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Cost-effectiveness of gastric band surgery for overweight but not obese adults with type 2 diabetes in the U.S

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Abstract

Aim—To determine the cost-effectiveness of gastric band surgery in overweight but not obese people who receive standard diabetes care.

Method—A microsimulation model (United Kingdom Prospective Diabetes Study outcomes model) was used to project diabetes outcomes and costs from a two-year Australian randomized trial of gastric band (GB) surgery in overweight but not obese people (BMI 25 to 30kg/m²) on to a comparable population of U.S. adults from the National Health and Nutrition Examination Survey (N=254). Estimates of cost-effectiveness were calculated based on the incremental cost-effectiveness ratios (ICERs) for different treatment scenarios. Costs were inflated to 2015 U.S. dollar values and an ICER of less than \$50,000 per QALY gained was considered cost-effective.

Results—The incremental cost-effectiveness ratio for GB surgery at two years exceeded \$90,000 per quality-adjusted life year gained but decreased to \$52,000, \$29,000 and \$22,000 when the health benefits of surgery were assumed to endure for 5, 10 and 15 years respectively. The cost-effectiveness of GB surgery was sensitive to utility gained from weight loss and, to a lesser degree, the costs of GB surgery. However, the cost-effectiveness of GB surgery was affected minimally by improvements in HbA1c, systolic blood pressure and cholesterol.

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Author Contributions

JMW, KMD, PMC and LN devised the study, JMW and FS collected and analyzed the data, and JMW, LN and PMC prepared the manuscript. All authors helped revise the manuscript.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.jdiacomp.2017.04.009>.

Conclusions—GB surgery for overweight but not obese people with T2D appears to be cost-effective in the U.S. setting if weight loss endures for more than five years. Health utility gained from weight loss is a critical input to cost-effectiveness estimates and therefore should be routinely measured in populations undergoing bariatric surgery.

Keywords

Bariatric surgery; Gastric band surgery; Type 2 diabetes; Cost-effectiveness; Overweight but not obese

1. Introduction

Type 2 diabetes (T2D) is a major determinant of ill-health and accounts for a significant and increasing proportion of health resources.¹ Each year, type 2 diabetes costs the US economy over \$245 billion.² This enormous economic burden highlights the need to appraise the cost-effectiveness of different diabetes treatment strategies.

Bariatric surgery is an effective weight loss therapy for obese people with type 2 diabetes that delivers superior glycemic outcomes when compared to standard diabetes care.^{3–5} Economic modeling of observational trial outcome data shows that bariatric surgery for obese people with T2D is cost-effective, with a cost-effectiveness ratio of less than \$15,000 per quality-adjusted life-year (QALY).^{6,7} In addition, our analysis of two-year outcome data from a randomized trial of gastric band (GB) surgery in obese people with recently-diagnosed diabetes showed that surgery was likely to be cost-saving in the Australian setting.⁸ However, the cost-effectiveness of GB surgery compared to usual care in non-obese people, who comprise around a third of diabetic adults in the U.S.,^{9,10} has not been assessed.

We previously reported 2-year outcomes of a randomized trial of GB surgery in overweight but not obese adults with recently-diagnosed type 2 diabetes who received multidisciplinary diabetes care vs. multidisciplinary diabetes care alone.¹¹ GB surgery delivered mean weight loss of 12 kg (95% CI 9 to 14 kg) and an incremental diabetes remission rate at 2 years of 44% (17 to 71%).

The aim of this evaluation was to describe the in-trial and projected U.S. cost-effectiveness of GB surgery combined with usual diabetes care versus usual care alone if the costs and results found in the trial population were extrapolated to the U.S. diabetes population.

2. Methods

2.1. Patient Data

The inclusion criteria for the randomized trial were patients aged between 18 and 65 years, with type 2 diabetes (T2D) of less than 5 years' duration and a BMI between 25 and 30 kg/m². Participants were randomized between November 2009 and June 2013 and were required to attend at least one consultation with a diabetes educator and a dietician, as well as at least six consultations with the study endocrinologist (JMW) over the first two years. The method of clinical and biochemical data collection has been described previously.¹¹ To model the effects of GB surgery on diabetes outcomes in the U.S., the same inclusion

criteria were applied to adults with self-reported diabetes from the National Health and Nutrition Examination Survey (NHANES) from 1999 to 2011. Briefly, NHANES is a nationally representative dataset of adults in the U.S. that has continuously collected cross-sectional data over a two-year period since 1999 (<http://www.cdc.gov/nchs/nhanes.htm>). Between 1999 and 2012 there were 254 U.S. adults with self-reported diabetes who would potentially have been suitable for inclusion into the clinical trial. The characteristics of the 48 participants who completed the RCT and of the 254 NHANES participants are presented in Supplemental Table 1. The groups differed with respect to ethnicity, smoking history and BMI.

