Cost-Effectiveness of Surgically Induced Weight Loss for the Management of Type 2 Diabetes: Modeled Lifetime Analysis

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OBJECTIVE — To estimate the cost-effectiveness of surgically induced weight loss relative to conventional therapy for the management of recently diagnosed type 2 diabetes in class I/II obese patients.

RESEARCH DESIGN AND METHODS — This study builds on a within-trial cost-efficacy analysis. The analysis compares the lifetime costs and quality-adjusted life-years (QALYs) between the two intervention groups. Intervention costs were extrapolated based on observed resource utilization during the trial. The proportion of patients in each intervention group with remission of diabetes at 2 years was the same as that observed in the trial. Health care costs for patients with type 2 diabetes and outcome variables required to derive estimates of QALYs were sourced from published literature. A health care system perspective was adopted. Costs and outcomes were discounted annually at 3%. Costs are presented in 2006 Australian dollars (AUD) (currency exchange: 1 AUD = 0.74 USD).

RESULTS — The mean number of years in diabetes remission over a lifetime was 11.4 for surgical therapy patients and 2.1 for conventional therapy patients. Over the remainder of their lifetime, surgical and conventional therapy patients lived 15.7 and 14.5 discounted QALYs, respectively. The mean discounted lifetime costs were 98,900 AUD per surgical therapy patient and 101,400 AUD per conventional therapy patient. Relative to conventional therapy, surgically induced weight loss was associated with a mean health care saving of 2,400 AUD and 1.2 additional QALYs per patient.

CONCLUSIONS — Surgically induced weight loss is a dominant intervention (it both saves health care costs and generates health benefits) for managing recently diagnosed type 2 diabetes in class I/II obese patients in Australia.

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Previous studies have concluded that surgically induced weight loss is a cost-effective intervention for managing severe obesity (1,2). However, no published studies have assessed the cost-effectiveness of surgically induced weight loss as an intervention for managing type 2 diabetes in obese patients.

A recent randomized controlled trial (RCT) confirmed observational evidence (3–5) that surgically induced weight loss leads to the remission of type 2 diabetes in the majority of obese patients. The 2-year RCT, which compared diabetes-related outcomes in 60 obese (mean BMI 37 kg/m^2) adults with recently diagnosed (<2 years) type 2 diabetes randomized to either surgical therapy (laparoscopic adjustable gastric banding [LAGB]) or conventional therapy, has previously been reported (6).

Previously, we reported the within-trial mean intervention costs as 13,400 AUD and 3,400 AUD per patient for surgical therapy and conventional therapy, respectively. The cost-efficacy for surgical therapy compared with conventional therapy was 16,600 AUD per case of type 2 diabetes remitted (7). The key strength of this study was the certainty of the results: the analysis was based directly on observed trial cost and efficacy data. The key limitations of this analysis were the short time horizon for analysis (2 years) and the disease-specific outcome metric (cases of type 2 diabetes remitted). Decreasing surgical therapy costs over time and the future cost burden of treating type 2 diabetes warrant analyses over a longer time horizon. Expansion of the benefit measurement to capture quality of life and life expectancy gains is also required to enable comparison with other cost-effectiveness analyses.

This study builds on the within-trial cost-efficacy analysis by extrapolating costs and outcomes from those observed over the 2-year trial to the lifetime of the trial population. It aims to determine the cost-effectiveness of surgically induced weight loss relative to conventional therapy for the management of type 2 diabetes in class I and II obese patients.

RESEARCH DESIGN AND METHODS

An incremental cost-effectiveness analysis was undertaken, where the net costs and effectiveness of surgical therapy compared with conventional therapy were calculated and expressed as an incremental cost-effectiveness ratio (ICER). Costs include the lifetime cost of the interventions and the health care costs to treat type 2 diabetes. Effectiveness results are expressed as the number of quality-adjusted life-years (QALYs) gained. Analysis was undertaken from a health care system perspective. The use of health care resources by government, private insurers, and patients is included in the cost analysis. Outcomes are primarily acquired by patients (rather than government and private insurers); therefore, QALYs are used as the unit of measure on the benefits side of the anal-

