Cost-Efficacy of Surgically Induced Weight Loss for the Management of Type 2 Diabetes

A randomized controlled trial

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OBJECTIVE — To determine the within-trial cost-efficacy of surgical therapy relative to conventional therapy for achieving remission of recently diagnosed type 2 diabetes in class I and II obese patients.

RESEARCH DESIGN AND METHODS — Efficacy results were derived from a 2-year randomized controlled trial. A health sector perspective was adopted, and within-trial intervention costs included gastric banding surgery, mitigation of complications, outpatient medical consultations, medical investigations, pathology, weight loss therapies, and medication. Resource use was measured based on data drawn from a trial database and patient medical records and valued based on private hospital costs and government schedules in 2006 Australian dollars (AUD). An incremental cost-effectiveness analysis was undertaken.

RESULTS — Mean 2-year intervention costs per patient were 13,400 AUD for surgical therapy and 3,400 AUD for conventional therapy, with laparoscopic adjustable gastric band (LAGB) surgery accounting for 85% of the difference. Outpatient medical consultation costs were three times higher for surgical patients, whereas medication costs were 1.5 times higher for conventional patients. The cost differences were primarily in the first 6 months of the trial. Relative to conventional therapy, the incremental cost-effectiveness ratio for surgical therapy was 16,600 AUD per case of diabetes remitted (currency exchange: 1 AUD = 0.74 USD).

CONCLUSIONS — Surgical therapy appears to be a cost-effective option for managing type 2 diabetes in class I and II obese patients.

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Obesity and type 2 diabetes are predicted to be two of the greatest public health problems of the coming decades globally (1). The two conditions are strongly linked (2), with weight control forming perhaps the most important component of type 2 diabetes management (3). Currently available lifestyle and pharmacological strategies only provide modest levels of weight loss for obese patients with type 2 diabetes (4–6). These patients incur lifelong and escalating direct health care costs estimated at 5,018 AUD annually in Australia (7) in 2006 and 6,600 USD annually in the U.S. (8) in 2007.

To date, weight loss surgery has failed to receive attention in clinical guidelines for the management of type 2 diabetes (9). One key concern has been described as uncertainty regarding its cost-effectiveness. Economic evaluation is uniquely placed to analyze the tradeoffs between the high upfront costs of weight loss surgery, its strong effectiveness results, and its potential to save future health care treatment costs. A recent randomized controlled trial (RCT) confirmed observational evidence (10–13) that surgically induced weight loss leads to the remission of type 2 diabetes in the majority of obese patients (14).

This economic evaluation sources data directly from the trial to determine, for the first time, the within-trial cost-efficacy of surgically induced weight loss relative to conventional therapy for remitting type 2 diabetes in obese patients.

RESEARCH DESIGN AND METHODS

— A health sector perspective was adopted for the economic evaluation, comprising direct health care costs to government, private insurers, and patients. An incremental cost-effectiveness analysis was undertaken, wherein the net costs and net efficacy of surgical therapy as compared with conventional therapy were calculated and expressed as an incremental cost-effectiveness ratio (ICER). The ICER was expressed as the cost per case of type 2 diabetes remitted.

Trial design and clinical results

A 2-year RCT involving 60 obese participants (BMI >30 and <40 kg/m^2) was conducted in Australia. It compared surgically induced loss of weight with conventional medical therapy (weight loss and behavior change) for the management of recently diagnosed (<2 years) type 2 diabetes. All patients had previously attempted to lose weight and were involved in a 3-month run-in period where a consulting endocrinologist recommended changes to optimize current diabetes management. Patients were then randomly assigned to the (unblinded) interventions. There were no statistically significant differences in demographics or values contributing to study outcomes between the two groups at baseline.

Conventional therapy reflected the best available medical management. It comprised consultation with a general

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Table 1—*Intervention costs and sources*