2.2. Costs and Utilities

2.2.1. Australian Costs—All Australian costs were recorded at the time they were incurred and inflated to 2015 U.S. dollar values (AU\$1 = US\$0.78). The cost of GB surgery of \$8680 was sourced from The Avenue Hospital (VIC, Australia). The rates of GB maintenance events (Supplemental Table 2) were based on our case series and their costs sourced from the Australian Medical Benefits Schedule as previously described.⁸ Other hospital episodes for all but two participants for whom data were not available (one in each group) were sourced from the Victorian Department of Health (Melbourne, Australia). Hospital episode costs were sourced from the 2011/2012 Australian Public Hospitals Cost Report.¹² Emergency room visits were priced according to the Victorian averages of US\$216 and US\$698 for same-day and overnight stays, respectively. Outpatient Medicare costs were obtained from the Australian Government Department of Human Services for all but one control group participant whose data were not available, and classified according to cost type (Supplemental Table 3). Drug costs for diabetes medication were sourced from the 2015 Australian Pharmaceutical Benefits Schedule as previously described.¹¹ ScHARR utility score conversion software from the University of Sheffield¹³ was used to derive 'standard gamble' SF-6D utility scores from SF-36v1_US surveys administered at baseline and at 2 years.

2.2.2. U.S. Costs—All U.S. costs were inflated to 2015 U.S. dollar values with unit costs derived from *RedBook* and from relevant peer-reviewed literature. The U.S. costs of GB surgery and maintenance were sourced from a previous analysis of obese people.⁶ The U.S. costs of glucose-lowering medications used by the clinical trial participants are presented in Supplemental Table 4 and the U.S. costs associated with diabetes care and diabetic complications in Table 2 and Supplemental Table 5.

2.3. UKPDS Risk Engine Outcome Modeling

The UKPDS outcomes model¹⁴ is a stochastic microsimulation model that projects rates of death and diabetes complications (myocardial infarction or failure, stroke, amputation, blindness and end-stage renal failure) and their associated quality of life and direct health cost implications (from a societal perspective) based on key risk factors including age, sex, diabetes duration, vascular history, smoking status, lipid profile, systolic blood pressure and HbA1c. To simulate the effects of each treatment strategy in the NHANES cohort of 254 individuals, their baseline values for HbA1c, total cholesterol, HDL cholesterol and systolic blood pressure were adjusted according to the observed outcomes of the clinical trial

(Supplemental Table 6). To model durable effects of GB surgery, 2-year values were carried forward. The initial health utility was set at 0.713, the mean baseline utility of the RCT population. Other UKPDS risk engine inputs are presented in Supplemental Table 5. Modeling incorporated 10,000 loops and 999 bootstraps for 40 years.

2.4. Economic Analyses for a U.S. Population

Base case analyses assumed a 3% discount rate for costs and QALYs and that the effects of each treatment endured for 10 years reflecting durable control of these risk factors with usual diabetes care¹⁵ and sustained benefits of weight loss on systolic blood pressure, HbA1c, HDL cholesterol and health utility.¹⁶

2.5. Statistical Analyses

For the randomized trial results, an intention-to-treat analysis was performed and the two treatment groups were compared using Student's t-test. For results projected for the U.S. population, survey weights were applied to the outputs for each of the 254 NHANES participants as recommended (www.cdc.gov/nchs/nhanes). The weighted values for paired GB and usual care simulations were then compared to determine the impact of GB surgery on diabetes costs and QALYs in the U.S. population of overweight but not obese people with T2D using paired t-tests and ANOVA. Data were analyzed using Prism (v6.0b; Graphpad, CA) and SAS (v9.4; SAS Institute, NC) software and are presented as mean $\pm$ SD or mean (95% CI). The sensitivity analyses tested the effects of the following changes to base-case assumptions: duration of surgical benefit 5 or 15 years; annual discount nil or 5%pa; costs and diabetes QALYs halved or doubled; and health utility gain from weight loss at the upper and lower limits of the 95% confidence interval. To provide a visual representation of the results, costs and health outcomes were mapped onto the cost-effectiveness plane and reported as acceptability curves as previously described.¹⁷ For both analyses, data for the uncertainty surrounding the cost of GB surgery were lacking, so we assumed the standard deviation was equal to half of its cost.