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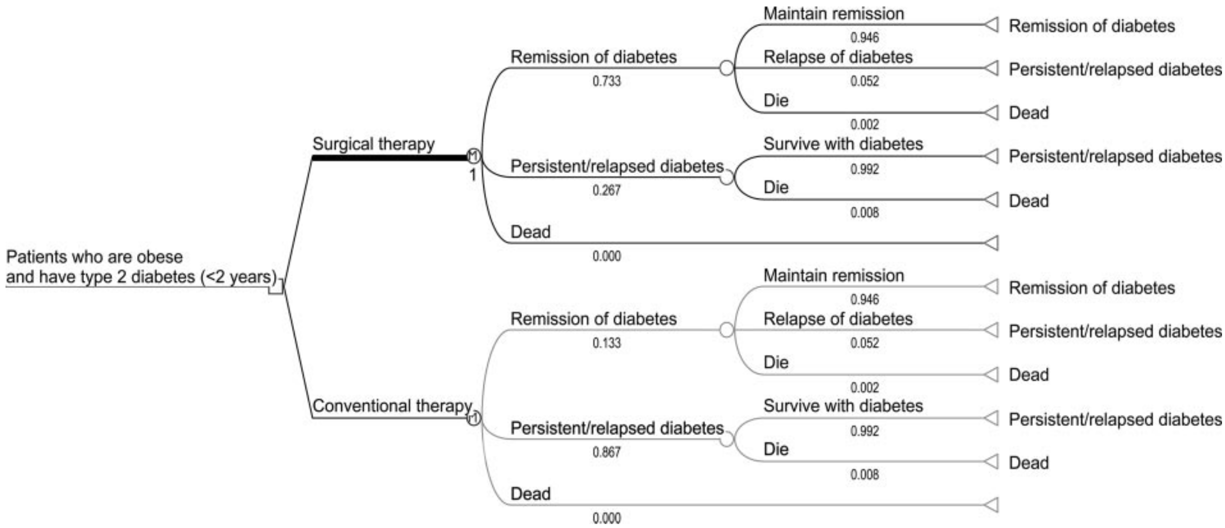

Figure 1—*Markov model: health states and first cycle annual transition probabilities.*

ysis. Discounted (3% per annum) costs and QALYs were estimated. Costs are reported in 2006 Australian dollars (AUD). Costs sourced from alternative years are presented in 2006 values by applying the relevant price deflators (8). The midyear 2006 currency exchange rate, according to the XE currency Web site (9) was 1 AUD to 0.74 USD.

Modeling

Model structure. A Markov model that is representative of the natural history of type 2 diabetes for patients managed by either surgical therapy or conventional was constructed using TreeAge Pro Suite 2008 with links to Excel. Three health states were defined: type 2 diabetes remission, type 2 diabetes, and death. Health state transitions were limited to maintenance of the current health state or deterioration (Fig. 1). The model cycle length was 1 year, and half-cycle corrections were applied. Modeling was applied from the end of the 2-year RCT, with surgical and conventional therapy groups entering the model with their end-of-RCT mean age, mean BMI, diabetes status, and accumulated RCT intervention costs (see Table 2). The model was run until patients died or reached 99 years of age. Results of the model were generated using Monte Carlo simulation. Mean results are based on 20,000 random walks of the model.

Lifetime intervention pathways. The conventional therapy intervention was assumed to be implemented for the 2-year trial period. The surgical therapy intervention was assumed to be a lifetime program to monitor and maintain weight loss and the LAGB. Patients exiting the trial in type 2 diabetes remission (regardless of assigned intervention) were assumed to be monitored for maintenance of remission.

Variables within the model

Trial intervention effect. The trial intervention effect (type 2 diabetes status at end of trial) was applied as the relative risk of remission for surgical relative to conventional therapy patients. Uncertainty around the intervention effect was captured by assuming a normal probability distribution around the log of the relative risk reported for the RCT (6). Univariate probabilistic uncertainty analysis was undertaken to examine the effect of uncertainty around the relative risk using a Monte Carlo simulation. Simulation for 1,000 cohorts, each involving 20,000 iterations, was used to estimate the 95% uncertainty interval (UI) around the mean ICER and probabilities of acceptable cost-effectiveness. All patients were assumed to have a mean duration of type 2 diabetes of 3 years at the end of the trial. Therefore, benefits associated with diabetes remission accumulated after the trial period only.

Intervention costs. Surgical therapy maintenance costs were applied each year that surgical patients remained alive. The frequency of outpatient medical consultations and investigations was estimated by surgical experts at the Centre for Obesity Research and Education, Monash University, who have maintained a database of 4,500 LAGB patients over 14 years.