	Inclusions	Unit	Cost (AUD)	Source
LAGB surgery	Specialist medical personnel (surgeon, surgical assistant, or anesthetist)	Surgical procedure	3,000	Private medical specialist
	Hospital personnel costs	Surgical procedure	903	Private hospital
	LAGB prosthesis	Surgical procedure	3,264	Private hospital
	Theater supplies, nontheater supplies, and other expenses	Surgical procedure	1,654	Private hospital
Mitigation of surgical complications	Lap-band removal and replacement	Complication episode	8,821	Same as LAGB surgery
	Hospital admission due to port infection (4-day admission)	Complication episode	2,780	Public hospital
	Lap-band removal	Complication episode	5,557	Same as LAGB surgery minus prosthesis
Outpatient medical consultations	Surgeon/physician	Consultation	32.10	MBS item 23
	Surgeon/physician plus lap-band adjustment	Consultation	118.60	MBS items 23 & 14215
	Respiratory physician	Consultation	37.95	MBS item 105
	Endocrinologist	Consultation	37.95	MBS item 106
	Dietitian	Consultation	40.00	Dieticians Association of Australia
Outpatient medical pathology tests	*	Test	*	MBS (various)
Outpatient medical investigations	Barium meal	Investigation	89.95	MBS item 58909
	Sleep study	Investigation	519.60	MBS item 12203
	Ophthalmic assessments	Investigation	75.60	MBS item 104
Weight loss assistance therapies	Optifast	1 month of use	50	Commercial pharmacy
	Sibutramine	1 month of use	70	Commercial pharmacy
Medication	†	6 months of use	†	PBS (various)

*Not described due to extensive detail (included 13 pathology tests). †Not described due to extensive detail (included 83 medications/dose specifications across the categories of antihypertensives, diabetes, lipids, and other). MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Schedule.

physician, dietitian, nurse, or diabetes educator at least once every 6 weeks; medical therapies as determined by an experienced endocrinologist specializing in diabetes; and lifestyle modification programs to reduce energy intake and encourage physical activity. In addition to all aspects of conventional therapy, surgical therapy involved the placement of a laparoscopic adjustable gastric band (LAGB) (LAP-BAND System; Allergan Health, Irvine, CA) by an experienced surgeon and associated overnight hospital stay. Patient progress was reviewed by a member of the bariatric surgical team every 4–6 weeks, and adjustments to band volume were made using standard clinical criteria.

One surgical patient withdrew from the trial before surgery, and four medical patients withdrew during the first four months of the trial. Analysis was performed on an intention-to-treat basis. At the end of the 2-year trial period, remission of diabetes (defined as fasting glucose <126 mg/dl and A1C <6.2% while taking no glycemic therapy) was achieved by 22 of 30 (73%) surgical patients and 4 of 30 (13%) conventional therapy patients. Full details of the trial and efficacy results have been published previously (14).

Costs included

Trial intervention costs were included as follows: LAGB surgery, mitigation of surgical complications, outpatient medical consultations (surgeon/physician [including for lap-band adjustments], general practitioner, endocrinologist, respiratory physician, and dietitian), pathology, medical investigations, weight loss assistance therapies (sibutramine and optifast), and medication (diabetes, antihypertensives, lipids, and other).

Measurement of costs

LAGB surgery resource use was documented on patient case record forms by hospital clinical staff. Procedures to mitigate surgical complications were recorded in patient case files. Clinical staff recorded dates and descriptions of all outpatient medical consultations, pathology tests, and medical investigations into a trial database. A research nurse interviewed patients every 6 months during the trial to document utilization of weight loss assistance therapies and medication by type, dosage, and frequency. Six-month medication point estimates were assumed to be representative of medication use during the previous 6-month period. Actual pharmaceutical expenditure data held by the Australian government was accessed for all consenting patients (23 surgical and 17 medical) to validate medication costs.

Valuation of costs

LAGB surgery costs were sourced from a private hospital and private medical specialists to reflect the private provision of surgery, as is most common for LAGB in Australia. Lap-band prosthesis and weight loss assistance therapies were valued based on commercial prices. Unit costs for all other intervention resources were obtained from pricing schedules of the Australian government including the Medicare Benefits Schedule (MBS) (15) and Pharmaceutical Benefits Schedule (PBS) (16). Unit costs were applied to the resource measurements to obtain total costs per intervention arm of the study over the trial period. All costs are reported in 2006 AUD (Table 1). Costs sourced

Table 2—*Observed mean resource use per patient and costs by intervention group over the 2-year trial period*