3. Results

3.1. In-Trial Outcomes and Health Costs at Two Years

Table 1 describes resource utilization over the 2-year duration of the trial. Of the 48 participants who completed the study, 25 received usual diabetes care (control group) and 23 were assigned to receive gastric band surgery combined with usual care (GB group). One GB participant who declined surgery following randomization was included in the GB group according to the intention to treat convention. The higher hospital costs of GB participants reflected the up-front cost of surgery whereas their higher outpatient costs were primarily due to the need for more frequent outpatient medical practitioner consultation to review and adjust the band. These higher costs were partially offset by a lower cost of glucose- and lipid-lowering drugs.

Health utilities were derived from the SF-36 survey at baseline and 2 years. The mean $\pm$ SD health utility at baseline was 0.72 ± 0.14 and 0.71 ± 0.12 for the GB and control groups respectively (mean difference -0.00 ; 95% CI -0.08 to 0.07). After 2 years, the mean health

utility of GB participants increased by 0.08 (95% CI 0.01 to 0.15) to 0.80 ± 0.13 but remained relatively stable at 0.72 ± 0.14 in control participants.

The mean differences in health costs and utilities were \$7551 (95% CI \$3292 to \$11,810) and 0.08 (95% CI 0.01 to 0.16) respectively, equating to an incremental cost-effectiveness ratio (ICER) of GB surgery of \$94,388 for a within-trial analysis at 2 years' follow-up.

3.2. Cost Effectiveness of GB Surgery in the US Population

The UKPDS outcomes are presented in Supplemental Table 7. Estimated life expectancy for U.S. participants in NHANES were 23.94 and 24.09 years respectively (mean difference 0.16 years, 95% CI: 0.15 to 0.16) for the control and GB interventions, respectively. The corresponding quality-adjusted life expectancy (QALE) and cost of diabetes complications were 11.62 and 11.72 QALYs (difference 0.11; 95% CI 0.10 to 0.11) and \$52,900 and \$51,245 (difference -\$1653; 95% CI -\$1672 to -\$1635). The base case analysis presented in Table 2 assumed GB surgery delivered improved HbA1c, blood pressure and lipid ratio for ten years (Fig. 1). The ICER for GB surgery compared to usual care was \$29,007 per QALY gained, indicating likely cost-effectiveness relative to a \$50,000 per QALY threshold. The cost-effectiveness plane presented in Fig. 2a provides a visual representation of the uncertainty of the base case estimate whereas the cost acceptability curve (Fig. 2b) indicates GB surgery delivered an 81% chance of meeting the \$50,000 per QALY threshold.

Sensitivity analyses (Supplemental Table 8) showed that the cost-effectiveness of GB surgery was sensitive to the utility gained from weight loss, which in the base case was assumed to be 0.08 per annum for 10 years. The ICER climbed above the \$50,000 threshold when the utility gain was less than 0.03 per annum for 10 years. Other scenarios that increased the ICER above \$50,000 per QALY gained were if the cost of surgery and maintenance exceeded 150% of the base case assumptions or if the GB benefit endured no more than 5 years.

4. Discussion

We present the first analysis of the cost-effectiveness of bariatric surgery in an overweight but not obese population with T2D. The within-trial cost-effectiveness analysis of the original Australian study reveal GB surgery is not cost effective, with the ICER two years after surgery exceeding \$90,000 per QALY gained. However, when the benefits of GB surgery were assumed to last beyond 5 years, the ICER decreased to below \$50,000 per QALY gained for the U.S.-based analysis. Sensitivity analyses revealed that the long-term cost-effectiveness of GB surgery was most sensitive to the health utility gained from weight loss and, to a lesser extent, the up-front and maintenance costs of the gastric band.

Our findings build on earlier studies that suggest that bariatric surgery is a cost-effective treatment for obese people with T2D.^{6-8,18} The most comprehensive of these was by Hoerger et al.⁶ who used a similar microsimulation model to interpolate the health and economic outcomes of bariatric surgery in a severely obese ($BMI > 35 \text{ kg/m}^2$) NHANES population. If T2D had been diagnosed in the previous 5 years, gastric bypass and GB surgery were predicted to deliver respective ICERs (in 2015 U.S. dollars) of \$8500 and

