reflective of other guidelines[20]. Finally, the costs for maintenance in each health state were taken from an up-to-date study of the Australian population that matched patient’s healthcare costs to their BMI[21]. It is important to note many others in the field of obesity tend to clump together the categories of OB2 and OB3 as simply ≥35 BMI. Data were not available to make separate cost estimates for OB3; therefore, the costs for both OB2 and OB3 were assumed to be the same and the impact of this assumption is explored via sensitivity analysis over an appropriate range.

**Model parameters | Discount Rate | Time Horizon | Uncertainty**

Discounting is necessary in every health economic evaluation, because benefits incurred in the future are worth less than in the present, and costs incurred in the future tend to be preferred to incurring those costs now. Incurring costs in the present means the money is not available for investment (termed opportunity cost) and similarly, there is a desire in society to enjoy benefits now rather than in the future. Therefore, it is important to ‘discount’ future costs and benefits to reflect their decreasing value. This study employed a discount rate of 5%[22], and was applied for a lifetime horizon; this was 50 years to bring the total cohort up to the age of 80. The cycle length in the model was set at one year and a half cycle correction was applied for future health states and events. The uncertainty of parameters was explored via one-way and probabilistic sensitivity analyses. The ranges used for the parameters were taken from the published confidence intervals where available. However, for most of the costs the confidence interval ranges were not available; therefore, costs were varied between 50% and 100% because this is a sufficiently broad range to
capture the sensitivity of the incremental cost-effectiveness ratios (ICERs; this is the difference in costs between the new and old intervention divided by the difference in benefits, or QALYs). Choice of distributions for probabilistic sensitivity analysis depended on the input parameters under consideration (Table 1). All costs are reported in 2015 Australian dollars (AU$1 ≈ £0.45 ≈ US$0.70).

The rate of complications and subsequent reoperations of bariatric surgeries (AGB, RYGB and SG) varies considerably in the literature[9, 23-26]. For the base model, we used the systematic review by Puzziferri et al (2014)[9] to inform these rates, as this publication compared all three bariatric surgeries, and we assumed most complications would occur within the first 2 years (see Table 1). For scenario analysis, we used reoperation rates from studies with at least 10 years follow-up for AGB[23], and RYGB[26]. With AGB band removal comes complete weight regain[27]. Similar to another cost-effectiveness analysis[28], we assumed revision procedures with RYGB (and SG) resulted in patients maintaining their therapeutic weight loss. Weight regain with bariatric surgeries over time[24] was investigated in scenario analysis.
Results

All bariatric surgeries were effective (net gain in QALYs). Transition to lower BMI levels resulting from bariatric procedures was associated with a greater reduction in mortality, and hence increased survival for surgeries compared to UC. The ICERs for AGB, RYGB and SG were similar at $24,454, $22,645 and $27,523 respectively (Table 2). That is, on average, RYGB provides the best value for money compared with UC.

One-way sensitivity analysis, depicted using tornado diagrams, was conducted for the 3 interventions to identifying the key variables affecting the ICER (Figures 2a, 2b, 2c). The ICER for AGB was most sensitive to the health state costs, followed by the efficacy of UC (BMI reduction), surgery cost and AGB efficacy. The ICER for RYGB was most sensitive to the health state costs, surgery cost and discount rate (cost and QALYs). The ICER for SG was most sensitive to the health state costs, surgery cost, SG efficacy and discount rate. Overall, AGB had the greatest spread in the range of the ICER from varying key input parameters.

Figures 3a, 3b, 3c show the cost-effectiveness plane (CEP) for AGB, RYGB and SG versus UC respectively. In Australia, there is no official willingness to pay for a QALY, however unofficially this figure seems to rest at approximately $70,000[29]. The proportion of ICERs lying below the chosen threshold ($70,000) is the probability that the intervention is cost-effectiveness (i.e. acceptable value for money). The probability of cost-effectiveness was 64%, 75% and 71% for AGB, RYGB and SG, respectively. Further, the probability of cost saving (proportion of ICERs lying below zero on the x axis) was approximately 30%, 34% and 29% for AGB, RYGB and SG, respectively.
Subgroup analysis revealed gender to have no effect on the variation in ICERs (Table 2). When the model was run based on the assumption that full weight regain occurred within 5 and 10-year periods, none of the surgical procedures were cost-effective. However, cost-effectiveness was maintained when full weight regain occurred at approximately 20 years for all three bariatric surgeries. Starting the model with an older cohort predictably caused the ICER to be less cost-effective, however all the ICERs were still under the $70,000 threshold figure.