	Inclusions	Mean resource use per patient		Mean cost per patient (AUD)		
		Surgical	Conventional	Surgical	Conventional	Difference
LAGB surgery (private hospital)	Specialist medical personnel (surgeon, surgical assistant, or anesthetist)	0.97	—	8,527	0	8,527
	Hospital personnel costs	0.97	—			
	LAGB prosthesis	0.97	—			
	Theater supplies, nontheater supplies, and other expenses	0.97	—			
Mitigation of surgical complications	Lap-band removal and replacement	0.07	—	866	0	866
	Hospital admission due to port infection	0.03	—			
	Lap-band removal	0.03	—			
Outpatient medical consultations	Surgeon/physician	11.60	10.93	1,727	511	1,216
	Surgeon/physician plus lap-band adjustment	10.27	0.00			
	Respiratory physician	0.43	0.10			
	Endocrinologist	2.93	3.67			
	Dietitian	0.23	0.43			
Outpatient medical pathology tests	Not described	*	*	632	632	0
Outpatient medical investigations	Barium meal	1.00	—	690	702	−12
	Sleep study	1.03	1.20			
	Ophthalmic assessments	0.83	1.03			
Weight loss assistance therapies	Optifast (per month)	—	1.60	0	113	−113
	Sibutramine (per month)	—	0.47			
Medication	†	†	†	942	1,439	−498
Total				13,383	3,396	9,987

*Not provided due to extensive detail (pathology use was equivalent in both groups). †Not provided due to extensive detail (costs for the surgical therapy group were 13, 83, 86, and 194% relative to the conventional therapy group for diabetes, lipids, antihypertensives, and other medications, respectively).

from alternative years were inflated to 2006 values by applying the relevant Australian Institute of Health and Welfare health price deflators (17). The midyear 2006 currency exchange rate was 1 AUD to 0.74 USD according to XE currency exchange (http://www.xe.com).

Analysis

Diabetes-related outcomes were defined as in the RCT as the number of cases of diabetes remitted at 2-year follow-up. Costs reflect the interventions as implemented in the trial. Analysis of costs and outcomes was performed over a 2-year time horizon and on an intention-to-treat basis. Intervention costs were calculated (for patients who withdrew from the study) up to the point of exit and most recently collected diabetes status was assumed for the remainder of the trial. No discounting was applied to costs and outcomes. All calculations were performed using exact values. Results in the abstract and text were rounded to the nearest 100 AUD, and results in tables were rounded to the nearest 1 AUD.

RESULTS

Intervention resource use

Table 2 summarizes the mean resource use per patient by the intervention group. A mean resource-use value <1 indicates that the cost was not applicable to all patients (for example, only 4 of 30 patients experienced postoperative complications). Pathology (16 tests) and medication (83 categories) were measured in detail but excluded from the table due to extensive detail. Pharmaceutical expenditure data held by the Australian government for 23 surgical and 16 medical patients were very similar to the self-reported data for the complete samples utilized in the analysis.

Intervention costs

The total intervention cost per group of 30 patients was 401,500 AUD for surgical therapy and 101,900 AUD for medical therapy. Table 2 shows the mean costs per patient by resource category and intervention group. Surgical costs are based on mean hospital admission and operating theater times of 1.28 days and 54 min, respectively. Surgical therapy was significantly more resource intensive than conventional therapy, costing an additional 10,000 AUD per patient over 2 years. LAGB surgery accounted for 85% of this difference. Mean outpatient medical consultation costs were three times higher among surgical patients due to a greater number of consultations (mean number of consultations: 25 for surgical patients and 15 for conventional therapy patients) and higher consultation fees due to lap-band adjustments. Mean medication costs were 1.5 times higher for conventional patients, primarily due to greater use of diabetes medication (mean medication cost: 900 AUD per surgical patient and 1,400 AUD per conventional therapy patient).

Costs over time

During the first 6 months of the trial, mean intervention costs per patient were approximately sevenfold greater for surgical patients (10,500 AUD) than for conventional therapy patients (1,400 AUD).

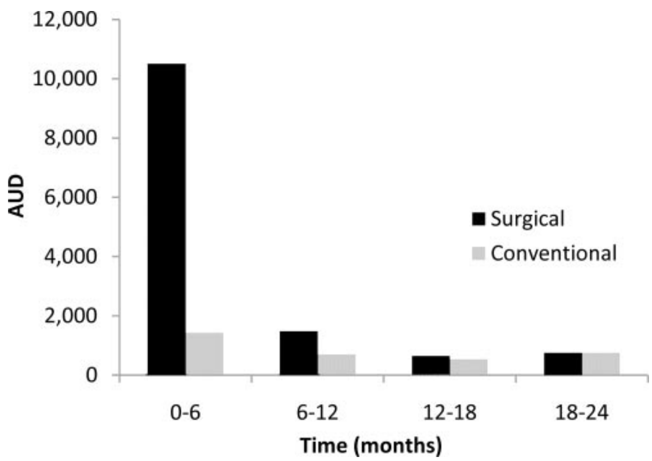

Figure 1—*Mean total intervention cost over time by intervention group.*

The difference between costs in each intervention group decreased with each subsequent 6-month period until the last 6 months of the trial, when intervention costs were equivalent in both groups (Fig. 1). Over time, mean 6-month medication costs per surgical patient decreased by more than one-half (Fig. 2).