Surgical therapy complication costs were applied each year that surgical patients remained alive. Lifetime complication rates were estimated based on published data (10) and consultation with the authors to extrapolate results over the lifetime. The cumulative probability of a complication was estimated to be 17% every 10 years. To derive annual costs, it was assumed that complication rates were independent and constant over time. Resource use for surgical procedures to mitigate complications was estimated by trial surgeons based on the LAGB surgery for trial patients (7) (with adaptations to operating time, length of admission, and prosthesis requirements [details available on request]). Surgical costs were sourced from a private hospital and private medical specialists to reflect private provision as is commonly practiced in Australia. LAGB prostheses were valued based on commercial prices.

Diabetes remission–monitoring costs were applied each year that patients were in the type 2 diabetes remission health state. Medication and outpatient consultation resource use was extrapolated from the surgical intervention group during the last 6 months of the trial. Medical investigations and pathology requirements were estimated by a physician with expertise in diabetes management. Unless otherwise specified, unit costs for all resources were obtained from the Australian 2006 Medicare Benefits Schedule (11) and Pharmaceutical Benefits Schedule (12).

Treatment costs. Mean annual health care costs for patients with type 2 diabetes were sourced from the DiabCo$t study (13), which collected self-reported medication (antidiabetes, insulin, hypoglycemic, lipid lowering, and blood pressure lowering), ambulatory consultation (general practitioner consultations, outpatient consultations, emergency ambulance, and emergency admissions), and in-hospital costs from 10,600 patients from the Australian Diabetes Supplies and Services Register in 2001. Some costs unrelated to type 2 diabetes are likely included because of the study's wide cost inclusion criteria. It is difficult to quantify this proportion; thus, a worst-case scenario estimate of 43%, as reported by the American Diabetes Association, was assumed (14). Health care costs for patients with type 2 diabetes (mean 5,000 AUD) were applied at 100% to patients with type 2 diabetes and 43% for patients in diabetes remission. The costs were provided disaggregated by diabetes duration and patient age and assigned based on these variables to simulate the escalation of costs with disease duration and aging (cost for diabetes remission based on a fixed duration of 5–10 years of disease).

Utility weights. Utility-based weights reflecting 1 year of quality-adjusted survival associated with type 2 diabetes status were assigned each year patients were alive. A mean utility weight equivalent to 0.80 (age range 51–65 years) reflecting the type 2 diabetes health state was sourced from the DiabCo$t study, which administered the EuroQol 5-domain (EQ-5D) questionnaire to the same population sample as that of the cost survey described above (13). Utility weights were assigned based on duration of disease.

As a result of an absence of evidence regarding the quality-adjusted survival associated with remission from type 2 diabetes, it was assumed that these patients have a similar quality of life to that of the general population. A fixed utility weight for the Australian general population (age range 51–65 years) of 0.84, also estimated using the EQ-5D (15), was assigned to these patients.

Transition probabilities. Annual probabilities for relapse of type 2 diabetes were applied to patients in the diabetes remission health state. The Swedish Obese Study (SOS) and the Greenville Series report that, for patients achieving diabetes remission after surgically induced weight loss, the mean duration of remission is 10 years and substantially greater than 16 years, respectively (3,5). An estimate at the lower end of this range (13 years) is adopted for the primary analysis and was converted to a constant annual probability for relapse.

Annual mortality probabilities were applied each year that patients were alive and were assigned based on type 2 diabetes status and age. Because of an absence of evidence regarding mortality risks for patients in remission from type 2 diabetes, this risk was assumed to be the same as that for patients without diabetes. Age-specific annual mortality probabilities for patients with and without diabetes were sourced from a 2008 study by Magliano et al. (16), which combined data from a national Australian cohort study (AusDiab) with national Australian mortality data. All model inputs and sources are summarized in Tables 1 and 2.

Uncertainty analysis

The impact of model variable uncertainty on the ICER was tested. Values tested reflected worst-case scenarios (i.e., decreasing cost-effectiveness of surgical therapy) and are described in Tables 1 and 2. The impact of combinations of variables likely to be related were tested, including *1*) combining all intervention costs in worst-case scenarios and *2*) combining intervention effect and duration of diabetes remission in worst-case scenarios. Uncertainty in modeling assumptions was also tested, including *1*) adding an additional LAGB surgical event to the lifetime intervention cost for each surgical patient (i.e., reflecting a routine LAGB replacement), *2*) applying fixed health care treatment costs and utilities associated with type 2 diabetes (i.e., excluding the effects of disease duration and age), *3*) applying type 2 diabetes mortality probabilities to all patients (i.e., assuming that the mortality probability of the population free of diabetes is not transferable to patients in type 2 diabetes remission), and *4*) introducing a 0.03% probability of postoperative mortality for LAGB patients (i.e., superseding the actual zero mortality found in a trial with a probability reported by a systematic review [17]). Threshold analysis was undertaken to identify the minimum duration of diabetes remission required to deem surgical therapy cost-effective, assuming a willingness to pay threshold of 50,000 AUD per QALY (18).