Finally, for the diabetic cohort, all procedures dominate usual care (Table 3). Varying the age of the diabetic cohort showed the opposite pattern to age-variation for the base case; the ICERs were increasingly cost-saving for the older cohorts.
Discussion

The QALYs gained for the various procedures are relatively similar, so the difference in their ICERs is chiefly due to costs (particularly between RYGB and SG). Although AGB has the lowest cost, it does not have the most cost-effective ICER due to the highest rate of complications requiring costly reoperations (see Table 1), and in particular band removal resulting in loss of treatment effect (complete weight regain). It was noted we assumed a conservative rate of 2% weight regain every 2 years for AGB lap band removal, which might explain the slight difference in results with a similar cost-effectiveness analysis of AGB versus RYGB (5% weigh regain over lifetime)[28].

Although AGB was not the most cost-effective option, it does have the added advantages of being a non-permanent, potentially reversible intervention, and therefore might be a preferred patient option. Since the rates of these reoperations and their associated impact on weight vary widely between patients, this study is limited by the lack of definitive data on the typical patient journey with AGB. Further, the need for AGB reoperations appears to be decreasing over time as the technique evolves (i.e. the Lap-Band AP era versus the Perigastric Era), which would improve our cost-effectiveness results of AGB relative to UC[26].

Costs of surgeries, as well as the cost of maintenance in the health the states themselves, were significant influencers of the ICER for the 3 interventional procedures. Additionally, for RYGB and SG, the ICERs were sensitive to the discount rate of QALYs. A potential reason for this is that both RYGB and SG result in greater QALY gain, so discounting this value has a
more pronounced effect on their ICER in comparison with AGB. Discounting has the effect of reducing the current values of both the future costs and benefits; as surgery incurs a cost in present period, discounting has little effect on this cost, but the costs for UC become relatively lower the higher the discount rate and the longer the future projections. Thus, interventions which incur costs now but benefits are in the future are less likely to be cost-effective compared with delaying interventions which incur costs further into the future. The sensitivity analysis also shows the importance of the BMI reduction of UC, particularly for AGB. When the reduction is BMI is varied to it’s maximum it causes the ICER to be cost-ineffective relative to UC. For this study, the UC treatment effect was taken from Chang et al (2014); however, it should be noted that this was based on observational studies as this was the only point estimate available.

Probabilistic sensitivity analysis (PSA) shows that all the procedures exhibit a high probability of being cost-effective. Decision makers vary in the degree to which they consider PSA in their evaluations, however the range of 64%-75% - obtained in this study - can be considered sufficiently high. Based on the PSA results, all the procedures are good candidates for potential introduction into the Australian public healthcare system.

Subgroup analysis showed that males exhibit similar results to females, so gender should not feature in the selection criteria of bariatric patients. Varying the initial health state (obesity classification) showed that all procedures remain cost-effective when starting in OB2, because patients are able to transition to lower BMI categories thus gaining more QALYs and incurring less costs. The conclusion to be drawn from this is that bariatric surgery should be encouraged for individuals at a BMI level of 35 and over, as the procedures would
still be cost-effective. However, this also means more pressure on the healthcare system because expanding the selection criteria to include lesser obese individuals requires higher initial investments, as a greater proportion of the population would be eligible for surgery. Varying the data sources for reoperation rates associated with AGB and RYGB (from longer follow-up) showed they both remained cost-effective, but AGB was now more cost-effective than RYGB.

Weight regain in the future is a potential problem for bariatric procedures rendering them cost-ineffective. No conclusive evidence can be found as to the pattern of weight regain post-surgery, as some studies demonstrate that patients gain some of the weight lost, whilst others show that patients lose even more weight after year 1[9]. Realistically, the assumption of full weight regain is perhaps extreme, however modelling it in such a way does highlight an important aspect for consideration, namely follow-up care. If these procedures are to be utilised efficiently, then there must be robust follow-up care packages in place in order to prevent patients from regaining the weight[30, 31].

Variation of the starting cohort’s age showed that the procedures are still cost-effective, however to a lesser degree than starting the entire cohort at the youngest age (30 years old). This result is not surprising as younger patients continue to gain benefits from the procedures for a longer period of time in comparison to their older counterparts[32]; the older the starting cohort, the higher the ICER.

The ICERs for the diabetic cohort are the most encouraging as all the interventions dominate usual care. Type-2 diabetes mellitus (T2DM) is a major co-morbidity for obese
patients, and typically the costs gradually increase as patients advance in age[33]. As a result, the high cost-savings that are incurred due to remission of T2DM renders the procedures much more cost-effective than the base case. An intriguing finding was that when the diabetic cohort was varied by age, it was found that the ICER becomes more cost-effective the older the patient is. This is directly opposite to age variation for the base case. Diabetes costs are much higher for an older cohort and, as part of the model; these costs are less affected by discounting and therefore result in larger cost-savings when compared to UC.