\$14,500 per QALY gained. Two other analyses have reported the economic impact of GB surgery on people with T2D and less severe obesity (BMI 30 to 40 kg/m²).^{8,18} Both were based on the results of trials run by our center and used Markov models to extrapolate two-year outcomes over at least 20 years. They reported ICERs for GB surgery of ~\$3000 or less, highly favorable findings that were biased by the assumption, subsequently discredited,^{19–21} that short-term remission from diabetes after bariatric surgery would endure for more than a decade. In addition, these analyses assumed that, following remission of diabetes, the risk of developing complications decreased to that observed in the non-diabetic population. This assumption ignores the atherogenic impact of ‘metabolic memory’ in diabetes,²² and is at odds with recent findings from the Swedish Obese Subjects cohort that showed bariatric surgery in people with T2D only protected against vascular complications if it was performed within a year of being diagnosed with T2D.²¹

The base case ICER for GB surgery in this study of overweight people was \$29,000, which was substantially higher than the ICERs observed in the aforementioned analyses of obese populations.^{6,8,18} This is perhaps not surprising since the potential for weight loss and improved cardiovascular outcomes after GB surgery correlate with BMI.²³ Nonetheless, GB surgery for overweight but not obese people with T2D meets the cost-effectiveness threshold of \$50,000,²⁴ and is cheaper than other accepted T2D interventions such as intensive glucose- and cholesterol-lowering therapy.²⁵

The cost-effectiveness of GB surgery in this study was sensitive to the health utility gained from weight loss per se rather than from reduced rates of diabetes complications as a consequence of improvements in risk factors. Hoerger et al.⁶ also identified this in their analysis of the economic impact of bariatric surgery in obese people with T2D, which assumed an annual gain in health utility following GB surgery of 0.07, a figure based on studies of the impact of weight loss on quality of life. We assumed a similar value of 0.08 based on measured changes in SF-36-derived health utility observed two years after GB surgery in our cohort. Notably, sensitivity analyses indicated that an annual health utility gain of as little as 0.03, if sustained for ten years, would render GB surgery cost-effective.

Our analysis has several other limitations. First, the long-term effects of GB surgery in the overweight U.S. population with T2D have been extrapolated from two-year outcomes of a trial that enrolled people willing to be randomized to either GB surgery or medical care. The BMI, ethnic and unmeasured cultural differences between the populations of the U.S., Australian and the United Kingdom (used to design the UKPDS risk engine) are potential sources of uncertainty. Second, a minority of the population used to generate the UKPDS risk equations experienced substantial weight loss, so we have assumed that these equations are valid when changes in risk factors result from weight loss rather than changes in medical therapy. Third, we assumed weight loss at two years endured for at least five years. This assumption is justified by the long-term outcomes observed in obese patients,^{26,27} and by our recently-published five-year outcome data²⁸ but may not be reproducible in centers lacking GB expertise. Fourth, our findings might not apply to overweight people who have had T2D for more than five years and the generalizability of our findings to populations with longer-standing diabetes is unknown. Longer disease duration in obese people with T2D is associated with lower rates of diabetes remission and lesser protection from diabetes

complications after bariatric surgery,²¹ factors that may lead to less favorable cost-effectiveness estimates. This highlights the importance of incorporating robust measures of health utility into future trials of bariatric surgery. Finally, our findings provide little insight into the economic impact of other procedures such as gastric bypass and sleeve gastrectomy in this population. Dedicated economic evaluation of the effects of these operations in an overweight cohort is needed to clarify this important question.

Rates of GB surgery both in the U.S. and globally have fallen dramatically over the last decade due to the rise of sleeve gastrectomy (SG).²⁹ Whether this trend persists will depend on whether long-term outcomes of SG, when they become available, justify its substantially higher short-term risks.³⁰ Our findings argue for increased uptake of GB surgery to treat overweight people with T2D because people with relatively minor excess weight are much less likely to accept the higher risks and irreversible nature of SG or roux-en-Y gastric bypass.

In summary, GB surgery in combination with multidisciplinary care was cost-effective compared to multidisciplinary care alone for overweight U.S. adults with T2D. The cost-effectiveness of GB surgery in this context is critically dependent on the durability of weight loss and its impact on health utility. The cost-effectiveness of GB surgery recommends it as a treatment strategy for the increasing population of overweight adults with T2D both in the U.S. and in other countries.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.

Projected effect of GB surgery on diabetes risk factors in the context of usual diabetes care in the U.S. population. The effects of usual care (squares) and of GB surgery combined with usual care (circles) on HbA1c, systolic blood pressure (SBP) and lipid ratio (Chol/HDL) that were applied to 254 overweight NHANES participants with T2D.

Fig. 2.