RESULTS — Based on the assumptions and model parameters described, and relative to conventional therapy patients, surgical therapy patients gained a mean 9.4 additional years in diabetes remission, 1.6 additional life-years (undiscounted), and 1.2 discounted QALYs.

Mean discounted costs per patient were as follows: 98,900 AUD for surgical therapy and 101,400 AUD for conventional therapy. The health care cost to treat type 2 diabetes was the overwhelming cost driver and cost differential between the two intervention groups.

Relative to conventional therapy, surgically induced weight loss was a dominant alternative (associated with health care savings and health benefits) for managing type 2 diabetes in obese patients. On average, surgical therapy was associated with health care savings of 2,400 AUD and an additional 1.2 discounted QALYs per patient (95% CI dominant to 48,400 per QALY for ICER). The probability of surgical therapy being dominant and cost-effective was 57 and 98%, respectively. Results are summarized in Table 3.

Uncertainty in model values and assumptions either maintained the dominant status of surgical therapy or shifted it into a very cost-effective status (< 7,000 AUD per QALY), with the following exceptions. Worst-case scenarios for the intervention effect and the annual cost of treating type 2 diabetes shifted the economic status of surgical therapy from dominant to cost-effective (39,700 AUD and 13,400 AUD per QALY, respectively). Combining the intervention effect and duration of diabetes remission in worst-case scenarios also shifted the economic status of surgical therapy to cost-effective (48,200 AUD per QALY). Detailed uncertainty results are listed in an online appendix (available at http://care.diabetesjournals.org/cgi/content/full/dc08-1749/DC1). Threshold analysis indicated that surgical therapy is cost-effective when the mean duration of remission from type 2 diabetes is at least 2 years and dominant when the mean duration of remission is at least 10 years.

CONCLUSIONS — Discounted results from this analysis suggest that both health gains and health care cost savings are likely realized by substituting conventional therapy with surgical therapy for obese patients presenting with recently diagnosed type 2 diabetes. Strictly from a cost perspective (disregarding quality of life and life expectancy benefits of diabetes remission), this analysis suggests that after 10 years the return on investment of surgical therapy is fully recovered through savings in health care costs to

Table 1—*Cost inputs for cost-effectiveness model (constant annual per patient)*

	Measurement		Valuation			Uncertainty analysis	
	Annual units/ probability	Source	Unit cost (AUD)	Annual cost (AUD)	Source	Annual cost (AUD)	Source
Surgical therapy maintenance (surgical patients)							
Outpatient medical consultations							
Surgeon/physician/general practitioner	2	CORE case series data and expert opinion*	32	64	MBS 2006 (ref. 11)		
Surgeon/physician/general practitioner plus lap band adjustment	2	CORE case series data and expert opinion*	119	237	MBS 2006 (ref. 11)		
Medical investigations							
Barium meal (tests)	0.3	CORE case series data and expert opinion*	90	27	MBS 2006 (ref. 11)		
Gastroscopy (investigations)	0.2	CORE case series data and expert opinion*	157	31	MBS 2006 (ref. 11)		
Subtotal				360		720	Expert opinion: increase by 100%
Surgical therapy complications (events)							
Gastric prolapse	0.01	O'Brien 2002 (ref. 10) and extrapolation	5,758†	57	Private hospital		
Erosion of the band into the stomach	0.001	O'Brien 2002 (ref. 10) and extrapolation	14,691†	15	Private hospital		
Port infection	0.002	O'Brien 2002 (ref. 10) and extrapolation	2,695†	5	Private hospital		
Band removal	0.004	O'Brien 2002 (ref. 10) and extrapolation	5,134†	21	Private hospital		
Subtotal				98		196	Expert opinion: increase by 100%
Type 2 diabetes remission monitoring							
Outpatient medical consultations							
General physician	0.1	Extrapolated from RCT (ref. 7)	32	3	MBS 2006 (ref. 11)		
Endocrinologist	1.4	Extrapolated from RCT (ref. 7)	38	53	MBS 2006 (ref. 11)		
Dietitian	0.1	Extrapolated from RCT (ref. 7)	40	4	MBS 2006 (ref. 11)		
Pathology							
Routine pathology	1	CORE case series data and expert opinion*	20	20	MBS 2006 (ref. 11)		
Outpatient medical investigations							
Ophthalmic assessment (tests)	0.5	CORE case series data and expert opinion*	76	38	MBS 2006 (ref. 11)		