It should be noted that the diabetic subgroup analysis was subject to some important assumptions. The cost value of diabetes was taken from Lee et al (2013), and applied on top of the ongoing costs for each health state. These health state costs were taken from Buchmueller & Johar (2015) who also appear to have included diabetes costs for the various BMI categories. The issue of double counting was sidestepped by making sure the diabetes costs were added to all the states to establish consistency. Another important assumption was that diabetes costs were modelled to gradually increase at a rate of 5%, which is the rate of increase of complications as shown by Huang et al (2014)[33]. There is no consensus in the literature as to the exact increase of diabetes costs over a lifetime, however the figure of 5% is reflective of the general pattern.

Whilst diabetes is an important co-morbidity for obesity, obese patients typically have other co-morbidities such as depression, obstructive sleep apnoea, heart disease, asthma and cancer; however no reliable data in the literature is available to account for the effect of bariatric surgery on these co-morbidities [2, 21]. A related limitation regarding
complications of surgery was the lack of data of their frequency as well as the changes in the associated utility weights. The probability of complications multiplied by their costs was applied only to the first cycle as the literature suggests that complications typically occur within the first year post-surgery. In addition, no utility decrements were applied to the complications, as these would be very small values and unlikely to affect the results.
Conclusion

From a decision-making perspective relating to the Australian public healthcare system, this study has shown that bariatric surgery (AGB, RYGB or SG) is a cost-effective option for the management of obesity in adults, relative to UC. Specifically, RYGB was more cost-effective than AGB and SG, but these results were sensitive to the rates of reoperations used for the modelled analyses. In addition, for diabetic patients who are obese, any of the procedures are considered cost-effective as they dominate usual care. Following bariatric surgery, a structured follow-up care program is crucial to prevent patients from regaining their weight.

Disclosure

The authors have no conflicts of interest or pecuniary interests to declare.
References

[34] RTWSA. Public hospital fee schedule and guidelines. 2015.
Legends uploaded separately at the end of manuscript as requested:

**Figure 1**: Markov model structure; note that patients can move into the death state from any of the other BMI based health states

**Figure 2**: One-way sensitivity analysis, using tornado diagrams, on lower and upper confidence intervals of model parameters for (a) adjustable gastric banding (AGB) vs. usual care (UC), (b) Roux-En Y gastric bypass vs. UC, and (c) sleeve gastrectomy vs. UC


**Figure 3**: Cost-effectiveness planes for (a) adjustable gastric banding (AGB) versus usual care (UC), (b) Roux-En Y gastric bypass vs. UC, and (c) sleeve gastrectomy vs. UC. This graph represents a scatter plot of simulations from the Markov model. The line represents the $70,000/QALY Australian threshold, and any points lying below the line are cost-effective ICERs; the proportion of these cost-effective ICERs relative to the total is the probability of cost-effectiveness for the intervention

Abbreviations: ICER: incremental cost-effectiveness ratio, QALY = quality-adjusted life year, inc: incremental, vs = versus
**TABLE NOTES**

**Table 1:** Abbreviations: AGB: Adjustable gastric banding, RYGB: Roux-En-Y gastric bypass, SG: Sleeve gastrectomy, UC: Usual care, NW: Normal weight category, OW: Overweight category, OB1: Obesity 1 category, OB2: Obesity 2 category, OB3: Obesity 3 category, BMI: Body Mass Index, incl: including

*Included 2 consultant appointments (MBS # 133), pre-anaesthesia appointment (MBS # 17615), dietician appointment (MBS # 10954), psychologist appointment (MBS # 10968), exercise physiologist (MBS # 10953), renal test (MBS 12527), and blood test (MBS # 65070)[7, 16]*

**Included consultant appointment, 5 dietician appointment, and 5 blood tests[7, 16]**

*** Included GP management plan (MBS # 721), 5 dietician appointments, 2 psychologist appointments, 2 exercise physiologist appointments, 2 blood tests, 196 packets of optifast (~$3.08 per packet) and orlistat (PBS # 4570M) over 2 year duration[7, 16, 20]

**** The 2% band removal rate was applied over 2 years in model (follow up was 2 years in Puzziferri et al (2014). With band removal, we have assumed 88% of patients completely regain their weight (Lanthaler et al 2009 [27]).

**Table 2:** Abbreviations: UC: Usual care, AGB: Adjustable gastric banding, RYGB: Roux-En-Y gastric bypass, SG: Sleeve gastrectomy, QALY: Quality-adjusted life year, ICER: Incremental cost-effectiveness ratio, OB3: Obesity 3 category, OB2: Obesity 2 category

* This applies equally to all bariatric surgery interventions (AGB, RYGB, SG) after initial modelled weight loss

** For AGB: Shen et al 2015 [23]; For RYGB: O’Brien et al 2013
Table 3: Abbreviations: AGB: Adjustable gastric banding, ICER: incremental cost-effectiveness ratio, UC: Usual care, RYGB: Roux-En-Y gastric bypass, SG: Sleeve gastrectomy

* ICERs lie in the South West quadrant so usual care is dominated by all types of bariatric surgery (AGB, RYGB, SG)