Cost effectiveness plane and cost acceptability curve for the base case analysis. The cost-effectiveness plane (a) shows the mean difference in cost and effect as 95% CI and 95% confidence ellipse. The cost acceptability curve (b) indicates the probability that the cost per quality-adjusted life year gained is cost-effective as a function of the decision-maker's ceiling cost-effectiveness ratio.

Table 1

Direct per capita health costs in the Australian setting over the 2-year trial period according to treatment group.

	GB group (N = 23)	Control group (N = 25)	Difference (95% CI)	P-value
Hospital costs				
LAGB surgery	8377 ± 2108	0 ± 0	8377 (7529 to 9225)	<0.0001
Other hospital costs	2533 ± 6486	3161 ± 6136	-628 (-4380 to 3123)	0.7375
Total hospital costs	10,899 ± 7118	3161 ± 6136	7737 (3797 to 11,677)	0.0003
Outpatient costs				
Medical practitioner consultations and procedures	2007 ± 817	1512 ± 584	495 (80 to 911)	0.0206
Gastric band adjustments	846 ± 394		846 (687 to 1005)	<0.0001
Allied health consultations	217 ± 106	389 ± 232	-172 (-279 to -65)	0.0023
Investigations	1735 ± 655	1542 ± 529	193 (-156 to 543)	0.271
Total outpatient costs	4806 ± 1626	3443 ± 1043	1363 (564 to 2161)	0.0013
Diabetes-related medication costs				
Glucose-lowering drugs	176 ± 409	1139 ± 1434	-963 (-1587 to -339)	0.0033
Blood pressure-lowering drugs	141 ± 206	275 ± 281	-134 (-278 to 10)	0.0676
Lipid-lowering drugs	366 ± 403	816 ± 691	-449 (-782 to -116)	0.0092
Anti-platelet drugs	9 ± 30	56 ± 158	-47 (-115 to 20)	0.1677
Total diabetes-related medication costs	693 ± 653	2287 ± 1747	-1593 (-2373 to -814)	0.0002
Total health costs	16,398 ± 8258	8848 ± 6348	7551 (3292 to 11,810)	0.0009
Change in health utility (0 to 24 months)	0.08 ± 0.16	0.00 ± 0.10	0.08 (0.01 to 0.15)	0.0367
ICER			94,387	

Costs were incurred in the Australian health system and are presented in 2015 U.S. dollars. Data are mean ± SD or mean difference (95% CI). A full description of outpatient costs is provided in Supplemental Table 2. One GB participant randomized to the GB group who did not undergo GB surgery has been included in the GB group for analysis according to intention to treat conventions.

Table 2

UKPDS model inputs and base case cost-effectiveness analysis.

	Cost	Utility change	Reference
UKPDS inputs			
Annual cost of diabetes without complications	1418	n/a	Note ²
Event costs (fatal)			
Ischaemic heart disease	25,376	n/a	31
Myocardial infarction	25,302	n/a	31
Heart failure	24,694	n/a	32
Stroke	46,972	n/a	33
Amputation	9397	n/a	32
Blindness	2975	n/a	32
Renal failure	81,899	n/a	31
Event costs (non-fatal)			
Ischaemic heart disease	22,249	−0.09	32
Myocardial infarction	44,343	−0.055	31
Heart failure	24,694	−0.108	32
Stroke	29,709	−0.164	33
Amputation	9397	−0.28	32
Blindness	2975	−0.074	32
Renal failure	81,899	−0.164	31
Subsequent annual costs			
Ischaemic heart disease	3418	−0.09	32
Myocardial infarction	2698	−0.055	31
Heart failure	10,427	−0.108	32
Stroke	5923	−0.164	31
Amputation	0	−0.28	31
Blindness	2975	−0.074	32
Renal failure	81,899	−0.263	31
Cost effectiveness analysis			
Costs			
GB surgery year 1	16,534		6
GB follow-up (years 2 to 10)	12,816		6
Diabetes complications	−1653		UKPDS RE
Glucose-lowering medication	−4201		Red Book 2011
Cost difference (GB surgery– usual care)	23,496		
QALYs			
Diabetes complications		0.11	UKPDS RE
Utility gain from weight loss		0.7	Note ³
Total		0.81	

	Cost	Utility change	Reference
ICER	29,007		

¹Costs and QALYs were discounted 3% pa.

²The annual cost of diabetes without complications comprised \$94 for self-monitoring without insulin, \$828 for metformin monotherapy and \$496 for outpatient visits. Sources: Red Book 2011 and National Center for Health Statistics. National Health Interview Survey diabetes supplement. Hyattsville MD: NCHS, 2006.

³Described in text.

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