Table 1—*Continued*

	Measurement		Valuation			Uncertainty analysis	
	Annual units/ probability	Source	Unit cost (AUD)	Annual cost (AUD)	Source	Annual cost (AUD)	Source
Prescription medication							
Antihypertensives		Extrapolated from RCT (ref. 7)	86‡	86	PBS 2006 (ref. 12)		
Diabetes		Extrapolated from RCT (ref. 7)	15‡	15	PBS 2006 (ref. 12)		
Lipids		Extrapolated from RCT (ref. 7)	121‡	121	PBS 2006 (ref. 12)		
Other		Extrapolated from RCT (ref. 7)	71‡	71	PBS 2006 (ref. 12)		
Subtotal				411		822	Expert opinion: increase by 100%
Health care costs for patients with type 2 diabetes (100% applied to patients with type 2 diabetes; 43% applied to patients in remission)							
Annual cost				3,281–12,221§ (mean 5,018)	DiabCo$t study (ref. 13)	2,732	AIHW (ref. 26)

*Centre for Obesity Research and Evaluation (CORE) database and consultation with surgical experts (data unpublished). †Detailed unit-cost calculations available on request. ‡Refer to cost-efficacy paper for costing methods, based on surgical therapy cohort cost for trial months 18–24. §Assigned based on duration of disease and patient age. Detailed data by duration of disease (5-year categories) and age (10-year categories) available on request. These data are being prepared for publication by DiabCo$t. AIHW, Australian Institute of Health and Welfare; MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Schedule.

treat type 2 diabetes in the surgical group.

These results underestimate the potential benefits of surgical therapy. First, this analysis captures only one benefit: the remission of type 2 diabetes. The surgical intervention also facilitated significant and sustained weight loss (mean BMI from 37 to 29 kg/m^2). The analysis did not seek to capture non–diabetes-related *1*) health care cost savings associated with a reduction in obesity-related morbidity (19), *2*) improvements in quality of life attributable to weight loss after bariatric surgery (20), or *3*) survival benefits of weight loss after bariatric surgery (19,21). Second, the analysis did not endeavor to capture the substantial benefits from glycemic control demonstrated by surgical patients who did not achieve type 2 diabetes remission. Third, we did not apply a differential duration of diabetes remission to conventional therapy patients, despite evidence that nonsurgical interventions fail to demonstrate maintenance of weight loss over time (22), which may correlate with faster diabetes relapse. Finally, no benefits were applied to the trial period.

Comparison with the literature

Previous studies have found surgically induced weight loss to be a cost-effective intervention for managing obesity (1,2). This study finds surgically induced weight loss for managing type 2 diabetes in the obese population to be superior from an economic perspective because it is generates both cost savings and health benefits. The cost-saving result is consistent with findings from a 2008 U.S. study by Cremieux et al. (23), which found, based on a third-party payer perspective of actual patient costs, that the initial investment in bariatric surgery was offset by downstream health care savings after 4 years.

Resource assumptions employed by our study differ from previous economic evaluations of LAGB surgery. Efficiency gains in LAGB surgery techniques are captured by adopting significantly lower (actual RCT) mean operating and admission durations. Safety gains are captured by including (actual RCT) zero operative mortality. We employed a more comprehensive approach to estimating complication rates, including all serious perioperative complications and extrapolating rates over the lifetime of patients. Optimal schedules for maintaining weight loss are captured through a rigor-

Table 2—*Epidemiological, clinical, and RCT inputs for cost-effectiveness model (annual per patient)*