Cost-efficacy

Relative to conventional therapy, surgical therapy facilitated remission of an additional 18 cases of type 2 diabetes at an additional cost of 299,600 AUD, equivalent to (an additional) 16,600 AUD per (additional) case of diabetes remitted.

CONCLUSIONS

— This economic evaluation of options for managing type 2 diabetes in obese patients was based directly on data drawn from an RCT. The data are therefore less prone to the types of bias and uncertainty that are likely to affect a modeled study. The results suggest that for a decision maker interested in the immediate future (a time horizon of 2 years) an additional 16,600 AUD of direct health care investment is required to remit an additional case of recently diagnosed type 2 diabetes through surgically induced weight loss.

The cost per case of diabetes remitted is not a metric commonly utilized by decision makers. The comparable ICER for conventional therapy relative to no intervention (no costs and no benefits) over the same time horizon is 25,500 AUD per case of diabetes remitted. Therefore, the ICER for surgical therapy (relative to conventional therapy, 16,600 USD) is lower than the comparable figure for conventional therapy (relative to no intervention, 25,500 USD). This suggests that within a 2-year time horizon the surgical therapy program is below the currently accepted cost-effectiveness threshold.

The analysis provides an estimate of just one benefit: the remission of type 2 diabetes. We have not attempted to capture health care savings associated with the reduction of other obesity-related morbidities or the improvements of quality of life associated with weight loss. Furthermore, the outcome measure (cases of diabetes remitted) does not capture the substantial improvements in glycemic control demonstrated by the surgical patients who did not achieve diabetes remission. Therefore, results underestimate the cost-efficacy of surgical therapy.

The key strength of this analysis (the use of observed, within-trial cost and efficacy data) is also one of its limitations. It restricts the analysis to a 2-year time horizon, which may limit the relevance of results to government policy makers interested in long-term intervention costs, health care system savings due to disease prevention, quality-of-life gains, and mortality gains. Our next study uses this cost-efficacy analysis as the basis to model these variables and reports the lifetime cost per quality-adjusted life-year for surgical therapy relative to conventional therapy trial populations. Modeling cost-effectiveness over a longer time period is particularly important for this study because of the likely differential pathways in medium-term weight loss and associated diabetes remission across intervention groups (18,19) and because our analysis indicated that the cost differential between the intervention and control group decreased with time.

The generalizability of results to other populations may be limited due to different intervention effects and complication rates (for example, due to variable expertise of surgical teams) or health care costs (which may vary across countries). As discussed in an editorial of the *Journal of the American Medical Association* regarding the original RCT (20), the trial was not powered to detect low-probability events including postoperative mortality (21). However, there is evidence to show that the trial results (zero operative mortality) have been replicated under nontrial conditions (22). Data are not available regarding the average resource use of LAGB patients in other parts of the world. The trend toward shorter stays under outpatient LAGB in the U.S. suggests that the Australian costs may be relatively high. In conclusion, from an economic perspective, surgically induced weight loss appears to be a cost-effective intervention for managing recently diagnosed type 2 diabetes in obese patients.

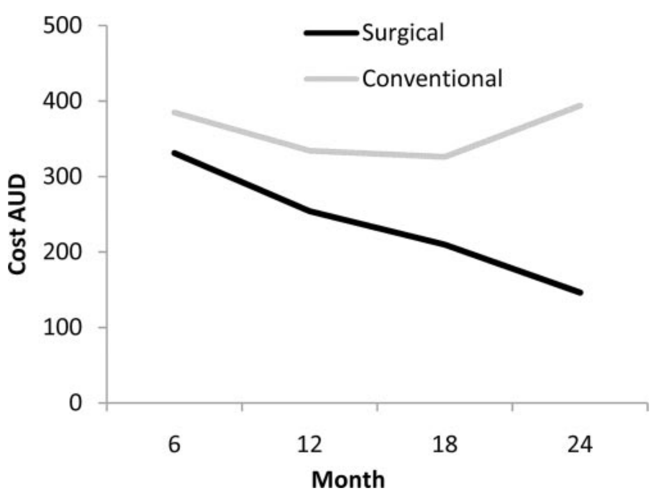

Figure 2—*Mean medication cost per patient over time by intervention group.*

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