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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/m^2) 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.
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.

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

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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/m^2. 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 Sheffield[13] 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 model[14] 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 care[15] 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 ± 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