	Intervention group				Uncertainty analysis	
	All	Surgical	Conventional	Source	Variable value tested	Source
Profile of each intervention group (commencement of model)						
Demographic						
Sample size (patients)		30	30	RCT (ref. 6)		
Mean age (years)		49	49			
Sex (female)		17	16	RCT (ref. 6)		
Diabetes status						
Relative risk of remission in surgical relative to conventional therapy patients		Probability distribution (mean 5.5 [95% CI 2.2–14])		RCT (ref. 6)	2.2	Lower boundary of RCT 95% CI (ref. 6)
Mean no. with type 2 diabetes remission (patients)			4	RCT (ref. 6)		
Mean duration of type 2 diabetes (years)		3	3	RCT (ref. 6)		
Mean BMI (kg/m^2)		29	37	RCT (ref. 6)		
2-year RCT intervention cost (AUD)		13,383	3,396	Cost-efficacy analysis (ref. 7)		
Utility weights reflecting quality of life associated with type 2 diabetes						
Type 2 diabetes	0.67–0.81* (mean 0.80)			DiabCo$t study (ref. 13)	0.82	Expert opinion: utility loss at 50%
Type 2 diabetes remission	0.84			Hawthorne study (ref. 15)		
Transition probabilities						
Annual probability for relapse to type 2 diabetes	0.052†			Greenville and SOS studies (ref. 3,5)	0.067†	SOS (ref. 5)
Annual mortality probability: type 2 diabetes (Age 49–99 years)	0.008–0.328‡			AusDiab study (ref. 16)		
Annual mortality probability: type 2 diabetes remission (Age 49–99 years)	0.002–0.332‡			AusDiab study (ref. 16)		

*Assigned based on duration of disease. Detailed data by duration of disease (5-year categories) available on request (unpublished data). being prepared for publication by DiabCo$t. †Equivalent to mean duration of remission of 13 years (0.052) and 10 years (0.067). ‡Detailed data by age available on request. AIHW, Australian Institute of Health and Welfare; MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Schedule.

Table 3—*Model results (lifetime means per patient)*

	Surgical	Conventional	Difference
Undiscounted			
Years in diabetes remission	11.4	2.1	9.4
Total life-years	32.1	30.5	1.6
QALYs	24.9	22.6	2.3
Discounted at 3% for both costs and benefits			
Costs (AUD)			
2-year RCT intervention	13,383	3,397	9,987
Surgical intervention maintenance	6,477		6,477
Surgical intervention complications	1,768		1,768
Type 2 diabetes remission—monitoring costs	16,479	2,874	13,605
Health care costs to treat type 2 diabetes	60,824	95,105	(34,281)
Total cost	98,931	101,376	(2,444)
Effectiveness			
Total life-years	20.0	19.2	0.7
QALYs	15.7	14.5	1.2
Cost-effectiveness			
Cost per life-year gained	Dominant		
Cost per QALY	Dominant		
Probability of dominance	57%		
Probability of cost-effectiveness at willingness-to-pay threshold	98%		

Dominant: generates health care savings and health benefits. Willingness–to–pay threshold, 50,000 AUD per QALY.

ous postoperative follow-up schedule (20 consultations in the first 2 years and 4 per year thereafter per patient), as discussed in the associated cost-efficacy analysis (7).

Limitations

The transferability of diabetes remission duration results from the Greenville Series and SOS to this RCT is uncertain—the Greenville Series because research suggests that the surgical technique employed, gastric bypass surgery, contributes to diabetes remission through mechanisms independent of weight loss (24) and the SOS study because weight loss (the driver of type 2 diabetes remission through LAGB [6]) was poorly sustained, contrary to sustained weight loss anticipated for the LAGB trial population (25). Additionally, the duration of type 2 diabetes for patients in our RCT (all recently diagnosed) was likely substantially shorter than that of the Greenville and SOS studies, which may correlate with improved diabetes remission outcomes for our trial patients.

To simulate outcomes in the period after the trial, we made assumptions about the costs, diabetes relapse rate, and mortality rate for patients in remission from diabetes. While our assumptions were based on the best available data, the possibility that some were wrong was tested by extensive uncertainty analyses.

The generalizability of cost-effectiveness results to other populations may be limited due to different intervention effects, complication rates, or health care costs. Results are only directly transferable to the clinical population with class I and II obesity and recently diagnosed type 2 diabetes in Australia.

In conclusion, the RCT demonstrated the health benefits of substantial weight loss for the obese patient with recently diagnosed type 2 diabetes. The present study shows that this benefit can be achieved with associated cost savings. Substantial weight loss should be sought in all such patients, and if nonsurgical measures are unsuccessful, the option of LAGB should be discussed.

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